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This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential. As confidentially submitted to the Securities and Exchange Commission on September 11, 2019

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

## FORM 20-F/A
**(amendment No. 2)**

**(Mark One)**

☒ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

☐ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended _____**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from _____ to _____**

**OR**

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of event requiring this shell company report**

**Commission file number [●]**

# Avita Medical Limited

**(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)**

**Australia**
**(Jurisdiction of incorporation or organization)**

**Level 7, 330 Collins Street**
**Melbourne VIC 3000 Australia**
**Tel: +61 (0) 3 8689 9997**
**Fax: +61 (0) 8 9474 7742**

**(Address of principal executive offices)**

**Securities registered or to be registered pursuant to Section 12(b) of the Act.**

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered or to be registered |
|---|---|---|
| **American Depositary Shares (each representing 20 Ordinary Shares)** | **CELS** | **The NASDAQ Stock Market LLC** |

**Securities registered or to be registered pursuant to Section 12(g) of the Act. None**

**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

**The number of ordinary shares, as of September 9, 2019 is 1,872,884,836**

**The number of American Depositary Shares, as of September 9, 2019 is 25,598,816**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☐

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Emerging Growth Company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☐

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## INTRODUCTION

Avita Medical Limited was incorporated under the laws of the Commonwealth of Australia on December 21, 1992. The principal listing of our ordinary shares and to purchase our ordinary shares is the Australian Securities Exchange, or ASX. Our American Depositary Share ("ADS") securities trade over the counter in the United States on the OTCQX market. We are filing this registration statement on Form 20-F in anticipation of the listing of our ADSs on the NASDAQ Capital Market under the symbol "CELS". We have appointed Bank of New York Mellon to act as our American Depositary Share ("ADS") registrar and transfer agent to register and deliver our ADS in the United States for the Nasdaq Stock Market. As used in this registration statement, the terms "we," "us," "our," "Avita," and the "Company" mean Avita Medical Limited and its subsidiaries, unless otherwise indicated.

Our consolidated financial statements appearing in this registration statement on Form20-F are prepared in Australian dollars and in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our consolidated financial statements appearing in this registration statement on Form 20-F comply with IFRS.

In this registration statement, all references to "U.S. dollars" or "US$" are to the currency of the United States of America, and all references to "Australian dollars" or "A$" are to the currency of Australia.

Statements made in this registration statement on Form20-F concerning the contents of any contract, agreement or other documents are summaries of such contracts, agreements or documents and are not complete descriptions of all of their terms. If we filed any of these documents as an exhibit to this registration statement or to any registration statement or annual report that we previously filed, you may read the document itself for a complete description of its terms.

Except for the historical information contained in this registration statement on Form20-F, the statements contained in this registration statement on Form 20-F are "forward-looking statements" which reflect our current view with respect to future events and financial results. We urge you to consider that statements which use the terms "anticipate," "believe," "do not believe," "expect," "plan," "intend," "estimate," and similar expressions are intended to identify forward-looking statements. We remind investors that forward-looking statements are merely predictions and therefore inherently subject to uncertainties and other factors and involve known and unknown risks that could cause the actual results, performance, levels of activity, or our achievements, or industry results, to be materially different from any future results, performance, levels of activity, or our achievements expressed or implied by such forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to publicly release any update or revision to any forward-looking statements to reflect new information, future events or circumstances, or otherwise after the date hereof. Please see the Risk Factors section that appears in "Item 3. Key Information – D. Risk Factors."

## PART I

### ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

#### A. Directors and Senior Management

For the names, business addresses and functions of our directors and senior management, see "Item 6. Directors, Senior Management and Employees – A. Directors and Senior Management" and "Item 6. Directors, Senior Management and Employees – C. Board Practices."

#### B. Advisers

Our principal legal adviser is K&L Gates LLP, 925 Fourth Avenue, Suite 2900, Seattle, Washington 98104, United States of America and 25/525 Collins St, Melbourne VIC 3000, Australia.

#### C. Auditors

Our statutory auditor for Australia and U.S. reporting purposes is Grant Thornton Audit Pty Ltd Level 43 Central Park,152-158 St Georges Terrace Perth, WA 6000 Australia.

### ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

### ITEM 3. KEY INFORMATION

#### A. Selected Financial Data

Our consolidated financial statements appearing in this registration statement on Form20-F are prepared in Australia dollars in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our consolidated financial statements appearing in this registration statement on Form 20-F comply with IFRS.

The following table summarizes our historical consolidated financial data and should be read together with our consolidated financial statements, the notes to our consolidated financial statements and the sections titled "Selected consolidated financial data" and "Management's discussion and analysis of financial condition and results of operations" contained elsewhere in this Registration Statement on Form 20-F.

We derived the summary consolidated statements of profit or loss or other comprehensive income data and consolidated statements of financial position data for the fiscal years ended June 30, 2018, 2017 and 2016 from our audited consolidated financial statements included elsewhere in this Registration Statement on Form 20-F. We have derived the unaudited condensed consolidated statements of profit or loss or other comprehensive income for the half-year ended December 31, 2018 and 2017, and the unaudited condensed consolidated statement of financial position data as of December 31, 2018, from our unaudited condensed consolidated financial statements, included elsewhere in this Registration Statement. We have prepared the unaudited financial information on a basis consistent with our audited consolidated financial statements and have included, in our opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair statement of the financial information set forth in those statements. The summary financial data included in this section are not intended to replace the financial statements and related notes included elsewhere in this Registration Statement. Our historical results are not necessarily indicative of our future performance, and our interim results are not necessarily indicative of the results to be expected for the full fiscal year.

| | Years ended June 30, | | | Half-year ended December 31, | |
|---|---|---|---|---|---|
| **(In Australian dollars)** | **2018** | **2017** | **2016** | **2018** | **2017** |
| **Consolidated statements of profit or loss or other comprehensive income:** | | | | | |
| Sale of goods | A$ 1,198,861 | A$ 901,376 | A$ 1,002,007 | A$ 1,813,195 | A$ 607,761 |
| Cost of sales | (511,646) | (463,285) | (401,568) | (570,315) | (264,833) |
| Gross profit | 687,215 | 438,091 | 600,439 | 1,242,880 | 342,928 |
| BARDA income | 10,104,081 | 6,886,236 | 2,424,357 | 5,009,137 | 3,856,716 |
| Other income | 68,617 | 344,734 | 120,160 | 103,626 | 37,595 |
| Total other income | 10,172,698 | 7,230,970 | 2,544,517 | 5,112,763 | 3,894,311 |
| Operating costs | | | | | |
| Sales and marketing expenses | (8,936,441) | (5,201,761) | (5,042,189) | (6,931,241) | (2,815,698) |
| Product development expenses | (12,606,127) | (11,161,970) | (6,018,184) | (7,080,042) | (5,058,518) |
| Corporate and administrative expenses | (5,360,553) | (2,264,594) | (2,371,747) | (6,865,250) | (2,873,511) |
| Share-based payment expenses | (1,835,157) | (1,587,243) | (956,658) | (1,043,694) | (726,856) |
| Finance costs | (26,586) | (12,754) | (21) | (14,807) | (13,253) |
| Total operating costs | (28,764,864) | (20,228,322) | (14,388,799) | (21,935,034) | (11,487,836) |
| Loss from continuing operations before income tax benefit | (17,904,951) | (12,559,261) | (11,243,843) | (15,579,391) | (7,250,597) |
| Profit for the period from discontinued operations | — | — | 2,493,947 | — | — |
| Income tax benefit | 1,385,796 | 1,048,237 | 971,881 | — | — |
| Loss for the period | (16,519,155) | (11,511,024) | (7,778,015) | (15,579,391) | (7,250,597) |
| Other comprehensive income (loss) | | | | | |
| Foreign currency translation | 563,279 | (83,293) | (169,100) | 1,374,144 | (55,390) |
| Fair value gain (loss) on available for sale financial assets | — | (265,261) | 265,261 | — | — |
| Other comprehensive income (loss) for the period, net of tax | 563,279 | (348,554) | 96,161 | 1,374,144 | (55,390) |
| Total other comprehensive loss for the period | A$(15,955,876) | A$(11,859,578) | A$ (7,681,854) | A$(14,205,247) | A$ (7,305,987) |
| Earnings per share | | | | | |
| Basic and diluted loss per share from continuing operations | A$(1.77) cents | A$(1.72) cents | A$(1.56) cents | A$(1.59) cents | A$(0.91) cents |
| Basic and diluted loss per share from discontinued operations | — | — | A$(0.05) cents | — | — |

| (In Australian dollars) | As of June 30, 2018 | As of June 30, 2017 | As of June 30, 2016 | As of December 31, 2018 |
|---|---|---|---|---|
| **Consolidated statements of financial position data:** | | | | |
| Cash and cash equivalents | A$14,825,532 | A$3,790,491 | A$4,171,879 | A$ 30,342,360 |
| Total current assets | 22,274,431 | 7,280,541 | 8,508,418 | 34,953,776 |
| Total assets | 23,017,014 | 7,667,921 | 8,602,909 | 36,347,382 |
| Total current liabilities | 3,883,117 | 2,546,089 | 1,750,392 | 5,017,066 |
| Total equity | 18,999,559 | 5,121,832 | 6,852,517 | 31,247,284 |

Exchange Rate Information

We publish our consolidated financial statements in Australian dollars. In this Registration Statement, references to dollars, "$" or "A$" are to Australian dollars currency and references to "U.S. dollars" or "US$" are to U.S. currency. Solely for informational purposes, this Registration Statement contains translations of certain Australian dollars into or from U.S. dollars at specified rates. These translations should not be construed as representations that the Australian dollars amounts actually represent such U.S. dollar amounts or could be converted into or from U.S. dollars at the rate indicated or at any other rate. Unless otherwise stated herein, the translations of Australian dollars into or from U.S. dollars have been made at A$1.00 to US$0.7399, the Buying Rate on June 30, 2018.

The following tables set forth, for the periods and dates indicated, certain information regarding the rates of exchange of A$1.00 into US$ based on rates published by the Reserve Bank of Australia (RBA). Each period end rate is the average ask price for the day. The average rate is the average of all the ask prices for the given time period. The high rate is the highest bid rate for the given time period. The low rate is the lowest bid rate for the given time period. We make no representation that any Australian dollar or U.S. dollar amounts could have been or could be, converted into U.S. dollars or Australian dollars, as the case may be, at any particular rate, the rates stated below, or at all.

The Australian dollar is convertible into U.S. dollars at freely floating rates. There are no legal restrictions on the flow of Australian dollars between Australia and the U.S.

| Year Ended June 30, | At Period End | Average Ratio | High | Low |
|---|---|---|---|---|
| 2014 | A$0.9420 | A$0.9187 | A$0.9672 | A$0.8716 |
| 2015 | A$0.7680 | A$0.8382 | A$0.9452 | A$0.7590 |
| 2016 | A$0.7426 | A$0.7283 | A$0.7812 | A$0.6867 |
| 2017 | A$0.7692 | A$0.7545 | A$0.7724 | A$0.7202 |
| 2018 | A$0.7399 | A$0.7753 | A$0.8105 | A$0.7355 |

| Month | High | Low |
|---|---|---|
| July 2018 | A$0.7467 | A$0.7360 |
| August 2018 | A$0.7441 | A$0.7213 |
| September 2018 | A$0.7296 | A$0.7103 |
| October 2018 | A$0.7200 | A$0.7034 |
| November 2018 | A$0.7316 | A$0.7130 |
| December 2018 | A$0.7375 | A$0.7051 |
| January 2019 | A$0.7268 | A$0.6945 |
| February 2019 | A$0.7260 | A$0.7072 |
| March 2019 | A$0.7145 | A$0.7009 |
| April 2019 | A$0.7200 | A$0.7025 |

**B. Capitalization and Indebtedness**

The table below sets forth our total indebtedness and shows our capitalization as of June 30, 2018. You should read this table in conjunction with our consolidated financial statements included in this Registration Statement on Form 20-F, together with the accompanying notes and the other information appearing under the heading "Item 5. Operating and Financial Review and Prospects".

| | As of June 30, 2018 (In Australian Dollars) |
|---|---|
| Cash and cash equivalents | A$ 14,825,532 |
| Long-term debt | A$ — |
| Contributed equity | 162,801,028 |
| Accumulated losses | (148,592,879) |
| Reserves | 4,791,410 |
| Total | 18,999,559 |
| Total capitalization | A$ 18,999,559 |

**C. Reasons for the Offer and Use of Proceeds**

Not applicable.

**D. Risk Factors**

Our business faces significant risks. You should carefully consider all of the information set forth in this registration statement, including the following risk factors. Our business, results of operations, and financial condition could be materially and adversely affected by any of these risks, and in such event, the trading price of our ordinary shares, which underlie our ADSs, would likely decline and you might lose all or part of your investment. This registration statement also contains forward-looking statements that involve risks and uncertainties and our results could materially differ from those anticipated in these forward-looking statements. See "Special Note Regarding Forward-Looking Statements" at the beginning of Item 5.

**Risks Related to Our Business**

***We have experienced significant losses, expect losses to continue for the foreseeable future and may never achieve or maintain profitability.***

Although we have begun full scale marketing and sales of our RECELL System in the U.S. and other jurisdictions, such sales have been limited to date and we have not yet obtained profitability. We had a total comprehensive loss of A$16,519,155, A$11,511,024 and A$7,778,015 for our fiscal years ended June 30, 2018, 2017 and 2016, respectively. We have incurred a cumulative deficit of A$148,592,879 through June 30, 2018. We anticipate that we may continue to incur losses at least until margins from U.S. sales of the RECELL System are adequate to fund operating expenses. We may not be able to successfully achieve or sustain profitability. Successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure.

***We may be unsuccessful in obtaining additional approvals for our RECELL System for the treatment of pediatric burns, trauma wounds and skin conditions such as vitiligo.***

Although our Premarket Approval (PMA) application for the RECELL System was approved by the U.S. Food and Drug Administration (FDA) for use the treatment of acute thermal burn wounds in patients 18 years and older in September 2018, it has not been approved for additional indications such as pediatric burns or trauma wounds, or for the treatment of vitiligo. We plan to expand into each of these indications and will need to

apply for a supplement to our PMA approval with the FDA in connection with each proposed additional indication. While clinical trials for such uses are presently underway or planned, there can be no assurance that we will ever receive approval by the FDA for the use of our RECELL System for such additional applications. Such a failure of approval would have a material negative effect to our future prospects.

***We are dependent on our contract with the U.S. Biomedical Advanced Research and Development Authority (BARDA), and if we do not continue to receive funding under this contract, we may need to obtain alternative sources of funding.***

We have a contract with BARDA valued currently at US$50.4 million (approximately A$68.1 million) related to funding for the development of the RECELL System and future use of the product to assist disaster preparedness and response in the U.S. for mass casualties involving burn victims. As of December 31, 2018, we had received cumulative payments of US$17.18 million (A$22.6 million) under the BARDA contract. Under the contract BARDA has agreed to fund and provide technical support for the development of the RECELL System including two randomized, controlled pivotal clinical trials, Compassionate Use and Continued Access programs, development of the health economic model demonstrating the cost savings associated with the RECELL System, and two randomized, controlled clinical trials in pediatric burn patients. Also included in the BARDA contract is a provision for the future procurement of the RECELL System by BARDA under a vendor-managed inventory system to bolster disaster preparedness. There can be no assurances that BARDA will not terminate the contract and changes in government agenda and annual budgets may result in changing priorities and funding mandates at BARDA. Any reduction or delay in BARDA funding may force us to seek alternative funding, which may not be available on non-dilutive terms, terms favorable to us or at all, or cease our development programs related to the BARDA contract.

***Development and commercialization of any products requires successful completion of the regulatory approval process and may suffer delays or fail.***

In the U.S., as well as other jurisdictions, we have been and will be required to apply for and receive regulatory authorization before we can market our products. Although our RECELL System has been approved for use in the treatment of acute thermal burn wounds in patients 18 years and older in the U.S., we will have to apply for a supplement to our PMA approval to market the product for use in the treatment of pediatric burns, trauma injuries and vitiligo. In China and Australia, the RECELL System is approved use for the treatment of burns, acute wounds, scars and vitiligo. In Europe the product has been approved for the treatment of burns, chronic wounds, scars and vitiligo. We will require additional approvals from regulatory authorities within these countries to market the product for the treatment of other indications, and from any other jurisdictions in which we seek to market the product. This process can be time consuming and complicated and may result in unanticipated delays or fail altogether. To secure marketing authorization, an applicant generally is required to submit an application that includes the data supporting preclinical and clinical safety and effectiveness as well as detailed information on the manufacturing and control of the product, proposed labeling and other additional information. Before marketing authorization is granted, regulatory authorities may require the inspection of the manufacturing facility or facilities and quality systems (including those of third parties) at which the product candidate is manufactured and tested, as well as potential audits of the non-clinical and clinical trial sites that generated the data cited in the marketing authorization application.

We cannot predict whether any additional marketing authorizations will ultimately be granted or how long the applicable regulatory authority or agency will take to do so. Regulatory agencies, including the FDA, have substantial discretion in the approval process. In addition, the approval process and the requirements governing clinical trials vary from country to country. The policies of the FDA or other regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay the necessary approval of any products we may develop and commercialize. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or elsewhere. If we are slow or unable to adapt to new or changed requirements, or if we are not able to maintain

regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Additionally, any future regulatory approvals that we receive may also contain requirements for costly post-marketing testing and surveillance to monitor the safety and effectiveness of the product. Once a product is approved, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submission of safety and other post-marketing reports, registration and continued compliance with good manufacturing practices for any clinical trials that we conduct post-approval.

***Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that product candidate in other jurisdictions.***

Obtaining and maintaining regulatory approval for a product in one jurisdiction does not guarantee that we will be able to obtain or maintain similar approval in other jurisdictions, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for use of our RECELL System for the treatment of pediatric burns, trauma injuries and/or vitiligo, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries if not currently approved today. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a medical device must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

***We may encounter substantial delays in any further clinical studies necessary to support any regulatory applications for additional commercial applications of our technology.***

We cannot guarantee that any preclinical testing or clinical trials will be conducted as planned or completed on schedule, if at all. As a result, we may not achieve the expected clinical milestones necessary for approval by the FDA, or other regulators, for the use of our RECELL System for additional applications in the United States or other countries.

A failure can occur at any stage of testing. Events that may prevent successful or timely commencement, enrollment or completion of clinical development include:

- delays in raising, or inability to raise, sufficient capital to fund the planned trials;
- delays in reaching a consensus with regulatory agencies on trial design;
- changes in trial design;
- inability to identify, recruit and train suitable clinical investigators;
- inability to add new clinical trial sites;
- delays in reaching agreement on acceptable terms for the performance of the trials with prospective clinical research organizations and clinical trial sites;
- delays in recruiting suitable clinical sites and patients (i.e., subjects) to participate in clinical trials;
- imposition of a clinical hold by regulatory agencies for any reason, including negative clinical results, safety concerns or as a result of an inspection of manufacturing or clinical operations or trial sites;
- failure by any relevant parties to adhere to clinical trial requirements;

- failure to perform in accordance with the FDA's current Good Clinical Practices, or cGCP, or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays caused by clinical trial sites not completing a trial;
- failure to demonstrate adequate effectiveness;
- occurrence of serious adverse events in clinical trials that are associated with the product candidates that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- disagreements with regulatory agencies in the interpretation of the data from our clinical trials.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete clinical trials for our product candidates. If we are not able to successfully complete clinical trials or are not able to do so in a timely and cost-effective manner, we will not be able to obtain regulatory approval for the use of our RECELL System for additional applications, all of which could have a material adverse effect on our business, financial condition and results of operations.

***We may be unsuccessful in commercializing our RECELL System, or other future products, due to unfavorable pricing regulations or third-party coverage and reimbursement policies.***

We cannot guarantee that we will receive favorable pricing and reimbursement for use of our products. The rules and regulations that govern pricing and reimbursement for medical products vary widely from country to country or from indication to indication, and within the U.S. can also vary widely from one health system or hospital to the next. In some foreign jurisdictions, including the European Union, the government largely controls pricing of medical products. In other countries, coverage negotiations must occur at the regional or hospital level. Pricing negotiations can take considerable time after the receipt of marketing approval for a medical product.

As a result, even after obtaining regulatory approval for a product in a particular country, we may be subject to price regulations or limited reimbursement, which may delay or limit our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our total investment in our RECELL System or other future products, even after obtaining regulatory approval.

If we are unable to promptly obtain coverage and profitable payment rates from hospital budget, government-funded and private purchasers for the RECELL System or any future products, this could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***We have limited financial resources and will likely require additional financings to continue the development and commercialization of our RECELL System or any future products, which may cause dilution to our existing shareholders or place restrictions on our operations. If additional financing is not available, we may have to postpone, reduce or cease operations.***

If we are unable to achieve profitability sufficient to permit us to fund our operations and other planned actions, we may be required to raise additional capital. There can be no assurance that such capital would be available on favorable terms, or at all. If we raise additional capital through the issuance of equity or convertible debt securities, the percentage ownership held by existing shareholders may be reduced, and the market price of our ordinary shares which underlie our ADSs could fall due to an increased number of shares available for sale in the market. Debt financing, if available, may involve restrictive covenants, which may limit our operating

flexibility with respect to certain business matters. If we are unable to secure additional capital as circumstances require, we may not be able to fund our planned activities or continue our operations.

***We have limited experience manufacturing our products in large-scale commercial quantities and we may face manufacturing risks that may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our business and operating results.***

Our success depends, in part, on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have a manufacturing facility located in Ventura, California where we produce, package and warehouse the RECELL System. We also rely on certain global third-party manufacturers such as Baxter International Inc., Hospira (a division of Pfizer), and Becton Dickinson and Company, for production of some of the components used in the RECELL System. If our facility, or the facilities of our third-party contract manufacturers, suffers damage, or a force majeure event, this could materially impact our ability to operate.

We are also subject to other risks relating to our manufacturing capabilities, including:

- Quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, who are required to meet our quality specifications, some of whom are our single-source suppliers for the products they supply;
- failure to secure raw materials, components and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- inability to secure raw materials, components and materials of sufficient quality to meet the exacting needs of medical device manufacturing;
- failure to maintain compliance with quality system requirements or pass regulatory quality inspections;
- inability to increase production capacity or volumes to meet demand; and
- inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements.

These risks could be exacerbated by our limited experience as an entity with large-scale commercial manufacturing. As demand for our products increases, we will have to invest additional resources to purchase raw materials and components, sub-assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently to meet demand for our products, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. It may not be possible for us to manufacture our products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations. In addition, the Company is continually identifying additional third-party manufacturers who could serve if necessary as replacement manufacturers should the need arise.

***Product recalls or inventory losses caused by unforeseen events may adversely affect our operating results and financial condition.***

Our products are manufactured, stored and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture, storage and distribution of our product candidates, subjects us to risks. In addition, process deviations or unanticipated effects of approved process changes may result in production runs of our RECELL System not complying with stability requirements or specifications. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories and in some cases product recalls, with consequential reputational damage and the risk of product

liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches. In the event our production efforts require a recall or result in an inventory loss, our operating results and financial condition may be adversely affected.

***If we fail to manage our growth effectively, our business could be disrupted.***

Our future financial performance and ability to successfully commercialize our products, which is not guaranteed, and to compete in the market will depend, in part, on our ability to manage any future growth effectively. We expect to make significant investments to facilitate our future growth through, among other things:

- new product development;
- clinical development of our RECELL System to such areas as pediatric burns, trauma injuries and vitiligo;
- clinical trials for additional indications; and
- funding of our marketing and sales infrastructure.

Any failure to manage future growth effectively could have a material adverse effect on our business and results of operations.

***Our growth and success depend on our ability to attract and retain additional highly qualified and skilled sales and marketing, research and development, operational, managerial and finance personnel.***

Competition for skilled personnel is intense and the unexpected loss of an employee with a particular skill could have a material adverse effect on our operations until a replacement can be found and trained. If we cannot attract and retain skilled scientific and operational personnel for our research and development and manufacturing operations on acceptable terms, we may not be able to develop and commercialize our products. Further, any failure to effectively integrate new personnel could prevent us from successfully growing our company.

***We currently report our financial results under IFRS, which differs in certain significant respects from U.S. GAAP.***

Currently we report our financial statements under IFRS. There have been and there may in the future be certain significant differences between IFRS and Generally Accepted Accounting Principles in the United States ("U.S. GAAP"), including differences related to revenue recognition, intangible assets, share-based compensation expense, income tax and earnings per share, and in the timing, frequency and format of annual and periodic financial statements. As a result, our financial information and reported earnings for historical or future periods could be significantly different if they were prepared in accordance with U.S. GAAP. In addition, we do not intend to provide a reconciliation between IFRS and U.S. GAAP unless it is required under applicable law. As a result, you may not be able to meaningfully compare our financial statements under IFRS with those companies that prepare financial statements under U.S. GAAP.

**Risks Relating to our Industry and Intellectual Property**

***We face competition from the existing standard of care and any future potential changes in medical practice and technology and the possibility that our competitors may develop products, treatments or procedures that are similar, more advanced, safer or more effective than ours.***

The medical device, biotechnology and pharmaceutical industries, specifically relating to the areas where we currently or intend to market our RECELL System, are intensely competitive and subject to significant changes due to technology and medical practice standards. We may face competition from any number of different sources with respect to any products we develop and commercialize.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products, treatments or procedures that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our RECELL System or any future products we develop. Many of our current or future competitors may have significantly greater financial resources and experience and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we may have. Mergers and acquisitions in the pharmaceutical, medical device, and biotechnology industries or wound care markets may result in increased concentration of resources among a smaller number of our competitors. Other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***We could be subject to product liability lawsuits, which could result in costly and time-consuming litigation and significant liabilities.***

The development of medical device products, such as our RECELL System, involves an inherent risk of product liability claims and associated financial liability and adverse publicity. Any products we may develop could be found to be harmful or to contain harmful substances and exposes us to substantial liability and risk of litigation or may force us to discontinue production. We may be unable to obtain or maintain insurance on reasonable terms or otherwise protect ourselves against potential product liability claims that could impede or prevent further business development of any products we may create and commercialize. Furthermore, a product liability claim could damage our reputation, whether or not such claims are covered by insurance or have merit. A product liability claim against us or the withdrawal of a product from the market could have a material adverse effect on our business or financial condition. Furthermore, product liability lawsuits, regardless of their success, would likely be time consuming and expensive to resolve and would divert management's time and attention, which could seriously harm our business.

***If we are unable to effectively protect our intellectual property, we may not be able to operate our business and third parties may be able to use and profit from our technology, both of which would impair our ability to be competitive***

Our success will be heavily dependent on our ability to obtain and maintain meaningful patent protection for our technologies and products throughout the world. Patent law relating to the scope of claims in the technology fields in which we will operate is still evolving. The amount of ongoing protection for our proprietary rights therefor is uncertain. We will rely on patents to protect a significant part of our intellectual property and to enhance our competitive position. However, our presently pending or future patent applications may be denied, and any patent previously issued to us or our subsidiaries may be challenged, invalidated, held unenforceable or circumvented. Furthermore, the patent protections we have been granted may not be broad enough to prevent competitors from producing products similar to ours. In addition, the laws of various foreign countries in which we plan to compete, such as China, may not protect our intellectual property to the same extent as do the laws of the U.S. If we fail to obtain adequate patent protection for our proprietary technology, our ability to be commercially competitive will be materially impaired.

In the ordinary course of business and as appropriate, we intend to apply for additional patents covering both our technologies and products, as we deem appropriate. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or developing competing products and technologies. In addition, because patent law is evolving in the life science industry, the patent positions of companies like ours are uncertain. As a result, the validity and enforceability of our patents cannot be predicted with certainty.

***We may find it difficult to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on all of our technologies and products in every jurisdiction is expensive. Competitors could reverse engineer our technologies in jurisdictions where we have not obtained patent protection to develop their own products. These products may compete with our products and may not be covered by any patent claims or other intellectual property rights.

The laws of some countries do not protect intellectual property rights to the same extent as the laws of the U.S. and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. This lack of protection, particularly in relation to biotechnology, could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert the efforts and attention of key personnel from other aspects of our business.

***We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.***

If we choose to go to court to stop someone else from using the inventions claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would distract our key personnel, consume time and other resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that a court will decide that these patents are invalid or unenforceable and that we do not have the right to stop the other party from using the inventions or, even if the validity or enforceability of these patents is upheld, the court may refuse to stop the other party because the competitors' activities do not infringe our rights.

***If third parties make claims of intellectual property infringement against us, or otherwise seek to establish their intellectual property rights equal or superior to ours, we may have to spend time and money in response and potentially discontinue certain of our operations.***

While we currently do not believe it to be the case, third parties may claim that we are employing their proprietary technology without authorization or that we are infringing on their patents. If such claims were made, we could incur substantial costs coupled with diversion of our management and key technical personnel in defending against these claims. Furthermore, parties making claims against us may be able to obtain injunctive or other equitable relief which could effectively halt our ability to further develop, commercialize and sell products. In the event of a successful claim of infringement, courts may order us to pay damages and obtain one or more licenses from third parties. We may not be able to obtain these licenses at a reasonable cost, if at all. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing available products and have a material negative effect on our business.

***Any suits filed against us by third-parties alleging we infringe their intellectual property rights could harm our business and operating results as well as our reputation.***

There is considerable patent and other intellectual property activity in the industry in which we operate. We may be unaware of intellectual property rights of others that may cover some or all of our technology. Additionally, notwithstanding our receipt of a patent, a third-party may nevertheless challenge the validity of one or more claims included in the patent, which may require significant expenditure of funds, as well as time and effort by key personnel, to defend our claims.

***Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.***

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and

Education Reconciliation Act, or the Health Care Reform Law, was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. healthcare industry. The Health Care Reform Law, among other things, (i) subjects biologic products to potential competition by lower-cost biosimilars, (ii) addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, (iii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and (v) promotes a new Medicare Part D coverage gap discount program.

In addition, other legislative changes have been proposed and adopted in the U.S. since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2% Medicare payment reductions went into effect. Additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

***Our operations are subject to anti-corruption laws, including Australian bribery laws and the U.S. Foreign Corrupt Practices Act. (FCPA) and other anti-corruption laws that apply in countries where we do business.***

Anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under these anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other laws including trade related laws. If we are not in compliance with these laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity.

Likewise, any investigation of any potential violations of these laws by respective government bodies could also have an adverse impact on our reputation, our business, results of operations and financial condition

**Risks Relating to Our Ordinary Shares and ADSs**

***We have never paid a dividend on our ordinary shares and do not intend to do so in the foreseeable future, and consequently, investors' only opportunity to realize a return on their investment in our company is through the appreciation in the price of our ordinary shares.***

We do not anticipate paying cash dividends on our ordinary shares in the foreseeable future and intend to retain all earnings, if any, for our operations. If we decided to pay dividends at some future time, we may not have sufficient funds legally available to do so. Even if funds are legally available for distribution, we may be

unable to pay any dividends to our shareholders because of limitations imposed by a lack of liquidity. Accordingly, our shareholders may have to sell some or all of their ordinary shares in order to generate cash flow from their investment. Our shareholders may not receive a gain on their investment when they sell their ordinary shares and may lose some or all of their investment. Any determination to pay dividends in the future on our ordinary shares will be made at the discretion of our board of directors and will depend on our results of operations, financial conditions, contractual restrictions, restrictions imposed by applicable law, capital requirements, and other factors that our board of directors deems relevant.

***As long as we remain subject to the rules of the Australian Stock Exchange and if we list on NASDAQ, we will be unable to access equity capital without shareholder approval if such equity capital sales would result in an equity issuance above regulatory thresholds and consequently we may be unable to obtain financing sufficient to sustain our business if we are unsuccessful in soliciting requisite shareholder approvals.***

Our ability to access equity capital is currently limited by ASX Listing Rule 7.1 (and ASX Listing Rule 7.1A, if shareholder approval for ASX Listing Rule 7.1A additional capacity is obtained annually), which provides that a company must not, subject to specified exceptions (including approval by shareholders), issue or agree to issue during any consecutive 12-month period any equity securities, or other securities with rights to conversion to equity, if the number of those securities exceeds 15% (plus an additional 10%, if ASX Listing Rule 7.1A approval is obtained) of the number of securities in the same class on issue at the commencement of that 12-month period.

Our equity issuances will be limited by Rule 7.1 (and 7.1A, if applicable) as long as we continue to be listed on the ASX and this constraint may prevent us from raising the full amount of equity capital needed for operations without prior shareholder approval. There are also restraints on a single shareholder holding more than 20% of the issued share capital. See Risk Relating to Takeovers below.

If we are successful in listing on NASDAQ (which approval is further discussed in Item 9.C under the heading “Markets”), we will be subject to NASDAQ Listing Rule 5635(d), commonly referred to as the NASDAQ 20% Rule, which requires shareholder approval of a transaction other than a public offering involving the sale, issuance, or potential issuance by a company of ordinary shares (or securities convertible into or exercisable for ordinary shares) equal to 20% or more of the ordinary shares, or 20% or more of the voting power outstanding before the issuance for less than the greater of book or market value of the shares. While less restrictive than ASX Listing Rule 7.1 (unless ASX Listing Rule 7.1A approval is obtained, in which case it is more restrictive), the operation of the NASDAQ 20% rule could limit our ability to raise capital through issuance of shares or convertible securities without jeopardizing our listing status. If we were to violate the NASDAQ 20% rule, assuming we obtain initial listing approval, our company would be subject to delisting from NASDAQ and share prices and trading volumes would likely suffer.

***There is no assurance that our NASDAQ listing application will be approved and that it will be successful.***

Although our ADSs are currently quoted on the OTCQX, we intend to be listed on the NASDAQ Capital Market in 2019. There is no assurance that our NASDAQ listing application will be approved or that an active public market for our ADSs will further develop or be sustained (which approval is further discussed in Item 9.C under the heading “Markets”).

Further, if an active public market in the U.S. for the ADSs does not further develop, the market price and liquidity of the ADSs may be materially and adversely affected. While we have applied for the listing of the ADSs on the NASDAQ Capital Market, a liquid public market in the U.S. for the ADSs may not further develop or be sustained after the transition from the OTCQX market to the NASDAQ Capital Market. In the past, following periods of volatility in the market price of a company’s securities, shareholders often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of senior management and, if adversely determined, could have a material adverse effect on our results of operations and financial condition.

***The market price and trading volume of our ordinary shares and ADSs may be volatile and may be affected by variability in our company's performance from period to period and economic conditions beyond management's control.***

The market price of our ordinary shares and ADSs may be highly volatile and could be subject to wide fluctuations. This means that our shareholders could experience a decrease in the value of their ordinary shares regardless of our operating performance or prospects. The market prices of securities of companies operating in the medical device and biotech sectors have often experienced fluctuations that have been unrelated or disproportionate to the operating results of these companies. In addition, the trading volume of our ordinary shares and ADSs may fluctuate and cause significant price variations to occur. If the market price of our ordinary shares declines significantly, our shareholders may be unable to resell our ordinary shares at or above their purchase price, if at all. There can be no assurance that the market price of our ordinary shares will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of our ordinary shares or result in fluctuations in their price and trading volume include:

- actual or expected fluctuations in our operating results;
- actual or expected changes in our growth rates or our competitors' growth rates;
- results of clinical trials of our product candidates;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- reports of one or more patient serious adverse events;
- publication of research reports by securities analysts about us or our competitors in the industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations of exchange rates between the U.S. dollar and the Australian dollar;
- issuances by us of debt or equity securities;
- litigation involving our company, including: shareholder litigation; investigations or audits by regulators into the operations of our company; or proceedings initiated by our competitors or clients;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- sales or perceived potential sales of the ADSs or ordinary shares by us, our directors, senior management or our shareholders in the future;
- short selling or other market manipulation activities;
- announcement or expectation of additional financing efforts;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks;
- our inability to raise additional capital, limiting our ability to continue as a going concern;
- changes in market prices for our product or for our raw materials;
- changes in market valuations of similar companies;
- changes in key personnel for us or our competitors;

- speculation in the press or investment community;
- changes or proposed changes in laws and regulations affecting our industry;
- conditions in the financial markets in general or changes in general economic conditions.

***The requirements of being a public company in the U.S. may strain our resources and divert management's attention.***

As a public company, we will be subject to the reporting requirements of the U.S. Securities Exchange Act of 1934, as amended (the "Exchange Act"), the U.S. Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), the Dodd-Frank Act, the listing standards of the NASDAQ Capital Market as applicable to a foreign private issuer, which are different in some material respects from those required for a U.S. public company, as well as the reporting requirements under the ASX. We expect that the requirements of these rules and regulations will increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and place significant strain on our personnel, systems and resources. As a result of disclosure of information in this filing or future filings required of a public company, our business and financial condition will become more visible, which may result in threatened or actual litigation, including by competitors, shareholders or third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

***As a foreign private issuer, if and after our shares are listed on the NASDAQ Capital Market, we will be permitted and intend to follow certain home-country corporate governance practices in lieu of certain NASDAQ requirements applicable to U.S. issuers, affording less protection to holders of our ordinary shares.***

As a foreign private issuer, if and after our ADSs are listed on the NASDAQ Capital Market, we will be permitted to follow certain home-country corporate governance practices in lieu of certain NASDAQ requirements. We intend to avail ourselves of all such exemptions available to us, including without limitation, the following:

- As a company incorporated in Australia and listed on the ASX, we expect to follow our home country practice with respect to the composition of our Board and committees;
- Unlike the NASDAQ requirements, the corporate governance practice and requirements in Australia do not require us to have a majority of our board of directors to be independent, but if we do not do so, the Company is required to disclose annually to all shareholders which corporate governance recommendations (such as having a majority of our board of directors to be independent) have not been adhered to, why they have not been and what has been done in place of compliance with those recommendations;
- Our Board is not required under home country regulations to hold regular executive sessions (but is free to do so at any time) where only independent directors are present (but any director with a personal interest in the outcome of an item being voted on is excluded from the deliberation and/or voting, unless the Board determines otherwise) and we do not intend to do so if our listing on NASDAQ is approved.

Such Australian home-country practices may afford less protection to holders of our ordinary shares than would be available to our shareholders if we were incorporated in the U.S., governed by U.S. law and subject to all applicable NASDAQ regulations. At any general meeting of shareholders a resolution put to the vote of the meeting must be decided on a show of hands unless a poll is effectively demanded, and the demand is not withdrawn. On a show of hands, each member present in person and each other person present as a proxy, attorney or representative of a member has one vote. On a poll, each member present in person has one vote for

each share held by the member and each person present as proxy, attorney or representative of a member has one vote for each share held by such member that the person represents. Voting based on a show of hands may make it more difficult for shareholders to influence our management. NASDAQ rules require that the quorum required for a meeting of shareholders be not be less than 33 1/3 percent of the outstanding shares of the Company's ordinary shares, however, we intend to follow our home-country corporate governance practices with respect to quorum, and as a result, the quorum required for an ordinary meeting of shareholders will consist of at least three shareholders present in person, or by proxy, attorney or representative appointed pursuant to our Constitution. As required for foreign private issuers, each NASDAQ requirement with which we do not intend to comply, if and after our ordinary shares are listed on the NASDAQ Capital Market, is listed below under Item 6.C, together with a description of our applicable home-country practice. Please refer also to Item 9.C under the heading "Markets" for further discussion about the status of our NASDAQ listing application.

***We are a "foreign private issuer" under the rules and regulations of the SEC and are thus exempt from a number of rules under the Exchange Act and will be permitted to file less information with the SEC than a company incorporated in the U.S.***

As a "foreign private issuer" under the Exchange Act, we are exempt from certain rules under the Exchange Act and will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act, or to comply with Regulation FD, which restricts the selective disclosure of material nonpublic information. In addition, we will be exempt from certain disclosure and procedural requirements applicable to proxy solicitations under Section 14 of the Exchange Act. Our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act. Accordingly, there may be less publicly available information concerning us than there is for a company domiciled in the U.S., and such information may not be provided as promptly as it is currently provided by companies domiciled in the U.S. If we lose our status as a foreign private issuer, we will no longer be exempt from such rules and, among other things, will be required to file periodic reports and financial statements with the SEC as if we were a company incorporated in the U.S. The costs incurred in complying with these additional requirements could be substantial.

***The dual listing of our ordinary shares and the ADSs may adversely affect the liquidity and value of the ADSs.***

After the ADSs are listed on the NASDAQ Capital Market, our ordinary shares will continue to be listed on the ASX. Although the ADSs currently trade on the OTCQX market, we cannot predict the effect of the transition of this dual listing to trading on of the ADSs on NASDAQ Capital Market will have on the value of our ordinary shares and ADSs. However, the dual listing of our ordinary shares and ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the further development of an active trading market for the ADSs in the U.S. The price of the ADSs could also be adversely affected by trading in our ordinary shares on the ASX.

Changes in foreign currency exchange rates could impact amounts you receive as a result of any dividend or distribution we declare on our ordinary shares.

Any significant change in the value of the Australian dollar may impact amounts you receive in U.S. dollars as a result of any dividend or distribution we declare on our ordinary shares as a holder of our ADSs.

More specifically, at present any dividends that we may pay on our ordinary shares will be in Australian dollars. The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses, including any such fees or expenses incurred to convert any such Australian dollars into U.S. dollars. You will receive any such distributions in U.S. dollars in proportion to the number of our ordinary shares your ADSs represent. Depreciation of the U.S. dollar against the Australian dollar would have a negative effect on any such distribution payable to you.

***Holders of our ADSs have fewer rights than shareholders under Australian law, and their voting rights are limited by the terms of the deposit agreement.***

The rights of shareholders under Australian law to take actions, such as voting their shares, receiving dividends and distributions, examining our accounting books and records, bringing derivative actions, and exercising appraisal rights, are available only to shareholders of record. Because the depositary, through its custodian agents, is the record holder of the ordinary shares underlying the ADSs, only the depositary can exercise those rights in connection with the deposited shares.

Holders of ADSs may exercise their voting rights only in accordance with the provisions of the deposit agreement. For more information see the description of the deposit agreement in Item 12C. Upon receipt of voting instructions from them in the manner set forth in the deposit agreement, the depositary will make efforts to vote the shares underlying the ADSs in accordance with the instructions of ADS holders. The depositary and its agents may not be able to send voting instructions to holders of ADSs or carry out their voting instructions in a timely manner. Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of ADSs may not be able to exercise their right to vote. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

***Holders of ADSs may not receive distributions on our ordinary shares or any value for them if it is illegal or impractical to make them available to such holders.***

The depositary of our ADSs has agreed to pay holders of ADSs the cash dividends or other distributions it or the custodian for our ADSs receives on our ordinary shares or other deposited securities after deducting its fees and expenses. Holders of ADSs will receive these distributions in proportion to the number of our ordinary shares that such ADSs represent. However, the depositary is not responsible for making such payments or distributions if it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act of 1933, as amended (the "Securities Act"), but that are not properly registered or distributed pursuant to an applicable exemption from registration. The depositary is not responsible for making a distribution available to any holders of ADSs if any registration or other governmental approval required for such distribution cannot be obtained after reasonable efforts. We have no obligation to take any other action to permit distributions on our ordinary shares to holders of ADSs. This means that holders of ADSs may not receive the distributions we make on our ordinary shares if it is illegal or impractical to make them available to such holders. These restrictions may materially reduce the value of our ADSs.

***Holders of ADSs may be subject to transfer limitations.***

The ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any government or governmental body or legal requirement, or under any provision of the deposit agreement, or for any other reason.

***ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.***

The deposit agreement governing the ADSs representing our shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs, including in respect of claims under federal securities laws, against us or the

depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court.

However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement or the ADSs. Neither do we believe that any condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs of compliance with any provision of the Securities Act or the Exchange Act or the rules and regulations promulgated by the SEC thereunder. Neither does the waiver provision serve as a waiver of our or the depositary's compliance with federal securities laws. If you or any other holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with such matters, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

***We are incorporated under the laws of Australia, and U.S. investors may face difficulties in protecting their interests, and their ability to protect their rights through the U.S. federal courts may be limited.***

It may be difficult to bring and enforce actions against us because we are incorporated under the laws of Australia. Some or all of our directors will reside in various jurisdictions outside the U.S. As a result, it may be difficult for investors to effect service of process within the U.S. upon our non-U.S. directors, or enforce judgments obtained in the U.S. courts against us or our non-U.S. directors.

In addition, there is some doubt as to whether the courts of Australia and other countries would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the federal or state securities laws of the U.S. or would hear actions against us or those persons based on those laws. Some remedies available under the laws of U.S. jurisdictions, including some remedies available under the U.S. federal securities laws, may not be allowed in Australia courts. Therefore, a final judgment for the payment of money rendered by any federal or state court in the U.S. based on civil liability, whether or not based solely on U.S. federal or state securities laws, may not be enforceable in countries other than the U.S.

***If research analysts publish unfavorable commentary or downgrade our ordinary shares it could adversely affect our share price and trading volume.***

The trading market for our ordinary shares will depend, in part, on the research and reports that research analysts publish about us and our business and industry. If one or more research analysts downgrade our shares, publish unfavorable commentary about the Company or cease publishing reports about us or our business, the price of our ordinary shares could decline. If one or more of the research analysts ceases coverage of our

company or fails to publish reports on us regularly, demand for our ordinary shares could decrease, which could cause our share price or trading volume to decline.

***We may be classified as a passive foreign investment company for U.S. federal income tax purposes, which could subject U.S. investors in our ordinary shares to significant adverse U.S. income tax consequences.***

Depending upon the value of our ordinary shares, which underlie the value of our ADSs, and the nature of our assets and income over time, we could be classified as a "passive foreign investment company", or "PFIC", for U.S. federal income tax purposes. Based upon our current income and assets and projections as to the value of our ordinary shares, we do not presently expect to be a PFIC for the current taxable year or the foreseeable future. While we do not expect to become a PFIC, if among other matters, our market capitalization is less than anticipated or subsequently declines, we may be a PFIC for the current or future taxable years. The determination of whether we are or will be a PFIC will also depend, in part, on the composition of our income and assets, which will be affected by how, and how quickly, we use our liquid assets. Because PFIC status is a factual determination made annually after the close of each taxable year, including ascertaining the fair market value of our assets on a quarterly basis and the character of each item of income we earn, we can provide no assurance that we will not be a PFIC for the current taxable year or any future taxable year.

If we were to be classified as a PFIC in any taxable year, a U.S. holder (as defined in Item 10E under the heading "*U.S. Federal Income Tax Considerations"*) would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non-U.S. corporation that doses not distribute all of its earnings on a current basis. Further, if we are classified as a PFIC for any year during which a U.S. holder holds our ordinary shares, we generally will continue to be treated as a PFIC for all succeeding years during which such U.S. holder holds our ordinary shares. For more information see Item 10E.2 under the heading "*U.S. Federal Income Tax Considerations – Passive Foreign Investment Company Rules*".

**Risks Relating to Takeovers**

***Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our ordinary shares, which could constrain our share price and reduce investor returns.***

We are incorporated in Australia and are subject to the takeover laws of Australia, including the Australian Corporations Act 2001 ("Corporations Act"). Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in a company's issued voting shares if the acquisition of that interest will lead to a person's voting power in such company increasing from 20% or below to more than 20%, or increasing from a starting point that is above 20% and below 90% without prior shareholder approval or the acquisition otherwise being exempt under the Corporations Act. Australian takeovers laws may discourage takeover offers being made for us or may discourage the acquisition of large numbers of our ordinary shares. This may have the ancillary effect of depriving or limiting our shareholders' strategic opportunities to sell their ordinary shares and may restrict the ability of our shareholders to obtain a premium from such transactions. See Item 10D under the heading, "*The Foreign Acquisitions and Takeovers Act 1975*."

***Our constitution and applicable Australian laws and regulations may adversely affect our ability to take actions that could be beneficial to our shareholders.***

As an Australian company we are subject to different corporate requirements than a corporation organized under the laws of the U.S. Our Constitution, as well as the Corporations Act, set forth various rights and obligations that are unique to Australian companies. These requirements operate differently than from many U.S. companies and may limit or otherwise adversely affect our ability to take actions that could be beneficial to our shareholders. Prior to investing in our ordinary shares investors should carefully review the summary of these matters set forth under Item 10B, under the heading "*Memorandum and Articles of Association*", as well as the copy of our complete Constitution, which is included as an exhibit to this registration statement.

## ITEM 4. INFORMATION ON THE COMPANY

### A. History and Development of the Company

We were incorporated under the laws of the Commonwealth of Australia on December 21, 1992 and commenced operating under the name "AVITA Medical Limited" October 6, 2008. The registered office is located at c/o Mertons Corporate Services Pty Ltd Level 7 330 Collins Street Melbourne VIC 3000, Australia, telephone number is +61 (0) 3 8689 9997 and fax number +61 (0) 8 9474 7742. Our corporate office and principal U.S. office is located at 28159 Avenue Stanford, Suite 220, Valencia, CA 91355, telephone number is+1 661 367 9170. Our address on the Internet is https://avitamedical.com. The information on, or accessible through, our website is not part of this registration statement on Form 20-F.

### B. Business Overview

We are a regenerative medicine company with a technology platform positioned to address unmet medical needs in burn injuries, trauma injuries, chronic wounds, and dermatological and aesthetics indications. Our patented and proprietary platform technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. The medical devices work by preparing Spray-On Skin™ Cells, an autologous cellular suspension comprised of the patient's skin cells necessary to regenerate natural healthy epidermis. This autologous suspension is sprayed onto the areas of the patient requiring treatment.

Our first U.S. product, the RECELL® System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018 for the treatment of acute thermal burn injuries in patients 18 years and older. The RECELL System is used to prepare Spray-On Skin Cells using a small amount of a patient's own skin, providing a new way to treat severe burns that significantly reduces the amount of donor skin required. The RECELL System is designed to be used at the point of care alone or in combination with split-thickness skin autografts depending on the depth of the burn injury. Compelling data from prospective, randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use globally, demonstrate that the RECELL System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings.

The RECELL System is Therapeutic Goods Administration (TGA)-registered in Australia and China Food and Drug Administration (CFDA)-cleared in China for use in the treatment of burns, acute wounds, scars and vitiligo. In Europe, the RECELL System received CE-mark approval for the treatment of burns, chronic wounds, scars and vitiligo.

#### Markets and Limitations of Standard of Care

Acute Thermal Burns

Acute thermal burns are life-threatening and debilitating injuries that are among the most expensive traumatic injuries to manage because of complex surgical procedures, long and costly hospitalization, rehabilitation and scar treatment. In the U.S., the largest market for the treatment of burns, approximately 486,000 people seek treatment for burns each year. Of these, at least 40,000 have burn injuries severe enough to require in-patient treatment, and it is estimated that 3,300 die each year. The majority of patients treated on an in-patient basis in the U.S. are treated in specialized burn centers. Countries outside the U.S. are smaller markets for the treatment of burns. For example, in Japan, the second largest healthcare market in the world, approximately 6,000 patients with severe burns treated in hospitals each year.

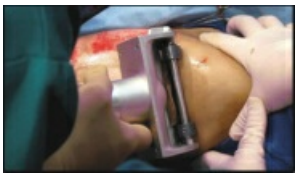
The severity of the burn is generally assessed based on the extent of the area burned, and the depth of the burns. The extent of the patient's burn injury is typically described in terms of percent of total body surface area, or "TBSA." For example, a burn covering an average sized adult arm would be roughly a 9% TBSA, while a

burn covering an entire leg would be roughly an 18% TBSA. The depth of the burn, referred to in terms of "degree" is generally classified into four categories:

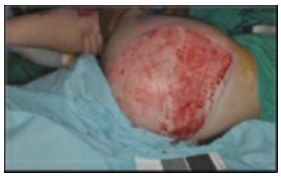
- Superficial or first-degree burns: Burns that do not penetrate through the epidermis and typically heal naturally.
- Partial-thickness or second-degree burns: Characterized by extending through the epidermis and including varying amounts of damaged dermis. Can be further subdivided into superficial and deep partial-thickness burns.
- Full thickness or third-degree burns: Characterized by injury to the entire dermal tissue down to the subcutaneous fat.
- Fourth-degree burns: Such burns are rare and extend beyond the subcutaneous fat tissue into the underlying structures, such as muscle or bone.

Burn treatment is dictated by the depth and extent of the injury, and deeper and more extensive injuries are most commonly treated with autologous split-thickness skin grafts (STSG) to achieve definitive closure of the burn wound. In a STSG, or autograft, the donor skin is harvested from a healthy part of the patient using a device called a dermatone as detailed in the pictures below. The donor skin is then transferred to the burn injury that has been prepared (debrided or cleaned).

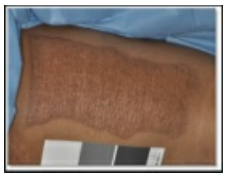
**Harvesting of Donor Skin for Use in Autografting**



Harvesting skin from donor site for autograft



Donor site wound created while harvesting skin for autograft



Typical donor site scar 52 weeks post procedure

Treatment with STSG creates additional trauma for the patient due to the harvesting of healthy donor skin. Although the use of STSG has been a standard treatment for more than 50 years, grafting is associated with significant pain, pruritus, infection, dyschromia, dyspigmentation, delayed healing, and hypertrophic scarring of the donor site.

The clinical benefits of earlier intervention for burn wounds are well recognized and include increased survival, reduced hospital length of stay, decreased pain duration, and reduced infection-related complications. However, in large TBSA injuries, the patient may not have enough donor skin available to allow for immediate treatment of the entire area of burn injuries with traditional grafting techniques. The lack of available healthy donor skin in patients with high TBSA burn injuries is often the central problem impacting time to autografting and definitive closure of the wounds. In severely burned patients, doctors often must wait until the donor sites have healed so that they can reharvest from the site, resulting in delays in treatment and healing, requiring multiple procedures and extended hospital time. While waiting for donor skin the burn wounds may be temporarily covered by allogenic skin graft, for example allograft (cadaver skin) or xenograft (typically pig skin). The overall cost of treatment with STSG is expensive, for example approximately US$579,000 and 59.4 days in hospital for a patient with a 40% TBSA mixed or full-thickness burn.

Because of the limited donor skin available for harvest in patients with high TBSA injuries, researchers have developed alternatives such as cultured epidermal autografts (CEA) in which a skin biopsy is taken from a patient and the cells are grown into sheets of skin in a laboratory and then returned for autografting onto the

patient. Limitations associated with CEAs, including Epicel® from Vericel Corporation, include the time to grow the sheets of skin (approximately three weeks), the fact that the skin grown contains only keratinocytes and therefore lack the melanocytes that provide pigmentation, and the high cost. As a result, CEAs have been lifesaving in very high TBSA patients (> 30% TBSA) but in the U.S. the use of CEAs have been limited to approximately 100 patients per year.

Trauma Wounds (Soft Tissue Injuries)

Trauma wounds or soft tissue injuries include abrasions, lacerations, punctures, gunshot wounds, crush wounds, and degloving. Severe traumatic wounds may require surgical intervention to close the wound and stabilize the patient. The most common trauma injuries requiring autografting are degloving and crush wounds. The harvesting and autografting procedures for trauma wounds are similar to the treatment of severe burn injuries, as are the limitations and shortcomings. Patients requiring autografting for trauma wounds are often treated in trauma centers in hospitals by plastic surgeons. Approximately half of the surgeons treating patients with severe burns requiring autografting in the U.S. also treat trauma patients requiring autografting, therefore the soft tissue injury market complements our commercialization efforts related to the U.S. burn market.

Vitiligo and Other Dermatological Indications

Vitiligo is a disease that causes the loss of skin pigmentation or color in patches which tend to increase in size over time. The extent and rate of color loss from vitiligo is unpredictable, can affect the skin on any part of the body, and may also affect hair and the inside of the mouth. Non-segmental vitiligo is the most common variant and impacts the majority of patients and is characterized by symmetrical patches that appear on both sides of the body; as on hands and knees.

Vitiligo occurs when melanocytes, the pigment-producing skin cells, die or stop producing melanin, the pigment that gives skin, hair and eyes color. Vitiligo is believed to be an autoimmune disorder in which a patient's immune system attacks and destroys the melanocytes in the skin. It may also be caused by heredity factors or a triggering event, such as sunburn, stress or exposure to industrial chemicals. Vitiligo affects people of all skin types, but it may be more noticeable in people with darker skin. The condition is not life-threatening or physically painful but can significantly alter physical appearance, have negative emotional and psychological consequences, and impair quality of life.

Vitiligo cannot be cured at present, and medical treatments generally fall into one of two categories:

- Treatments to arrest the spread of vitiligo, such as steroid creams andnon-steroidal anti-inflammatory creams. There are also a number of therapies under development designed to target the underling autoimmune disease. One challenge in terms of achieving the desired patient outcome is that stopping the spread of vitiligo will not restore pigmentation to the areas already damaged.
- Treatments to restore pigmentation include makeup and coverups, dermabrasion, laser, drug-light combinations, and autografts.

Survey results reveal a low level of patient satisfaction with current treatment options. The majority of vitiligo patients in the U.S. are treated by dermatologists. In 2016, China accounted for the highest prevalence in the world with 7.7 million cases, followed by the U.S. 2.6 million cases, Japan with 2.1 million and the EU with 1.4 million.

We expect to explore potential benefits of variants of the RECELL System platform in the aesthetics markets, estimated to be a US$10 billion market in the U.S. alone in 2018. As part of this program the Company may also target certain orphan diseases, such as epidermolysis bullosa and Hutchinson-Gilford progeria syndrome (HGPS) which are both rare genetic condition that require more effective treatments.

Chronic Wounds

The chronic and other hard-to-heal wound market consists of a broad population of more than 6 million patients in the U.S. suffering from condition such as venous leg ulcers, diabetic foot ulcers, pressure ulcers and non-healing surgical wounds. Chronic and other hard-to-heal wounds represent a US$25 billion burden to the U.S. healthcare system. Chronic and hard-to-heal wounds are caused by impairment in the biochemical and cellular healing processes due to local or systemic conditions and generally can take weeks or months to heal, if not longer. Such wounds can lead to significant morbidity, including pain, infection, impaired mobility, hospitalization, reduced productivity, amputation and mortality.

Venous Leg Ulcers:

Venous leg ulcers (VLUs) are associated with poor venous return (ischemia), primarily occurring as a result of age, obesity, previous leg injuries, deep venous thrombosis, and phlebitis. Venous ulcers are often recurrent, and an open ulcer can persist for weeks to many years. Treatment options for venous ulcers include leg elevation, compression therapy, dressings, pentoxifylline, and aspirin therapy. Surgical management is also indicated for ulcers that are large, of prolonged duration, or refractory to conservative measures. The refractory nature of these ulcers increases the risk of morbidity and mortality and they have a significant impact on patient quality of life. The financial burden of venous ulcers is estimated to be $2 billion per year in the U.S.

Diabetic Foot Ulcers:

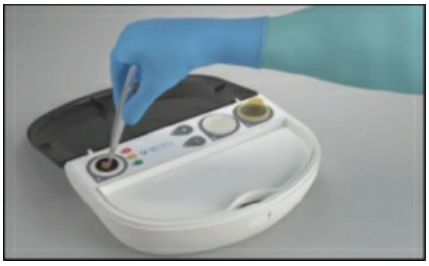
A diabetic foot ulcer (DFU) is an open sore or wound and is commonly located on the bottom of the foot. Approximately 5% to 7% of people with diabetes currently have or previously had a DFU, and approximately 25% will develop a DFU in their lifetime. Of those who develop a foot ulcer, 6% will be hospitalized due to infection or other ulcer-related complication. DFUs are the leading cause of non-traumatic lower extremity amputations in the U.S. In the U.S., it is estimated that 1.3 million people have DFUs, and over US$15 billion was spent on the care of this condition. Depending on the severity of the DFU, treatment includes offloading therapy to help redistribute foot pressure away from the ulcer, advanced wound dressings, and negative pressure wound therapy. For DFUs that require surgical closure, autografts, skin substitutes, or biologics can be utilized.

**The RECELL System**

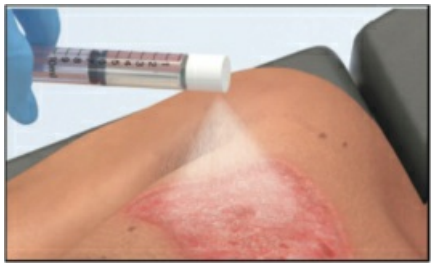
The RECELL® Autologous Cell Harvesting System (RECELL System) uses a small amount of a patient's own skin to prepareSpray-On Skin Cells, an autologous cellular suspension comprised of the patient's skin cells necessary to regenerate natural healthy epidermis. These Spray-On Skin Cells are prepared using the RECELL System at the point of care in as little as 30 minutes, providing a new way to treat thermal burns and other wounds or defects of the skin. The regenerative skin cell suspension includes keratinocytes, fibroblasts, and melanocytes, all of which play a critical role in wound healing. The ability of the RECELL System to retain melanocytes in the cell suspension is notable as these cells are fragile and are critical for the restoration of natural pigmentation to the area treated.

The RECELL System is a single-use (disposable), stand-alone, battery operated, autologous cell harvesting device containing enzymatic and buffer solutions, sterile surgical instruments, and actuators to achieve the disaggregation and delivery of skin cells. A small skin sample from a patient is enzymatically and mechanically processed in the RECELL System at the point of care to isolate skin cells and to produce a suspension of Spray-On Skin Cells for immediate delivery onto a prepared wound bed. The RECELL System can be used to prepare enough suspension to treat a wound up to 80 times the size of the donor skin sample. For example, a skin sample approximately the size of a credit card can be used to treat a wound that covers an adult patient's entire back.

**Preparation and Application of Spray-On Skin Cells Using the RECELL System**



Processing of skin sample in RECELL System to prepare Spray-On Skin Cells



Application of Spray-On Skin Cells to a patient's burn injury

In the U.S., the RECELL System is approved by the FDA for use in the treatment of acute thermal burn wounds in patients 18 years and older. The RECELL System is approved for use by appropriately-licensed healthcare professionals at the patients point of care to prepare autologous Spray-On Skin Cells for direct application to acute partial-thickness burns, or application in combination with meshed autografting for acute full-thickness burns. In the U.S., the RECELL System is produced in a configuration that allows the preparation of up to 24 ml of cell suspension which can be used to cover an acute wound area up to 1,920 $cm^2$, or approximately 10% of a patient's body.

In Australia, the RECELL System is TGA-registered for the treatment of burns, acute wounds, scars and vitiligo. In China, the RECELL System is CFDA-cleared for the treatment of burns, acute wounds, scars and vitiligo. The RECELL system is produced in a configuration that allows for treatment of up to 320 $cm^2$ for the markets in Australia and China. In Europe, the RECELL System received CE-mark approval for the treatment of burns, chronic wounds, scars and vitiligo.

**The RECELL System Clinical Results and Ongoing and Planned Clinical Trials**

The September 2018 FDA approval of the RECELL System for use in the treatment of acute thermal burns in patients 18 and older was supported by two prospective, randomized, controlled pivotal clinical trials, one in deep partial-thickness (second-degree) burns and one in mixed and full-thickness (third-degree) burns. The randomized, controlled trials demonstrated that treatment using the RECELL System requires substantially less donor skin than required with conventional split-thickness autografts to achieve closure of burn wounds. Reduction in donor skin requirements provides key clinical benefits to patients and significant reductions in the cost of treatment. The results of these clinical studies have been published in peer-reviewed scientific publications and have been presented at burn meetings and other major scientific conferences. Presentations by key opinion leaders have been made at over 20 scientific conferences in 2018 and 2019, including presentations of the pivotal clinical trial results and the clinical results related to use of the RECELL System in the treatment of burns in specific subgroups of patients and types of burn injuries, including facial burns and large TBSA burns. Patients included in many of these presentations were treated as part of the FDA-approved Investigational Device Exemption (IDE) Compassionate Use and Continued Access programs made available to burn patients prior to the FDA approval.

In addition to and extensive clinical trial program in acute thermal burns in adults, earlier-stage clinical studies have been conducted in pediatric burns, scald injuries, treatment of donor sites, vitiligo, chronic wounds (venous leg ulcers and diabetic foot ulcers), scar hypopigmentation, and acute trauma.

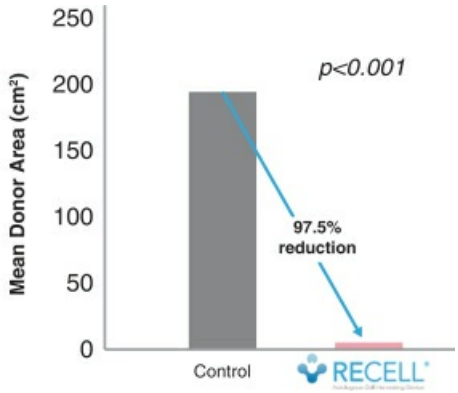
The RECELL System Clinical Results in Thermal Burns

*RECELL Pivotal Clinical Trial in Second-Degree Acute Thermal Burns*

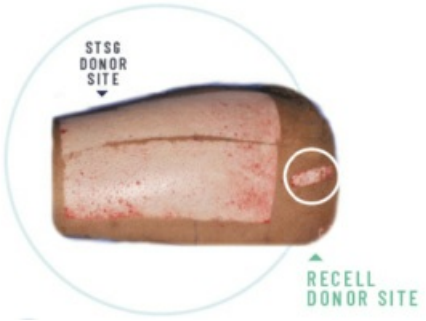
One of the two randomized, controlled clinical trials of the RECELL System supporting the September 2018 FDA approval was a study of patients with partial-thickness (second-degree burns) conducted at 12 U.S. burn centers. The pivotal trial evaluated 101 adult patients with thermal, partial-thickness burns covering 1% to 20% of their total body surface area. Patients served as their own control, and two comparable burn sites were selected for comparative testing on each patient. One burn site on each patient was treated with Spray-On-Skin Cells prepared using the RECELL System, while the other burn site was treated with the standard treatment, consisting of meshed autograft expanded 2:1.

During the pivotal trial, the patient donor skin required to be harvested to treat burn sites using the RECELL System was 97.5% less than the amount harvested to treat burn sites with the standard of care ($p<0.001$). Despite the statistically significant reduction in donor skin required to treat with the RECELL System, burn sites treated using the RECELL System achieved definitive closure and long-term outcomes, including durability, comparable to the burn sites treated with standard of care.

**Reduction in Donor Skin Requirements in Pivotal Trial in Second-Degree Burns**




Statistically significant reduction in donor skin requirement for use of the RECELL System in treatment versus standard 2:1 meshed autograft




Comparison of donor skin requirement for participant in clinical trial. Requirement for 2:1 mesh autograft (STSG) versus requirement for treatment using the RECELL System

Secondary endpoints measured in the trial highlighted additional clinical benefits of the significant reduction in donor skin harvested for treatment using the RECELL System, including:

- Significantly less donor-site pain (p£0.0025)
- Significantly higher patient satisfaction with donor-site appearance (p£0.0025)
- Significantly better donor-site scarring results (p£0.0025)
- Significantly greater incidence of donor-site healing at two weeks ($p<0.001$), with an odds ration of 4:3

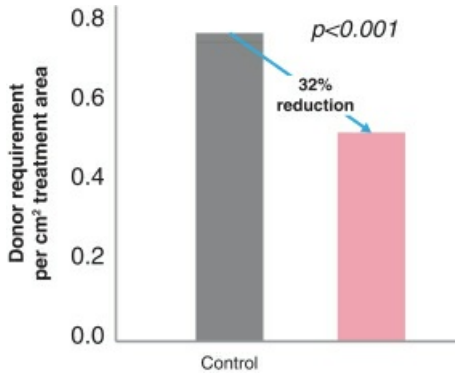
In the clinical trial, use of the RECELL System in the trial was safe and well tolerated with adverse experiences typical for the type of burn injury sustained. The results of this trial were published in a peer-reviewed scientific publication, the *Journal of Burn Care & Research*, in September 2018.

*RECELL Pivotal Clinical Trial in Third-Degree Acute Thermal Burns*

The second randomized, controlled clinical trial of the RECELL System supporting the September 2018 FDA approval was a study of patients with mixed and full-thickness (third-degree burns) conducted at seven U.S. burn centers. The pivotal trial evaluated 30 patients ranging in age from nine to 68 years old with thermal, mixed-thickness burns, including full-thickness burns, covering 5% to 46% of their total body surface area. Patients served as their own control, and two comparable burn sites were selected for comparative testing on each patient. One burn site was treated with the standard treatment, meshed autograft, while the other was treated with Spray-On-Skin Cells prepared using the RECELL System combined with more widely meshed autografts (for example, if a 2:1 meshed autograft was used to treat the control burn site, then a 3:1 meshed autograft used in combination with Spray-On Skin Cells was used to treat the RECELL site). The co-primary endpoints of the pivotal trial were reduction in donor skin requirements andnon-inferiority in complete wound closure.

The pivotal clinical trial achieved itsco-primary endpoints, demonstrating a statistically significant reduction in donor skin requirements versus standard of care while achieving comparable definitive wound closure. Treatment using the RECELL System achieved comparable healing, long-term scar and patient satisfaction outcomes using significantly less donor skin with no safety concerns. During the pivotal trial, the patient donor skin required to be harvested to treat burn sites with the RECELL System was 32% less than the amount harvested to treat burn sites with the standard of care ($p<0.001$). Despite the statistically significant reduction in donor skin required to treat using the RECELL System, eight weeks post treatment 92% of the burn sites treated using the RECELL System achieved complete healing versus 85% for the sites treated with the standard of care, demonstrating non-inferiority.

**Reduction in Donor Skin Requirements in Pivotal Trial in Second-Degree Burns**




Statistically significant reduction in donor skin requirement for use of the RECELL System in combination with widely-meshed autographs treatment versus standard meshed autograft.

Use of the RECELL System was safe and well tolerated with no device-related adverse events. The results of this trial were published online ahead of print in a peer-reviewed scientific publication, *Burns*, in December 2018, and will appear in the print version of the journal in 2019.

*BEACON Cost-Effectiveness Model Demonstrates Costs Savings Associated with use of RECELL System in Treatment of Severe Burns*

To investigate the value proposition and potential transformative health economic impact of the RECELL System in burn care, a hospital-perspective cost-effectiveness model was developed by IQVIA™, the Biomedical Advanced Research and Development Authority (BARDA), and AVITA Medical. The Burn-MCM (Medical Counter Measure) Effectiveness Assessment Cost Outcomes Nexus (BEACON) model evaluates how practice patterns, interventions and patient characteristics interact across all phases of care (wound assessment, debridement/excision, temporary coverage and permanent closure) to understand how patient and burn center outcomes change given the incorporation of a new burn care treatment, such as the RECELL System.

As described in a peer-reviewed scientific publication in *Advances in Therapy*, accepted in April 2019, the BEACON model uses sequential decision trees to depict the acute care pathway for burn patients, and then predicts how the RECELL System would modify treatment for patients with burns ranging from 10% to 40% TBSA. Clinical inputs were derived from randomized controlled trials, burn surgeon surveys and interviews, and the American Burn Association National Burn Repository. An accompanying budget impact model builds on the cost-effectiveness calculations to evaluate overall cost impact to a burn center or payor associated with incorporation of the RECELL System into patient care.

The BEACON model shows that treatment using the RECELL System for deep partial-thickness burns reduces total treatment costs by an average of 26%, or approximately US$37,000, for patients with 10% TBSA and 40%, or approximately US$150,000, for patients with 40% TBSA. For full-thickness burns, treatment using the RECELL System reduced total treatment cost by 3%, or approximately US$6,000, for patients with 10% TBSA, and by 42% or approximately US$243,000, for patients with 40% TBSA. The cost reductions are attributed to decreasing the length of hospital stay, the number of procedures required to close the burn wound, the donor site size and associated wound care, and number of downstream contracture release procedures. All cost savings estimates are net of the cost of the RECELL System.

The budget impact model was also used to calculate the annual budget impact of current standard of care for the treatment of burns versus treatment using the RECELL System for a burn center with 200 patients. The model determined that treatment using the RECELL System would reduce annual total treatment costs from approximately US$39.4 million to US$32.6 million, saving 17% or approximately US$6.8 million.

The BEACON model may be run for the specific demographics of an individual burn center or territory, allowing the burn institution or region to evaluate the potential benefits of the RECELL System within their specific population of burn patients. As described by researchers at a presentation at the American Burn Association 51st Annual Meeting in April 2019, the patient characteristics for the Arizona Burn Center (for example, age, burn depth, TBSA) were input into the BEACON model based on the 800 patients with 10% TBSA and greater burns treated in 2018 at the institution, and demonstrated:

- The Arizona Burn Center would save approximately US$28 million (16%) per year using the RECELL System versus the current standard of care (net of the cost of the RECELL System)
- The largest driver of the predicted cost savings is reduction in length of stay per patient, comprising 70% of the savings
- Also contributing to the estimated cost savings is an approximate 67% less autografting procedures, with reduction in operating room time contributing another 13% to the estimated cost savings

A similar presentation was made by researchers at the 31st Annual Southern Region Burn Conference in November 2018 which described the application of the BEACON model to the patient characteristics for the Firefighter Burn Center, Memphis, Tennessee, and University of Tennessee Health Science Center. The model determined that treating patients with the RECELL System alone, or in combination with widely spaced skin grafts, could reduce the burn center's costs by up to US$21 million per year compared to conventional treatment.

Major drivers of the cost savings included a decrease in length of hospital stay and a reduction in the number of surgeries and related resources (blood transfusions and dressings).

The BEACON model highlights the potential of the RECELL System to improve patient care in the treatment of severe burns, while also providing a technique for reducing the total cost of treatment.

Additional RECELL Clinical Results in Severe Burns

A series of studies have been presented at scientific conferences and evaluated multiple patient categories and burn types in more than 150 burn patients that were treated under FDA-approved Investigational Device Exemption (IDE) Compassionate Use and Continued Access programs made available to patients prior to the FDA approval. Many of these studies includes a class of patients or types of burn injuries that fall outside of the currently approved U.S. product labeling.

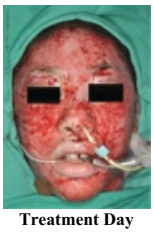
*RECELL in Treatment of Facial Burns*

Deep partial-thickness facial burns present a challenge in reconstructive surgery. Standard of care typically includes excision and allograft followed by split-thickness autografting. Limitations of the current treatment regimen includes dyspigmentation at the sites of the skin grafts and hypertrophic scaring at the seams of the grafts, resulting in substantial patient dissatisfaction with the outcome.

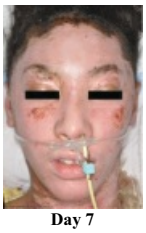
At the American Burn Association 50th Annual Meeting in April 2018, clinical researchers provided a retrospective review of clinical outcomes obtained in the treatment with the RECELL System of five patients with acute deep partial-thickness facial burn injuries under the Compassionate Use IDE program. Patients in the facial burn case studies ranged from 2 to 40 years of age and had burns covering 35% to 62% TBSA. Researchers reported that in this small study, treatment using the RECELL System provided equivalent or superior results to current treatments in facial burn care in terms of wound healing, and excellent cosmetic outcomes.

A representative patient in the trial was a12-year-old girl with 2nd-degree facial burn and widespread 3rd-degree burns, with total injuries encompassing a 62% TBSA. The patient had insufficient donor skin available for standard autografts. The healing of the patient's facial burns is highlighted in the progressions of photographs included below.

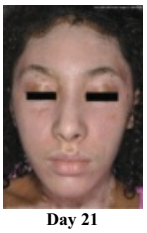
**Facial Burn Case Study**



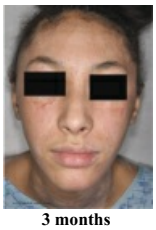
**Treatment Day**



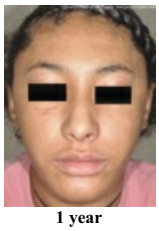
**Day 7**



**Day 21**



**3 months**



**1 year**

Researchers observed that the reintroduction of melanocytes as part of the cellular suspension prepared using the RECELL System resulted in an excellent cosmetic outcome. The patient did not require surgical revisions for facial contractures and was discharged from the hospital in 24 days.

*RECELL in Treatment of Pediatric Patients*

In patients with extensive burn injuries, lack of available donor skin is a major limitation achieving permanent closure, and the longer a wound remains open the more susceptible a patient is to infection. In the U.S., one-third of burn injuries occur in children, and the availability of donor skin for traditional meshed autografts is even more limited in pediatric patients with extensive injuries. The use of the RECELL System, a donor skin sparing technology that enables rapid definitive closure of burn wounds, has the potential to improve patient outcomes.

Interim results describing clinical outcomes for pediatric patients treated using the RECELL System were presented at the American Burn Association (ABA) 51st Annual Meeting in April 2019. The study included a total of 23 pediatric patients with a median age of 6.7 years old (ranging from 0.8 to 16.0) treated under FDA IDE Compassionate Use and Continued Access programs with mixed-depth and full-thickness (third-degree) burns. The presentation was selected as a “Best of the Best Abstract” out of more than 500 abstract submissions to the ABA meeting.

In this study of pediatric patients which included those with life-threatening thermal burn injuries,Spray-On Skin Cells prepared using the RECELL System were applied in combination with widely meshed split-thickness autografts to achieve definitive closure using minimal donor skin. A total of 107 burn wounds were treated in the study, and 98% achieved definitive healing within four weeks of treatment. Importantly, for patients with greater than 50% TBSA burns, treatment with the combination of Spray-On Skin Cells and widely meshed split-thickness autografts achieved the same high rate of healing at week four as patients with smaller burns (burns equal to or less than 50% TBSA) treated with the same combination. In addition, in the study the donor sites on all patients were treated with Spray-On Skin Cells, and 62.5% of the donor sites were healed within a week of treatment, and 100% were completely healed within two weeks of treatment. Researcher reported that the majority of burn sites had cosmetic outcomes rated as satisfactory or equivalent compared to uninjured skin and that the early healing of donor sites contributed to a decrease between harvest times for patients with limited donor skin availability.

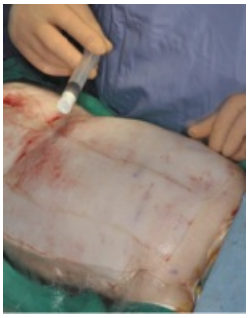
Two additional randomized, controlled clinical trials using the RECELL System in the treatment of pediatric patients are currently underway, and a third trial in this population is expected to begin in the middle of 2019.

*RECELL Treatment of Donor Sites*

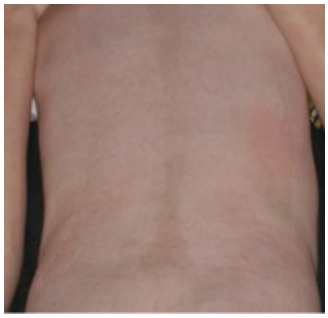
In large TBSA injuries a patient may not have enough donor skin available to allow for immediate treatment of the entire area of burn injuries with traditional autografting techniques. In severely burned patients with extensive injuries, surgeons often must wait until the donor sites have healed so that they can reharvest from the site, resulting in delays in treatment and healing and the need for multiple procedures and extended hospital time.

Interim results describing clinical outcomes associated with the treatment of donor sites using the RECELL System in patients with large TBSA burn were presented at the American Burn Association 51st Annual Meeting in April 2019 (the presentation was awarded Best in Category at the meeting). In the prospective observational study of 73 subjects with life-threatening thermal burn injuries treated under the Compassionate Use program, 426 donor sites wounds were treated with Spray-On Skin Cells prepared using the RECELL System. The mean TBSA of the patients in the study was 54% with burns ranging from 20% to 91% TBSA. Two weeks after treatment, 91% of the donor sites had healed in this vulnerable patient population, and 98% had healed by week eight. Donor sites treated using the RECELL System were able to be reharvested as early as seven days after treatment. No infection or delayed healing were reported for donor sites treated with Spray-On Skin Cells. Researchers noted that the ability to reharvest additional donor skin from a site in as little one week after treatment with the RECELL System is extremely beneficial in this population of patients with extensive life-threatening injuries and limited available donor skin.

A representative patient in the study was a16-month-old female with a 30% TBSA mixed depth thermal burn with donor sites taken from her back. Medical professionals applied Spray-On Skin Cells to her donor site wound. The donor sites were 100%re-epithelialized by within two weeks of treatment. At one-year follow-up the donor site wound had matching color, pigment, and texture to the surrounding skin. Treatment and healing of the patient's donor site is highlighted in the photographs included below.



Application of Spray-On Skin Cells prepared using the RECELL System to donor site wound



Healing of donor site wound one year after treatment using the RECELL System

A randomized, controlled clinical trial of the use of the RECELL System in the treatment of donor sites in pediatric patients is currently underway.

*RECELL in Treatment of Patients with Extensive Burns (Large TBSA Patients)*

In patients with extensive burn injuries, lack of available donor skin is a major limitation in achieving permanent closure, and the longer a wound remains open the more susceptible a patient is to infection. At the American Burn Association 51st Annual Meeting in April 2019 researchers presented data showing that the use of the RECELL System in combination with meshed autografts achieves definitive closure for patients with burn injuries greater than 50% TBSA and achieved comparable outcomes to patients with less severe injuries.

In this study of 35 patients with life-threatening thermal burn injuries,Spray-On Skin were applied in combination with widely meshed split-thickness autografts to achieve definitive closure using minimal donor skin. For patients with greater than 50% TBSA burns, 150 burn wounds were treated with the combination of Spray-On Skin Cells and widely meshed split-thickness autografts, with 95% of the wounds achieving complete wound closure two months after treatment. For patients with equal to or less than 50% TBSA burns, 53 burn wounds were treated with the same combination and the rate of healing was similar to the large TBSA patients, with 92% of wounds achieving full healing two months after treatment. Researchers reported that there was no device related adverse events and long-term durability was excellent.

Ongoing and Future Clinical Trials in Burns

*U.S. Pediatric Donor Site Study:*

In October 2018 we initiated a randomized, controlled clinical study in the U.S. to investigate the safety and effectiveness ofSpray-On Skin Cells prepared with the RECELL System compared to conventional care for healing of donor sites in pediatric patients (infants, children and adolescents aged one to 16 years). The study will evaluate a minimum of 50 patients who require autografting in approximately eight U.S. centers. Patients who are eligible for the study may be undergoing autografting for any reason, including burns, trauma, and reconstruction. The study is a matched-pairs design where patients will serve as their own control. For each patient, two donor sites of similar surface area will be selected and randomized to be treated with Spray-On Skin Cells or serve as the control (treated with standard dressings only).

The primary effectiveness endpoint is time in days for complete healing of the donor sites. Secondary and tertiary endpoints include:

- Donor site treatment preference by patient / guardian at week four
- Investigator donor site preference at week four
- Comparative itching of donor sites post treatment
- Blinded evaluator assessment of donor sites at week 24
- Patient / guardian assessment of donor sites at week 24
- Investigator assessment of healing at all visits
- Patient or parent / guardian reported donor site pain

Patients will be followed for one-year after treatment. The pediatric donor-site study is being 100% funded by Biomedical Advanced Research and Development Authority (BARDA) under the ongoing program. This study is intended to support U.S. regulatory approval for marketing of the RECELL System for patients under the age of 18.

*Australian Pediatric Scalds Study:*

In August 2018 a randomized, controlled clinical study of the use of the RECELL System in the treatment of significant superficial partial- and mid-thickness pediatric burns, including scald injuries, was initiated in Australia. The current standard of care for children with partial-thickness burns is cleaning of the wound followed by a dressing application. Limitations of the standard of care include delay in healing of the burn injury, scarring, and pain. The clinical trial will include approximately 90 patients under 18 years old. Patients will be randomized into one of three groups and will be treated either using the RECELL System and Biobrane® dressing, the Biobrane dressing alone, or standard care (silver impregnated silicone lined dressing). The primary endpoint will be days to re-epithelization of the burn injury. Secondary endpoints include pain, patient satisfaction and scarring.

*U.S. Pediatric Early Intervention Pediatric Study:*

In late 2019 we plan to initiate a randomized, controlled clinical study to investigate the safety and effectiveness of Spray-On Skin Cells prepared with the RECELL System compared to standard of care dressings for treatment of partial-thickness burns in pediatric patients (infants, children and adolescents aged one to 16 years). The study will evaluate 160 patients in up to 18 U.S. burn centers with burns of 5% to 30% TBSA. Half of the patients will be randomized to be treated using Spray-On Skin Cells. The other half will be randomized to serve in the control group and will be treated using standard dressings.

The primary measure of effectiveness is healing ten days after treatment, as assessed by a blinded evaluator. Secondary endpoints include:

- Healing time assessed from date of initial burn injury
- Pain recovery (i.e., trajectory for pain resolution) following treatment
- Incidence of conventional autografting to achieve healing

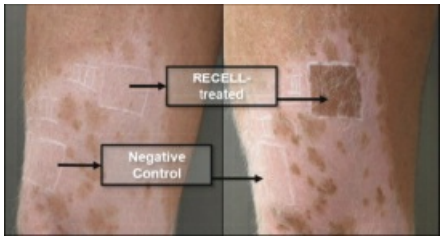
Patients will be followed for one-year after treatment. The pediatric early intervention study is being 100% funded by Biomedical Advanced Research and Development Authority (BARDA) under the ongoing program. This study is intended to support U.S. regulatory approval for marketing of the RECELL System for patients under the age of 18.

The RECELL System Clinical Results in Vitiligo

Small pilot studies investigating the use of the RECELL System in the treatment of vitiligo have been the subject of multiple peer-reviewed scientific publications and presentations at medical conferences. A representative pilot study was published in the *Journal of the American Academy of Dermatology* in July 2015. A total of ten patients with hypopigmentation were included in the study, five with stable segmental vitiligo, and five with piebaldism (a disorder of melanocyte development). The study was a randomized, intra-patient-controlled pilot study in which three depigmented sites were randomly allocated to be treated with the combination of $CO_2$ laser ablation followed by the application of Spray-On Skin Cells, $CO_2$ laser ablation alone, or no treatment.

The median repigmentation six months after treatment was 78% in the sites treated with the combination of $CO_2$ laser ablation followed by the application of Spray-On Skin Cells, compared to zero median repigmentation in the control groups consisting of treatment with $CO_2$ laser ablation alone or no treatment. The repigmentation for the sites treated with the combination of $CO_2$ laser ablation followed by the application of Spray-On Skin Cells was assessed as good or excellent by 70% of the patients. No adverse effects or long-term side effects were seen in the recipient sites. Researchers concluded that treatment with the combination of $CO_2$ laser ablation followed by the application of Spray-On Skin Cells resulted in a high percentage of repigmentation and was well tolerated in both stable segmental vitiligo and piebaldism patients. Photographs before and after treatment for a patient participating in the study are included below.

**Vitiligo Patient Pre- and Six-Months Post Treatment**




Baseline (pre-treatment) Six months after treatment

Similar results were described by researchers in a publication in the*British Journal of Dermatology* in November 2017. In addition to studies which have already been the subject of peer-reviewed publication, the RECELL System has been used extensively in the treatment of vitiligo patients in countries in which the product is approved for treatment, including China were the prevalence of vitiligo is high. In May 2019 use of the RECELL System in the treatment of vitiligo patients in China was the subject of two presentations at a European medical conference. We plan to commence U.S. clinical trials of the use of the RECELL System for the treatment of stable vitiligo under a program designed to support a supplement to the existing PMA approval.

The RECELL System Clinical History in Chronic Wounds

Small pilot studies using the RECELL System in the treatment of chronic wounds, particularly venous leg ulcers and diabetic foot ulcers, have been the subject of multiple peer-reviewed scientific publications and presentations at medical conferences. In addition to studies which have already been the subject of peer-reviewed publication, the RECELL System has been used in the treatment of chronic wound patients in countries in which the product is approved for treatment. A study published in the *Acta Vulnologica* in September 2012 included seven patients with 12 vascular ulcers which had remained open for more than 12 months. Each wound was prepared and then treated with Spray-On Skin Cells prepared using the RECELL System. Ulcer volume and depth decreased 50% to 80% within four weeks of treatment, and six of the wounds that had remained unhealed

for more than one year were completely closed within 24 weeks of treatment. Researchers concluded that treatment with the RECELL System allowed the repair process to restart in all 12 wounds, and that patients reported reduced pain within days of treatment.

In a study published in the *British Journal of Surgery* in January 2015, 88 patients with chronic wounds that had not healed for at least four weeks were evaluated. Patients were randomized to receive treatment with the combination of Spray-On Skin Cells and split-thickness autografts, or autografts alone. Results of the randomized, controlled study were as follows:

- Incidence of complete wound healing in the group of patients treated using the RECELL System was significantly higher (p=0.035) than in the control group (41 versus 34, respectively)
- Time to healing was significantly (p=0.001) shorter in the RECELL System group versus control (14 versus 20 days, respectively)
- Fewer complications (p=0.047) were seen in the RECELL System group versus control (4 versus 11, respectively)
- The RECELL System group had good elasticity and texture, similar color, and less scar tissue growth at borders versus control group
- Scarring was significantly less (p=0.005) in the RECELL System group versus control
- Patients had no recurrent ulcers in the RECELL System group but there were three new wounds in control group (one diabetic wound, one pressure wound, and one vascular wound). Secondary surgical intervention was required for these patients.

Researchers concluded that the combination of Spray-On Skin Cell and autografts is more effective and safer than autografts alone. Although the study involved treatment of a mix of chronic wounds, many were diabetic foot ulcers. The researchers suggest that the results show a broad range of potential applicability for the use of the RECELL System.

In a study published in the *International Wound Journal* in February 2015, 20 patients with chronic ulcers were evaluated in a single arm study. Patients participating in the study had arterial, diabetic, posttraumatic, or venous ulcers that had failed to heal after treatment with conventional therapies. Each wound was prepared and then treated with Spray-On Skin Cells prepared using the RECELL System. Within 60 days of treatment, 70% of the patients experience complete healing of their wounds. Five of the patients had 80% healing of their wounds within 60 days of treatment, and one patient at 50% healing at that time point. Patients also experienced a reduction in pain post treatment using the RECELL System and experienced no limitation in their ability to engage in normal daily activities. Color, texture and aesthetics results were rated as good. Researchers concluded that use of the RECELL System in the treatment of chronic wounds is simple minimally invasive, biocompatible and effective.

Due to the significant costs and risks of conducting larger-scale, late-stage clinical trials in the treatment of chronic wounds, we may elect to proceed with development of the RECELL System in more advanced clinical trials under the umbrella of a corporate collaboration to allow for participation in any future commercial success of the program while minimizing near-term resource requirements.

The RECELL System in Trauma Injuries (Soft-Tissue Injuries)

Case studies the use of the RECELL System in the treatment of trauma injuries (soft-tissue wounds) have been the subject of peer-reviewed scientific publications and presentations at medical conferences that cover a wider range of injuries or wounds of the skin. Patients with trauma injuries have also been treated using the RECELL System under the U.S. Compassionate Use program and in countries in which the product is approved for treatment. We plan to commence in 2019 a U.S. clinical trial of the use of the RECELL System for the treatment of trauma wounds under a program designed to support a supplement to the existing PMA approval.

The RECELL System in Other Indications

We expect to explore potential benefits of variants of the RECELL System platform in aesthetics markets, and as part of this initiative has exploratory programs underway in certain orphan diseases, such as epidermolysis bullosa and Hutchinson-Gilford progeria syndrome (HGPS).

**BARDA Contract**

We have a contract with Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, valued at least US$50.4 million (approximately A$68.14). The contract provides funding for the development of the RECELL System and future use of the product as a medical countermeasure to assist disaster preparedness and response in the U.S. for mass casualties involving burn injuries. We entered into the contract on September 29, 2015, and the scope was expanded as a result of amendments entered into as of June 24, 2016 and September 18, 2017. The contract terminates September 28, 2022 and may be terminated earlier at the option of BARDA.

Under the contract, BARDA provide funding and technical support for the development of the RECELL System. BARDA funded the completion of two randomized, controlled pivotal clinical trials, as well as Compassionate Use and Continued Access programs, and development of the health economic model demonstrating the cost savings associated with the RECELL System. BARDA has exercised a contract option to fund two randomized, controlled clinical trials in pediatric patients. The pediatric donor site study commenced in October 2018 and the pediatric early intervention study will commence in late 2019. Also included in the BARDA contract is provision for the future procurement of the RECELL System by BARDA under a vendor managed inventory system to bolster, at BARDA's option, disaster preparedness in the amount of US$7.6 million (approximately A$10.3 million), although BARDA also has the option of increasing the amount of the procurement. In connection with the BARDA contract, we anticipate that with respect to vendor-managed inventory systems, our margins may be lower. As the vendor-managed system is solely at BARDA's option, we are unable to predict when the Company will recognize revenue on this portion, if at all. As of December 31, 2018, we had received cumulative payments of A$22.6 million under the BARDA contract.

**Research and Development**

Our research and development efforts are focused on:

- Further clinical development of the RECELL System in additional indications such as pediatric burns, treatment of donor sites, trauma wounds and vitiligo.
- Further research and characterization of the characteristics of the RECELL System, the composition and activity of theSpray-On Skin Cells suspension, and the design of the device to support further development of the platform in other injuries and defects of the skin, and to expand the existing intellectual property estate.
- Expansion of the technology platform underlying the RECELL System, including combining the platform with other technologies, to allow development of the platform in other indications including orphan indications.

See "ITEM 4, Clinical Results and Ongoing and Planned Clinical Trials" for additional details on our ongoing research and development efforts.

**Manufacturing, Supply and Production**

We operate a production plant in Ventura, California, in a 23,040 square foot facility that we lease through September 30, 2021. We have the right to extend the lease, at our sole option, as a result of three, three-year, options that allow us to extend the lease up to an additional nine years in total. We produce the RECELL System in this facility under the current Good Manufacturing Practices (cGMP) requirements of the FDA and the

regulatory agencies of other jurisdictions in which we sell the RECELL System. As we seek regulatory approval in Japan and other new international countries for the RECELL System, the regulatory authorities of these counties are likely to review our manufacturing process, inspect our plant, and confirm that we meet all regulatory requirements. Any material future changes to our production processes for the RECELL System will have to be approved by the FDA and regulatory authorities in other jurisdictions.

All production requirements for the RECELL System, including devices required for U.S. and international sales and clinical trial requirements, have been manufactured at the Ventura facility since 2009. Up until June 30, 2018, the RECELL System was produced in the Ventura facility on our behalf by a Fortune 500 contract manufacturer who produced multiple GMP products for third parties. Due to a consolidation of facilities by the contract manufacturer, effective July 1, 2018 we entered into a series of agreements to take control of the Ventura plant, lease the facility, and acquire manufacturing equipment from the contract manufacturer at no cost.

Within the Ventura facility we perform the final manufacturing, assembly, packaging and warehousing of the RECELL System. Also included within the Ventura facility is a controlled warehouse designed to meet the vendor-managed inventory requirements of the BARDA program. We source multiple components, sub-assemblies and materials from third-party suppliers, who are required to meet our quality specifications. Included among the items procured from suppliers is porcine-derived trypsin, which is the enzyme key to the skin cell disaggregation performed using the RECELL System. Although we endeavor to have multiple sources of supply for key components, subassemblies and materials, some are procured from single source suppliers. We continue to evaluate methods of removing risk from the supply chain for the RECELL System, including ultimately moving to a recombinantly produced Trypsin.

We believe that our current manufacturing capacity at the Ventura facility is sufficient to meet the expected commercial demand for the RECELL System for burns and other indications currently under development.

**Marketing Sales and Distribution**

We sell the RECELL System in the U.S. through our own commercial organization consisting of 20 field sales personnel (consisting of Regenerative Tissue Specialists, Clinical Training specialists and regional managers). and the field sales team is supported by centralized marketing, reimbursement, sales operations and leadership personnel, and also receives clinical and scientific support from our Medical Affairs team. The field sales team was recruited and hired subsequent to the September 2018 FDA approval and were trained prior to our U.S. market launch of the RECELL System in January 2019. All of our field sales personnel have prior experience in the U.S. burn market and in the launch of new products. Each of the clinical training specialists responsible for training the surgeons and other medical personnel within the burn centers are experienced burn nurses.

The market for the treatment of burns in the U.S. is highly concentrated, with 134 burn centers and approximately 300 burn surgeons. Accordingly, we believe that our sales organization is of an appropriate size to reach the burn surgeons and other key decision makers associated with our initial target market of patients with burn injuries of 10% or greater TBSA treated on an in-patient basis within U.S. burn centers. As a result of the concentrated nature of the U.S. burn market, we do not have an external distribution or warehousing structure and ship the RECELL System directly from our Ventura facility to U.S. burn centers.

The objective of our field sale team is to build upon burn community awareness resulting from the extensive series of burn conference presentations and scientific publications to further expand the interest in clinical and economic benefits of the RECELL System among burn surgeons and other professionals who are not already experienced with the product. In addition, we have set a policy of not providing the RECELL System to a burn center or other institution until their site has been certified by us, which includes training in the use of the product and in the proper aftercare of the patient. Training of the burn sites is undertaken by the clinical training specialist component of our sales team, augmented from personnel by our Medical Affairs team. In general, we

expect most U.S. burn centers will follow the industry standard process of evaluating the RECELL System and then taking it through their hospital's Value Analysis Committees (VAC) prior to purchasing the product. This process can sometimes be a lengthy one taking six months to complete. As a result of the training requirements and the VAC process, we expect that the adoption of the RECELL System among U.S. burn centers will occur on a staggered basis over multiple years.

In the U.S., hospital and physician reimbursement associated with in-patient treatment using the RECELL System was in place prior to the commencement of commercial sales. For in-patient treatment of burn patients, U.S. hospitals are reimbursed under ICD-10 (International Classification of Diseases, Tenth Revision, Clinical Modification) codes based on diagnosis of a patient's injuries. For physicians, CPT (Current Procedural Terminology) codes for use in procedures using the RECELL System were recommended by the American Burn Association within one week of FDA approval. Future expansion, based on additional clinical data and subject to a supplement to our PMA, of the use of the RECELL System for the treatment of burns or other indications on an outpatient basis will require us to successfully obtain reimbursement for use of the product in that setting.

In February 2019 we entered into a collaboration with COSMOTEC, an M3 Group company, to market and distribute the RECELL System for the treatment of burns and other wounds in Japan. In China we have relied upon a series of one-year distributorships to allow awareness of the product to build while maintaining flexibility to undertake an alternative commercialization strategy as data to support the approval and use of the RESELL System in other indications becomes available. Our commercialization efforts in other regions in which the RECELL System is approved for sale is based on our assessment that the acute burn market in many countries is proportionately less than the market in the U.S., and the investments in a full marketing and sales resources and the effort to obtain reimbursement are not justified until we have obtained pivotal clinical results in additional indications. In Australia and Europe for the past year we have not engaged in any substantial promotion of the RECELL System but have limited our commercialization efforts to filing sales orders as received. As additional pivotal trial data for the RECELL System is generated in additional indications, we expect to commercialize the product in countries outside the U.S. through a combination of collaborations and direct efforts, depending upon the territory and the indication.

**Intellectual Property**

We seek to protect our intellectual property, core technologies and other know-how through a combination of patents, trademarks, trade secrets, non-disclosure and confidentiality agreements, licenses, assignments of invention and other contractual arrangements with our employees, consultants, partners, suppliers, customers and others. Additionally, we rely on our research and development program, clinical trials, know-how and marketing and distribution programs to advance our products and product candidates, and to expand our intellectual property rights. As of December 31, 2018, we have been granted a total of a total of 32 patents and have 15 pending patent applications worldwide.

The U.S. patents and patent applications provide coverage with expected expiration dates ranging from 2022 to 2033. U.S. patents covering the composition of matter related to the current RECELL System expire in 2022. We have filed a Patent Term Extension (PTE) application with the U.S. Patent and Trademark Office requesting an extension of the patent term of U.S. Patent No. 9,029,140, "Cell suspension preparation technique and device" as a result of the time required for the FDA regulatory process. If the term extension requested in the PTE application is approved, the patent term of U.S. Patent No. 9,029,140 will be extended to 2028. We expect that further research and characterization of the characteristics of the RECELL System, the composition and activity of the Spray-On Skin Cells solution, and the design of the device currently underway will provide additional claims, including composition of matter, for which we will be able to pursue additional U.S. and international patent applications. Patents and patent applications in key international markets parallel those in the U.S.

In addition to patent protection, we also rely on trade secrets, including unpatented know-how, technology innovation, drawings, technical specifications and other proprietary information in attempting to develop and

maintain our competitive position. We also rely on protection available under trademark laws, and we currently hold various registered trademarks and pending trademark applications, including the "RECELL,"," "Spray-On Skin Cells," and "REGENERATIVE EPIDERMAL SUSPENSION (RES)," in the U.S. and international markets.

While our policy is to obtain patents by application, license or otherwise, to maintain trade secrets and to seek to operate without infringing on the intellectual property rights of third parties, technologies related to our business have been rapidly developing in recent years. Additionally, patent applications that we may file or license from third parties may not result in the issuance of patents, and our issued patents and any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, we cannot predict the extent of claims that may be allowed or enforced in our patents nor be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications that also claim technology or therapeutics to which we have rights, we may have to participate in proceedings to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable to us. Moreover, because of the extensive time required for clinical development and regulatory review of a product we may develop, it is possible that, before the RECELL System can be commercialized in additional indications or jurisdictions and/or before any of our future products can be commercialized, related patents will have expired or will expire a short period following commercialization, thereby reducing the advantage of such patent. Loss or invalidation of certain of our patents, or a finding of unenforceability or limited scope of certain of our intellectual property, could have a material adverse effect on us. See "ITEM 3.D. Risk Factors – If we are unable to effectively protect our intellectual property, we may not be able to operate our business and third parties may be able to use and profit from our technology, both of which would impair our ability to be competitive."

**Competition**

The medical device, biotechnology and pharmaceutical industries are intensely competitive and subject to significant technological change and changes in practice. While we believe that our innovative technology, knowledge, experience and scientific resources provide us with competitive advantages, we may face competition from many different sources with respect to the RECELL System or any product candidates that we may seek to develop and commercialize in the future. Possible competitors may include medical device, pharmaceutical and wound care companies, academic and medical institutions, governmental agencies, medical practitioners, and public and private research institutions, among others. Any product that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

In addition, in the treatment of acute burns we face competition from the current standard of care, primarily split-thickness autografts. Although the RECELL System is complementary with autografts for the treatment of many burn injuries, we face competition from this traditional surgical procedure for many burn patients. However, based on our clinical trials, we believe that the RECELL System has a sustainable competitive clinical and economic advantages over the current standard of care. See "ITEM 4 – The RECELL System Clinical History and Ongoing and Planned Clinical Trials" for the results of our clinical trials.

**Government Regulations**

FDA and International Regulation

The production and marketing of the RECELL System and any additional product candidates developed in the future ongoing research and development activities are subject to regulation by numerous governmental authorities including the FDA in the United States and similar agencies in other countries throughout the world. Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) the FDA has jurisdiction over medical devices in the U.S. The FDA regulates, among other things, the research, testing, manufacturing,

safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. The FD&C Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device are categorized as Class III. These devices typically require submission and approval of a Premarket Approval Application, or PMA. The RECELL System is categorized as a Class III medical device, and in September 2018 the FDA approved our PMA for use in the treatment of acute thermal burns in patients 18 years and older. Approval of the RECELL System for use in the treatment of additional indications in the U.S. will require the submission to the FDA of a supplement to our PMA.

To support a PMA supplement or other application for approval in the U.S. or other regions, the completion of additional clinical and non-clinical studies and supporting development activities will likely be required. Clinical trials can take many years to complete and require the expenditure of substantial resources. The length of time varies substantially according to the type, complexity, novelty and intended use of the product candidate. We cannot make any assurances that once clinical trials are completed by us or a collaborative partner, we will be able to submit as scheduled a marketing approval request to the applicable governmental regulatory authority, or that such request and application will be reviewed and cleared by such governmental authority in a timely manner, or at all. Although we intend to make use of fast-track and abbreviated regulatory approval programs when possible and commercially appropriate, we cannot be certain that we will be able to obtain the clearances and approvals necessary for clinical testing or for manufacturing and marketing our product candidates. Delays in obtaining regulatory approvals could adversely affect the development and commercialization of our product candidates and could adversely impact our business, financial condition and results of operations. During the course of clinical trials and non-clinical studies, product candidates may exhibit unforeseen and unacceptable safety considerations. If any unacceptable side effects were to occur, we may, or regulatory authorities may require us to, interrupt, limit, delay or abort the development of our potential products.

Any products manufactured or distributed by us pursuant to regulatory approvals are subject to continuing regulation by the FDA and similar agencies in other countries, including manufacturing, periodic reporting, product sampling and distribution, advertising, promotion, compliance with any post-approval requirements imposed as a conditional of approval, recordkeeping and reporting requirements, including adverse events experiences. After approval, material changes to the approved product, such as adding new indications or other labeling claims, or changes to the manufacturing process, are subject to prior FDA and other agency review and approval. Medical device manufacturers and their subcontractors are required to register their establishments with the FDA, certain state agencies and international agencies and are subject to periodic announced and unannounced inspections by the FDA and these other agencies for compliance with cGMP requirements. We have an established process in place for categorization of vendor criticality and the associated activities for qualification and monitoring, which include but are not limited to, requiring certification of supplier in conformance to relevant cGMP regulations and other FDA and international agency regulatory requirements, approved supplier lists, and regular Company conducted audits. In addition, all goods and services purchased from suppliers by us must be purchased from only those suppliers on the approved supplier list. Furthermore, the Company itself will continue to comply with all relevant FDA requirements and regulations and any applicable international agency regulatory requirements in its continued manufacturing and promotion of its FDA approved commercial product.

The RECELL System is TGA-registered in Australia and CFDA-cleared in China for use in the treatment of burns, acute wounds, scars and vitiligo. In Europe, the RECELL System received CE-mark approval for the treatment of burns, chronic wounds, scars and vitiligo. In March 2019 we temporarily interrupted sales of the RECELL System in the EU. The sales interruption occurred after the notified body responsible for EU certificates reported open items related to administrative and procedural non-conformities. These open items are

limited to product distributed within the EU and are not related to product quality, performance or safety. While the temporary non-conformity caused us to suspend fulfilling any purchase requests in the EU, this action had no impact on the sale of products outside of the EU. We do not actively promote the products in the EU and its activity in the region is limited to filling purchase requests as they are received, therefore the financial impact to us of this temporary interruption was immaterial. On June 12, 2019, the notified body responsible for EU certificates closed all open administrative and procedural non-conformities previously announced and fully reinstated our EU certificates to allow the resumption of sales throughout the EU. In February 2019, our marketing partner COSMOTEC filed a Japan's Pharmaceuticals and Medical Devices Act ("JPMDA") application for approval to market the RECELL System in Japan for the treatment of burns and other wounds. The JPMDA has accepted the application and review is expected to take nine months to a year.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the companies to maintain books and records that accurately and fairly reflect all transactions of the companies, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. We are also subject to similar regulations under the Australian bribery laws and the U.S. Foreign Corrupt Practices Act (FCPA) and other anti-corruption laws that apply in countries where we do business.

**Environmental, Health and Safety Matters**

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, primarily in the United States, governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, air, water and ground contamination; air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage. Our operations at our Ventura manufacturing facility use biologic agents and produce waste materials and sewage. Our activities require permits from various governmental authorities including, local municipal authorities. Local authorities and the municipal water and sewage company conduct periodic inspections in order to review and ensure our compliance with the various regulations. We are no presently aware of any violations or deficiencies. These laws, regulations and permits could potentially require the expenditure by us for compliance or remediation.

If we fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. Should we be in violation of any such laws, we may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations. In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities which were previously permitted.

**Legal and Administrative Proceedings**

We are not party to any material legal or administrative proceedings, and we are not aware of any threatened material legal or administrative proceedings against us.

### C. Organizational Structure

As at March 31, 2019, we have a total of five subsidiaries and their corporate details and business activities are listed below:

| Subsidiary Name | Place of Incorporation | % held | Business scope |
|---|---|---|---|
| Avita Medical Americas, LLC | Delaware | 100 | U.S. operations |
| Avita Medical Europe Limited | United Kingdom | 100 | EMEA operations |
| Visiomed Group Pty Ltd | Australia | 100 | Asia Pacific Operations |
| C3 Operations Pty Ltd | Australia | 100 | Holding company |
| Infamed Pty Ltd | Australia | 100 | Inactive |

### D. Property, Plant and Equipment

Our principal corporate offices are located at 28159 Avenue Stanford, Suite 220, Valencia, California 91355. We lease the 17,481 facility under two lease agreements that, as amended, expire on January 31, 2021 with the right to extend the leases, at our sole option, for an additional three-years. Our production plant in Ventura, California, is a 23,040 square foot facility that we lease through September 30, 2021 with the right to extend the lease, at our sole option, as a result of three, three-year, options that allow us to extend the lease up to an additional nine years in total.

## ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

### Special Note Regarding Forward Looking Statements

*The following discussion and analysis include certain forward-looking statements with respect to the business, financial condition and results of operations of our company. The words "estimate," "project," "intend," "expect" and similar expressions are intended to identify forward- looking statements within the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated by such forward-looking statements, including those risk factors contained in Item 3.D. of this Registration Statement. You should read the following discussion and analysis in conjunction with our consolidated financial statements and the notes thereto included in this Registration Statement.*

### Background

Avita Medical Limited and our subsidiaries Avita Medical Americas, LLC, Avita Medical Europe Limited, Visiomed Group Pty Ltd, C3 Operations Pty Ltd and Infamed Pty Ltd, which we collectively refer to as the "Company," is a regenerative medicine company with a technology platform designed to address unmet medical needs in patients with burns, chronic wounds, and aesthetics indications. Our patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. Our lead product, the RECELL® System, uses a small amount of a patient's own skin to prepare Spray-On Skin Cells at the point of care in as little as 30 minutes. This autologous suspension of skin cells is then sprayed onto the areas of the patient requiring treatment. The RECELL System, was approved for sale in the U.S. for the treatment of acute thermal burns in patients 18 years and older by the Food and Drug Administration (FDA) in September 2018. We initiated our U.S. national market launch of the RECELL System in January 2019, although it did commence commercial shipments in the U.S. during the half-year ended December 31, 2018 in response to pre-launch demand from burn centers. During the year ended June 30, 2018 and the half-year ended December 31, 2018, the RECELL System was also sold on a limited basis in certain regions of the world in which the products were approved for sale, including Australia, China and Europe.

We believe that there are many factors and trends that may effect our financial condition and results of operations. Primarily and foremost, our revenue growth will be impacted most by market acceptance, adoption and penetration of our RECELL System. In addition, the Company is always pursuing expansion of labeling additional indications that could open new markets such as the treatment of leg and foot ulcers, vitiligo, chronic wounds and trauma injuries.

In this Registration Statement, all references to "U.S. dollars" or "US$" are to the currency of the U.S., and all references to "Australian dollars", "A$" or "AUD$" are to the currency of Australia.

For a description of the milestones that we have achieved since inception and through to the date of this report, see "Item 4. Information on the Company – A. History and Development of the Company."

**Critical Accounting Policies**

Our consolidated financial statements appearing in this registration statement on Form20-F are prepared in Australia dollars in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our consolidated financial statements appearing in this registration statement on Form 20-F comply with IFRS. As such, we are required to make certain estimates, judgments, and assumptions that management believes are reasonable based upon the information available. These estimates, judgments and assumptions affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the periods presented. The significant accounting policies listed in Note 2 to the consolidated financial statements that our management believes are the most critical to aid in fully understanding and evaluating our financial condition and results of operations under IFRS are discussed below.

Revenue Recognition

Revenue is recognized and measured at the fair value of the consideration received or receivable to the extent it is probable that the economic benefits will flow to the Company and the revenue can be reliably measured. The following specific recognition criteria must also be met before revenue is recognized:

Sale of Goods

Revenue from the sales of goods is recognized at a point in time when the Company satisfies performance obligations by transferring the promised goods to its customers. The Company recognizes contract liabilities for consideration received in respect of unsatisfied performance obligations and reports these amounts as other liabilities in the statement of financial position. Similarly, if the Company satisfies a performance obligation before it receives the consideration, the Company recognizes either a contract asset or a receivable in its statement of financial position, depending on whether something other than the passage of time is required before the consideration is due.

BARDA Income

The Company had been granted a BARDA contract in September 2015, wherein BARDA funded the Company to support the ongoing U.S. clinical regulatory program towards FDA Premarket Approval and Compassionate Use program, and clinical and health economics research in U S. pediatric burn care. BARDA income is recognized in the income statement when it is probable that the Company will receive the economic benefits of the contract and the amount can be reliably measured. The BARDA contract allows the Company to be reimbursed for costs incurred to fund the programs outlined above. The BARDA funds received are recognized in the period that the costs are incurred by the project.

Interest Income

Revenue is recognized as interest accrues using the effective interest method.

Share-based payments

The Company provides benefits to our employees (including executive management) in the form of share-based payments, whereby employees render services in exchange for shares or rights over shares (equity-settled transactions).

The Company has in place two employee share option plans which provide benefits to employees and are eligible to provide benefits to directors. The cost of these equity-settled transactions with employees is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by an external valuation firm using a binomial model. The cost of equity-settled transactions is recognized, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled (the vesting period), ending on the date on which the relevant employees become fully entitled to the award (the vesting date).

At each subsequent reporting date until vesting, the cumulative charge to profit or loss is the product of:

- the grant date fair value of the award;
- the current best estimate of the number of awards that will vest, taking into account such factors as the likelihood of employee turnover during the vesting period and the likelihood of non-market performance conditions being met; and
- the expired portion of the vesting period.

The charge to profit or loss for the period is the cumulative amount as calculated above less the amounts already charged in previous periods. There is a corresponding entry to equity.

The expense recognized by Avita Medical Limited for equity-settled awards only represents the expense associated with grants to employees of Avita Medical Limited, whereas the expense recognized by the Company is the total expense associated with all such awards.

Until an award has vested, any amounts recorded are contingent and will be adjusted if more or fewer awards vest than were originally anticipated to do so.

If the terms of an equity-settled award are modified, as a minimum, an expense is recognized as if the terms had not been modified. An additional expense is recognized for any modification that increases the total fair value of the share-based payment arrangement or is otherwise beneficial to the employee, as measured at the date of modification.

If an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. However, if a new award is substituted for the cancelled award and designated as a replacement award on the date that it is granted, the cancelled and new award are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect, if any, of outstanding options, is reflected as additional share dilution in the computation of diluted earnings per share.

Research and Development Payments

Expenditures during the research phase of a project are recognized as expenses when incurred. Development costs are capitalized only when technical feasibility studies identify that the project is expected to deliver future economic benefits and these benefits can be measured reliably.

Capitalized development costs have a finite useful life and amortized on a systematic basis based on the future economic benefits over the useful life of the project.

Research and Development Tax Incentive

The Company's research and development activities are eligible under an Australian Government tax incentive for eligible expenditure from 1 July 2012. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. For the years ended June 30, 2018, 2017 and 2016, the Company recorded other income of A$1,385,796, A$1,048,237 and A$971,881, respectively related to recognition of this tax incentive. The Australian R&D tax incentive scheme permits overseas activity to be claimed to the extent that the overseas activity does not exceed 50% of the total costs of activities for an eligible project. As of December 31, 2018, the Company evaluated the level overseas activity and concluded there was uncertainty as to the ability to meet this criteria. Additionally, at that time, the Federal Budget included a number of changes to the R&D tax incentive scheme which would place further limits on claimable amounts. These budget changes have since been formally placed on hold. In consideration of these uncertainties, no amounts were accrued for as at December 31, 2018.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations for the years ended June 30, 2018, 2017 and 2016 and the half-year ended December 31, 2018 and 2017, should be read in conjunction with our consolidated financial statements and related notes included in this registration statement in accordance with "Item 8. Financial Information".

### Year Ended June 30, 2018 compared to Year Ended June 30, 2017

Sale of goods of the RECELL devices totaled A$1,198,861 for the year ended June 30, 2018, an increase of A$297,485 or 33% over the A$901,376 recognized during fiscal 2017. The largest increase in sale of goods occurred in Asia Pacific which accounted for 59% of total commercial sales, while the sale of goods in EMEA comprised the remaining 41% of total commercial sales. Gross margins for the years ended June 30, 2018 was 57% compared to 49% for the same period in 2017, and we expect gross margins to further increase as sales ramp up within the U.S.

We believe that there are many factors and trends that may effect our financial condition and results of operations. Primarily and foremost, our revenue growth will be impacted most by market acceptance, adoption and penetration of our RECELL System. In addition, the Company is always pursuing expansion of labeling additional indications that could open new markets such as the treatment of leg and foot ulcers, vitiligo, chronic wounds and trauma injuries. With regard to the foregoing factors and additional indications, we believe that over the next several years, the most critical component of our changes of sales of goods will be market acceptance and adoption of the RECELL System for burns, followed by approval, market acceptance, adoption of the additional, and potentially other, indications noted above. Such market acceptance, adoption and penetration would have a material effect on our sales of goods.

Other income totaled A$10,172,698 for the year ended June 30, 2018, an increase of A$2,941,728 or 41% over the A$7,230,970 recognized during fiscal 2017. The majority of other income consisted of funding from the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services. Under the BARDA contract, income of A$10,104,081 was recognized during the year ended June 30, 2018 compared to income of A$6,886,236 for fiscal 2017. This increase was the result of an expansion of activities related to programs conducted under the BARDA contract during the year. Funding provided by BARDA during the year ended June 30, 2018 focused primarily on support of the U.S. PMA application for the RECELL System, the Continued Access and Compassionate Use programs which provide access to the RECELL System for U.S. patients while the PMA is under review, and development of a health economic model by a major health care information and technology provider to quantify the economic value of the RECELL System versus standard of care for the treatment of severe burns.

As the result of investments in commercial, manufacturing, leadership and system capabilities in preparation for the planned U.S. launch of the RECELL System and related research and development and corporate initiatives including the BARDA programs, operating expenses increased during the year ended June 30, 2018. Sales and marketing expenses totaled A$8,936,441, an increase of A$3,734,680 or 72% over the A$5,201,761 recognized during fiscal 2017. Product development expenses totaled A$12,606,127 an increase of A$1,444,157 or 13% over the A$11,161,970 recognized during fiscal 2017. Corporate and administrative expenses totaled A$5,360,553 for the year ended June 30, 2018, an increase of A$3,095,959 or 137% over the A$2,264,594 recognized during fiscal 2017. Total operating costs totaled A$28,764,864, an increase of A$8,536,542 or 42% over the A$20,228,322 recognized during fiscal 2017 and were in line with management expectations.

We recorded a foreign exchange gain of A$563,279 for the year ended June 30, 2018, compared to a foreign exchange loss of A$83,293 for the year ended June 30, 2017. Foreign exchange gain (loss) reflects the impact of changes in foreign currency exchange rates on cash and cash equivalents that we hold in U.S. dollars, and to a smaller extent in British Pounds and Euros. In 2018, the Australian dollar depreciated against the U.S. dollar, which had a favorable impact on the Australian dollar value due to the fact that the majority of our cash and cash equivalents were held in U.S. dollars. In 2017, the Australian dollar depreciated against the U.S. dollar, which had an unfavorable impact on the Australian dollar value due to the fact that the majority of our cash and cash equivalents were held in Australian dollars.

The net comprehensive loss after tax benefit for the year ended June 30, 2018 was A$15,955,876, an increase of A$4,096,298 or 35% over A$11,859,578 recognized during fiscal 2017. The increase in net comprehensive loss was driven by the higher operating costs described above, partially offset by the higher sale of goods and BARDA income recognized during the year ended June 30, 2018. As the Company continues its preparations for the planned launch of the RECELL System in the U.S., operating expenses are expected to rise in future periods and will be offset in part by revenues under the BARDA contract as well as from sale of goods.

**Year Ended June 30, 2017 compared to Year Ended June 30, 2016**

Sale of goods of the RECELL devices totaled A$901,376 for the year ended June 30, 2017, a decrease of A$101,631 or 10% over the A$1,002,007 recognized during fiscal 2017. The decrease was primarily due to a decrease in EMEA operating segment promotional efforts and product sales during fiscal 2017. Gross margins for the year ended June 30, 2017 was 49% compared to 60% for the same period in 2016 primarily due to part of lower sales volumes in EMEA operating segment by 21%.

Other income was A$7,230,970 for the year ended June 30, 2017, an increase of 184% compared to A$2,544,517 recognized during fiscal 2016, as BARDA income of A$6,886,236 was received during the year as compared to the previous year's BARDA income of A$2,424,357 which began in the third quarter of last year. The increase of BARDA income was due to the significant expansion of activities surrounding the Company's Premarket Approval Application (PMA) submission to the FDA in September 2017 for approval to market the RECELL System in the U.S.

As the result of investments in clinical trials and preparation for and support of the PMA for the RECELL System, and related research and development and corporate initiatives including the BARDA programs, operating expenses increased during the year ended June 30, 2017. Product development expenses totaled A$11,161,970 an increase of A$5,143,786 or 86% over the A$6,018,184 recognized during fiscal 2016. Sales and marketing expenses were consistent year over year and totaled A$5,201,761, an increase of A$159,572 or 3% over the A$5,042,189 recognized during fiscal 2017. Corporate and administrative expenses were consistent and totaled A$2,264,594 for the year ended June 30, 2017, a decrease of A$107,153 or 5% over the A$2,371,747 recognized during fiscal 2016. In addition, share-based expense for the year ended June 30, 2017 included share-based expenses related to the resignation of the former CEO in May 2017 totaling A$1,189,021. This expense results from an acceleration of the recognition of non-cash expenses attributable to the initial valuation of the shares awarded under the CEO long-term, incentive agreement. Total operating costs totaled A$20,228,322, an

increase of A$5,839,523 or 41% over the A$14,388,799 recognized during fiscal 2016 which were driven by the expanded operating activities noted above.

The net comprehensive loss after tax was A$11,859,578 an increase of A$4,177,724 or 54% over A$7,681,854 recognized during fiscal 2016. The increase in net loss was driven by higher operating costs described above, partially offset by higher revenue from BARDA. In addition, the prior year net comprehensive loss was reduced by a profit from discontinued operations (divestment of the respiratory business segment) of A$2,493,947.

**Year Ended June 30, 2016 compared to Year Ended June 30, 2015**

Sale of goods of the RECELL devices totaled A$1,002,007 for the year ended June 30, 2016, an increase of A$16,360 or 2% over the A$985,647 recognized during fiscal 2015. Gross margins for the year ended June 30, 2016 was 60% compared to 71% for the same period in 2015. During this period the Company moved from a direct sale to a distributor sale model in most markets. While this did support the modest revenue growth over the previous fiscal year, there was a concurrent reduction in margin.

Other income was A$2,544,517 for the year ended June 30, 2016, an increase of 1,011% compared to A$228,988 recognized during fiscal 2015, as BARDA income of A$2,424,357 was received and began in the third quarter of fiscal year 2016 for the expansion of activities surrounding the Company's PMA submission to the FDA in September 2017 for approval to market the RECELL System in the U.S.

As the result of investments in conduct of clinical trials and preparation for and support of the PMA for the RECELL System, and related research and development and corporate initiatives including the BARDA programs, operating expenses increased during the year ended June 30, 2016. Product development expenses totaled A$6,018,184 an increase of A$1,748,729 or 41% over the A$4,269,455 recognized during fiscal 2015. Sales and marketing expenses totaled A$5,042,189, an increase of A$349,555 or 7% over the A$4,692,634 recognized during fiscal 2015. Corporate and administrative expenses totaled A$2,371,747 for the year ended June 30, 2016, an increase of A$1,901,632 or 405% over the A$470,115 recognized during fiscal 2015. In addition, share-based expenses of A$956,658 for the year ended June 30, 2016 included a non-cash amount of A$902,959 which recognizes the appropriate valuation of the issuance of 40 million fully paid shares under the CEO Long Term Incentive Plan, announced on January 25, 2016, and which is subject to escrow and vesting conditions. The full valuation of the 40 million shares will be allocated over a five-year period as a non-cash expense. Total operating costs totaled A$14,388,799, an increase of A$4,943,244 or 52% over the A$9,445,555 recognized during fiscal 2015 which were driven by the expanded operating activities noted above.

The net comprehensive loss after tax was A$7,681,854 an increase of A$756,375 or 11% over A$6,925,479 recognized during fiscal 2015. The increase in net loss was driven by higher operating costs described above, partially offset by higher revenue from BARDA. In addition, the fiscal 2016 net comprehensive loss was reduced by a profit from discontinued operations (divestment of the respiratory business segment) of A$2,493,947 and a fair value gain on available for sale of financial assets of A$265,261.

**Half-Year Ended December 31, 2018 Compared to Half-Year Ended December 31, 2017**

Sale of goods of the RECELL devices totaled A$1,813,195 for the half-year ended December 31, 2018, an increase of A$1,205,434 or 198% over the A$607,761 recognized during the same period in 2017. The majority of the current-year increase in sales occurred in the U.S. as a result of the September 2018 FDA approval. U.S. sales during the half-year ended December 31, 2018 totaled A$1,101,991 compared to zero in the prior year. Gross margin for the half-year ended December 31, 2018 was 69% compared to 56% for the same period in 2017, and management expects gross margins to further increase as sales ramp up within the U.S.

Other income totaled $5,112,763 for the half-year ended December 31, 2018, an increase of A$1,218,452 or 31% over the A$3,894,311 recognized during same period in 2017. As in prior periods, the majority of other

income consisted of funding from BARDA. Under the BARDA contract, income of A$5,009,137 was recognized during the half-year ended December 31, 2018 compared to income of A$3,856,716 during the same period in 2017. This increase was the result of an expansion of activities related to programs conducted under the BARDA contract during the year. Funding provided by BARDA during the half-year ended December 31, 2018 focused primarily on support of the regulatory activities to support the U.S. approval of the RECELL System, the Continued Access and Compassionate Use programs which provide access to the RECELL System for U.S. patients prior to FDA approval, and two U.S. clinical trials in pediatric burn patients.

Operations for the half-year ended December 31, 2018 were focused primarily on preparation for the January 2019 U.S. market launch of the RECELL System, including the recruitment, hiring and training of 20 sales field force personnel. Additional activities included the commencement of product shipments in the U.S. after the September 2018 FDA approval of the RECELL System for the treatment of acute thermal burns, and the preparation for, or the conduct of, further development of RECELL. As the result of investments in commercial, manufacturing, and system capabilities for the U.S. market launch of the RECELL System and related initiatives, operating costs for the half-year ended December 31, 2018 totaled A$21,935,034, a A$10,447,198 or 91% increase over the A$11,487,836 incurred during the same period in the prior year and were in line with management expectations. Sales and marketing expenses for the half-year ended December 31, 2018 totaled A$6,931,241, an increase of A$4,115,543 or 146% over the A$2,815,698 recognized during for first six months of fiscal 2017. Product development expenses for the 2018 half-year totaled $7,080,042 an increase of A$2,021,524 or 40% over the A$5,058,518 recognized during the first half of fiscal 2017. Corporate and administrative expenses totaled A$6,865,250 for the six months ended December 31, 2018, an increase of A$3,991,739 or 139% over the A$2,873,511 recognized during the first six months of fiscal 2017.

Net comprehensive loss after tax for the half-year ended December 31, 2018 was A$14,205,247, a A$6,899,260 or 94% increase compared to A$7,305,987 incurred in the same period in the prior half-year. The increase in net loss was driven by the higher operating costs described above, partially offset by the higher sale of goods and other revenue achieved during the six months. As a result of the national launch of the RECELL System in the U.S. in January 2019, and the expansion of research and development, operating expenses will increase in future periods. These expenses are expected to be partially offset by increased sales of goods and revenues under the BARDA contract.

**B. Liquidity and Capital Resources**

We expect to utilize cash reserves until U.S. and international sales of our products reach a level sufficient to fund ongoing operations. The Company has historically funded its research and development activities, and more recently its substantial investment in sales and marketing activities, through raising capital by issuing securities in the Company, and it is expected that similar funding will be obtained to provide working capital if and when required. If the Company is unable to raise capital in the future, the Company may need to curtail expenditures by scaling back certain research and development or other programs.

During the year ended June 30, 2018 and subsequent to year end, the Company completed a series of equity transactions totaling gross proceeds of A$74,775,545 which were used to fund operations. Of the total gross proceeds, A$29,760,645 was received from transactions completed during the year ended June 30, 2018, and A$45,014,900 was received from transactions completed subsequent to June 30, 2018.

On October 11, 2017, the Company completed a placement of 100,982,978 fully paid ordinary shares at a price of A$0.045 per share raising gross proceeds of A$4,544,234. On November 7, 2017, the Company completed a rights offering of 276,502,853 fully paid ordinary shares at a price of A$0.045 per share raising gross proceeds of A$12,442,628. On 6 June 2018, the Company completed the first tranche of an institutional placement in which it issued 255,475,665 fully paid ordinary shares at a price of A$0.050 per share raising gross proceeds of A$12,773,783. The institutional placement included a second tranche totaling A$3.250 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an

Extraordinary General Meeting held on July 23, 2018, and the Company issued 65 million shares at a price of A$0.050 per share and received gross proceeds of A$3,250,000 on July 26, 2018. Also subsequent to year end, on December 4, 2018, the Company completed the first tranche of an institutional placement in which it issued 310,047,015 fully paid ordinary shares at a price of A$0.080 per share raising gross proceeds of A$24,803,761. The institutional placement included a second tranche totaling A$15.196 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on January 14, 2019, and the Company issued 189,952,985 shares at a price of A$0.080 per share and received gross proceeds of A$15,196,239 on January 14, 2019. In addition, on January 11, 2019 the Company completed a Share Purchase Plan under which it issued 22,061,250 shares of stock at a price of A$0.080 per share and received gross proceeds of A$1,764,900.

The Company benefits from cash inflows from the BARDA contract, awarded to the Company in September 2015 and subsequently expanded through a series of modifications. These payments from BARDA offset costs from various activities undertaken to support the FDA regulatory approval process for RECELL in the U.S., preparation for the planned commercial launch of RECELL in the U.S., and RECELL clinical programs in the U.S. Further, there were no material expenditure commitments from the BARDA contract. With the U.S. FDA approval of RECELL for the treatment of burns in September 2019, and the U.S. market launch of the product in January 2019, sales of goods are expected to be an increasing source of revenue in the future. Another anticipated source of revenue for the Company is the BARDA contract covering the initial purchase, delivery and storage of RECELL devices in the amount of US$7,594,620 (approximately A$10.3 million).

The Company’s research and development activities are eligible under an Australian Government tax incentive for eligible expenditure from July 1, 2012. Our management has assessed these activities and expenditure and to determine our likely eligibility under this incentive scheme. For the half year ended December 31, 2018 and the years ended June 30, 2017 and 2016, the Company received A$2,440,803, A$972,283 and A$654,060 respectively related to this tax incentive.

The Australian R&D tax incentive scheme permits overseas activity to be claimed to the extent that the overseas activity does not exceed 50% of the total costs of activities for an eligible project. As of December 31, 2018, the Company evaluated the level overseas activity and concluded there was uncertainty as to the ability to meet this criteria. Additionally, at that time, the Federal Budget included a number of changes to the R&D tax incentive scheme which would place further limits on claimable amounts. These budget changes have since been formally placed on hold. In consideration of these uncertainties, no amounts were accrued for as at December 31, 2018. The Company does not believe any reduction over time of these potential payments to have a material effect on its liquidity or capital resources.

As a result, we believe there is sufficient working capital to support the committed research and development programs and other activities over the next 12 months and the Company has the ability to realize its assets and pay its liabilities and commitments in the normal course of business.

The following table summarizes our cash flows for the periods presented:

| | As of June 30, | | | As of December 31, | |
|---|---|---|---|---|---|
| (In Australian dollars) | 2018 | 2017 | 2016 | 2018 | 2017 |
| Net cash used in operating activities | A$(16,372,024) | A$(8,557,524) | A$(7,938,557) | A$(10,458,479) | A$ (7,875,025) |
| Net cash (used in)/provided by investing activities | (498,749) | 195,245 | (47,849) | (722,472) | (63,672) |
| Net cash provided by financing activities | 27,934,920 | 8,238,129 | 9,360,830 | 25,364,339 | 15,980,605 |
| Net increase/(decrease) in cash and cash equivalents | 11,064,147 | (124,150) | 1,374,424 | 14,183,388 | 8,041,908 |
| Cash and cash equivalents at beginning of period | 3,790,491 | 4,171,879 | 2,966,555 | 14,825,532 | 3,790,491 |
| Impact of foreign exchange rate | (29,106) | (257,238) | (169,100) | 1,333,440 | (55,390) |
| Cash and cash equivalents at end of period | 14,825,532 | 3,790,491 | 4,171,879 | 30,342,360 | 11,777,009 |

Years Ended June 30, 2018, 2017 and 2016

Net cash used in operating activities was A$16,372,024, A$8,557,524 and A$7,938,557 during the years ended June 30, 2018, 2017 and 2016, respectively. Our payments to suppliers and employees during the years ended June 30, 2018, 2017 and 2016 were A$25,681,347, A$17,676,710 and A$14,894,221, respectively. The increase in payments to suppliers and employees is as the result of investments in commercial, manufacturing, leadership and system capabilities in preparation for the planned U.S. launch of the RECELL System and related research and development and corporate initiatives. Our operating activity receipts from customers for the years ended June 30, 2018, 2017 and 2016 of A$1,129,046, A$928,687 and A$1,079,549 consisted of commercial sales from Europe and Asia Pacific. Our operating activity receipts from BARDA and other income for the years ended June 30, 2018, 2017 and 2016 of A$8,141,207, A$7,094,061 and A$2,427,188. The BARDA program was received and began in the third quarter of fiscal year 2016 for the expansion of activities surrounding the Company's PMA submission to the FDA in September 2017 for approval to market the RECELL System in the U.S.

Net cash (used in)/provided by investing activities was A$(498,749), A$195,245 and A$(47,849) during the years ended June 30, 2018, 2017 and 2016, respectively. Cash flows used for investing activities was primarily attributable to payments for the purchase of a property and equipment. During the fiscal year 2017, the Company sold the respiratory business segment and the proceeds from the sale of financial assets was A$627,837.

Net cash provided by financing activities was A$27,934,920, A$8,238,129 and A$9,360,830 for the years ended June 30, 2018, 2017 and 2016. The Company completed a series of equity transactions and received proceeds from issuance of shares and options of A$29,760,563, A$9,048,102 and A$10,025,584 for the years ended June 30, 2018, 2017 and 2016.

We realized a foreign exchange loss of A$29,106, A$257,238 and A$169,100 for the years ended June 30, 2018, 2017 and 2016. The Australian dollar depreciated against the U.S. dollar by 3%, 4% and 3% for the years ended June 30, 2018, 2017 and 2016.

Half-Years Ended December 31, 2018 and 2017

Net cash used in operating activities was A$10,458,479 and A$7,875,025 during the half-years ended December 31, 2018 and 2017, respectively. Our payments to suppliers and employees during the half-years ended December 31, 2018 and 2017 were A$20,305,643 and A$11,943,480, respectively. The increase in

payments to suppliers and employees is as the result of investments in commercial, manufacturing, leadership and system capabilities in preparation for the planned U.S. launch of the RECELL System and related research and development and corporate initiatives. Our operating activity receipts from customers for the half-years ended December 31, 2018 and 2017 of A$1,204,802 and A$367,933 consisted of commercial sales from US, Europe and Asia Pacific. Our operating activity receipts from BARDA and other income for the half-years ended December 31, 2018 and 2017 of A$6,104,306 and A$3,676,182. This increase was the result of an expansion of activities related to programs conducted under the BARDA contract during the year. Funding provided by BARDA during the half-year ended December 31, 2018 focused primarily on support of the regulatory activities to support the U.S. approval of the RECELL System, the Continued Access and Compassionate Use programs which provide access to the RECELL System for U.S. patients prior to FDA approval, and two U.S. clinical trials in pediatric burn patients.

Net cash used in investing activities was A$722,472 and A$63,672 during the half-years ended December 31, 2018 and 2017, respectively. Cash flows used for investing activities was primarily attributable to payments for the purchase of property and equipment.

Net cash provided by financing activities was A$25,364,339 and A$15,980,605 for the half-years ended December 31, 2018 and 2017. The Company completed a series of equity transactions and received proceeds from issuance of shares and options of A$28,053,762 and A$17,028,964 for the half-years ended December 31, 2018 and 2017.

We realized a foreign exchange gain/(loss) of A$1,333,440 and A$(55,390) for the half-years ended December 31, 2018 and 2017. The Australian dollar appreciated/(depreciated) against the U.S. dollar by 8% and (3%) for the half-years ended December 31, 2018 and 2017.

Capital management

We aim to manage capital so that the Company continues as a going concern while also maintaining optimal returns to shareholders and benefits for other stakeholders. We also aim to maintain a capital structure that ensures the lowest cost of capital available to the Company. We regularly review the Company's capital structure and seek to take advantage of available opportunities to improve outcomes for the Company and its shareholders.

For the year ended June 30, 2018, there were no dividends paid and we have no plans to commence the payment of dividends. We have no current plans to issue further shares on the market but will continue to assess market conditions and the company's cash flow requirements to ensure the Company is appropriately funded.

There is no significant external borrowing at the reporting date. Neither the Company nor any of the subsidiaries are subject to externally imposed capital requirement.

**C. Research and Development, Patents and Licenses**

In recent years, we have continued our practice of building valuable research collaborations with institutes based primarily in the United States but also in Australia, China and Europe and other regions to enable us to develop a point-of-care solution for the potential treatment of a wide range of skin injuries or defects using a point of care, autologous Spray-On Skin Cells regeneration technology known as RECELL System. These collaborative arrangements ensure that we work with well-respected key option leaders and laboratories without incurring ongoing administrative and personnel costs. All clinical, research and development of RECELL System is performed in compliance with the appropriate governing authorities, regulators and standards. We maintain in-house general counsel and research and development project expertise to coordinate these research collaborations.

Our research and development expenses consist primarily of expenses for contracted research and development activities conducted by major contract research organizations on our behalf, including personnel,

testing facilities and other payments in accordance with our research and clinical agreements. Research and development expenses are included in the Product Development Expenses line item of our financial statements, and amounted to $3,266,098, $2,330,297 and $2,160,628 during the years ended June 30, 2018, 2017 and 2016, respectively.

**D. Trend Information**

While our RECELL System has reached commercialization for specific applications in certain jurisdictions, we seek to further our development and commercialization, and it is not possible for us to predict with any degree of accuracy the outcome of our business in the future.

**E. Off-Balance Sheet Arrangements**

During fiscal years ended June 30, 2016, 2017 and 2018, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

**F. Contractual Obligations**

The Company's furniture and IT equipment are held under lease arrangements. As of June 30, 2018, 2017 and 2016 the net carrying amount of the furniture and IT equipment held under lease arrangements are A$159,043, A$66,408 A$ nil, respectively. The Company's finance lease liabilities, which are secured by the related assets held under finance leases, are classified as follows:

| | June 30, 2018 |
|---|---|
| **Finance Lease Liabilities** | |
| Current | A$ 86,883 |
| Non-Current | A$ 72,160 |
| ***Total*** | A$ 159,043 |

| | Minimum Lease Payment Due | | | |
|---|---|---|---|---|
| | Within 1 Year | 1-5 Years | After 5 Years | Total |
| **June 30, 2018** | | | | |
| **Lease Payments** | A$ 114,650 | A$ 92,515 | — | A$207,165 |
| **Finance Charges** | (27,767) | (20,355) | — | (48,122) |
| **Net Present Values** | 86,883 | 72,160 | — | 159,043 |

The Company leases space under operating leases. Future minimum lease payments under such leases as of June 30, 2018 are as follows:

| | Minimum Lease Payment Due | | | |
|---|---|---|---|---|
| | Within 1 Year | 1-5 Years | After 5 Years | Total |
| **June 30, 2018** | A$ 525,919 | A$856,541 | — | A$1,382,460 |

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**A. Directors and Senior Management**

The following table sets forth our directors and senior management, their age and the positions they held as of the date of this registration statement on Form 20-F. All of our directors and senior management may be contacted at our registered office located at c/o Mertons Corporate Services Pty Ltd Level 7 330 Collins Street Melbourne VIC 3000, Australia.

| Name | Age | Position |
|---|---|---|
| Lou Panaccio(1) | 61 | Non-Executive Chairman |
| Dr. Michael Perry | 60 | Executive Director and Chief Executive Officer |

| Name | Age | Position |
|---|---|---|
| Erin Liberto | 45 | Chief Commercial Officer |
| Tim Rooney | 52 | Chief Administrative Officer and interim Chief Financial Officer |
| Andrew Quick | 48 | Chief Technology Officer |
| Donna Shiroma | 56 | General Counsel |
| Jeremy Curnock Cook(2) | 69 | Non-Executive Director |
| Louis Drapeau(3)(2) | 54 | Non-Executive Director |
| Damien McDonald(1) | 53 | Non-Executive Director |
| Professor Suzanne Crowe(4) | 68 | Non-Executive Director |

(1) Member of the Audit Committee
(2) Member of the Remuneration Committee and the Nomination Committee
(3) Chairman of the Audit Committee
(4) Chairman of the Remuneration Committee and the Nomination Committee

**Lou Panaccio** has served as Non-Executive Chairman of the Board of Directors since July 2014. Mr. Panaccio is a successful healthcare businessman with extensive experience leading companies from concept to commercialization. Mr. Panaccio possesses more than 30 years of executive leadership experience in healthcare services and life sciences, including more than 20 years of board-level experience. Mr. Panaccio is currently a Non-Executive Director of ASX50 company and one of the world's largest medical diagnostics companies, Sonic Healthcare Limited, where he has served since 2005. In addition, Mr. Panaccio is Non-Executive Director of Unison Housing Limited, Non-Executive Chairman of Genera Biosystems Limited, a publicly listed company (ASX) that develops and commercializes multiplexed molecular diagnostic tests, and a Non-Executive Director of Rhythm Biosciences Limited, a publicly listed (ASX) development-stage medical diagnostics company.

**Dr. Michael Perry** was appointed Chief Executive Officer and Executive Director in June 2017. Prior to this appointment, Dr. Perry had served as a Non-Executive Director commencing in February 2013. From 2016 to 2017, he served as Senior Vice President and Chief Scientific Officer of Global Business Development and Licensing for Novartis AG. From 2014 to 2016, Dr. Perry served as Chief Scientific Officer of Novartis' Cell and Gene Therapy Unit, and from 2012 to 2014 he served as Vice President and Global Head of Stem Cell Therapy for Novartis Pharmaceuticals Corp, a US affiliate of Switzerland-based Novartis AG. Dr. Perry previously served as the Global Head of R&D at Baxter Healthcare, President and CEO of Cell & Gene Therapy at Novartis affiliates Systemix Inc. and Genetic Therapy, Inc., VP Regulatory Affairs at Sandoz Pharmaceuticals Corp., Director of Regulatory Affairs at Schering-Plough Corporation, and Chairman, CEO or CMO at several early stage biotech companies. He also previously served as a Venture Partner with Bay City Capital, LLC, a life science investment firm managing venture capital funds, based in San Francisco California. Dr. Perry serves as a Director of Arrowhead Pharmaceuticals, a public (NASDAQ) development stage company focused on medicines that treat intractable diseases by silencing the genes, and AmpliPhi Biosciences Corporation, Inc., a public (NYSE) clinical-stage biotechnology company focused on the development of bacteriophage-based therapies for the treatment of antibiotic-resistant bacterial infections. He is also a Director at BioScience Managers Pty Ltd, a shareholder of the Company.

**Erin Liberto** has served as Chief Commercial Officer since August 2017. Ms. Liberto has more than 17 years of multifaceted global commercial experience developing, launching, managing, and optimizing healthcare portfolios with products that span therapeutic and aesthetic indications for international organizations including Allergan and Johnson & Johnson. Ms. Liberto's proficiency in long-term strategic planning has led to more than a dozen successful product launches across the U.S., Europe, and Asia Pacific. Ms. Liberto holds an International MBA with a concentration in Global Marketing from Thunderbird School of Global Management in Arizona and a Bachelor of Commerce from McMaster University in Canada.

**Tim Rooney** was appointed Chief Administrative Officer in December 2017 and is responsible for operations of the Company. Mr. Rooney was also appointed as our interim Chief Financial Officer in May 2019. Mr. Rooney

has served the Company in multiple roles since joining in October 2012 as Chief Financial Officer and Chief Operating Officer, including interim Chief Executive Officer from 2013 to 2015. Mr. Rooney has over 20 years of experience in senior finance and operations management in medical devices and pharmaceutical wholesale distribution, including PDI Enterprises, Inc., a pharmaceutical wholesale distributor, where he served as Chief Financial Officer and Chief Operating Officer from 1991 to 2007 and served in other roles starting in 1984. Mr., Rooney holds a B.S. degree in Business Administration, Finance from California State University, Northridge.

**Andrew Quick** was appointed Chief Technology Officer in April 2019 and previous to that served as Senior Vice President, Clinical Development beginning July 2010. Mr. Quick has more than 25 years of experience in medical device design, development, clinical research and medical affairs. Mr. Quick has previously held leadership positions in the development of diagnostic instrumentation and active implantable therapeutics, including most recently with Boston Scientific Neuromodulation / Advanced Bionics from 2006 to 2010 where he led U.S. investigational device and post-market clinical research in the cochlear implant business. He also served in a series of positions with SonaMed Corporation from 1994 to 2005, including Vice President, Products and Clinical Affairs. Mr. Quick has B.S. and M.S. degrees in Biomedical Engineering from Boston University.

**Donna Shiroma** has served as General Counsel since June 2018. Ms. Shiroma has more than 20 years of legal and compliance experience in the pharmaceutical and medical device industries and has played an instrumental role in transitioning companies from clinical to commercial entities. Prior to joining the Company, she served in roles of increasing responsibility as corporate counsel, general counsel, vice president of legal, chief privacy and compliance officer, and chief commercial officer for Astrex Pharmaceuticals from 2017 to 2018, Ascend Therapeutics from 2008 to 2017, PDL BioPharma from 2006 to 2008, and several Johnson & Johnson companies. Ms. Shiroma holds a B.S. in Environmental Sciences from University of California Berkley, and a Juris Doctor degree from Santa Clara University School of Law. She is licensed in the State of California as an attorney.

**Jeremy Curnock Cook** has served as a Non-Executive Director of the Board since October 2012. Mr. Curnock Cook is currently the Managing Director of Bioscience Managers Pty Ltd, a shareholder of the Company, responsible for the BM Asia Pacific Healthcare Fund, and serves as Chairman of International Bioscience Managers Ltd. He is the former head of the life science private equity team at Rothschild Asset Management, and was responsible for the launch of the first dedicated biotechnology fund for the Australian market and the conception and launch of the International Biotechnology Trust. Mr. Curnock Cook serves as a Non-Executive Director of Adherium Ltd, a public (ASX) company with a digital health platform focused on improving medication adherence and patient outcomes, and AmpliPhi Biosciences Corporation, Inc., a public (NYSE) clinical-stage biotechnology company focused on the development of bacteriophage-based therapies for the treatment of antibiotic-resistant bacterial infections. He also serves as an Alternate Director for Sea Dragon Limited, a public (NZX) company processing fish oils into marine bioactive compounds. Mr. Curnock Cook previously served as a Non-Executive Director of Phylogica Limited, a public (ASX) company developing next generation intracellular biological therapeutics.

**Louis Drapeau** has served as Non-Executive Director of the Board since January 2016. Mr. Drapeau has considerable expertise in both the biotech sector and with the financial reporting and other requirements of U.S. public companies. Mr. Drapeau is an Independent Director at AmpliPhi Biosciences Corporation, Inc., a public (NYSE) clinical-stage biotechnology company focused on the development of bacteriophage-based therapies for the treatment of antibiotic-resistant bacterial infections. Mr. Drapeau has held senior positions with Insite Vision Inc., Nektar Therapeutics and BioMarin Pharmaceutical, Inc., and served as an Audit Partner at Arthur Andersen LLP. Mr. Drapeau was previously an Independent Director at Bio-Rad Laboratories, a public (NYSE) company manufacturing products for the life science research and clinical diagnostics markets, and InterMune, Inc., a public (NASDAQ) commercial-stage biotech company. He has an MBA from Stanford University.

**Damien McDonald** has served as a Non-Executive Director since January 2016. Mr. McDonald has a proven track record of achieving value in the medical device space. Mr. McDonald is currently Chief Executive Officer and a Director of the Board of LivaNova plc, having previously served as Chief Operating Officer. LivaNova plc

is a public (NASDAQ) company that is a leader in cardiovascular and neuromodulation solutions. Prior to that, he was a Group Executive and Corporate Vice President at NYSE-listed Danaher Corporation, a multinational science and technology innovation company that acquires and produces life science and industrial products and brands, where he led a $1.5 billion group of dental consumable companies. Earlier in his tenure, Mr. McDonald was Group President of Kerr where he and his team focused on building a strong research and development pipeline while improving operational performance utilizing the Denaher Business System. He has also previously worked for Merck &Co, Johnson & Johnson and Zimmer. Mr. McDonald has B.S. degrees in both pharmacy and economics from the University of Queensland, a master's degree in International Economics from the University of Wales, and an MBA from IMD of Lausanne, Switzerland.

**Professor Suzanne Crowe AM** has served as a Non-Executive Director since January 2016. Australian-based, she is a physician-scientist and company director with extensive expertise in supporting companies with their medical and scientific strategies. Professor Crowe is a Principal Research Fellow of the Australian National Health and Medical Research Council. She is a Principal Specialist in Infectious Diseases at The Alfred Hospital, Melbourne and Adjunct Professor of Medicine and Infectious Diseases at Monash University, Melbourne, and has published more than 200 peer-reviewed papers. Professor Crowe is a member of the Australian Institute of Company Directors and is a Director of St Vincents Health Australia, the country's largest not-for-profit health and aged care provider. Professor Crowe was appointed as a Member of the Order of Australia (AM) in 2011 to recognize her service to medical research in HIV/AIDS. She has medical and MD degrees from Monash University, an internal medicine specialist qualification in Infectious Diseases from the Royal Australasian College of Physicians, and a Diploma in Medical Laboratory Technology from the Royal Melbourne Institute of Technology.

**B. Compensation**

**Remuneration Principles**

This Remuneration Report outlines the Director and Executive remuneration arrangements of the Company in accordance with the requirements of the Australian Corporations Act 2001 and its Regulations. For the purposes of this report Key Management Personnel (KMP) of the Company are defined as those persons having authority and responsibility for planning, directing and controlling the major activities of the Company, directly or indirectly, including any Director (whether Executive or otherwise) of the parent Company. For the purposes of this report, the term 'executive' encompasses the Chief Executive and Senior Executives of the Company.

During the year ended June 30, 2018 we appointed Erin Liberto as our Chief Commercial Officer effective August 28, 2017 and Donna Shiroma as General Counsel effective June 25, 2018. We also appointed Dale Sander as Chief Financial Officer effective December 5, 2017, and he served in that position until his resignation on May 15, 2019. On December 5, 2017 the Company also appointed of Timothy Rooney as Chief Administrative Officer, and effective May 15, 2019 Mr. Rooney was also appointed as our interim Chief Financial Officer.

Effective April 1, 2019 Andrew Quick was promoted from Senior Vice President Clinical Development to Chief Technology Officer. There were no other changes of Key Management Personnel after the reporting date and through the date of this registration statement on Form 20-F.

In prior years we identified a number of key areas for additional emphasis which has resulted in a review of remuneration practices, policies and plans associated with key management personnel remuneration. To develop an appropriate foundation for future practices the Remuneration Committee has a formal Remuneration Governance Framework which, at the core, consists of:

- A revised Remuneration & Nomination Committee Charter which now mandates the development and maintenance of other Remuneration Governance Framework elements;
- A Senior Executive Remuneration Policy;

- A Short-Term Incentive (STI) Policy & Procedure document; and
- A Long-Term Incentive (LTI) Policy & Procedure document.

Remuneration Committee

The Remuneration Committee of the Board of Directors of the Company is responsible for determining and reviewing remuneration arrangements for the Board and Executives.

The Remuneration Committee assesses the appropriateness of the nature and amount of remuneration of Executives on a periodic basis by reference to relevant employment market conditions with the overall objective of ensuring maximum stakeholder benefit from the retention of a high-quality Board and executive team.

Use of Remuneration Consultants

The Company did not make use of any external remuneration consultants during the financial year, although it did obtain from third parties industry benchmarking information.

Remuneration Framework, Philosophy and Policies

The performance of the Company depends upon the quality of its Directors and Executives. To prosper, the Company must attract, motivate and retain highly skilled Directors and Executives. To this end, the Company embodies the following principles in its remuneration framework:

- Provide competitive rewards to attract and retain high caliber Executives;
- Acceptability to shareholders through transparency and engagement, and ensuring that remuneration frameworks and practices are appropriate to the circumstances of the Company as it evolves;
- Performance linkage to and alignment with Executive compensation; and
- Establish appropriate, demanding performance hurdles as a prerequisite to payment of variable Executive remuneration.

The main focus of executives and of performance assessment for Fiscal 2018 was related to the U.S. PMA application for the RECELL System, related activities required to support FDA approval, and preparation for the planned market launch of the RECELL System in the U.S. For the current year, the primary focus is on the successful market launch of the RECELL System in the U.S., advancement of the Company's pipeline and successful completion of the listing of our ADSs on the NASDAQ Capital Market (US Quotation). Incentives are intended to be linked to shareholder value via milestone completion, clinical trial outcomes and total shareholder return.

Non-Executive Director Remuneration

**Objective**: The Board seeks to set aggregate remuneration at a level which provides the Company with the ability to attract and retain Directors of the highest caliber, whilst incurring a cost which is acceptable to shareholders.

**Policy**: The amount of aggregate remuneration sought to be approved by shareholders and the fee structure is to be commercially acceptable, competitive and subject to an annual review. The Board considers industry benchmarking data regarding the fees paid to Non-Executive Directors of comparable companies when undertaking the annual review process.

**Structure**: In accordance with best practice corporate governance, the structure ofNon-Executive Director and Senior Management remuneration is separate and distinct. The Constitution and the ASX Listing Rules

specify that the aggregate remuneration of Non-Executive Directors shall be determined from time to time by a general meeting. The latest determination was at the Annual General Meeting held on November 29, 2005 when shareholders approved an aggregate remuneration of $450,000 per year in respect of fees payable to Non-Executive Directors. Please refer to Table 2 of this report for the allocation of Directors' fees.

Each Director receives a fee for being a Director of the Company and includes attendance and participation at Board and committee meetings. The Non-Executive Directors do not participate in any incentive programs.

The remuneration of Non-Executive Directors for the year ended June 30, 2018 is detailed in Table 2 of this report.

Executive Remuneration (including Executive Directors)

**Objective**: The Company aims to reward Executives with a level and mix of remuneration commensurate with their position and responsibilities within the Company so as to:

- reward Executives for Company and individual performance against targets set by reference to appropriate benchmarks as well as to specific short- and long-term goals of the Company;
- align the interests of Executives with those of shareholders; and
- ensure total remuneration is competitive by market standards.

**Policy**: The Company's broad framework for the Remuneration Committee requires the committee to ensure that:

- executive remuneration packages may involve a balance between fixed and incentive pay, reflecting short and/or long-term performance objectives appropriate to the Company's circumstances and objectives;
- a proportion of executives' remuneration is structured in a manner designed to link reward to corporate and individual performances; and
- recommendations are made to the Board with respect to the quantum of bonuses to be paid to executives.

To the extent that the Company adopts a different remuneration structure for itsNon-Executive Directors, the Committee shall document its reasons for the purpose of disclosure to stakeholders.

**Structure**: The Remuneration Committee determines the level and make-up of the Chief Executive remuneration. The Committee takes advice from the Chief Executive with input from industry benchmarking data to set and approve all other executive remuneration. To assist in achieving the Company's objectives, the Remuneration Committee links the nature and number of officers' emoluments to the Company's performance. Remuneration may consist of the following key elements:

- Fixed Remuneration
- Variable Remuneration
    - Short Term Incentive (STI) and/or
    - Long Term Incentive (LTI)

The proportion of fixed remuneration and variable remuneration (potential short term and long-term incentives) is established for each Executive by the Remuneration Committee annually. Table 2 details the fixed and variable components for the Executives of the Company.

**Fixed Remuneration Objective and Structure**: The level of fixed remuneration is set so as to provide a base level of remuneration which is both appropriate to the position and is competitive in the market. During the 2018, 2017 and 2016 financial years there were no benefits paid in kind. Fixed remuneration is reviewed annually by the Remuneration Committee and the process consists of a review of Company-wide and individual performance and relevant comparative remuneration in the market.

**Variable Remuneration – Short Term Incentive (STI) Objective and Structure** The objective of variable remuneration is to link the achievement of the Company's operational targets with the remuneration received by the Executives charged with meeting those targets. The Company's STI objectives:

- Motivate Senior Executives to achieve the short-term annual objectives linked to Company success and shareholder value creation;
- Create a strong link between performance and reward;
- Share Company success with the Senior Executives that contribute to it; and
- Create a component of the employment cost that is responsive to short to medium term changes in the circumstances of the Company.

Variable remuneration is reviewed annually by the Remuneration Committee and the process consists of a review of Company-wide and individual performance and relevant comparative remuneration in the market.

**Variable Remuneration – Long Term Incentive (LTI) Objective and Structure** The objective of the LTI plan is to reward Executives in a manner that aligns remuneration with the creation of shareholder value and to create an element of remuneration that supports the executive team working together to achieve this outcome over the long term. The LTI plan is also a key component of the Company's retention strategy. The Company has two LTI plans available for use with senior executives and staff. At the 2014 AGM, shareholders approved a Performance Rights Plan. At the General Meeting of shareholders on August 24, 2015, shareholders approved a share loan plan for senior executives. Currently no loans are outstanding under the share loan plan.

LTI for 2018 financial year

In addition to the before mentioned CEO Long Term Incentive Plan (Operating and Financial Review), 9,110,000 share options were granted during FY18. The Company has two separate LTI plans that it can use as part of incentivizing senior executives and staff for achieving targeted Key Performance Indicators (KPIs) including financial and non-financial targets, corporate metrics and individual measures of performance.

**Remuneration of Key Management Personnel**

Table 1: Employment Contracts

The following table outlines the specified terms of the relevant employment contracts for the Key Management Personnel of the Company:

| Role | Name | Contract duration | Period of notice | Termination payments provided for by contract |
|---|---|---|---|---|
| CEO and Executive Director | Dr. Michael Perry | Open ended contract | 12-month notice period | 12 months |
| CFO | Dale Sander(1) | Open ended contract | 6-month notice period | 6 months |
| CAO | Timothy Rooney(2) | Open ended contract | 12-month notice period | 12 months |
| CCO | Erin Liberto | Open ended contract | 6-month notice period | 6 months |

| Role | Name | Contract duration | Period of notice | Termination payments provided for by contract |
|---|---|---|---|---|
| SVP, Clinical Development | Andrew Quick(3) | Open ended contract | 3-month notice period | Payment in lieu of notice only, no other benefits specified |
| Non-Executive Chairman | Lou Panaccio | Open ended contract | No notice period-subject to Avita constitution | Payment in lieu of notice only, no other benefits specified |
| All other Non-Executive Directors | Jeremy Curnock Cook | Open ended contract | No notice period-subject to Avita constitution | Payment in lieu of notice only, no other benefits specified |
| | Louis Drapeau | Open ended contract | No notice period-subject to Avita constitution | Payment in lieu of notice only, no other benefits specified |
| | Damien McDonald | Open ended contract | No notice period-subject to Avita constitution | Payment in lieu of notice only, no other benefits specified |
| | Professor Suzanne Crowe | Open ended contract | No notice period-subject to Avita constitution | Payment in lieu of notice only, no other benefits specified |

(1) Mr. Sander resigned as Chief Financial Officer effective May 15, 2019.
(2) Mr. Rooney was appointed interim Chief Financial Officer effective May 15, 2019.
(3) Mr. Quick was promoted to Chief Technology Officer effective April 1, 2019.

Table 2: Remuneration for the year ended June 30, 2018

| | Short-term Benefits | | | | Post-employment Benefits | Equity-settled Share-based Payments | | Total | Proportion of Element of Remuneration Related to Performance (Other than Options Issued) | | Proportion of Elements of Remuneration Not Related to Performance(1) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Salary, fees and leave A$ | Profit share and bonuses A$ | Non-monetary benefits A$ | Other benefits A$ | Pension and superannuation A$ | Shares/ Units A$ | Options/ Rights A$ | A$ | Non-salary Cash-based Incentives % | Shares/ Units % | % |
| **Non-Executive Directors** | | | | | | | | | | | |
| Lou Panaccio | | | | | | | | | | | |
| Non-Executive Chairman | 58,758 | — | — | — | 7,481 | 19,992 | — | 86,231 | 0% | 0% | 91% |
| Jeremy Curnock Cook | 61,040 | — | — | — | — | — | — | 61,040 | 0% | 0% | 100% |
| Louis Drapeau | 60,811 | — | — | — | — | — | — | 60,811 | 0% | 0% | 100% |
| Damien McDonald | — | — | — | — | — | 61,128 | — | 56,549 | 0% | 0% | 100% |
| Suzanne Crowe | 45,989 | — | — | — | 5,296 | 9,755 | — | 61,040 | 0% | 0% | 91% |
| **Sub-total** | **226,598** | — | — | — | **12,777** | **90,875** | — | **330,250** | | | |
| **Other Key Management Personnel & Executives** | | | | | | | | | | | |
| Michael Perry | | | | | | | | | | | |
| CEO(2) | 663,926 | 515,159 | 27,608 | — | 43,148 | 536,679 | 401,752 | 2,188,272 | 24% | 25% | 34% |
| Timothy Rooney | | | | | | | | | | | |
| CAO and Interim CFO | 441,683 | 147,893 | 16,550 | — | 23,106 | — | 136,647 | 765,879 | 24% | 0% | 63% |
| Dale Sander | | | | | | | | | | | |
| CFO(3) | 379,908 | 246,299 | 31,660 | 270,450 | 23,193 | — | 80,727 | 1,032,237 | 19% | 0% | 68% |
| Erin Liberto | | | | | | | | | | | |
| CCO | 398,353 | 147,893 | 41,897 | — | 22,530 | — | 207,097 | 817,770 | 18% | 0% | 57% |
| Andrew Quick | | | | | | | | | | | |
| CTO | 403,853 | 119,723 | 36,807 | — | 23,592 | — | 181,914 | 765,889 | 16% | 0% | 61% |
| Donna Shiroma | | | | | | | | | | | |
| GC | 419,319 | 117,519 | 13,632 | — | 27,075 | — | 302,915 | 880,460 | 13% | 0% | 52% |
| **Sub-total** | **2,707,042** | **1,294,486** | **168,154** | **270,450** | **162,644** | **536,679** | **1,311,052** | **6,450,507** | | | |
| **Totals** | **2,933,640** | **1,294,486** | **168,154** | **270,450** | **175,421** | **627,554** | **1,311,052** | **6,780,757** | | | |

(1) The percentage disclosed does not include the value of options expensed during the year or pension and superannuation benefits paid per the requirements of corporations act (Australia) 2001. Thus, the sum of the percentages for compensation related to performance and compensation not related to performance disclosed for certain individuals may be less than 100%.

(2) On November 30, 2017, 50,000,000 Restrictive Stock Units, issued as part of a long term incentive, or "LTI," each equal to one ordinary share, were issued to Dr. Michael Perry based on the following milestones:

a. Tenure – a total of 16,666,666 LTIs issued but to vest over the three-year period commencing July 1, 2017;

b. Company Share Price – a total of 16,666,666 LTIs issued but to vest in three equal tranches subject to the Volume Weighted Average Price (VWAP) of Company share price (as at close of trade on the ASX on relevant date) achieving multiples of 2x, 3x and 4x the Company's share price at the time of shareholder approval; and

c. Milestone performance – a total of 16,666,668 LTIs issued, but to vest in two equal tranches with one tranche to vest upon the achievement of the following milestones: (1) FDA PMA approval of RECELL for burns, and (2) Initial BARDA procurement under CLIN2 of the BARDA Contract

(3) Mr. Sander resigned and Chief Financial Officer effective May 15, 2019.

Table 3: Compensation of Key Management Personnel

| | 2019 A$ | 2018 A$ | 2017 A$ |
|---|---|---|---|
| Short-term employee benefits | 4,396,280 | 3,770,141 | 2,933,510 |
| Post-employment employee benefits | 445,871 | 90,512 | 112,034 |
| Share-based payment | 1,938,606 | 1,596,368 | 1,215,809 |
| **Total compensation** | **6,780,757** | **5,457,021** | **4,261,353** |

Table 4: Option Holdings of Key Management Personnel

The fair value of options granted as remuneration and as shown in the above table has been determined in accordance with Australian Accounting Standards and will be recognized as an expense over the relevant vesting period to the extent that conditions necessary for vesting are satisfied. Options issued to key management personnel have vesting criteria corresponding to the following conditions:

- Tenure with the Company
- Revenue target
- FDA PMA approval of RECELL for burns
- Initial BARDA procurement under CLIN2 of the BARDA Contract
- US Quotation

| | Balance at | Grant Details | | | Exercised | | Balance at | Vested | | | Unvested | Unvested |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | July 1, 2018 No. | Issued Date | No. | Value A$ | No. | Value A$ | June 30, 2019 | Exercisable | Unexercisable | Total at June 30, 2019 | Balance at June 30, 2019 | Total at June 30, 2019 |
| Michael Perry | — | November 30, 2018 | 15,000,000 | 812,500 | — | — | 15,000,000 | 10,833,333 | — | 10,833,333 | 4,166,667 | 4,166,667 |
| Timothy Rooney | 7,800,000 | — | — | — | 1,750,000 | 131,950 | 6,050,000 | 4,330,000 | — | 4,330,000 | 1,720,000 | |
| | | November 1, 2018 | 500,000 | 32,839 | — | — | 500,000 | — | — | — | 500,000 | |
| | | November 30, 2018 | 3,420,000 | 196,822 | — | — | 3,420,000 | — | — | — | 3,420,000 | |
| | | November, 30 2018 | 360,000 | 84,816 | — | — | 360,000 | — | — | — | 360,000 | 6,000,000 |
| Andrew Quick | 4,518,750 | — | — | — | — | — | 4,518,750 | 3,211,250 | — | 3,211,250 | 1,307,500 | |
| | | November 1, 2018 | 500,000 | 32,839 | — | — | 500,000 | — | — | — | 500,000 | |
| | | November 30, 2018 | 3,021,250 | 173,873 | — | — | 3,021,250 | — | — | — | 3,021,250 | |
| | | April 1, 2019 | 4,040,000 | 759,722 | — | — | 4,040,000 | — | — | — | 4,040,000 | 8,868,750 |
| Troy Barring | 1,110,000 | — | — | — | 1,110,000 | 34,474 | — | — | — | — | — | — |
| Erin Liberto | 4,000,000 | — | — | — | — | — | 4,000,000 | 2,300,000 | — | 2,300,000 | 1,700,000 | |
| | | November 1, 2018 | 2,110,000 | 138,574 | — | — | 2,110,000 | — | — | — | 2,110,000 | |
| | | November 30, 2018 | 5,970,000 | 343,574 | — | — | 5,970,000 | — | — | — | 5,970,000 | 9,780,000 |
| Dale Sander(1) | 4,000,000 | — | — | — | 4,000,000 | 199,200 | — | — | — | — | — | — |
| Donna Shiroma | 3,000,000 | — | — | — | — | — | 3,000,000 | 1,520,000 | — | 1,520,000 | 1,480,000 | |
| | | November 1, 2018 | 2,610,000 | 171,412 | — | — | 2,610,000 | — | — | — | 2,610,000 | |
| | | November 30, 2018 | 6,470,000 | 372,349 | — | — | 6,470,000 | — | — | — | 6,470,000 | 10,560,000 |
| | **24,428,750** | | **44,001,250** | **3,119,320** | **6,860,000** | **365,624** | **61,570,000** | **22,194,583** | **—** | **22,194,583** | **39,375,417** | **39,375,417** |

(1) Mr. Sander resigned as Chief Financial Officer effective May 15, 2019.

Other Equity-related Transactions with Key Management Personnel

Other than set forth below, there have been no other transactions involving equity instruments apart from those described in the tables above, relating to options and shareholdings:

On November 30, 2018, the shareholders of the Company approved and Dr. Perry was issued 15,000,000 options to purchase ordinary shares at an exercise price of A$0.0820. The vesting of such options is based on (i) tenure of Dr. Perry, (ii) the Company's Share Price and (iii) milestone performance by the Company as follows:

(a) *Tenure* – a total of 7,499,999 options issued for immediate vesting and over the two-year period commencing July 1, 2017;

(b) *Company Share Price* – a total of 5,000,001 options issued but to vest in three equal tranches subject to the Volume Weighted Average Price (VWAP) of Company share price (as at close of trade on the ASX on relevant date) achieving multiples of 2x, 3x and 4x the Company's share price at the time of shareholder approval; and

(c) *Milestone performance* – a total of 2,500,000 options issued, but to vest upon the achievement of initial BARDA procurement under CLIN2 of the BARDA Contract.

Other Transactions with Key Management Personnel and/or their Related Parties

There were no other transactions conducted between the Company and KMP or their parties, apart from those disclosed above relating to equity and compensation, that were conducted other than in accordance with normal employees, customer or supplier relationships on terms no more favorable than those reasonably expected under arm's length dealings with unrelated persons.

### C. Board Practices

#### Introduction

Our Board of Directors is elected by and accountable to our shareholders. It currently consists of six directors, the executive Chairman, four non-executive directors and our Chief Executive Officer who also serves as an Executive Director. The Chairman of our Board of Directors is responsible for the management of the Board of Directors and its functions.

#### Election of Directors

Directors are elected at our annual general meeting of shareholders. Under our Constitution, a director, other than a managing director, must not hold office for more than three years or beyond the third annual general meeting following his or her appointment (whichever is the longer period) without submitting himself for re-election. Our Board of Directors has the power to appoint any person to be a director, either to fill a vacancy or as an additional director (provided that the total number of directors does not exceed the maximum allowed by law), and any director so appointed may hold office only until the next annual general meeting when he or she shall be eligible for election.

#### Corporate Governance

***ASX Corporate Governance Principles***

In Australia there are no mandatory corporate governance structures and practices that must be observed by a company listed on the ASX. Instead, the ASX Corporate Governance Council has published the ASX Best Practice Guide, which contains what are called the "Recommendations," which articulate eight core principles (and associated recommendations) which are intended to provide a reference point for companies about their corporate governance structures and practices, and against which companies must report.

Under ASX listing Rule 4.10.3, companies are required to provide a statement in their annual report to shareholders disclosing the extent to which they have followed the Recommendations in the reporting period. Where a company has not followed all the Recommendations, it must identify the Recommendations that have not been followed, the reasons for not following them, and what (if any) alternative governance practices it adopted in lieu of the recommendation during that period. It is not mandatory to follow the Recommendations. We believe we are in material compliance with the ASX Corporate Governance Principles.

Set forth below are the material provisions of the ASX Corporate Governance Principles together with the reasons, where applicable, for variations therefrom:

1. Lay solid foundations for management and oversight. Companies should clearly delineate the respective roles and responsibilities of board and management and regularly review their performance.

2. Structure the Board to be effective and add value. Listed companies should have a board of an appropriate size and collectively have the skills, commitment and knowledge of the entity and the industry in which it operates, to enable it to discharge its duties effectively and to add value. During the year ended June 30, 2018, we did not follow this Recommendations in the following area:

    a. No formal performance evaluation of the Board was conducted for the year ended June 30, 2018 as the Board believes that the Company is not of a size, nor is its our financial affairs of such complexity, to warrant such an exercise. The Board recognizes the importance of performance evaluations and will continually assess the necessity and timing of future performance evaluation.

3. Instill a culture of acting lawfully, ethically and responsibly. A listed entity should instill and continually reinforce a culture across the organization of acting lawfully, ethically and responsibly.

4. Safeguard the integrity of corporate reports. A listed entity should have appropriate processes to verify the integrity of its corporate reports

5. Make timely and balanced disclosure. A listed entity should promote timely and balanced disclosure of all material matters concerning it that a reasonable person would expect to have a material effect on the price or value of its securities. During the year ended June 30, 2018, we did not follow this Recommendations as we only adopted written policies designed to promote timely and balanced disclosure in accordance with ASX Listing Rule disclosure requirements for the year ending June 30, 2019. Our executive officers and members of our Board of Directors are aware of the obligations for continuous disclosure under the ASX Listing Rules and meet on a regular basis to ensure compliance.

6. Respect the rights of security holders. A listed entity should provide its security holders with appropriate information and facilities to allow them to exercise their rights as security holders effectively.

7. Recognize and manage risk. A listed entity should establish a sound system of risk management and periodically review the effectiveness of that framework.

8. Remunerate fairly and responsibly. A listed entity should pay director remuneration sufficient to attract and retain high quality directors and design its executive remuneration to attract, retain and motivate high quality senior executives and to align their interests with the creation of value for security holders and with the entity's values and risk appetite.

**Non-Executive and Independent Directors**

Australian law does not require a company to appoint a certain number of independent directors to its board of directors or audit committee. However, under the ASX Corporate Governance Principles and Recommendations, the ASX recommends, but does not require, that a ASX-listed company have a majority of independent directors on its board of directors and that the audit committee be comprised of independent directors, within the meaning of the rules of the ASX.

Our Board of Directors currently have five directors, of which we view four are independentnon-executive directors within the meaning of the ASX Corporate Governance Principles and Recommendations, and our audit committee consists of three independent non-executive directors. Accordingly, we currently comply with the Recommendations.

Under NASDAQ Marketplace Rules, in general a majority of our Board of Directors must qualify as independent directors within the meaning of the NASDAQ Marketplace Rules and our audit committee must have at least three members and be comprised only of independent directors, each of whom satisfies the respective "independence" requirements of NASDAQ and the U.S. Securities and Exchange Commission.

The Board of Directors does not have regularly scheduled meetings at which only independent directors are present. The Board of Directors does meet regularly, and independent directors are expected to attend all such meetings. Our practices are consistent with the Recommendations, in that the Recommendations do not provide that independent directors should meet separately from the Board of Directors.

Our Board of Directors has determined that each of Lou Panaccio, Jeremy Curnock Cook, Louis Drapeau, Damien McDonald and Suzanne Crowe qualifies as an independent director under the requirements of the ASX, NASDAQ Marketplace Rules and U.S. Securities and Exchange Commission.

**Committees of the Board of Directors**

*Audit Committee.* NASDAQ Marketplace Rules require us to establish an audit committee comprised of at least three members, each of whom is financially literate and satisfies the respective "independence" requirements of the U.S. Securities and Exchange Commission and NASDAQ and one of whom has accounting or related financial management expertise at senior levels within a company.

Our Audit Committee assists our Board of Directors in overseeing the accounting and financial reporting processes of our company and audits of our financial statements, including the integrity of our financial statements, compliance with legal and regulatory requirements, our independent public accountants' qualifications and independence, and independent public accountants, and such other duties as may be directed by our Board of Directors. The Audit Committee is also required to assess risk management.

Our Audit Committee currently consists of three board members, each of whom satisfies the "independence" requirements of the U.S. Securities and Exchange Commission, NASDAQ Marketplace Rules and ASX Rules. Our Audit Committee is currently composed of Messrs. Drapeau, Panaccio and McDonald. Each qualifies as an "independent director" within the meaning of NASDAQ Marketplace Rules. Mr. Drapeau is the chairman of the audit committee. The audit committee meets at least two times per year.

*Remuneration (Compensation) Committee.* Our Board of Directors has established a Remuneration Committee, which is comprised by majority of independent directors, within the meaning of NASDAQ Marketplace Rules. The Remuneration Committee is responsible for reviewing the salary, incentives and other benefits of our directors, senior executive officers and employees, and to make recommendations on such matters for approval by our Board of Directors. The Remuneration Committee is also responsible for overseeing and advising our Board of Directors with regard to the adoption of policies that govern our compensation programs. Ms. Crowe and Messrs. Drapeau and Cook are the current members of the Remuneration Committee and each qualifies as an "independent director" within the meaning of NASDAQ Marketplace Rules. Ms. Crowe is the chairman of this committee.

*Nomination Committee.* Our Board of Directors has established a Nomination Committee. Ms. Crowe and Messrs. Drapeau and Cook are the current members of the Nomination Committee and each qualifies as an "independent director" within the meaning of NASDAQ Marketplace Rules. Ms. Crowe is the chairman of this committee. The Nomination Committee is responsible for identifying individuals qualified to become members of our Board of Directors, recommending to our Board of Directors nominees for election at meetings of our shareholders or to fill vacancies that arise on our Board of Directors, and recommending to our Board of Directors qualified and experienced directors to serve on the committees of our Board of Directors.

**Directors' Service Contracts**

For details of directors' service contracts providing for benefits upon termination of employment, see "Item 6. Directors, Senior Management and Employees – B. Compensation – Service Agreements."

**Indemnification of Directors and Officers**

Our Constitution provides that, we may indemnify a person who is, or has been, an officer of our company, to the full extent permissible by law, out of our property against any liability incurred by such person as an officer in defending proceedings, whether civil or criminal, and whatever their outcome.

In addition, our Constitution provides that to the extent permitted by law, we may pay, or agree to pay, a premium in respect of a contract insuring a person who is or has been an officer of our company or one of our subsidiaries against any liability:

- incurred by the person in his or her capacity as an officer of our company or a subsidiary of our company, and
- for costs and expenses incurred by that person in defending proceedings relating to that person acting as an officer of Avita, whether civil or criminal, and whatever their outcome.

We maintain a directors' and officers' liability insurance policy. We have established a policy for the indemnification of our directors and officers against certain liabilities incurred as a director or officer, including costs and expenses associated in successfully defending legal proceedings.

**D. Employees**

As of June 30, 2019, we had 95 full-time employees, of which 80 were located in the U.S., two were located in Europe and one in Australia. Of these full-time employees, 30 are engaged in sales and marketing activities, 14 are engaged in research and development activities, 21 are engaged in manufacturing, quality and regulatory activities and 20 are engaged in corporate administrative activities. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

**E. Share Ownership**

**Beneficial Ownership of Senior Management and Directors**

The beneficial ownership of senior management and directors are set out in Item 7 (A).

**F. Stock Option Plan**

In November 2014, we adopted the Employee Share Plan and the Incentive Option Plan (collectively, the 2016 Plans). The Employee Share Plan was amended at the 2018 AGM. Under the 2016 Plans, we may issue stock options or other share-based instruments representing up to 7.5% of our ordinary shares outstanding, or a total of 139,832,968 ordinary shares based on the number of ordinary shares currently outstanding. Any increase in the maximum number of ordinary shares issuable under the 2016 Plans is subject to shareholder approval or to an increase in the total number of ordinary shares outstanding.

The purpose of the 2016 Plans is to promote the success of our Company by incentivizing our employees and directors to contribute to the creation of shareholder value. Under the 2016 Plans, we may issue to employees and directors of our Company and its subsidiaries, from time to time, options to purchase ordinary shares or other share-based instruments. To date, the 2016 Plans have only been used to issue options to purchase ordinary shares to employees.

The 2016 Plans are administered by the Remuneration Committee. Subject to Board approval where required by applicable law, the Remuneration Committee has the authority, in its sole discretion, to grant options under the 2016 Plans, to interpret the provisions of the 2016 Plans, and to prescribe, amend, and rescind rules and regulations relating to the 2016 Plans or any issue or grant thereunder as it may deem necessary or advisable, subject to any other approval if required by applicable law. All decisions made by the Remuneration Committee pursuant to the provisions of the 2016 Plans will be final, conclusive and binding on all persons.

The number of shares issued or options granted, the exercise price and option term or options granted, the vesting schedule and escrow periods of shares issued and options granted, under the 2016 Plans are determined

by the Remuneration Committee, in accordance with the provisions of the 2016 Plans, and specified in an offer document from our Company and accepted by the eligible person, subject to the terms of the 2016 Plans. Options granted under the 2016 Plans will be unlisted and exercisable at an exercise price equal to less than market value of an ordinary share on the ASX at the date of grant, or such other exercise price that the Remuneration Committee determines to be appropriate under the circumstances. The term of an option granted under the 2016 Plans will be determined by the Remuneration Committee; however, no option will be exercisable after the expiration of ten years from the date of its grant. Except as otherwise provided in the 2016 Plans or determined by the Remuneration Committee and set forth in an offer document, the issuance of shares and exercise of options granted under the 2016 Plans will (i) vest over a four year period in four equal installments, 25% at the end of each year from the date of grant, and /or (ii) will be subject to other performance criteria and hurdles, as determined by the Remuneration Committee.

A summary of the status of the 2016 Plans and predecessor plans, as of June 30, 2018, 2017 and 2016, and the changes for the years ended on those dates, is presented below:

| | As of June 30, | | | | | |
|---|---|---|---|---|---|---|
| | 2018 | | 2017 | | 2016 | |
| | Amount | Weighted average exercise price | Amount | Weighted average exercise price | Amount | Weighted average exercise price |
| Options outstanding at the beginning of the year | $ 2,281,533 | $ 0.09 | $ 1,606,936 | $ 0.14 | $ 1,382,775 | $ 0.14 |
| Granted | 584,800 | 0.06 | 1,760,497 | 0.08 | 431,661 | 0.16 |
| Expired | (521,036) | 0.13 | (700,900) | 0.14 | (207,500) | 0.14 |
| Forfeiture | (67,067) | 0.08 | (385,000) | 0.15 | — | — |
| Options outstanding at the end of the year | $ 2,278,230 | $ 0.08 | $ 2,281,533 | $ 0.08 | $ 1,606,936 | $ 0.15 |
| Options exercisable at the end of the year | $ 914,139 | $ 0.09 | $ 438,639 | $ 0.09 | $ 1,606,936 | $ 0.15 |

## ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### A. Major Shareholders

The following table sets forth information regarding shares of our common stock beneficially owned as of April 30, 2019 by: (i) each of our executive officers and directors; (ii) all the executive officers and directors as a group; and (iii) each person known by us to beneficially own five percent or more of the outstanding ordinary shares.

| Name of Beneficial Owner | Ordinary Shares | Options to Purchase Ordinary Shares Exercisable Within 60 Days | Restricted Security Units (RSUs) Vested or Vesting Within 60 Days | Total Share and Share-Based Holdings(1) | % Ownership(2) |
|---|---|---|---|---|---|
| **5% or more shareholders** | | | | | |
| Redmile Group, LLC(1) | 250,000,000 | — | — | 250,000,000 | 13.4% |
| Karst Peak Capital Limited(2) | 196,154,563 | — | — | 196,154,563 | 10.5% |
| Blackcrane Capital, LLC(3) | 124,345,592 | — | — | 124,345,592 | 6.7% |
| Phillip Asset Management Ltd. atf BioScience Managers Translation Fund(4) | 95,833,334 | — | — | 95,833,334 | 5.14% |
| **Names executive officers and directors** | | | | | |
| Lou Panaccio | 1,648,564 | — | — | 1,648,564 | * |
| Dr. Michael Perry(4) | 61,654 | 10,833,333 | 36,111,109 | 47,006,906 | 2.5% |
| Erin Liberto | — | 2,050,000 | — | 2,050,000 | * |
| Timothy Rooney | — | 5,220,000 | — | 5,220,000 | * |
| Andrew Quick | — | 3,307,500 | — | 3,307,500 | * |
| Donna Shiroma | — | — | — | — | * |
| Jeremy Curnock Cook(4) | — | — | — | — | * |
| Louis Drapeau | 33,938 | — | — | 33,938 | * |
| Damien McDonald | 578,402 | — | — | 578,402 | * |
| Professor Suzanne Crowe | 106,910 | — | — | 106,910 | * |
| **All executive officers and directors as a group (10 persons)** | 2,429,468 | 23,174,583 | 36,111,109 | 61,715,160 | 3.3% |

* Represents beneficial ownership of less than 1% of the outstanding ordinary shares.

(1) Consists of 122,918,007 ordinary shares held by Redmile Offshore II Master Fund Ltd. and 127,081,993 ordinary shares held by Redmile Strategic Master Fund LP. Redmile Group, LLC is the investment manager/adviser of Redmile Offshore II Master Fund Ltd. and Redmile Strategic Master Fund LP. Based solely on disclosures provided by Redmile Group, LLC to the ASX, these ordinary shares are owned by certain investment limited partnerships, pooled investment vehicle(s), separately managed accounts, etc. for which Redmile Group, LLC serves as the general partner and/or investment manager. Jeremy Green, as the majority managing member and owner of Redmile Group, LLC, may be deemed to beneficially own securities owned by such investment limited partnerships, pooled investment vehicle(s), separately managed accounts, etc. The principal business address of each of Redmile Group, LLC and Mr. Green is One Letterman Drive, Bldg D, Ste D3-300, San Francisco, CA 94129.

(2) Consists of 117,801,410 ordinary shares held by Karst Peak Asia Master Fund and 37,896,043 ordinary shares held by Vermilion Peak Fund. Karst Peak Capital Limited is the discretionary investment manager to Karst Peak Asia Master Fund and Vermilion Peak Fund. Based solely on disclosures provided by Karst Peak Capital Limited (KCPL) to the ASX, Adam Leitzes is the director of KPCL and may be deemed to have both voting power and disposal power over the shares. The address for KPCL is Kinwick Centre, Suite 1705, 32 Hollywood Road, Central, Hong Kong.

(3) Consists of 59,445,952 ordinary shares and 3,244,982 ADSs, each ADS representing 20 ordinary shares or 64,899,640 ordinary shares in total underlying the ADSs. Blackcrane Capital, LLC holds 59,276,225 ordinary shares and 3,184,060 ADSs, with 63,681,200 ordinary shares underlying the ADSs. Blackcrane Overseas Alpha Fund, LLC holders 169,727 ordinary shares and 11,099 ADSs, with 221,980 ordinary shares underlying the ADSs. Blackcrane Capital, LLC is the discretionary investment manager of Blackcrane Overseas Alpha Fund, LLC. Daniel Kim holds 49,823 ADSs with 996,460 ordinary shares underlying the ADSs. Mr. Kim has a relevant interest in the securities held by Blackcrane Capital, LLC and Blackcrane Overseas Alpha Fund as he holds voting power of more than 20% in Blackcrane Capital, LLC. The address of Blackcrane Capital, LLC is 500 108th Avenue NE, STE 960, Bellevue, WA 98004.

(4) Excludes 81,747,669 ordinary shares held in the name of One Funds Management Limited (Asia Pac Health Fund II A/C) which is managed and beneficially owned by BioScience Managers Pty Ltd of which Mr. Curnock Cook is an officer and Dr. Perry is a Director.

As of April 2, 2019, 38.2% of our ordinary shares were held in Australia, 16.4% of our ordinary shares were held in Hong Kong, 42.4% of our ordinary shares were held in the United States including ordinary shares underlying ADSs.

The Company is not aware that it is directly owned or controlled by another corporation, any foreign government or any other natural or legal person(s) severally or jointly. The Company is not aware of any arrangement, the operation of which may result in a change of control of the Company.

**B. Related Party Transactions**

Other than employment matters and indemnification agreements between our directors and executive officers, related party transactions were limited to director fees, consultancy fees and travel reimbursements paid under normal terms and conditions to Bioscience Managers Pty Ltd of which Jeremy Curnock Cook is an officer and Dr. Michael Perry is a director. Consultancy services provided were assistance in product development, customer relations, recruitment and sales by Dr. Perry prior to becoming an officer of the Company in June 2017, as well as one other employee of Bioscience Managers Pty Ltd. Total fees paid to Bioscience Managers Pty Ltd were A$157,728, A$128,987 and A$59,675 for the years ended June 30, 2018, 2017 and 2016, respectively.

**C. Interests of Experts and Counsel**

Not applicable.

**ITEM 8. FINANCIAL INFORMATION**

**A. Consolidated Statements and Other Financial Information**

Our audited financial statements for the fiscal years ending June 30, 2018, 2017, and 2016 are included in Item 18 of this registration statement on Form 20-F.

**Legal Proceedings**

We are not involved in any significant legal, arbitration or governmental proceedings. We are not aware of any pending significant legal, arbitration or governmental proceedings with respect to Avita.

**Dividend Distribution Policy**

We have never paid cash dividends to our shareholders. We intend to retain future earnings for use in our business and do not anticipate paying cash dividends on our ordinary shares in the foreseeable future. Any future dividend policy will be determined by the Board of Directors and will be based upon various factors, including our results of operations, financial condition, current and anticipated cash needs, future prospects, contractual restrictions and other factors as the Board of Directors may deem relevant.

**B. Significant Changes**

On September 20, 2018, the U.S. Food and Drug Administration (FDA) approved the Company's application to market the RECELL System to treat patients with acute thermal burns in the U.S.

Subsequent to June 30, 2018 the Company completed a series of equity transactions in in which the Company received a total of A$45,014,900 in gross proceeds. During the year ended June 30, 2018 the Company completed an institutional placement of shares to international and Australian institutional and sophisticated investors. The institutional placement included a second tranche totaling A$3.250 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on July 23, 2018, and the net proceeds of A$3.041 million were received by the Company on July 26, 2018. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on July 23, 2018, and the Company issued 65 million shares at a price of A$0.050 per share and received gross proceeds of A$3,250,000 on July 26, 2018. Also subsequent to year end, on December 4, 2018 the Company completed the first tranche of an institutional placement of in which it issued 310,047,015 fully paid ordinary shares at a price of A$0.080 per share raising gross proceeds of A$24,803,761. The institutional placement included a second tranche totaling A$15.196 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on January 14, 2019, and the Company issued 189,952,985 shares at a price of A$0.080 per share and received gross proceeds of A$15,196,239 on January 14, 2019. In addition, on January 11, 2019 the Company complete a Share Purchase Plan under which it issued 22,061,250 shares of stock at a price of A$0.080 per share and received gross proceeds of A$1,764,900.

See also Item 10A under the heading "*History of Share Capital*" for a listing of recent equity offerings.

## ITEM 9. THE OFFER AND LISTING

### A. Offer and Listing Details

**Australian Securities Exchange**

Our ordinary shares have traded on the ASX under the ticker symbol "AVH" since our initial public offering on September 8, 1993. The following table sets forth, for the periods indicated, the high and low market quotations for our ordinary shares as quoted on the ASX:

| | Per Ordinary Share (A$) | |
|---|---|---|
| | High | Low |
| | A$ | A$ |
| **Fiscal Year Ended June 30,** | **ASX** | **ASX** |
| 2014 | .128 | .075 |
| 2015 | .106 | .054 |
| 2016 | .137 | .052 |
| 2017 | .129 | .065 |
| 2018 | .080 | .046 |
| **Fiscal Year Ended June 30, 2016:** | | |
| First Quarter | .106 | .052 |
| Second Quarter | .101 | .079 |
| Third Quarter | .137 | .082 |
| Fourth Quarter | .124 | .079 |
| **Fiscal Year Ended June 30, 2017:** | | |
| First Quarter | .129 | .079 |
| Second Quarter | .121 | .094 |
| Third Quarter | .112 | .077 |
| Fourth Quarter | .084 | .065 |
| **Fiscal Year Ended June 30, 2018:** | | |
| First Quarter | .080 | .049 |
| Second Quarter | .072 | .049 |
| Third Quarter | .067 | .053 |
| Fourth Quarter | .083 | .048 |
| **Month Ended:** | | |
| July 2018 | .105 | .077 |
| August 2018 | .142 | .086 |
| September 2018 | .140 | .089 |
| October 2018 | .097 | .070 |
| November 2018 | .084 | .077 |
| December 2018 | .135 | .079 |
| January 2019 | .155 | .125 |
| February 2019 | .295 | .130 |
| March 2019 | .540 | .285 |
| April 2019 | .510 | .325 |

**OTCQX Market**

Our ADSs have traded over the counter in the U.S. on the OTCQX under the ticker symbol "AVMXY" since May 14, 2012. We intend to apply with the NASDAQ Capital Market to have our ADSs traded on the

NASDAQ Capital Market. The following table sets forth, for the periods indicated, the high and low market quotations for our ADSs as quoted on the OTCQX:

| | Per ADS (US$) | |
|---|---|---|
| | High | Low |
| | US$ | US$ |
| **Fiscal Year Ended June 30,** | | |
| 2014 | 2.74 | 1.47 |
| 2015 | 2.16 | 0.98 |
| 2016 | 2.46 | 0.93 |
| 2017 | 2.24 | 1.15 |
| 2018 | 1.47 | 0.75 |
| **Fiscal Year Ended June 30, 2016:** | | |
| First Quarter | 1.51 | 0.93 |
| Second Quarter | 1.95 | 1.23 |
| Third Quarter | 1.89 | 1.35 |
| Fourth Quarter | 2.46 | 1.42 |
| **Fiscal Year Ended June 30, 2017:** | | |
| First Quarter | 1.95 | 1.35 |
| Second Quarter | 2.24 | 1.43 |
| Third Quarter | 1.86 | 1.53 |
| Fourth Quarter | 1.71 | 1.15 |
| **Fiscal Year Ended June 30, 2018:** | | |
| First Quarter | 1.47 | 0.79 |
| Second Quarter | 1.43 | 0.75 |
| Third Quarter | 1.25 | 0.88 |
| Fourth Quarter | 1.09 | 0.77 |
| **Month Ended:** | | |
| July 2018 | 1.28 | 0.92 |
| August 2018 | 1.65 | 1.21 |
| September 2018 | 2.15 | 1.20 |
| October 2018 | 1.92 | 1.31 |
| November 2018 | 1.75 | 1.17 |
| December 2018 | 1.31 | 1.06 |
| January 2019 | 1.92 | 1.09 |
| February 2019 | 2.25 | 1.84 |
| March 2019 | 4.37 | 1.87 |
| April 2019 | 7.67 | 4.26 |

### B. Plan of Distribution

Not applicable.

### C. Markets

Our ordinary shares are listed and traded on the Australian Securities Exchange Ltd., or ASX. Although our ADSs are currently quoted on the OTCQX, we intend to be listed on the NASDAQ Capital Market in the first half of 2019. There is no assurance that our NASDAQ listing application will be approved or that an active public market for our ADSs will further develop or be sustained.

**D. Selling Shareholders**

Not Applicable.

**E. Dilution**

Not Applicable.

**F. Expenses of the Issue.**

Not Applicable.

## ITEM 10. ADDITIONAL INFORMATION

**A. Share Capital**

As at the date of this Registration Statement, there is no concept of authorized share capital and par value for companies incorporated in Australia. The Company can issue unlimited number of Ordinary Shares without par value. The Company only has one class of Ordinary Shares.

As at June 30, 2017 and 2018, we had 669,930,538 and 934,312,458 Ordinary Shares issued, outstanding and fully paid, respectively.

**Ordinary Shares**

Each of our Ordinary Share entitles the holder thereof to one vote at any meeting of Avita's shareholders. The holder of Ordinary Shares are entitled to receive if, as and when declared by the Board, dividends in such amount as shall be determined by the Board. The holders of Ordinary Shares have the right to receive the Company's remaining property in the event of a liquidation, dissolution or winding up, whether voluntary or involuntary.

**Options**

The Company has 111,639,164 share options outstanding at the date of this Registration Statement and 43,193,804 share options available for future grant.

**History of Share Capital**

For the dates described below, the Company issued Ordinary Shares as follows:

| Date | Description of Issuance | Number of Ordinary Shares Issued | Total (A$) |
|---|---|---|---|
| January 11, 2019 | We sold 22,061,250 Ordinary Shares under a Share Purchase Plan at a price of A$0.080 per share, raising gross proceeds of A$1,764,900. | 22,061,250 | A$1,764,900 |
| December 4, 2018 | We sold 500,000,000 Ordinary Shares to institutional investors at a price of A$0.080 per share, raising gross proceeds of A$40,000,000 and incurring A$2,923,858 in expenses. | 500,000,000 | A$40,000,000 |
| June 6, 2018 | We sold 320,475,665 Ordinary Shares to institutional investors at a price of A$0.050 per share, raising gross proceeds of A$16,023,783 and incurring A$1,042,720 in expenses. | 320,475,665 | A$16,023,783 |
| November 7, 2017 | We sold 276,502,853 Ordinary Shares in a rights offering at a price of A$0.045 per share raising gross proceeds of A$12,442,628 and incurring A$636,067 in expenses. | 276,502,853 | A$12,442,628 |

| Date | Description of Issuance | Number of Ordinary Shares Issued | Total (A$) |
|---|---|---|---|
| October 11, 2017 | We sold 100,982,978 Ordinary Shares at a price of A$0.045 per share raising gross proceeds of A$4,544,234 and incurring A$248,720 in expenses. | 100,982,978 | A$4,544,234 |
| July 11, 2016 | We sold 100,164,831 Ordinary Shares at a price of A$0.09 per share raising gross proceeds of A$9,048,102 and incurring A A$506,452 in expenses. | 100,164,831 | A$9,048,102 |

**B. Memorandum and Articles of Association**

**General**

Our constituent document is entitled the Company's "Constitution". The Constitution is subject to the Listing Rules of the Australian Securities Exchange ("Listing Rules") and the Australian Corporations Act 2001 (Cth) ("Corporations Act"). The Company may modify or replace its Constitution, or a provision of the Constitution, by special resolution of shareholders.

**Objects and Purposes**

As a public company we have all the rights, powers and privileges of a natural person. Our Constitution, which is not required to have an objects or purposes clause, does not provide for or prescribe any specific objects or purposes.

**The Powers of the Directors**

Under the provisions of our Constitution, our directors may exercise all the powers of our company in relation to:

*Management of Company*

The business of our Company is managed by the directors who may exercise all the powers of our Company that are not by the Corporations Act. by the Listing Rules or by the Constitution, required to be exercised by the shareholders in general meeting.

*Specific powers of Directors*

Without limiting the generality of the above paragraph, the directors may exercise all the powers of the Company to borrow or raise money through equity or debt offerings and to issue debentures or give any other security for a debt, liability or obligation of the Company or of any other person.

**Other Provisions in the Constitution with Respect to the Directors**

Subject to complying with the Corporations Act and the Listing Rules regarding disclosure of and voting on matters involving material personal interests of the directors, their associates and their related or controlled entities, under the provisions of our Constitution, a director may participate in, vote on and be counted in a quorum for any meeting, resolution or decision of the directors and may be present at any meeting where any matter is being considered by the directors.

Under the provisions of our Constitution, the non-executive directors may be remunerated for their services as directors (up to a maximum aggregate amount as determined approved by the Shareholders in general meeting) in individual amounts as determined by the Board. The remuneration of both non-executive and

executive directors must comply with the Corporations Act and the Listing Rules. The Listing Rules provide that a company must not increase the total amount of non-executive directors' fees payable by it without the approval of its shareholders. The Corporations Act places a limit upon the level of termination benefits that can be paid to a person who holds a managerial or executive office upon that person's retirement from that office or position.

Subject to the Corporations Act, the Listing Rules and our Constitution, a director must retire from office by no later than the third annual general meeting following his or her appointment or election or 3 years, whichever is longer. If eligible, that retiring director may also seek re-election at the annual general meeting at which that director retires. This requirement for resignation does not apply to the Managing Director.

A candidate for election as a director is not required to hold any ordinary shares to be eligible for election.

**Members to Approve Significant Changes to Company Activities**

The Listing Rules stipulate that the directors must not make a significant change to the nature or scale of a company's activities or sell or otherwise dispose of the main undertaking of a listed entity without the prior approval of the Australian Securities Exchange and of the shareholders in general meeting.

**Rights, Preferences and Restrictions Attached to Our Ordinary Shares**

The concept of authorized share capital no longer exists in Australia and as a result, our "authorized share capital" is unlimited. All our outstanding ordinary shares are validly issued and fully paid. Our ordinary shares have no redemption provisions or sinking fund provisions. The rights attached to our ordinary shares include:

*Dividend Rights.* Our shareholders have the right to share in our profits distributed as a dividend and any other permitted distribution. Subject to the Corporations Act, our Constitution and the rights of persons entitled to shares with special rights to a dividend (at present there are none), the directors may determine that a dividend is payable, fix the amount and the time for payment and authorize the payment or crediting by the Company to, or at the direction of, each member entitled to that dividend. No dividend is payable except in accordance with the Corporations Act (as amended from time to time) and no dividend carries interest as against the Company.

*Voting Rights.* At any general meeting of shareholders a resolution put to the vote of the meeting must be decided on a show of hands unless a poll is effectively demanded, and the demand is not withdrawn. On a show of hands, each member present in person and each other person present as a proxy, attorney or representative of a member has one vote. On a poll, each member present in person has one vote for each share held by the member and each person present as proxy, attorney or representative of a member has one vote for each share held by such member that the person represents.

The quorum required for an ordinary meeting of shareholders consists of at least three shareholders present in person, or by proxy, attorney or representative appointed pursuant to our Constitution. A meeting adjourned for lack of a quorum generally is adjourned to the same day in the following week at the same time and place. At the reconvened meeting, the required quorum consists of any two members present in person, or by proxy, attorney or representative appointed pursuant to our Constitution.

An ordinary resolution requires approval by the holders of a majority of the voting rights represented at the meeting, in person, by proxy, or by written ballot and voting thereon. Under the Corporations Act, a special resolution, such as amending our Constitution ,winding-up, or other changes as specified in our Constitution, requires approval of a special majority, representing the holders of no less than 75% of the voting rights represented at the meeting in person, by proxy or by written ballet, entitled to vote and voting thereon.

*Rights in the Event of Liquidation.* If the Company is wound up, after satisfaction of all liabilities to creditors, the Shareholders are entitled to participate equally pro-rata (per Share owned) in the distribution of the assets of the Company (both capital and surplus), subject only to any amounts unpaid (if any) on their Shares.

**Changing Rights Attached to Shares**

Our Constitution does not set out a procedure for varying rights attached to our ordinary shares. The Corporations Act provides that if a company has a constitution that does not set out the procedure for varying or cancelling rights attached to shares in a class of shares of a company with share capital, those rights may be varied or cancelled only by a special resolution of the shareholders of the company and a special resolution of the relevant class; or with the written consent of members with at least 75 per cent of the votes in the class.

**Annual and Extraordinary General Meetings**

Our directors must convene an annual meeting of shareholders at least once every calendar year, within five months of our last fiscal year-end balance date (the fiscal year end date currently being June 30,). Notice of at least 28 calendar days prior to the date of every general meeting is required. The directors or a director may also convene and arrange to hold a general meeting of the Company whenever they think fit. In addition, a general meeting may be convened by one or more shareholders holding in the aggregate at least 5% of the votes that may be cast at the general meeting. A general meeting must be called not more than 21 calendar days after the request is made by the requesting shareholders and must be held not later than two months after the shareholder request is given to the Company.

**Limitations on the Rights to Own Securities in Our Company**

The Corporations Act takeovers provisions apply to acquisitions of ASX-listed Australian companies. A person cannot acquire a relevant interest (i.e. a controlling interest) in voting securities of an entity that is subject to the takeovers provisions if that would result in any person's voting power exceeding 20% (or the voting power increasing, if it is already over 20%), except via a specified exception (such as a takeover bid or scheme of arrangement or an incremental increase of up to 3% every 6 calendar months). The most common takeover structures in Australia are an off-market takeover bid and a scheme of arrangement.

**Ownership Threshold Above Which Shareholder Ownership Must be Disclosed**

Under the Corporations Act, any person who increases their voting power from below to above 5% (or already has voting power of 5% or more and increases or decreases that power by at least 1%) needs to publicly disclose that fact within two business days of that change occurring via the filing of a substantial holding notice with the ASX and upon the Company.

**Changes in Our Capital**

Subject to the Listing Rules and the Corporations Act, the powers of the Company to issue and cancel shares in the Company and grant options over unissued shares in the Company are vested in the directors. Listing Rule 7.1 provides that (subject to certain exceptions) prior approval of shareholders is required for an issue of securities if the issue of those securities will, when aggregated with all the securities issued by the Company during the previous 12 months without prior shareholder approval, exceed 15% of the number of shares on issue at the commencement of that 12 month period. In addition, Listing Rule 7.1A permits eligible entities that have obtained shareholder approval (by special resolution at its most recent annual general meeting) to issue an additional 10% of the entity's issued ordinary securities. The ability to issue securities under listing rule 7.1A is in addition to the Company's ability to issue 15% of its fully paid ordinary shares under Listing Rule 7.1

**C. Material Contracts**

Except for contracts entered into in the ordinary course of business, the only contracts entered into by Avita within two years immediately preceding this Registration Statement that are still in effect, which may be regarded as material are as follows:

BARDA Contract

We have a contract with Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, valued at least US$50.4 million (approximately A$68.14 million). The contract provides funding for the development of the RECELL System and future use of the product to assist disaster preparedness and response in the U.S. for mass casualties involving burn injuries. We entered into the contract on September 29, 2015, and the scope was expanded as a result of amendments entered into as of June 24, 2016 and September 18, 2017. The contract terminates September 28, 2022 and may be terminated earlier at the option of BARDA.

Under the contract, we have agreed to undertake, and BARDA have agreed to fund and provide technical support for, the development of the RECELL System including two randomized, controlled pivotal clinical trials, Compassionate Use and Continued Access programs, development of the health economic model demonstrating the cost savings associated with the RECELL System, and two randomized, controlled clinical trials in pediatric burn patients. Also included in the BARDA contract is provision for the future procurement of the RECELL System by BARDA under a vendor-managed inventory system to bolster disaster preparedness in the amount of US$7.6 million (approximately A$10.3 million), although BARDA has the option of increasing the amount of the procurement. As of December 31, 2018, we had received cumulative payments of A$22.6 million under the BARDA contract.

### D. Exchange Controls and Australian Tax Matters

#### Exchange Controls

Australia has largely abolished exchange controls on investment transactions. The Australian dollar is freely convertible into U.S. dollars. In addition, there are currently no specific rules or limitations regarding the export from Australia of profits, dividends, capital or similar funds belonging to foreign investors, except that certain payments to nonresidents must be reported to the Australian Transaction Reports and Analysis Centre, which monitors such transaction, and amounts on account of potential Australian tax liabilities which may be required to be withheld unless a relevant taxation treaty can be shown to apply. Article 11.8 of the free trade agreement between Australia and the US provides that all transfers relating to a covered investment is to be made freely and without delay into and out of each territory. Such transfers include inter alia contributions to capital, including the initial contribution; profits, dividends (subject to any applicable withholding tax deduction), capital gains and proceeds from the sale of all or any part of the covered investment or from the partial or complete liquidation of the covered investment.

#### The Foreign Acquisitions and Takeovers Act 1975

Under Australian law, in certain circumstances foreign persons are prohibited from acquiring more than a limited percentage of the shares in an Australian company without approval from the Australian Treasurer. These limitations are set forth in the Australian Foreign Acquisitions and Takeovers Act, or the Takeovers Act.

Under the Takeovers Act, as currently in effect, any foreign person, together with associates, or parties acting in concert, is prohibited (without approval) from acquiring 20% or more of the shares (or voting / disposal rights attaching to shares) in any ASX listed company. “Associates” is a broadly defined term under the Takeovers Act and includes:

- spouses, lineal ancestors and descendants, and siblings;
- any person with whom the person is acting, or proposes to act, in concert;
- partners, officers of companies, the company, employers and employees, and corporations;
- their shareholders related through substantial shareholdings or voting power;
- corporations whose directors are controlled by the person, or who control a person; and
- associations between trustees and substantial beneficiaries of trust estates.

In addition, a foreign person may not acquire shares in a company having total assets of A$266 million or more (or A$1,154 million or more in case of non sensitive companies where it is a private (non-government) U.S. investor(s)) if, as a result of that acquisition, the total holdings of all foreign persons and their associates will exceed 40% in aggregate without the approval of the Australian Treasurer.

If the necessary approvals are not obtained, the Treasurer may make an order requiring the acquirer to dispose of the shares it has acquired within a specified period of time. At present, we do not have total assets of A$266 million or more. At this time, our total assets do not exceed any of the above thresholds and therefore no approval would be required from the Australian Treasurer. Nonetheless, should our total assets exceed the threshold in the future, we will be mindful to monitor the holdings for foreign persons (together with the associates) to ensure that the thresholds will not be exceeded without the Australian Treasurer's approval.

Each foreign person seeking to acquire holdings in excess of the above caps (including their associates, as the case may be) would need to complete an application form setting out the proposal and relevant particulars of the acquisition/shareholding. The Australian Treasurer then has 30 days to consider the application and make a decision. However, the Australian Treasurer may extend the period by up to a further 90 days by publishing an interim order. The Australian Treasurer has issued a guideline titled Australia's Foreign Investment Policy which provides an outline of the policy. As for the risk associated with seeking approval, the policy provides that the Treasurer will reject an application if it is contrary to the national interest.

If the level of foreign ownership exceeds 40% at any time (or if one individual not ordinarily resident in Australia, a foreign corporation or a foreign government holds at least 20%), we would be considered a foreign person under the Takeovers Act. In such event, we would be required to obtain the approval of the Australian Treasurer for our company, together with our associates, to acquire (i) more than 20% of an Australian company or business with assets totaling over A$266 million (or A$1,154 million if we were considered a private US investor); or (ii) any direct or indirect ownership in certain real estate interests.

The percentage of foreign ownership in our company would also be included in determining the foreign ownership of any Australian company or business in which we may choose to invest. Since we have no current plans for any such investments or acquisitions and do not currently own any relevant real estate interests, any such approvals required to be obtained by us as a foreign person under the Takeovers Act will not affect our current or future ownership or lease of real estate interests in Australia.

Our Constitution does not contain any additional limitations on a nonresident's right to hold or vote our securities. Australian law requires the transfer of shares in our company to be made in writing. No stamp duty will be payable in Australia on the transfer of ordinary shares quoted on the NASDAQ.

**The Financial Transactions Reports Act 1988**

The Financial Transactions Reports Act 1988 is an act of the Parliament of the Commonwealth of Australia, designed to facilitate the administration and enforcement of Australia's taxation laws. It provides for the reporting of certain financial transactions and transfers, including the export or import of currency exceeding $10,000 to Australian Transaction Reports and Analysis Centre.

**The Income Tax Assessment Act of 1936 and the Income Tax Assessment Act of 1997 (collectively, the "Tax Act")**

The Income Tax Assessment Act 1936 and the Income Tax Assessment Act 1997 (collectively, the "Tax Act") is the principal law governing the imposition of Federal taxes in Australia (except goods and services tax and a number of specific taxes such as fringe benefits tax and stamp duties).

Under the Tax Act, in some circumstances overseas residents are obliged to pay income tax in Australia on income derived from Australian sources or property.

**Taxation of Dividends for Non-Australian Resident Shareholders**

Non-Australian residents may be liable to pay Australian tax on income derived from Australian sources. One mechanism by which that tax is paid (for nonresidents who have no permanent establishment or fixed base in Australia or where the income is not connected with a permanent establishment or fixed base) is known as withholding tax. Dividends paid by a resident Australian company to a resident of the United States of America who; (a) is entitled to the benefits of the Australia/US Double Tax Agreement ("DTA"); and (b) is beneficially entitled to the dividends; and (c) holds less than 10% of the voting power in the relevant Australian company, are subject to withholding tax at the rate of 15% to the extent the dividends are 'unfranked'.

The rate of withholding tax is 5% if, the shareholder, is resident of the United State and is a company that holds at least 10% of the voting power in the company paying the dividend.

The rate of withholding tax on dividends is normally 30%, but in accordance with the DTA, the rate may be reduced in the circumstances outlined above.

Under Section 128B(3) of the Income Tax Assessment Act 1936, to the extent that dividends paid to nonresidents have been franked, such dividends are exempt from withholding tax. "Franked dividends" is the expression given to dividends when the profits out of which those dividends are paid have been taxed at company level and such tax is allocated or imputed to the dividend. Accordingly, an Australian company paying fully franked dividends to a nonresident is not required to deduct any withholding tax. Dividends on which withholding tax has been paid are generally not subject to any further Australian tax. In other words, the withholding tax should represent the final Australian tax liability in relation to those dividends. Where the dividend is paid out of foreign sourced income (such as foreign branch income and capital gains) that is declared to be conduit foreign income, no withholding tax is payable. Distributions of conduit foreign income are treated as non assessable nonexempt income of the foreign resident.

Dividends paid to Australian resident shareholders are subject to a different taxation regime.

We have not paid any cash dividends since our inception and we do not anticipate the payment of cash dividends in the foreseeable future. See Item 8.A. "Financial Statements and Other Financial Information–Dividend Distribution Policy."

**Capital Gains Tax**

Capital gains tax in Australia is payable on net assessable 'real gains' over the period in which the shares have been held, that is, the difference between the selling price and the total cost price calculated under Australian tax law. Nonresident shareholders will not be subject to Australian capital gains tax on any gain made on a sale or other disposal of ordinary shares in an Australian resident company, unless the nonresident shareholders, together with their associates, hold 10% or more of the total paid up share capital at (a) the time of disposal, or (b) any 12 month period in the 2 years prior to disposal.

Nonresident shareholders who own 10% or more of the paid up share capital will be subject to Australian capital gains tax if more than 50% of the assets held by the company directly or indirectly (based on market value), consists of real property situated in Australia (including land and lease holder interests) or Australian mining, quarrying or prospecting rights.

In some cases, if the shares have been held for more than 12 months, certain Australian resident taxpayers who have made a capital gain may be eligible for a discount of up to 50% of the gross gain. Capital losses may be available to offset capital gains. The capital gains discount is not available to non resident individuals on gains accrued after 8 May 2012.

**Stamp Duty**

Any transfer of shares or ADS through trading on the ASX and NASDAQ, whether by Australian residents or foreign residents, should not be subject to stamp duty on the assumption that the company does not have substantial real property holdings.

**Australian Death Duty**

Australia does not have estate or death duties. Generally, no capital gains tax liability is realized upon the inheritance of a deceased person's shares. The disposal of inherited shares by beneficiaries, may, however, give rise to a capital gains tax liability.

**Goods and Services Tax**

The issue or transfer of shares will not incur Australian goods and services tax and does not require a stockholder to register for Australian goods and services tax purposes.

**E. U.S. Federal Income Tax Considerations**

The following discussion summarizes certain U.S. federal income tax consequences to a U.S. Holder, as defined below, who purchases our ADSs and ordinary shares. This discussion assumes that investors will hold their ADSs or ordinary shares as capital assets (generally, property held for investment). This discussion does not discuss all aspects of U.S. federal income taxation which may be important to particular investors in light of their individual circumstances, including investors subject to special taxation, such as:

- banks and financial institutions;
- brokers and dealers in securities or currencies;
- insurance companies;
- tax-exempt organizations and retirement plans;
- grantor trusts;
- S corporations;
- persons holding ADSs or ordinary shares as part of hedging, conversion, constructive sale, straddle or other integrated transactions;
- persons who acquired their ordinary shares upon the exercise of employee stock options or otherwise as compensation;
- persons who have elected the mark-to-market method of accounting;
- persons who own 10% or more of our ADSs or shares;
- real estate investment trusts or regulated investment companies;
- U.S. persons whose "functional currency" is not the U.S. dollar;
- certain former citizens or long-term residents of the United States; and
- Non-U.S. Holders (as defined below).

This discussion is based in part on representations by the depositary and assumes that each obligation under the deposit agreement and any related agreement will be performed in accordance with its terms. Furthermore, the discussion below is based upon the provisions of the Internal Revenue Code of 1986, as amended (the "Code"), and U.S. Treasury regulations, rulings and judicial decisions hereunder as of the date hereof. Such authorities are subject to change, possibly on a retroactive basis, which may result in U.S. federal income tax consequences different from those discussed below.

**A person considering an investment in our ADSs or ordinary shares is urged to consult its tax advisor concerning U.S. federal, state, local and non-U.S. income and other tax consequences.**

A U.S. Holder is a beneficial owner of ADSs or ordinary shares that is for U.S. federal income tax purposes:

- a citizen or resident individual of the United States;
- a corporation or other entity taxable as a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation, regardless of its source; or
- a trust if it is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

A beneficial owner of ADSs or ordinary shares that is not a U.S. Holder is referred to herein as a "Non-U.S. Holder."

If a partnership or limited liability company treated as a partnership for U.S. federal income tax purposes holds ADSs or ordinary shares, the tax treatment of a partner or member will generally depend on the status of the partner or member and the activities of the partnership or such limited liability company. A partner of a partnership or a member of such a limited liability company holding ADSs or ordinary shares is urged to consult its tax advisors regarding an investment in our ADSs or ordinary shares.

***ADSs.*** In general, for U.S. federal income tax purposes, a U.S. Holder of ADSs will be treated as the owner of the underlying ordinary shares that are represented by such ADSs. Deposits and withdrawals of ordinary shares in exchange for ADSs will not be subject to U.S. federal income taxation.

***Distributions on ADSs or ordinary shares.*** Unless the passive foreign investment company rules, as discussed below, apply, the gross amount of the distributions in respect of the ADSs or ordinary shares will be subject to tax as dividend income to the extent of our current and accumulated earnings and profits, as determined under U.S. federal income tax principles. Subject to certain limitations, dividends paid to non-corporate U.S. Holders, including individuals, may be eligible for a reduced rate of taxation if we are deemed to be a "qualified foreign corporation" for U.S. federal income tax purposes, provided that such holder satisfies certain holding period requirements with respect to the ownership of our ADSs or ordinary shares.

Subject to the exceptions discussed below, a corporation is a qualified foreign corporation if it is:

- a foreign corporation that is eligible for the benefits of a comprehensive income tax treaty with the United States that includes an exchange of information program; or
- a foreign corporation if its stock with respect to which a dividend is paid or its ADSs backed by such stock are readily tradable on an established securities market within the United States.

Although we believe that we are a qualified foreign corporation because the ADSs will be traded on an established U.S. securities market and, as discussed below, we believe that we were not a passive foreign investment company for our 2018 tax year, no assurance can be given in this regard. In addition, our status as a qualified foreign corporation may change. A U.S. Holder that exchanges its ADSs for ordinary shares may not be eligible for the reduced rate of taxation on dividends if the ordinary shares are not deemed to be readily tradable on an established securities market within the United States.

Dividends will be includable in a U.S. Holder's gross income on the date actually or constructively received by the depositary, in the case of ADSs or, in the case of ordinary shares, by such U.S. Holder. These dividends will not be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations.

To the extent we pay dividends on the ADSs or ordinary shares in a currency other than the U.S. dollar, the U.S. dollar value of such dividends should be calculated by reference to the exchange rate prevailing on the date of actual or constructive receipt of the dividend, regardless of whether the foreign currency is converted into U.S. dollars at that time. If the foreign currency is converted into U.S. dollars on the date of actual or constructive receipt of such dividends, the tax basis of the U.S. Holder in such foreign currency will be equal to its U.S. dollar value on that date and, as a result, the U.S. Holder generally should not be required to recognize any foreign currency exchange gain or loss. Dividends paid in respect of the ADSs or ordinary shares generally will be treated as income from sources outside the United States.

To the extent that the amount of any distribution exceeds our current and accumulated earnings and profits, the distribution will first be treated as a tax-free return of capital, causing a reduction in the adjusted basis of the ADSs or ordinary shares, and the balance in excess of adjusted basis will be taxed as capital gain.

***Sale, exchange or other disposition of ADSs or ordinary shares.*** Unless the passive foreign investment company rules, as discussed below, apply, upon the sale, exchange or other disposition of ADSs or ordinary shares a U.S. Holder generally will recognize capital gain or loss equal to the difference between the amount realized upon the sale, exchange or other disposition and the adjusted tax basis of the U.S. Holder in the ADSs or ordinary shares. The capital gain or loss generally will be long-term capital gain or loss if, at the time of sale, exchange or other disposition, the U.S. Holder has held the ADS or ordinary share for more than one year. Net long-term capital gains of non-corporate U.S. Holders, including individuals, are eligible for reduced rates of taxation. The deductibility of capital losses is subject to limitations. Any gain or loss that a U.S. Holder recognizes generally will be treated as gain or loss from sources within the United States for U.S. foreign tax credit limitation purposes.

***Additional tax on net investment income.*** An additional 3.8% federal income tax may be assessed on net investment income (including dividends, other distributions, and gain realized on the sale of ADSs or ordinary shares) earned by certain U.S. Holders. This tax does not apply to U.S. Holders who hold ADSs or ordinary shares in the ordinary course of certain trades or businesses.

***Passive foreign investment company rules.*** In general, we will be classified as a passive foreign investment company for any taxable year in which either (a) at least 75% of our gross income is passive income or (b) at least 50% of the value (determined on the basis of a quarterly average) of our assets is attributable to assets that produce or are held for the production of passive income. For this purpose, passive income generally includes dividends, interest, royalties, rents (other than rents and royalties derived in the active conduct of a trade or business and not derived from a related person), annuities and gains from assets that produce passive income. If we own directly or indirectly at least 25% by value of the equity shares of another corporation, we will be treated for purposes of the passive foreign investment company tests as owning a proportionate share of the assets of the other corporation, and as receiving directly a proportionate share of the other corporation's income.

We believe, based on our present and projected composition of our income and valuation of our assets, we were not classified as a passive foreign investment company for U.S. federal income tax purposes for our 2018 tax year, although no assurance can be given in this regard. Whether we are a passive foreign investment company for any particular taxable year is determined on an annual basis and will depend on the composition of our income and assets, including goodwill. The calculation of goodwill will be based, in part, on the then market value of our capital stock, which is subject to fluctuation. Accordingly, there can be no assurance that we will not be classified as a passive foreign investment company in the current or any future taxable year.

If we are a passive foreign investment company for any taxable year during which a U.S. Holder has an equity interest in our company, unless the U.S. Holder makes a mark-to-market election as discussed below, such U.S. Holder will be subject to special tax rules in any future taxable year regardless of whether we are classified as a passive foreign investment company in such future years with respect to (a) "excess distributions" and (b) gain from the disposition of stock. Excess distributions are defined generally as the excess of the amount

received with respect to the equity interests in the taxable year over 125% of the average annual distributions received in the shorter of either the three previous years or a U.S. Holder's holding period before the taxable year and must be allocated ratably to each day of the U.S. Holder's holding period. The amount allocated to the current taxable year or any year before we became a passive foreign investment company will be included as ordinary income in a U.S. Holder's gross income for that year. The amount allocated to other prior taxable years will be taxed as ordinary income at the highest rate in effect for a U.S. Holder in that prior year and the tax is subject to an interest charge at the rate applicable to deficiencies in income taxes. The entire amount of any gain realized upon the sale or other disposition of the equity interests will be treated as an excess distribution made in the year of sale or other disposition and as a consequence will be treated as ordinary income and, to the extent allocated to years prior to the year of sale or disposition with respect to which we were a passive foreign investment company, will be subject to the interest charge described above.

In certain circumstances, instead of being subject to the excess distribution rules discussed above, a U.S. Holder may make an election to include gain on the ADSs or ordinary shares of a passive foreign investment company as ordinary income under a mark-to-market method, provided that the ADSs or ordinary shares are regularly traded on a qualified exchange. Under current law, the mark-to-market election is only available for ADSs or ordinary shares that are regularly traded within the meaning of U.S. Treasury regulations on certain designated U.S. exchanges and foreign exchanges that meet trading, listing, financial disclosure and other requirements to be treated as a qualified exchange under applicable U.S. Treasury regulations. The Nasdaq Stock Market is a qualified exchange.

If a U.S. Holder makes a mark-to-market election, the U.S. Holder will include each year as ordinary income, rather than capital gain, the excess, if any, of the fair market value of the U.S. Holder's ADSs or ordinary shares at the end of the taxable year over such U.S. Holder's adjusted basis in the ADSs (or ordinary shares, if applicable) and will be permitted an ordinary loss in respect of the excess, if any, of the adjusted basis of these ADSs or ordinary shares over their fair market value at the end of the taxable year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. Holder's basis in the ADSs or ordinary shares will be adjusted to reflect any such income or loss amounts. Any gain or loss on the sale of the ADSs or ordinary shares will be ordinary income or loss, except that this loss will be ordinary loss only to the extent of the previously included net mark-to-market gain.

If we are a passive foreign investment company, then under certain circumstances a U.S. Holder must file Internal Revenue Service Form 8621.

***Information Reporting and Back-up Withholding.*** The Foreign Account Tax Compliance Act ("FATCA") generally requires that individuals that hold certain specified foreign financial assets worth in excess of certain thresholds of $50,000 or more, depending on the individual's circumstances, report such ownership to the IRS using IRS Form 8938. The definition of specified foreign financial assets includes not only financial accounts maintained in foreign financial institutions, but also, unless held in accounts maintained by a financial institution, any stock or security issued by a non-U.S. person, any financial instrument or contract held for investment that has an issuer or counterparty other than a U.S. person and any interest in a foreign entity. A U.S. Holder may be subject to this reporting requirement unless such holder's ADSs or ordinary shares are held in an account at a domestic financial institution. The penalty for failing to file Form 8938 is substantial.

U.S. holders generally are subject to information reporting requirements with respect to dividends on, or proceeds from the disposition of, our ordinary shares. In addition, a U.S. holder may be subject, under certain circumstances, to backup withholding at a rate of up to 24% with respect to dividends paid on, or proceeds from the disposition of, our ordinary shares unless the U.S. holder provides proof of an applicable exemption or correct taxpayer identification number, and otherwise complies with the applicable requirements of the backup withholding rules. A U.S. holder of our ordinary shares who provides an incorrect taxpayer identification number may be subject to penalties imposed by the IRS. Amounts withheld under the backup withholding rules are not an additional tax and may be refunded or credited against the U.S. holder's U.S. federal income tax liability, provided the required information is furnished to the IRS.

A U.S. Holder is urged to consult its tax advisor concerning the U.S. federal income tax consequences of an investment in our ADSs or ordinary shares if we are or become a passive foreign investment company, including the possibility of making a mark-to-market election.

**F. Dividends and Paying Agents**

Not applicable.

**G. Statement by Experts**

The consolidated financial statements of Avita Medical Limited for the year ended June 30, 2018, 2017 and 2016 has been audited by Grant Thornton Audit Pty Ltd Level 43 Central Park, 152-158 St Georges Terrace Perth, WA 6000 Australia, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements are included in reliance upon the report of such firm given upon their consent and authority as experts in accounting and auditing.

**H. Documents on Display**

We will be subject to the reporting requirements of the United States Securities and Exchange Act of 1934, as amended, or the Exchange Act, as applicable to "foreign private issuers" as defined in Rule 3b-4 under the Exchange Act. As a foreign private issuer, we are exempt from certain provisions of the Exchange Act. Accordingly, our proxy solicitations are not subject to the disclosure and procedural requirements of regulation 14A under the Exchange Act, transactions in our equity securities by our officers and directors are exempt from reporting and the "short-swing" profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we will file with the U.S. Securities and Exchange Commission an annual report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm, and we will submit reports to the U.S. Securities and Exchange Commission on Form 6-K containing (among other things) press releases and unaudited financial information for the first six months of each fiscal year. We post our annual report on Form 20-F on our website promptly following the filing of our annual report with the U.S. Securities and Exchange Commission. The information on our website is not incorporated by reference into this annual report.

This document and the exhibits thereto and any other document we file pursuant to the Exchange Act may be inspected without charge and copied at prescribed rates at the U.S. Securities and Exchange Commission public reference room at 100 F Street, N.E., Room 1580, Washington D.C. 20549. You may obtain information on the operation of the Securities and Exchange Commission's public reference room in Washington, D.C. by calling the U.S. Securities and Exchange Commission at 1-800-SEC-0330.

The U.S. Securities and Exchange Commission maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding registrants that make electronic filings with the U.S. Securities and Exchange Commission using its EDGAR (Electronic Data Gathering, Analysis, and Retrieval) system.

The documents concerning our company that are referred to in this document may also be inspected at the offices located at Level 7, 330 Collins Street, Melbourne VIC 3000 Australia.

**I. Subsidiary Information**

See Item 4C, under the heading "*Organizational Structure.*"

## ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Please see the Company's audited financial statements for the year ended June 20, 2018, at Item 18 under Note 19 "Financial Risk management Objectives and Policies" for a description of interest rate risk, foreign currency risk, credit risk and liquidity risk and how such risks affect the Company.

## ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

### A. Debt Securities

Not applicable.

### B. Warrants and Rights

Not applicable.

### C. American Depositary Shares

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares, also referred to as ADSs. Each ADS will represent 20 shares (or a right to receive 20 shares) deposited with National Australia Bank Ltd., as custodian for the depositary in Melbourne, Australia. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Australian law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR.

#### Dividends and Other Distributions

***How will you receive dividends and other distributions on the shares?***

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

***Cash***. The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See Item 10D "Exchange Controls and Australian Tax Matters" and Item 10E "U.S. Federal Income Tax Considerations" for more information. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.*

***Shares***. The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

***Rights to purchase additional shares***. If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. *In that case, you will receive no value for them.*The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

***Other Distributions***. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you*.

**Deposit, Withdrawal and Cancellation**

***How are ADSs issued?***

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp

taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

***How can ADS holders withdraw the deposited securities?***

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

***How do ADS holders interchange between certificated ADSs and uncertificated ADSs?***

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

**Voting Rights**

***How do you vote?***

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of the Commonwealth of Australia and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

*Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.* In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to Deposited Securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 45 days in advance of the meeting date.

**Fees and Expenses**

| ***Persons depositing or withdrawing shares or ADS holders must pay*:** | ***For*:** |
|---|---|
| $5.00 (or less) per 100 ADSs (or portion of 100 ADSs) | Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property |
| | Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates |
| $.05 (or less) per ADS | Any cash distribution to ADS holders |
| A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs | Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders |
| $.05 (or less) per ADS per calendar year | Depositary services |
| Registration or transfer fees | Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares |
| Expenses of the depositary | Cable and facsimile transmissions (when expressly provided in the deposit agreement) |
| | Converting foreign currency to U.S. dollars |
| Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes | As necessary |
| Any charges incurred by the depositary or its agents for servicing the deposited securities | As necessary |

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when

buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

**Payment of Taxes**

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

**Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities**

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender or of those ADSs or cancel those ADSs upon notice to the ADS holders.

**Amendment and Termination**

***How may the deposit agreement be amended?***

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

***How may the deposit agreement be terminated?***

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist our shares from an exchange on which they were listed and do not list the shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

**Limitations on Obligations and Liability**

***Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs***

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;

- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

**Requirements for Depositary Actions**

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

**Your Right to Receive the Shares Underlying your ADSs**

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

**Direct Registration System**

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated

ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

**Shareholder communications; inspection of register of holders of ADSs**

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

**Jury Trial Waiver**

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law. Notwithstanding the foregoing, ADS holders cannot waive compliance with federal securities laws and the rules and regulations promulgated thereunder.

**D. Other Securities**

Not applicable.

## PART II

### ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

### ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

### ITEM 15. CONTROLS AND PROCEDURES

**Disclosure Controls and Procedures**

Not applicable.

**Changes in Internal Control over Financial Reporting**

During the year ended June 30, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### ITEM 16. RESERVED

Not applicable.

### ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Not applicable.

### ITEM 16B. CODE OF ETHICS

Not applicable.

### ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Not applicable.

### ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

### ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

### ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

**ITEM 16G. CORPORATE GOVERNANCE**

Not applicable.

**ITEM 16H. MINE SAFETY DISCLOSURES**

Not applicable.

## PART III

### ITEM 17. FINANCIAL STATEMENTS

The following financial statements and notes thereto (as applicable) in Australian dollars are filed with and incorporated herein as part of this registration statement on Form 20-F, beginning on page F-1 following the signature page of this Form 20-F:

- audited consolidated financial statements of the Company for the years ended June 30, 2018, 2017 and 2016, prepared in accordance with IFRS as issued by the IASB, including: consolidated statements of profits or loss and other comprehensive loss, consolidated statements of financial position, consolidated statements of cash flows, consolidated statements of changes in equity and notes to the consolidated financial statements.
- Unaudited condensed consolidated financial statements of the Company for the half-year ended December 31, 2018 and 2017, prepared in accordance with IFRS as issued by the IASB, including, including: consolidated statements of profits or loss and other comprehensive loss, consolidated statements of financial position, consolidated statements of cash flows, consolidated statements of changes in equity and notes to the consolidated financial statements.

### ITEM 18. FINANCIAL STATEMENTS

We have elected to provide financial statements pursuant to Item 17. See the Index to the Financial Statements on pageF-1 following the signature page of this Form 20-F.

### ITEM 19. EXHIBITS

The following exhibits are filed as part of this registration statement:

| Exhibit | Description |
|---|---|
| 1.1* | Corporations Act Constitution of Avita Medical Limited |
| 2.1* | Form of Deposit Agreement among the registrant, The Bank of New York Mellon, as Depositary, and all owners and holders from time to time of American Depositary Shares issued thereunder |
| 4.1* | Employee Incentive Option Plan |
| 4.2* | Employee Share Plan |
| 4.3 + | Award/Contract, dated September 29, 2015 by and between the registrant and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (BARDA) |
| 4.4 + | Award/Contract, dated September 29, 2015, by and between the registrant and BARDA |
| 4.5 + | Amendment of Solicitation/Modification of Contract, dated June 24, 2016, by and between the registrant and BARDA |
| 4.6 + | Amendment of Solicitation/Modification of Contract, dated September 28, 2017, by and between the registrant and BARDA |
| 4.7 + | Amendment of Solicitation/Modification of Contract, dated July 2, 2018, by and between the registrant and BARDA |
| 4.8 | Lease Agreement between the registrant and Hartco Ventura Inc., dated January 25, 2018 |
| 4.9 | Lease Agreement between the registrant and RIF III – Avenue Stanford, LLC, dated October 3, 2016, as amended |
| 8.1* | List of subsidiaries of the registrant |

* Previously filed
\+ Confidential treatment has been requested as to certain portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this registration statement on its behalf.

**Avita Medical Limited**

/*s*/

By:
Title: Chief Executive Officer

Date: , 2019

## INDEX TO THE FINANCIAL STATEMENTS

**Avita Medical Limited**

**INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS AS OF JUNE 30, 2018, 2017 AND 2016**



**INDEX TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AS OF JUNE 30, 2018 AND FOR THE HALF-YEAR ENDED DECEMBER 31, 2018 AND 2017**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Avita Medical Ltd.

**Opinion on the financial statements**

We have audited the accompanying consolidated statement of financial position of Avita Medical Ltd. and subsidiaries (the "Company") as of June, 30 2018 and 2017, the related consolidated statements of profit or loss and other comprehensive income, consolidated changes in equity, and consolidated statement of cash flows for each of the three years in the period ended June 30, 2018 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2018, in conformity with International Financial Reporting Standards, as issued by the International Accounting Standards Board.

**Basis for opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON AUDIT PTY LTD

We have served as the Company's auditor since 2011.

Perth, Western Australia
July 19, 2019

**Consent of Independent Registered Public Accounting Firm**

We have issued our report dated July 19, 2019 with respect to the consolidated financial statements of Avita Medical Ltd contained in the Registration Statement. We consent to the use of the aforementioned report in the Registration Statement and to the use of our name as it appears under the caption "Experts."

/s/ GRANT THORNTON AUDIT PTY LTD

Perth, Western Australia, Australia
July 19, 2019

**AVITA MEDICAL LIMITED**
**CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE LOSS**
**(IN AUSTRALIAN DOLLARS)**

| | Notes | Year Ended June 30, 2018 | 2017 | 2016 |
|---|---|---|---|---|
| **Continuing operations** | | | | |
| Sale of goods | 4 | A$ 1,198,861 | A$ 901,376 | A$ 1,002,007 |
| Cost of sales | 4 | (511,646) | (463,285) | (401,568) |
| **Gross profit** | | **687,215** | **438,091** | **600,439** |
| BARDA income | 4 | 10,104,081 | 6,886,236 | 2,424,357 |
| Other income | 4 | 68,617 | 344,734 | 120,160 |
| **Total other income** | | **10,172,698** | **7,230,970** | **2,544,517** |
| **Operating costs** | | | | |
| Sales and marketing expenses | | (8,936,441) | (5,201,761) | (5,042,189) |
| Product development expenses | | (12,606,127) | (11,161,970) | (6,018,184) |
| Corporate and administrative expenses | | (5,360,553) | (2,264,594) | (2,371,747) |
| Share-based payment expenses | 18 | (1,835,157) | (1,587,243) | (956,658) |
| Finance costs | 4 | (26,586) | (12,754) | (21) |
| Total operating costs | | **(28,764,864)** | **(20,228,322)** | **(14,388,799)** |
| Loss from continuing operations before income tax benefit | | **(17,904,951)** | **(12,559,261)** | **(11,243,843)** |
| Profit for the period from discontinued operations | | — | — | 2,493,947 |
| Income tax benefit (net) | 6 | 1,385,796 | 1,048,237 | 971,881 |
| **Loss for the period** | 5 | **(16,519,155)** | **(11,511,024)** | **(7,778,015)** |
| **Other comprehensive income (loss)** | | | | |
| *Items that may be reclassified subsequently to profit and loss:* | | | | |
| Foreign currency translation | | 563,279 | (83,293) | (169,100) |
| Fair value gain on available for sale financial assets | | — | (265,261) | 265,261 |
| **Other comprehensive income (loss) for the period, net of tax** | | **563,279** | **(348,554)** | **96,161** |
| **Total other comprehensive loss for the period** | | **A$(15,955,876)** | **A$(11,859,578)** | **A$ (7,681,854)** |
| Loss for the period attributable to owners of the parent | | (16,519,155) | (11,511,024) | (7,778,015) |
| **Total comprehensive loss attributable to owners of the parent** | | **A$(15,955,876)** | **A$(11,859,578)** | **A$ (7,681,854)** |
| **Continuing Operations** | | | | |
| Basic loss per share attributable to ordinary equity holders of the parent | 5 | A$ (1.77) cents | A$ (1.72) cents | A$ (1.56) cents |
| Diluted loss per share attributable to ordinary equity holders of the parent | 5 | A$ (1.77) cents | A$ (1.72) cents | A$ (1.56) cents |
| **Discontinued Operations** | | | | |
| Basic loss per share attributable to ordinary equity holders of the parent | 5 | — | — | A$ (0.05) cents |
| Diluted loss per share attributable to ordinary equity holders of the parent | 5 | — | — | A$ (0.05) cents |

The accompanying notes form part of the consolidated financial statements.

**AVITA MEDICAL LIMITED**
**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**
**(IN AUSTRALIAN DOLLARS)**

| | Notes | June 30, 2018 | 2017 |
|---|---|---|---|
| **ASSETS** | | | |
| **Current assets** | | | |
| Cash and cash equivalents | 7 | A$ 14,825,532 | A$ 3,790,491 |
| Trade and other receivables | 8 | 5,437,357 | 2,070,534 |
| Prepayments and other assets | | 855,716 | 382,026 |
| Inventories | 9 | 1,155,826 | 1,037,490 |
| **Total current assets** | | **22,274,431** | **7,280,541** |
| **Non-current assets** | | | |
| Plant and equipment | 10 | 742,583 | 387,380 |
| **Total non-current assets** | | **742,583** | **387,380** |
| **TOTAL ASSETS** | | **A$ 23,017,014** | **A$ 7,667,921** |
| **LIABILITIES** | | | |
| **Current liabilities** | | | |
| Trade and other payables | 11 | 3,487,582 | 2,363,734 |
| Provisions | 12 | 395,535 | 182,355 |
| **Total current liabilities** | | **3,883,117** | **2,546,089** |
| Finance lease | | 134,338 | — |
| **Total non-current liabilities** | | **134,338** | **—** |
| **TOTAL LIABILITIES** | | **A$ 4,017,455** | **A$ 2,546,089** |
| **NET ASSETS** | | **A$ 18,999,559** | **A$ 5,121,832** |
| **EQUITY** | | | |
| Equity attributable to equity holders of the parent: | | | |
| Contributed equity | 13 | 162,801,028 | 134,806,022 |
| Accumulated losses | 14 | (148,592,879) | (132,218,352) |
| Reserves | | 4,791,410 | 2,534,162 |
| **TOTAL EQUITY** | | **A$ 18,999,559** | **A$ 5,121,832** |

The accompanying notes form part of the consolidated financial statements.

**AVITA MEDICAL LIMITED**
**CONSOLIDATED STATEMENT OF CASH FLOWS**
**(IN AUSTRALIAN DOLLARS)**

| | Notes | Year Ended June 30, 2018 | 2017 | 2016 |
|---|---|---|---|---|
| **Cash flows from operating activities** | | | | |
| Payments to suppliers and employees | | A$(25,681,347) | A$(17,676,710) | A$(14,894,221) |
| Interest paid | | (26,586) | (12,754) | (21) |
| BARDA receipts and other income received | | 8,141,207 | 7,094,061 | 2,427,188 |
| Receipts from customers | | 1,129,046 | 928,687 | 1,079,549 |
| R&D tax refund received | | — | 972,283 | 654,060 |
| Interest received | | 65,656 | 123,709 | 110,364 |
| Government grants received | | — | 13,200 | 6,965 |
| Proceeds from disposal of discontinued operations | | — | — | 2,029,478 |
| Net cash from discontinued operations | | — | — | 648,081 |
| **Net cash flows used in operating activities** | 15 | **(16,372,024)** | **(8,557,524)** | **(7,938,557)** |
| **Cash flows from investing activities** | | | | |
| Payments for plant and equipment | | (498,749) | (432,592) | (48,289) |
| Proceeds from the sale of financial assets | | — | 627,837 | — |
| Proceeds from disposal of plant and equipment | | — | — | 440 |
| **Net cash flows (used in)/provided by investing activities** | | **(498,749)** | **195,245** | **(47,849)** |
| **Cash flows from financing activities** | | | | |
| Proceeds from issuance of shares and options | | 29,760,563 | 9,048,102 | 10,025,584 |
| Capital raising expenses | | (1,825,643) | (506,452) | (664,754) |
| Purchase of finance leased asset | | — | (303,521) | — |
| **Net cash flows provided by financing activities** | | **27,934,920** | **8,238,129** | **9,360,830** |
| **Net increase/(decrease) in cash and cash equivalents** | | **11,064,147** | **(124,150)** | **1,374,424** |
| **Cash and cash equivalents at beginning of period** | | **3,790,491** | **4,171,879** | **2,966,555** |
| Impact of foreign exchange | | (29,106) | (257,238) | (169,100) |
| **Cash and cash equivalents at end of period** | 7 | **A$ 14,825,532** | **A$ 3,790,491** | **A$ 4,171,879** |

The accompanying notes form part of the consolidated financial statements.

**AVITA MEDICAL LIMITED**
**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**
**(IN AUSTRALIAN DOLLARS)**

| | Contributed equity | Accumulated losses | Share-based payment reserve | Foreign currency translation reserve | Total |
|---|---|---|---|---|---|
| **At July 1, 2017** | **A$134,806,022** | **A$(132,218,352)** | **A$ 2,811,179** | **A$(277,017)** | **A$ 5,121,832** |
| Loss for the period | — | (16,519,155) | — | — | (16,519,155) |
| Other comprehensive income | | | | | |
| Foreign currency translation | — | — | — | 563,279 | 563,279 |
| **Total comprehensive loss for the year** | **—** | **(16,519,155)** | **—** | **563,279** | **(15,955,876)** |
| *Transactions with owners in their capacity as owners:* | | | | | |
| Expired options | — | 141,188 | (141,188) | — | — |
| Forfeiture options | — | 3,440 | (31,832) | — | (28,392) |
| Share-based payments | — | — | 1,866,989 | — | 1,866,989 |
| New shares | 29,846,859 | — | — | — | 29,846,859 |
| Cost of share placement | (1,851,853) | — | — | — | (1,851,853) |
| **Balance at June 30, 2018** | **A$162,801,028** | **A$(148,592,879)** | **A$ 4,505,148** | **A$ 286,262** | **A$ 18,999,559** |

The accompanying notes form part of the consolidated financial statements.

**AVITA MEDICAL LIMITED**
**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

| | Contributed equity | Accumulated losses | Employee equity benefit reserve | Available for sale reserve | Foreign currency translation reserve | Total |
|---|---|---|---|---|---|---|
| **At July 1, 2016** | **A$126,264,372** | **A$(121,108,408)** | **A$1,625,016** | **A$ 265,261** | **A$(193,724)** | **A$ 6,852,517** |
| Loss for the period | — | (11,511,024) | — | — | — | (11,511,024) |
| Other comprehensive income | | | | | | |
| Foreign currency translation | — | — | — | — | (83,293) | (83,293) |
| MVP Shares | — | — | — | (265,261) | — | (265,261) |
| **Total comprehensive loss for the year** | **—** | **(11,511,024)** | **—** | **(265,261)** | **(83,293)** | **(11,859,578)** |
| *Transactions with owners in their capacity as owners:* | | | | | | |
| Expired Options | — | 401,080 | (401,080) | — | — | — |
| Share-based expenses | — | — | 1,587,243 | — | — | 1,587,243 |
| New shares | 9,048,102 | — | — | — | — | 9,048,102 |
| Cost of share placement | (506,452) | — | — | — | — | (506,452) |
| **Balance at June 30, 2017** | **A$134,806,022** | **A$(132,218,352)** | **A$2,811,179** | **A$ —** | **A$(277,017)** | **A$ 5,121,832** |

The accompanying notes form part of the consolidated financial statements.

**AVITA MEDICAL LIMITED**
**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

| | Contributed equity | Accumulated losses | Employee equity benefit reserve | Available for sale reserve | Foreign currency translation reserve | Total |
|---|---|---|---|---|---|---|
| **At July 1, 2015** | **A$117,044,332** | **A$(113,457,640)** | **A$ 654,816** | **A$ —** | **A$ (24,624)** | **A$ 4,216,884** |
| Loss for the period | — | (7,778,015) | — | — | — | (7,778,015) |
| Other comprehensive income | — | — | — | — | — | — |
| - Foreign currency translation | — | — | — | — | (169,100) | (169,100) |
| **Total comprehensive loss for the year** | **—** | **(7,778,015)** | **—** | **—** | **(169,100)** | **(7,947,115)** |
| *Transactions with owners in their capacity as owners:* | | | | | | |
| Expired options | — | 127,247 | (127,247) | — | — | — |
| Share-based expenses | — | — | 956,658 | — | — | 956,658 |
| MVP shares | — | — | — | 265,261 | — | 265,261 |
| New options | — | — | 140,789 | — | — | 140,789 |
| New shares | 10,025,584 | — | — | — | — | 10,025,584 |
| Cost of share placement | (805,544) | — | — | — | — | (805,544) |
| **Balance at June 30, 2016** | **A$126,264,372** | **A$(121,108,408)** | **A$1,625,016** | **A$265,261** | **A$(193,724)** | **A$ 6,852,517** |

The accompanying notes form part of the consolidated financial statements.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**
**(IN AUSTRALIAN DOLLARS)**

## 1. CORPORATE INFORMATION

Avita Medical Limited, the parent entity, is a company limited by shares incorporated in Australia whose shares are publicly traded on the Australian Securities Exchange.

The nature of the operations and principal activities of the Company are described in the Business Overview.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### a) Basis of preparation and statement of compliance

The consolidated financial statements are general purpose consolidated financial statements that have been prepared in accordance with the requirements of the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). The Company's consolidated financial statements include the assets and liabilities of all subsidiaries of the Company as at June 30, 2018 and the results of the subsidiaries for the year then ended. Inter-entity transactions with, or between, subsidiaries are eliminated in full on consolidation.

Except for cash flow information, the financial report has been prepared on an accrual basis and is based on historical costs, modified, where applicable, for financial liabilities and assets held at fair value through profit or loss and is presented in Australian dollars which is the Company's functional and presentation currency.

### b) New and amended accounting standards and interpretations adopted by the Company

The Company has adopted all of the new, revised or amended Accounting Standards and Interpretations issued by the IASB that are mandatory for the current reporting period.

The adoption of these Accounting Standards and Interpretations did not have any significant impact on the financial performance or position of the Company.

### c) Changes in accounting policy

IFRS 15 Revenue from Contracts with Customers and IFRS 9 Financial Instruments (2014) became effective for periods beginning on or after January 1, 2018. Accordingly, the Company applied IFRS 15 and IFRS 9 for the interim period ended December 31, 2018. Changes to the Company's accounting policies arising from these standards are summarized below:

**IFRS 9 Financial Instruments**

IFRS 9 Financial Instruments replaces IAS 39 Financial Instruments: Recognition and Measurement requirements. It makes major changes to the previous guidance on the classification and measurement of financial assets and introduces an 'expected credit loss' model for impairment of financial assets.

The adoption of this standard has no impact on the current or previous reporting period and as such there have been no adjustments to the opening balance of retained earnings.

**IFRS 15 – Revenue from contracts with customers**

Revenue is comprised mainly from funding from BARDA and from the sale of goods. To determine whether to recognize revenue, the Company follows a five-step process:

1. Identifying the contract with a customer,

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)**

**c) Changes in accounting policy (continued)**

2. Identifying the performance obligations,
3. Determining the transaction price,
4. Allocating the transaction price to the performance obligation,
5. Recognizing revenue when performance obligation is satisfied.

Revenue from the sales of goods is recognized at a point in time, when the Company satisfies performance obligations by transferring the promised goods to its customers. The Company recognizes contract liabilities for consideration received in respect of unsatisfied performance obligations and reports these amounts as other liabilities in the statement of financial position. Similarly, if the Company satisfies a performance obligation before it receives the consideration, the Company recognizes either a contract asset or a receivable in its statement of financial position, depending on whether something other than the passage of time is required before the consideration is due.

The adoption of this standard has no impact on the current or previous reporting period and as such there have been no adjustments to the opening balance of retained earnings.

**Accounting Standards issued but not yet effective and not been adopted early by the Company**

**IFRS 16 Leases**

***IFRS 16:***

- replaces IAS 17 Leases and some lease-related Interpretations,
- requires all leases to be accounted for 'on-balance sheet' by lessees, other than short-term and low value asset leases,
- provides new guidance on the application of the definition of lease and on sale and lease back accounting,
- largely retains the existing lessor accounting requirements in IAS 17,
- requires new and different disclosures about leases.

Based on the entity's assessment, it is expected that the first-time adoption of IFRS 16 for the year ending June 30, 2020 will have a material impact on the transactions and balances recognized in the financial statements, in particular:

- lease assets and financial liabilities on the balance sheet will increase by A$1,108,610 and A$1,195,801 respectively (based on the facts at the date of the assessment),
- there will be a reduction in the reported equity as the carrying amount of lease assets will reduce more quickly than the carrying amount of lease liabilities,
- EBIT in the statement of profit or loss and other comprehensive income will be higher as the implicit interest in lease payments for former off-balance sheet leases will be presented as part of finance costs rather than being included in operating expenses,

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### c) Changes in accounting policy (continued)

- operating cash outflows will be lower and financing cash flows will be higher in the statement of cash flows as principal repayments on all lease liabilities will now be included in financing activities rather than operating activities. Interest can also be included within financing activities.

### (d) Basis of consolidation

The consolidated financial statements comprise the financial statements of Avita Medical Limited and its subsidiaries ('the Company') as at the reporting date each year. The Parent controls a subsidiary if it is exposed, or has rights, to variable returns from its involvement with the subsidiary and has the ability to affect those returns through its power over the subsidiary. All subsidiaries have a reporting date of June 30.

In preparing the consolidated financial statements, all intercompany balances and transactions, income and expenses and profit and losses resulting from intercompany transactions have been eliminated in full. Subsidiaries are fully consolidated from the date on which control is obtained by the Company and cease to be consolidated from the date on which control is transferred out of the Company.

### (e) Segment reporting

An operating segment is a component of an entity that engages in business activities from which it may earn revenues and incur expenses (including revenues and expenses relating to transactions with other components of the same entity), whose operating results are regularly reviewed by the entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its performance, and for which discrete financial information is available. This includes start-up operations which are yet to earn revenues. Management will also consider other factors in determining operating segments such as the existence of a line manager and the level of segment information presented to the Board of Directors.

Operating segments have been identified based on the information provided to the chief operating decision makers – being the Chief Executive Officer. The company aggregates two or more operating segments when they have similar economic characteristics, and the segments are similar in each of the following respects:

- Nature of the products and services;
- Nature of the production processes;
- Type or class of customer for the products and services;
- Methods used to distribute the products or provide the services; and if applicable
- Nature of the regulatory environment.

Operating segments that meet the quantitative criteria as prescribed by IFRS 8 Operating Segments are reported separately. However, an operating segment that does not meet the quantitative criteria is still reported separately where information about the segment would be useful to users of the financial statements.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (f) Revenue recognition

Revenue is recognized and measured at the fair value of the consideration received or receivable to the extent it is probable that the economic benefits will flow to the Company and the revenue can be reliably measured. The following specific recognition criteria must also be met before revenue is recognized:

*Sale of goods*

Revenue from the sale of goods is recognized when the significant risks and rewards of ownership of the goods have passed to the buyer and the costs incurred or to be incurred in respect of the transaction can be measured reliably. Risks and rewards of ownership are considered passed to the buyer at the time of shipment of the goods to the customer.

*BARDA income*

The Company had been granted a BARDA contract in September 2015, wherein BARDA funded the Company to support the ongoing U.S. clinical regulatory program towards FDA Premarket Approval and Compassionate Use program, and clinical and health economics research in U.S. pediatric burn care. Barda income is recognized in the income statement when it is probable that the Company will receive the economic benefits of the contract and the amount can be reliably measured. The BARDA contract allows the Company to be reimbursed for costs incurred to fund the programs outlined above. The BARDA funds received are recognized in the period that the costs are incurred by the project.

*Interest income*

Revenue is recognized as interest accrues using the effective interest method.

### (g) Government and other grants

Government grants are recognized when there is reasonable assurance that the grant will be received, and all attaching conditions will be complied with.

When the grant relates to an expense item, it is recognized as income over the periods necessary to match the grant on a systematic basis to the costs that it is intended to compensate. Grants are not credited directly to shareholders equity.

When the grant relates to an asset, the fair value is credited to deferred income and is released to the profit or loss over the expected useful life of the relevant asset by equal annual instalments.

### (h) Leases

The determination of whether an arrangement is, or contains, a lease is based on the substance of the arrangement and requires an assessment of whether the fulfilment of the arrangement is dependent on the use of a specific asset or assets and the arrangement conveys a right to use the asset.

*Company as a lessee*

Finance leases, which transfer to the Company substantially all the risks and benefits incidental to ownership of the leased item, are capitalized at the inception of the lease at the fair value of the leased asset or, if lower, at the

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)**

**(h) Leases (continued)**

present value of the minimum lease payments. Lease payments are apportioned between the finance charges and reduction of the lease liability so as to achieve a constant rate of interest on the remaining balance of the liability. Finance charges are recognized as an expense in profit or loss.

Capitalized leased assets are depreciated over the shorter of the estimated useful life of the asset and the lease term if there is no reasonable certainty that the Company will obtain ownership by the end of the lease term.

Operating lease payments are recognized as an expense in profit or loss on a straight-line basis over the lease term. Operating lease incentives are recognized as a liability when received and subsequently reduced by allocating lease payments between rental expense and reduction of the liability.

**(i) Cash and cash equivalents**

Cash and cash equivalents in the consolidated statement of financial position comprises of cash at bank and in hand and short-term deposits with an original maturity of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

For the purposes of the consolidated statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above, net of outstanding bank overdrafts. Bank overdrafts are included within interest-bearing loans and borrowings in current liabilities on the consolidated statement of financial position.

**(j) Trade and other receivables**

Trade receivables, which generally have 30- to 90-day terms, are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method, less an allowance for impairment.

Collectability of trade receivables is reviewed on an on-going basis at an operating unit level. Individual debts that are known to be uncollectible are written off when identified. An impairment provision is recognized when there is objective evidence that the Company will not be able to collect the receivable. Financial difficulties of the debtor, default payments and debts more than 90 days overdue may be considered objective evidence of impairment. The amount of the impairment loss is the receivable carrying amount compared to the present value of estimated future cash flows, discounted at the original effective interest rate.

**(k) Inventories**

Inventories are valued at the lower of cost and net realizable value. Costs incurred in bringing each product to its present location and condition are accounted for at purchase cost on a first-in, first-out basis. Assembly costs as invoiced by a third party are factored into the cost of finished goods.

Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

**(l) Foreign currency translation**

*Functional and presentational currency*

Both the functional and presentational currency of Avita Medical Limited and its Australian subsidiaries is Australian dollars ($). The United Kingdom's subsidiary's functional currency is Pound Sterling and the United

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (l) Foreign currency translation (continued)

States' subsidiary's functional currency is United States Dollars. These are translated to the presentational currency (see below).

*Transactions and balances*

Transactions in foreign currencies are initially recorded in the functional currency by applying the exchange rates ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the reporting date.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate as at the date of the initial transaction. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined.

*Translation of Company functional currency to presentational currency*

The results of the overseas subsidiaries are translated into Australian Dollars as at the date of each transaction. Assets and liabilities are translated at exchange rates prevailing at reporting date. Profit and loss items are translated at average rates and equity items are translated at the date of each transaction. Exchange variations resulting from the translation are recognized in the foreign currency translation reserve in equity.

On consolidation, exchange differences arising from the translation of the net investment in overseas subsidiaries are taken to the foreign currency translation reserve. If an overseas subsidiary were sold, the proportionate share of exchange differences would be transferred out of equity and recognized in profit or loss.

### (m) Income tax and other taxes

Current tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities based on the current period's taxable income. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the reporting date. Included in income tax benefits are research and development claims.

Deferred income tax is provided on all temporary differences at the reporting date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred income tax liabilities are recognized for all taxable temporary differences except:

- when the deferred income tax liability arises from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination and that, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- when the taxable temporary difference is associated with investments in subsidiaries, associates or interests in joint ventures, and the timing of the reversal of the temporary difference can be controlled and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred income tax assets are recognized for all deductible temporary differences, carry-forward of unused tax credits and unused tax losses, to the extent that it is probable that taxable profit will be available against which

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)**

**(m) Income tax and other taxes (continued)**

the deductible temporary differences and the carry-forward of unused tax credits and unused tax losses can be utilized, except:

- when the deferred income tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- when the deductible temporary difference is associated with investments in subsidiaries, associates or interests in joint ventures, in which case a deferred tax asset is only recognized to the extent that it is probable that the temporary difference will reverse in the foreseeable future and taxable profit will be available against which the temporary difference can be utilized.

The carrying amount of deferred income tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilized.

Unrecognized deferred income tax assets are reassessed at each reporting date and are recognized to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realized, or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset only if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred tax assets and liabilities relate to the same taxable entity and the same taxation authority.

*Tax consolidation legislation*

Avita Medical Limited and its wholly-owned Australian controlled entities implemented the tax consolidation legislation as of July 1, 2003.

The parent entity, Avita Medical Limited, and the controlled entities in the tax consolidated Company continue to account for their own current and deferred tax amounts. The Company has applied the group allocation approach in determining the appropriate amount of current taxes and deferred taxes to allocate to members of the tax consolidated group.

In addition to its own current and deferred tax amounts, Avita Medical Limited also recognizes the current tax liabilities (or assets) and the deferred tax assets arising from unused tax losses and unused tax credits assumed from controlled entities in the tax consolidated group.

Assets or liabilities arising under tax funding agreements with the tax consolidated entities are recognized as amounts receivable from or payable to other entities in the Company.

Any difference between the amounts assumed and amounts receivable or payable under the tax funding agreement are recognized as a contribution to (or distribution from) wholly-owned tax consolidated entities.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (m) Income tax and other taxes (continued)

*Other taxes*

Revenues, expenses and assets are recognized net of the amount of Goods and Services Tax (GST) except:

- when the GST incurred on a purchase of goods and services is not recoverable from the taxation authority, in which case the GST is recognized as part of the cost of acquisition of the asset or as part of the expense item as applicable; and
- receivables and payables, which are stated with the amount of GST included.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the consolidated statement of financial position.

Cash flows are included in the consolidated statement of cash flows on a gross basis and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the taxation authority is classified as part of operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the taxation authority.

### (n) Plant and equipment

The Company's fixed assets are stated at cost less accumulated depreciation and any accumulated impairment losses. Depreciation are computed based on the straight-line method over the estimated useful lives of the various classes of assets. The ranges of estimated useful lives for the principal classes of assets are as follows:

- Laboratory equipment – 5 years
- Computer equipment – 5 years
- Fixtures and fittings – 7 years

The Company reviews its long-lived assets for impairment annually, or when events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable. An asset is considered impaired when the fair value, which is the expected undiscounted cash flows over the remaining useful life, is less than the net book value. The excess of the net book value over its fair value is charged as impairment loss to profit and loss account.

Repairs and maintenance are recognized in profit or loss during the financial period in which they are incurred. Gains and losses on disposal are determined by comparing the proceeds on disposal with the carrying amount and are included in profit or loss.

### (o) Trade and other payables

Trade payables and other payables are carried at amortized cost and due to their short-term nature, they are not discounted. They represent liabilities for goods and services provided to the Company prior to the end of the financial year that are unpaid and arise when the Company becomes obliged to make future payments in respect of the purchase of these goods and services. The amounts are unsecured and are usually paid within 30 days of recognition.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (p) Interest-bearing loans and borrowings

All loans and borrowings are initially recognized at the fair value of the consideration received less directly attributable transaction costs.

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest method. Fees paid on the establishment of loan facilities that are yield related are included as part of the carrying amount of the loans and borrowings.

Borrowings are classified as current liabilities unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the reporting date.

*Borrowing costs*

Borrowing costs, other than borrowing costs relating to qualifying assets, are recognized as an expense when incurred.

### (q) Financial instruments

*Recognition, initial measurement and derecognition*

Financial assets and financial liabilities are recognized when the Company becomes a party to the contractual provisions of the financial instrument and are measured initially at fair value adjusted by transactions costs, except for those carried at fair value through profit or loss, which are measured initially at fair value. Subsequent measurement of financial assets and financial liabilities are described below.

Financial assets are derecognized when the contractual rights to the cash flows from the financial asset expire, or when the financial asset and all substantial risks and rewards are transferred. A financial liability is derecognized when it is extinguished, discharged, cancelled or expires.

*Classification and subsequent measurement of financial assets*

For the purpose of subsequent measurement, financial assets other than those designated and effective as hedging instruments are classified into the following categories upon initial recognition:

- Loans and receivables;
- Financial assets at Fair Value Through Profit or Loss (‘FVTPL’);
- Held-To-Maturity (‘HTM’) investments; or
- Available-For-Sale (‘AFS’) financial assets.

All financial assets except for those at FVTPL are subject to review for impairment at least at each reporting date to identify whether there is any objective evidence that a financial asset or a group of financial assets is impaired. Different criteria to determine impairment are applied for each category of financial assets, which are described below.

All income and expenses relating to financial assets that are recognized in the Statement of Profit or Loss and Other Comprehensive Income are presented within finance costs, finance income or other financial items, except for impairment of trade receivables which is presented within other expenses.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (q) Financial instruments (continued)

*Loans and receivables*

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. After initial recognition, these are measured at amortized cost using the effective interest method, less provision for impairment. Discounting is omitted where the effect of discounting is immaterial. The Company's cash and cash equivalents, trade and most other receivables fall into this category of financial instruments.

Individually significant receivables are considered for impairment when they are past due or when other objective evidence is received that a specific counterparty will default. Receivables that are not considered to be individually impaired are reviewed for impairment in groups, which are determined by reference to the industry and region of a counterparty and other shared credit risk characteristics. The impairment loss estimate is then based on recent historical counterparty default rates for each identified group.

*AFS financial assets*

AFS financial assets are non-derivative financial assets that are either designated to this category or do not qualify for inclusion in any of the other categories of financial assets.

All AFS financial assets are measured at fair value. Gains and losses are recognized in other comprehensive income and reported within the AFS reserve within equity, except for impairment losses and foreign exchange differences on monetary assets, which are recognized in profit or loss. When the asset is disposed of or is determined to be impaired the cumulative gain or loss recognized in other comprehensive income is reclassified from the equity reserve to profit or loss and presented as a reclassification adjustment within other comprehensive income. Interest calculated using the effective interest method and dividends are recognized in profit or loss within 'finance income'.

Reversals of impairment losses for AFS debt securities are recognized in profit or loss if the reversal can be objectively related to an event occurring after the impairment loss was recognized. For AFS equity investments impairment reversals are not recognized in profit loss and any subsequent increase in fair value is recognized in other comprehensive income.

*Classification and subsequent measurement of financial liabilities*

The Company's financial liabilities include borrowings, trade and other payables. Financial liabilities are measured subsequently at amortized cost using the effective interest method, except for financial liabilities held for trading or designated at FVTPL, that are carried subsequently at fair value with gains or losses recognized in profit or loss. All derivative financial instruments that are not designated and effective as hedging instruments are accounted for at FVTPL.

### (r) Provisions and employee leave benefits

Provisions are recognized when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (r) Provisions and employee leave benefits (continued)

When the Company expects some or all of a provision to be reimbursed, for example under an insurance contract, the reimbursement is recognized as a separate asset but only when the reimbursement is virtually certain. The expense relating to any provision is presented in profit or loss net of any reimbursement.

Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the reporting date using a discounted cash flow methodology. The risks specific to the provision are factored into the cash flows and as such a risk-free government bond rate relative to the expected life of the provision is used as a discount rate. If the effect of the time value of money is material, provisions are discounted using a current pre-tax rate that reflects the time value of money and the risks specific to the liability. The increase in the provision resulting from the passage of time is recognized in finance costs.

*Employee leave benefits*

Liabilities for wages and salaries, including non-monetary benefits, annual leave and accumulating sick leave expected to be settled within 12 months of the reporting date are recognized in respect of employees' services up to the reporting date. They are measured at the amounts expected to be paid when the liabilities are settled. Expenses for non-accumulating sick leave are recognized when the leave is taken and are measured at the rates paid or payable.

### (s) Share-based payment transactions

The Company provides benefits to employees (including Key Management Personnel) in the form of share-based payments, whereby employees render services in exchange for shares or rights over shares (equity-settled transactions).

The Company has in place an Employee Share Option Plan (ESOP) which provides benefits to Senior Executives.

The cost of these equity-settled transactions with employees is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by an external valuer using a binomial model.

The cost of equity-settled transactions is recognized, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled (the vesting period), ending on the date on which the relevant employees become fully entitled to the award (the vesting date).

At each subsequent reporting date until vesting, the cumulative charge to profit or loss is the product of:

(i) the grant date fair value of the award;

(ii) the current best estimate of the number of awards that will vest, taking into account such factors as the likelihood of employee turnover during the vesting period and the likelihood of non-market performance conditions being met; and

(iii) the expired portion of the vesting period.

The charge to profit or loss for the period is the cumulative amount as calculated above less the amounts already charged in previous periods. There is a corresponding entry to equity.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (s) Share-based payment transactions (continued)

The expense recognized by Avita Medical Limited in relation to equity-settled awards only represents the expense associated with grants to employees of the parent. The expense recognized by the Company is the total expense associated with all such awards.

Until an award has vested, any amounts recorded are contingent and will be adjusted if more or fewer awards vest than were originally anticipated to do so. Any award subject to a market condition is considered to vest irrespective of whether or not that market condition is fulfilled, provided that all other conditions are satisfied.

If the terms of an equity-settled award are modified, as a minimum an expense is recognized as if the terms had not been modified. An additional expense is recognized for any modification that increases the total fair value of the share-based payment arrangement, or is otherwise beneficial to the employee, as measured at the date of modification.

If an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. However, if a new award is substituted for the cancelled award and designated as a replacement award on the date that it is granted, the cancelled and new award are treated as if they were a modification of the original award, as described in the previous paragraph.

The dilutive effect, if any, of outstanding options is reflected as additional share dilution in the computation of diluted earnings per share.

### (t) Contributed equity

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

Basic loss per share is calculated as net loss attributable to members of the parent, adjusted to exclude any costs of servicing equity (other than dividends), divided by the weighted average number of ordinary shares.

Diluted loss per share is calculated as net loss attributable to members of the parent, adjusted for:

- costs of servicing equity (other than dividends);
- the after-tax effect of dividends and interest associated with dilutive potential ordinary shares that have been recognized as expenses; and
- other non-discretionary changes in revenues or expenses during the year that would result from the dilution of potential ordinary shares;
- divided by the weighted average number of ordinary shares and dilutive potential ordinary shares, adjusted for any bonus element.

### (u) Research and development costs

Expenditures during the research phase of a project are recognized as expenses when incurred. Development costs are capitalized only when technical feasibility studies identify that the project is expected to deliver future economic benefits and these benefits can be measured reliably.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (u) Research and development costs (continued)

Capitalized development costs have a finite useful life and amortized on a systematic basis based on the future economic benefits over the useful life of the project.

### (v) Going concern

These financial statements have been prepared on the basis of going concern, which contemplates the continuity of normal business activities and the realization of assets and settlement of liabilities in the ordinary course of business. During the financial year ended June 30, 2018, the Company has generated a loss for the period of A$16,519,155 (2017: A$11,511,024 and 2016: A$7,778,015) and the Company has used cash in operations of A$16,372,024 (2017: A$8,557,524 and 2016: A$7,938,557).

During the year ended June 30, 2018 and subsequent to year end, the Company completed a series of equity transactions totaling gross proceeds of A$74,775,545 which were used to fund operations. Of the total gross proceeds, A$29,760,645 was received in transactions completed during the year ended June 30, 2018, and A$45,014,900 was received in transactions completely subsequent to June 30, 2018.

On October 11, 2017 the Company completed a placement of 100,982,978 fully paid ordinary shares at a price of A$0.045 per share raising gross proceeds of A$4,544,234. On November 7, 2017 the Company completed a rights offering of 276,502,853 fully paid ordinary shares at a price of A$0.045 per share raising gross proceeds of A$12,442,628. On June 6, 2018 the Company completed the first tranche of an institutional placement in which it issued 255,475,665 fully paid ordinary shares at a price of A$0.050 per share raising gross proceeds of A$12,773,783. The institutional placement included a second tranche totaling A$3.250 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on July 23, 2018, and the Company issued 65 million shares at a price of A$0.050 per share and received gross proceeds of A$3,250,000 on July 26, 2018.

Also subsequent to year end, on December 4, 2018 the Company completed the first tranche of an institutional placement of in which it issued 310,047,015 fully paid ordinary shares at a price of A$0.080 per share raising gross proceeds of A$24,803,761. The institutional placement included a second tranche totaling A$15.196 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on January 14, 2019, and the Company issued 189,952,985 shares at a price of A$0.080 per share and received gross proceeds of A$15,196,239 on January 14, 2019. In addition, on January 11, 2010 the Company complete a Share Purchase Plan under which it issued 22,061,250 shares of stock at a price of A$0.080 per share and received gross proceeds of A$1,764,900.

The Company also benefits from cash inflows from the series of BARDA contracts, the first of which was awarded to the Company in September 2015. These payments from BARDA offset the costs from various activities undertaken to support the FDA regulatory approval process for RECELL in the U.S., preparation for the planned commercial launch of RECELL in the U.S., and other RECELL clinical programs in the U.S. Another anticipated source of capital for the Company is the potential triggering of the BARDA contract covering the initial purchase, storage and delivery of RECELL devices in the amount of US$7,594,620 (~A$10.2m).

The Company expects to be utilizing cash reserves until U.S. and international sales of its products reach the level to fund ongoing operations. The Company has historically funded its research and development activities

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### (v) Going concern (continued)

through raising capital by issuing securities in the Company, and it is expected that similar funding will be obtained to provide working capital as and when required. If the Company is unable to raise capital in the future, the Company may need to curtail expenditures by scaling back certain research and development or other programs.

As a result of the above, the directors are satisfied that there is sufficient working capital to support the committed research development programs and other activities over the next 12 months and the Company has the ability to realize its assets and pay its liabilities and commitments in the normal course of business. Accordingly, the directors have prepared the financial report on a going concern basis.

## 3. SIGNIFICANT ACCOUNTING JUDGEMENTS, ESTIMATES AND ASSUMPTIONS

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements and estimates on historical experience and on other various factors it believes to be reasonable under the circumstances, the result of which form the basis of the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

Management has identified the following critical accounting policies for which significant judgements, estimates and assumptions are made. Actual results may differ from these estimates under different assumptions and conditions and may materially affect financial results or the financial position reported in future periods.

### (a) Significant accounting estimates and assumptions

*Share-based payment transactions*

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using a binomial model, using the assumptions detailed in note 18 (g).

The accounting estimates and assumptions relating to equity-settled share-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact expenses and equity.

### (b) Significant accounting judgments

*Estimation of useful lives of assets*

The estimation of the useful lives of assets has been based on historical experience. In addition, the condition of the assets is assessed at least once per year and considered against the remaining useful life. Adjustments to useful lives are made when considered necessary. Depreciation charges are included in note 4(d).

*Impairment of non-financial assets other than goodwill*

The Company assesses impairment of all assets at each reporting date by evaluating conditions specific to the Company and to the particular asset that may lead to impairment. These include product and manufacturing

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 3. SIGNIFICANT ACCOUNTING JUDGEMENTS, ESTIMATES AND ASSUMPTIONS (CONTINUED)

### (b) Significant accounting judgments (continued)

performance, technology, economic and political environments and future product expectations. If an impairment trigger exists, the recoverable amount of the asset is determined. This involves value in use calculations, which incorporate a number of key estimates and assumptions.

*Taxation*

The Company's accounting policy for taxation requires management's judgement as to the types of arrangements considered to be a tax on income in contrast to an operating cost. Judgement is also required in assessing whether deferred tax assets and certain deferred tax liabilities are recognized on the consolidated statement of financial position. Deferred tax assets, including those arising from unrecouped tax losses, capital losses and temporary differences, are recognized only where it is considered more likely than not that they will be recovered, which is dependent on the generation of sufficient future taxable profits.

Assumptions about the generation of future taxable profits depend on management's estimates of future cash flows. These depend on estimates of future production and sales volumes, operating costs, capital expenditure, dividends and other capital management transactions. Judgements are also required about the application of income tax legislation. These judgements and assumptions are subject to risk and uncertainty, hence there is a possibility that changes in circumstances will alter expectations, which may impact the amount of deferred tax assets and deferred tax liabilities recognized on the consolidated statement of financial position and the amount of other tax losses and temporary differences not yet recognized. In such circumstances, some or all of the carrying amounts of recognized deferred tax assets and liabilities may require adjustment, resulting in a corresponding credit or charge to profit or loss.

## 4. REVENUES AND EXPENSES

| | | Year Ended June 30, | | |
|---|---|---|---|---|
| | | 2018 | 2017 | 2016 |
| **(a)** | **Revenue** | | | |
| | Sale of goods | A$1,198,861 | A$901,376 | A$1,002,007 |
| | **Total revenue** | **A$1,198,861** | **A$901,376** | **A$1,002,007** |

The Company had been granted a BARDA contract in September 2015, wherein BARDA will fund the Company to support the ongoing U.S. clinical regulatory program towards FDA Premarket Approval and Compassionate Use program, and clinical and health economics research in U.S. pediatric burn care. The objectives support BARDA's overarching goal of building burn care preparedness, by securing effective medical countermeasures for burn injuries for use in case of a mass casualty.

| | | Year Ended June 30, | | |
|---|---|---|---|---|
| | | 2018 | 2017 | 2016 |
| **(b)** | **Other income** | | | |
| | BARDA income | A$10,104,081 | A$6,886,236 | A$2,424,357 |
| | Other income | 68,617 | 344,734 | 120,160 |
| | **Total other income** | **A$10,172,698** | **A$7,230,970** | **A$2,544,517** |

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(IN AUSTRALIAN DOLLARS)

## 4. REVENUES AND EXPENSES (CONTINUED)

| | | Year Ended June 30, 2018 | 2017 | 2016 |
|---|---|---|---|---|
| **(c)** | **Finance costs** | | | |
| | Other loans | A$26,586 | A$12,754 | A$21 |
| | | **A$26,586** | **A$12,754** | **A$21** |

| | | Year Ended June 30, 2018 | 2017 | 2016 |
|---|---|---|---|---|
| **(d)** | **Depreciation, impairment and amortization included in profit or loss** | | | |
| | Depreciation | A$143,546 | A$139,703 | A$83,724 |
| | (Profit)/Loss on disposal of plant and equipment | — | (1,347) | 440 |
| | | **A$143,546** | **A$138,356** | **A$84,164** |

| | | Year Ended June 30, 2018 | 2017 | 2016 |
|---|---|---|---|---|
| **(e)** | **Cost of sales** | A$511,646 | A$463,285 | A$401,568 |

| | | Year Ended June 30, 2018 | 2017 | 2016 |
|---|---|---|---|---|
| **(f)** | **Lease payments and other expenses included in profit or loss** | A$463,095 | A$418,193 | A$283,412 |

| | | Year Ended June 30, 2018 | 2017 | 2016 |
|---|---|---|---|---|
| **(g)** | **Employee benefits expense** | | | |
| | Salaries and wages | A$ 8,057,869 | A$6,143,458 | A$4,669,718 |
| | Share-based expenses | 1,835,157 | 1,587,243 | 956,658 |
| | Defined contribution superannuation expense | 374,435 | 341,586 | 311,435 |
| | | **A$10,267,461** | **A$8,072,287** | **A$5,937,811** |

## 5. LOSS PER SHARE

Basic loss per share amounts are calculated by dividing the net loss for the year by the weighted average number of ordinary shares outstanding during the year.

Diluted earnings per share amounts are calculated by dividing the net loss for the year by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on the conversion of all the dilutive potential ordinary shares into ordinary shares.

The following reflects the income and share data used in the basic and diluted loss per share computations:

| | Year Ended June 30, 2018 | 2017 | 2016 |
|---|---|---|---|
| Net loss for the period | A$ (16,519,155) | A$ (11,511,024) | A$ (7,778,015) |
| Weighted average number of ordinary shares for basic and diluted loss per share | 934,312,458 | 669,930,538 | 498,786,987 |

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 5. LOSS PER SHARE (CONTINUED)

Transactions involving ordinary shares or potential ordinary shares that would change the number of ordinary shares or potential ordinary shares outstanding between the reporting date and the date of the completion of these financial statements are disclosed in Note 25 to the consolidated financial statements.

A total of 29,131,664 options (2017: 24,797,286 and 2016: 11,147,289) were not included in the dilutive loss per share calculation as they are anti-dilutive.

## 6. INCOME TAX

| | Year Ended June 30 | | |
|---|---|---|---|
| | **2018** | **2017** | **2016** |
| **(a) Income tax expense** | | | |
| The major components of income tax benefit are: | | | |
| *Current income tax benefit:* | | | |
| Current income tax benefit – R&D Claim | A$ (1,420,752) | A$ (1,048,634) | A$ (971,881) |
| Adjustment for prior year tax | 34,956 | — | — |
| Income tax benefit reported in profit or loss – R&D Claim | A$ (1,385,796) | A$ (1,048,634) | A$ (971,881) |
| **(b) Numerical reconciliation of income tax expense to prima facie tax payable** | | | |
| Loss from continuing operations before income tax expense | A$(17,904,569) | A$(12,559,261) | A$(11,243,843) |
| Profit for the period from discontinued operations | — | — | 2,493,947 |
| | **(17,904,569)** | **(12,559,261)** | **(8,749,896)** |
| Tax at the Australian rate of 27.5% (2017: 27.5% and 2016: 30%) | $ (4,923,756) | $ (3,767,778) | $ (2,624,969) |
| Tax effect of amounts which are not deductible/(taxable) in calculating taxable income: | | | |
| Other | 1,464,746 | 792,798 | 921,793 |
| Tax losses not brought to account | 3,537,629 | 2,974,980 | 1,703,176 |
| Research and development tax offset | (1,420,751) | (1,048,634) | (971,881) |
| Adjustment for prior year research and development tax offset | 34,955 | — | — |
| Adjustment due to change in tax rate | 66,341 | — | — |
| | **(1,240,836)** | **(1,048,634)** | **(971,881)** |
| Movement in deferred tax asset | — | 41,629 | 451,777 |
| Deferred tax assets not brought to account as realization is not considered probable | (144,960) | (41,629) | (451,777) |
| **Income tax benefit** | **A$ (1,385,796)** | **A$ (1,048,634)** | **A$ (971,881)** |

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(IN AUSTRALIAN DOLLARS)

## 6. INCOME TAX (CONTINUED)

| | As of June 30, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| **(c) Non-current assets – Deferred tax assets** | | | |
| The balance comprises temporary differences attributable to: | | | |
| Provisions | A$ 122,243 | A$ 48,513 | A$ 82,074 |
| Property, plant and equipment | 10,155 | 12,945 | 13,905 |
| Intangible assets | 1,025,616 | 735,400 | 611,343 |
| Other | 2,378 | (766) | — |
| **Total deferred tax assets** | **1,160,392** | **796,092** | **707,322** |
| Set off deferred tax liabilities pursuant to set-off provisions | — | — | — |
| | **1,160,392** | **796,092** | **707,322** |
| Deferred tax assets not brought to account as realization is not considered probable | (1,160,392) | (796,092) | (707,322) |
| **Deferred tax assets recognized** | **A$ —** | **A$ —** | **A$ —** |

| Movements – Consolidated | Provisions | Plant and equipment | Intangible assets | Other | Total |
|---|---|---|---|---|---|
| **At June 30, 2015** | **A$ 56,525** | **A$15,713** | **A$ 963,007** | **A$(1,164)** | **A$1,034,081** |
| (Charged) / credited to the consolidated statement of profit or loss and other comprehensive income | 25,459 | (1,808) | (351,664) | 1,164 | (326,849) |
| **At June 30, 2016** | **81,984** | **13,905** | **611,343** | **—** | **707,232** |
| (Charged) / credited to the consolidated statement of profit or loss and other comprehensive income | (33,561) | (960) | 124,057 | (766) | 88,770 |
| **At June 30, 2017** | **48,423** | **12,945** | **735,400** | **(766)** | **796,002** |
| (Charged) / credited to the consolidated statement of profit or loss and other comprehensive income | 73,730 | (2,790) | (219,044) | 3,144 | (144,960) |
| (Charged) / credited directly to equity | — | — | 509,260 | — | 509,260 |
| **At June 30, 2018** | **A$122,153** | **A$10,155** | **A$1,025,616** | **A$ 2,378** | **A$1,160,302** |

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 6. INCOME TAX (CONTINUED)

### Tax losses

The Company has income tax losses for which no deferred tax asset is recognized on the consolidated statement of financial position of A$111,722,828 (2017: A$100,140,383 and 2016: A$89,534,487) which are available indefinitely for offset against future taxable profits subject to continuing to meet relevant statutory tests. The total losses of the Company are broken down in the following table:

| Jurisdiction | Total Losses | Relevant Tax Rate | Relevant Tax |
|---|---|---|---|
| Australia | A$ 42,786,807 | 27.50% | A$11,766,372 |
| United States | 28,875,605 | 21.00% | 6,063,877 |
| United Kingdom | 40,060,416 | 19.00% | 7,611,479 |
| **Total** | **A$111,722,828** | | **A$25,441,728** |

### Unrecognized temporary differences

At June 30, 2018, there is no recognized or unrecognized deferred income tax liability (2017 and 2016: A$nil) for taxes that would be payable on the unremitted earnings of certain of the Company's subsidiaries. The Company has no liability for additional taxation should unremitted earnings be remitted (2017 and 2016: A$nil).

### Tax consolidation

***(i)*** *Members of the tax consolidated group and the tax sharing arrangement*

Avita Medical Limited and its 100% owned Australian resident subsidiaries formed a tax consolidated group with effect from July 1, 2003. Avita Medical Limited is the parent entity of the tax consolidated group. Members of the group have not entered into a tax sharing arrangement or a tax funding arrangement.

***(ii)*** *Tax effect accounting by members of the tax consolidated group*

No amounts have been recognized as tax consolidation contribution adjustments in preparing the accounts of Avita Medical Limited.

## 7. CURRENT ASSETS – CASH AND CASH EQUIVALENTS

| | As of June 30, 2018 | 2017 |
|---|---|---|
| Cash at bank and in hand | **A$14,825,532** | **A$3,790,491** |
| Short term deposits | — | — |
| | **A$14,825,532** | **A$3,790,491** |

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 8. CURRENT ASSETS – TRADE AND OTHER RECEIVABLES

| | As of June 30, 2018 | 2017 |
|---|---|---|
| Trade receivables | A$ 263,421 | A$ 259,012 |
| Allowance for doubtful debts | (23,452) | (88,859) |
| | 239,969 | 170,153 |
| R&D Tax claim | 2,434,430 | 1,048,634 |
| BARDA and other receivables | 2,762,958 | 851,747 |
| **Carrying amount of trade and other receivables** | **A$5,437,357** | **A$2,070,534** |

### (a) Allowance for impairment loss

Trade receivables are non-interest bearing and are generally on 30 to 90-day terms. An allowance for impairment loss is made when there is objective evidence that the Company will not be able to collect the debts. Bad debts are written off when identified. Financial difficulties of the debtor, default payments or debts more than 90 days overdue are considered objective evidence of impairment. The amount of the impairment loss is the receivable carrying amount compared to the present value of estimated future cash flows, discounted at the original effective interest rate.

A gain of A$nil (2017: A$nil) has been recognized by the Company in the current year on recovery of these previously impaired receivables.

Movements in the allowance for impairment loss were as follows:

| | As of June 30, 2018 | 2017 |
|---|---|---|
| At July 1 | A$ 88,859 | A$ — |
| Received during the year | — | — |
| Write off during the year | (88,859) | — |
| Charge for the year | 23,452 | 88,859 |
| **At June 30** | **A$ 23,452** | **A$88,859** |

At June 30, the aging analysis of trade receivables is as follows:

| | | Total | 0-30 days | 31-60 days | 61-90 days | +91 days PDNI* | +91 days CI** |
|---|---|---|---|---|---|---|---|
| 2018 | Consolidated | 263,421 | 129,979 | 82,406 | 6,173 | 42,792 | 2,071 |
| 2017 | Consolidated | 259,012 | 95,180 | 32,866 | 40,374 | 1,733 | 88,859 |

* Past due not impaired (“PDNI”)
** Considered impaired (“CI”)

The Company’s trade receivables past due but not considered impaired amounted to A$23,452 at June 30, 2018 (2017: A$nil). Payment terms on these amounts have not been re-negotiated however each operating unit has been in direct contact with the relevant debtor and is satisfied that payment will be received in full.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 8. CURRENT ASSETS – TRADE AND OTHER RECEIVABLES (CONTINUED)

### (a) Allowance for impairment loss (continued)

Other balances within trade and other receivables which have similar terms as trade receivables do not contain impaired assets and are not past due. It is expected that these other balances will be received when due.

### (b) Fair value and credit risk

Due to the short-term nature of these receivables, their carrying value is assumed to approximate their fair value. The maximum exposure to credit risk is the fair value of receivables. Collateral is not held as security, nor is it the Company's policy to transfer (on-sell) receivables to special purpose entities.

### (c) Foreign exchange and interest rate risk

Detail regarding foreign exchange and interest rate risk exposure is disclosed in Note 20.

## 9. CURRENT ASSETS – INVENTORIES

| | As of June 30, | |
|---|---|---|
| | 2018 | 2017 |
| Raw materials and components at cost | A$ 778,947 | A$ 804,052 |
| Finished goods at cost | 376,879 | 233,438 |
| **Total inventories at cost** | **A$1,155,826** | **A$1,037,490** |

A provision of A$42,412 (2017: A$1,660 and 2016: A$1,766) has been allocated against raw materials to reduce the carrying amount of certain inventory items to nil net realizable value. The change in provision of inventory has been included in the cost of sales line item as a cost of inventories in the consolidated statement of profit or loss and other comprehensive income.

**Inventory expense**

Inventories recognized as an expense as a result of expiration for the year ended June 30, 2018 totaled A$38,107 (2017: A$408,052 and 2016: A$182,150).

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(IN AUSTRALIAN DOLLARS)

## 10. NON-CURRENT ASSETS – PLANT AND EQUIPMENT

**Reconciliation of carrying amounts at the beginning and end of the period**

| | *Plant and Equipment* |
|---|---|
| **Year ended June 30, 2018** | |
| At July 1, 2017, net of accumulated depreciation | A$ 387,380 |
| Additions | 498,749 |
| Depreciation charge for the year | (143,546) |
| **As of June 30, 2018, net of accumulated depreciation** | **A$ 742,583** |
| **As of June 30, 2018** | |
| Cost | A$1,448,142 |
| Accumulated depreciation | (705,559) |
| **Net carrying amount** | **A$ 742,583** |

| | *Plant and Equipment* |
|---|---|
| **Year ended June 30, 2017** | |
| At July 1, 2016, net of accumulated depreciation | A$ 94,491 |
| Additions | 432,592 |
| Depreciation charge for the year | (139,703) |
| **As of June 30, 2017, net of accumulated depreciation** | **A$ 387,380** |
| **As of June 30, 2017** | |
| Cost | A$1,307,367 |
| Accumulated depreciation | (919,987) |
| **Net carrying amount** | **A$ 387,380** |

## 11. CURRENT LIABILITIES – TRADE AND OTHER PAYABLES

| | As of June 30, 2018 | 2017 |
|---|---|---|
| Trade payables | A$ 271,913 | A$ 990,040 |
| Accruals and other payables | 3,215,669 | 1,373,694 |
| **Carrying amount of trade and other payables** | **A$3,487,582** | **A$2,363,734** |

### (a) Fair value

Due to the short-term nature of these payables, their carrying value is assumed to approximate their fair value.

### (b) Interest rate, foreign exchange and liquidity risk

Information regarding interest rate, foreign exchange and liquidity risk exposure is set out in Note 20.

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
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## 12. CURRENT LIABILITIES – PROVISIONS

| | As of June 30, 2018 | 2017 |
|---|---|---|
| Provision for annual leave (i) | A$376,535 | A$136,822 |
| Provision for long service leave (ii) | 19,000 | 45,533 |
| | **A$395,535** | **A$182,355** |

**Employee benefits**

(i) A provision is recognized for annual leave due to employees at the end of the year.

(ii) A provision is recognized for long service leave due to employees at the end of the year.

## 13. CONTRIBUTED EQUITY

| | As of June 30, 2018 | 2017 |
|---|---|---|
| *Ordinary shares* | | |
| Authorized, issued and fully paid | 162,801,028 | 134,806,022 |

Fully paid ordinary shares carry one vote per share and carry the right to dividends.

| *Movement in ordinary shares on issue* | Number | A$ |
|---|---|---|
| At July 1, 2016 | 532,751,995 | 126,264,372 |
| New shares | 139,467,859 | 9,048,102 |
| Capital issue costs | — | (506,452) |
| At July 1, 2017 | 673,219,854 | 134,806,022 |
| New shares | 633,658,471 | 29,846,859 |
| Cancelled shares | (29,500,000) | — |
| Capital issue costs | — | (1,851,853) |
| **At June 30, 2018** | **1,277,378,325** | **162,801,028** |

**Capital management**

When managing capital, management's objective is to ensure the entity continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. Management also aims to maintain a capital structure that ensures the lowest cost of capital available to the entity. The Company regularly reviews the capital structure and seeks to take advantage of available opportunities to improve outcomes for the Company and its shareholders.

For the year ended 30 June 2018, there were no dividends paid and management has no plans to commence the payment of dividends. Management has no current plans to issue further shares on the market but will continue to assess market conditions and the company's cash flow requirements to ensure the company is appropriately funded.

The Company monitors capital on the basis of the gearing ratio, however there is no significant external borrowing at the reporting date. Neither the Company nor any of the subsidiaries are subject to externally imposed capital requirement.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 14. ACCUMULATED LOSSES AND RESERVES

### (a) Movements in accumulated losses were as follows:

| | As of June 30, | |
|---|---|---|
| | **2018** | **2017** |
| Balance July 1 | A$(132,218,352) | A$(121,108,408) |
| Net loss attributable to owners of Avita Medical Limited | (16,519,155) | (11,511,024) |
| Transfer from expired / lapsed options | 141,188 | 401,080 |
| Cancelled options | 3,440 | — |
| **Balance June 30** | **A$(148,592,879)** | **A$(132,218,352)** |

### (b) Nature and purpose of reserves

*Employee equity benefits reserve*

The employee equity benefits reserve is used to record the value of share-based payments provided to employees, including Key Management Personnel, as part of their remuneration. Refer to note 17 for further details of these plans.

*Foreign currency translation reserve*

The foreign currency translation reserve is used to record exchange differences arising from the translation of the financial statements of foreign subsidiaries.

*Available for sales reserve*

Available for sale reserve is used to record the gain from measuring financial assets at fair value.

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(IN AUSTRALIAN DOLLARS)

## 15. CONSOLIDATED STATEMENT OF CASH FLOWS RECONCILIATION

| | 2018 | June 30, 2017 | 2016 |
|---|---|---|---|
| **Reconciliation of net loss after tax to net cash flows from operations** | | | |
| Loss from ordinary activities after tax | A$(16,519,155) | A$(11,511,024) | A$(7,778,015) |
| ***Adjustments for non-cash items:*** | | | |
| Depreciation | 143,546 | 139,703 | 83,724 |
| Share options expensed | 1,835,157 | 1,587,243 | 956,658 |
| Share options cancelled classified as financing activities | 62,681 | | |
| R&D claim accrual | (1,385,414) | | |
| Foreign exchange differences | 592,385 | — | — |
| Investment | — | — | (453,892) |
| Loss on disposal of PPE | — | — | 3,124 |
| ***Changes in assets and liabilities:*** | | | |
| (Increase)/decrease in inventories | (118,336) | 333,132 | (776,105) |
| Increase in trade and other receivables | (1,980,566) | (49,040) | (516,052) |
| (Increase) / decrease in prepayments | (473,690) | (156,756) | 17,892 |
| Increase in trade and other payables | 1,258,186 | 1,125,116 | 494,561 |
| Increase/(decrease) in provisions | 213,182 | (25,898) | 29,549 |
| **Net cash used in operating activities** | **A$(16,372,024)** | **A$ (8,557,524)** | **A$(7,938,557)** |

## 16. RELATED PARTY DISCLOSURE

### (a) Subsidiaries

The consolidated financial statements include the financial statements of Avita Medical Limited and the subsidiaries listed in the following table:

| *Name* | *Country of Incorporation* | *% Equity interest at June 30, 2018* | *% Equity interest at June 30, 2017* | *% Equity interest at June 30, 2016* | *Investment ($) at June 30, 2018* | *Investment ($) at June 30, 2017* |
|---|---|---|---|---|---|---|
| C3 Operations Pty Ltd | Australia | 100% | 100% | 100% | A$ — | A$ — |
| Avita Medical Europe Ltd | United Kingdom | 100% | 100% | 100% | — | — |
| Avita Medical Americas LLC | United States | 100% | 100% | 100% | — | — |
| Infamed Pty Limited | Australia | 100% | 100% | 100% | — | — |
| Visiomed Group Pty Ltd | Australia | 100% | 100% | 100% | 4,643,888 | 4,643,888 |
| | | | | | **A$ 4,643,888** | **A$ 4,643,888** |

### (b) Ultimate parent

Avita Medical Limited is the ultimate parent entity in the wholly-owned company.

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(IN AUSTRALIAN DOLLARS)

## 16. RELATED PARTY DISCLOSURE (CONTINUED)

### (c) Key Management Personnel

The total remuneration paid to key management personnel of the Company during year is detailed below.

| | Year ended June 30, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Short-term employee benefits | A$3,770,141 | A$2,933,510 | A$1,904,993 |
| Post-employment employee benefits | 90,512 | 112,034 | 108,486 |
| Share-based expenses | 1,596,368 | 1,215,809 | 902,959 |
| **Total compensation** | **A$5,457,021** | **A$4,261,353** | **A$2,916,438** |

Refer to the remuneration report contained the Directors' Report for details of the remuneration paid or payable to each member of the Company's key management personnel for the year ended June 30, 2018.

The total amount of transactions entered into with Key Management Personnel for the year ended June 30, 2018 were A$157,728 Consultancy fees (2017: A$128,987 and 2016: A$59,675) paid under normal terms and conditions to Bioscience Managers Pty Ltd of which Mr. Curnock Cook is an officer and Dr. Michael Perry is a director.

### (d) Transactions with related parties

*Subsidiaries of the Company*

During the reporting period, inter-company other revenue was made of A$2,819,592 (2017: A$2,087,051 and 2016: A$1,995,041) by Avita Medical Europe Ltd and Avita Medical Americas LLC to Avita Medical Limited. These have been eliminated on consolidation.

*Employees*

Contributions to superannuation funds on behalf of employees are disclosed in note 4(g).

*Terms and conditions of transactions with related parties*

Outstanding balances at year end are unsecured, interest free and settlement occurs in cash.

## 17. SHARE-BASED PAYMENT PLANS

### (a) Recognized share-based payment expenses

The expense recognized for employee services received during the year is shown in the table below:

| | Year ended June 30, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| Expenses arising from equity-settled share-based payment transactions | A$1,835,157 | A$1,587,243 | A$956,658 |
| **Total expense arising from share-based payment transactions** | **A$1,835,157** | **A$1,587,243** | **A$956,648** |

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 17. SHARE-BASED PAYMENT PLANS (CONTINUED)

### (a) Recognized share-based payment expenses (continued)

The share-based payment plans are described below. There have been share-based plan forfeitures during fiscal 2018 and 2017.

### (b) Types of share-based payment plans

**Employee Share Option Plan (ESOP)**

Share options are granted to Senior Executives and employees under the Employee Share Option Plan at the discretion of the Board. The exercise price of the options is based on a weighted average market price of the shares preceding the date of grant. The options vest at the time of grant and the contractual life of each option granted is ten years. There are no cash settlement alternatives.

Subject to shareholder approval, options may also be granted to Directors at the discretion of the Board. The exercise price of the options is based on a weighted average market price of the shares preceding the date of grant. The options vest either at the time of grant or are subject to performance conditions at the discretion of the Board and the contractual life of each option granted is three years. There are no cash settlement alternatives.

### (c) Summaries of options granted under ESOP arrangements

The following table illustrates the number (No) and weighted average exercise price (WAEP) of, and movements in, share options issued during the year:

| | *2018 No* | *2018 WAEP* | *2017 No* | *2017 WAEP* | *2016 No* | *2016 WAEP* |
|---|---|---|---|---|---|---|
| Outstanding at the beginning of the year | 24,797,286 | A$ 0.09 | 11,147,289 | A$ 0.14 | 9,441,250 | A$ 0.14 |
| Expired during the year | (3,937,289) | 0.13 | (4,710,000) | 0.14 | (1,450,000) | 0.14 |
| Forfeiture | (838,333) | 0.08 | (2,500,000) | 0.15 | — | — |
| Granted during the year | 9,110,000 | 0.06 | 20,859,997 | 0.08 | 3,156,039 | 0.16 |
| **Outstanding at the end of the year** | **29,131,664** | **A$0.078** | **24,797,286** | **A$0.084** | **11,147,289** | **A$ 0.149** |

As at the reporting date, there were 29,131,664 unissued ordinary shares under options represented by:

1,110,000 exercisable at A$0.08 expiring December 31, 2018 issued to an employee on July 1, 2017.

17,910,415 exercisable at A$0.085 expiring May 18, 2027 issued to employees on May 18, 2017.

1,072,916 exercisable at A$0.082 expiring May 26, 2027 issued to an employee on May 26, 2017.

1,038,333 exercisable at A$0.08 expiring June 27, 2027 issued to employees on June 27, 2017.

4,000,000 exercisable at A$0.063 expiring September 6, 2027 issued to an employee on September 6, 2017.

4,000,000 exercisable at A$0.061 expiring January 3, 2028 issued to an employee on January 3, 2018.

Option holders do not have any right, by virtue of the option, to participate in any share issue of the Company or any related corporate body.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

**17. SHARE-BASED PAYMENT PLANS (CONTINUED)**

**(c) Summaries of options granted under ESOP arrangements (continued)**

***Shares issued as a result of the exercise of options***

During the financial year and up to the date of this report, no options were exercised to acquire fully paid ordinary shares in the Company.

**(d) Weighted average remaining contractual life**

The weighted average remaining contractual life for the share options outstanding as at June 30, 2018 is 9.52 years (2017: 9.39 years and 2016: 2.88 years).

**(e) Range of exercise price**

The range of exercise prices for options outstanding at the end of the year was A$0.061—A$0.126 (2017: A$0.079—A$0.14 and 2016: A$0.10—A$0.175).

As the range of exercise prices is wide, refer to Section (c) above for further information in assessing the number and timing of additional shares that may be issued and the cash that may be received upon exercise of those options.

**(f) Weighted average fair value**

The weighted average fair value of options granted during the year was A$247,089 (2017: A$578,879 and 2016: A$191,589). The total fair value of the options granted during the year is A$247,089 (2017: A$578,879 and 2016: A$191,589).

**(g) Option pricing model: ESOP and Investor**

**Equity-settled transactions**

The fair value of the equity-settled share options granted under the ESOP is estimated at the date of grant using a Binomial Model taking into account the terms and conditions upon which the options were granted.

The options issued in the period have vesting criteria based on the following performance conditions:

- Tenure with the Company
- Revenue target
- FDA PMA approval of RECELL for burns
- Initial BARDA procurement under CLIN2 of the BARDA Contract
- US Quotation

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
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**17. SHARE-BASED PAYMENT PLANS (CONTINUED)**

**(g) Option pricing model: ESOP and Investor (continued)**

**i)** On May 18, 2017, 17,910,415 options were granted to employees at an exercise price of A$0.085 expiring on May 18, 2027. The following table lists the inputs to the models used for the options granted to employees each year:

| | 2018 | 2017 |
|---|---|---|
| Grant date | 05/18/2017 | 05/18/2017 |
| Share price at date of grant | A$ 0.08 | A$ 0.08 |
| Dividend yield (%) | 0% | 0% |
| Expected volatility (%) | 90% | 90% |
| Risk-free interest rate (%) | 1.5% | 1.5% |
| Expected life of option | 3,650 | 3,650 |
| Fair value at date of grant | A$ 0.075 | A$ 0.075 |
| Option exercise price (A$) | A$ 0.085 | A$ 0.085 |

At year end, 7,808,333 options were unvested.

**ii)** On May 26, 2017, 1,072,916 options were granted to employees at an exercise price of A$0.082 expiring on May 26, 2027. The following table lists the inputs to the models used for the options granted to employees each year:

| | 2018 | 2017 |
|---|---|---|
| Grant date | 05/26/2017 | 05/26/2017 |
| Share price at date of grant | A$ 0.086 | A$ 0.086 |
| Dividend yield (%) | 0% | 0% |
| Expected volatility (%) | 90% | 90% |
| Risk-free interest rate (%) | 1.5% | 1.5% |
| Expected life of option | 3,650 | 3,650 |
| Fair value at date of grant | A$ 0.070 | A$ 0.070 |
| Option exercise price (A$) | A$ 0.082 | A$ 0.082 |

At year end, 938,333 options were unvested.

**iii)** On June 27, 2017, 1,876,666 options were granted to employees at an exercise price of A$0.08 expiring on June 27, 2027. The following table lists the inputs to the models used for the options granted to employees each year:

| | 2018 | 2017 |
|---|---|---|
| Grant date | 06/27/2017 | 06/27/2017 |
| Share price at date of grant | A$ 0.067 | A$ 0.067 |
| Dividend yield (%) | 0% | 0% |
| Expected volatility (%) | 90% | 90% |
| Risk-free interest rate (%) | 1.5% | 1.5% |
| Expected life of option | 3,650 | 3,650 |
| Fair value at date of grant | A$ 0.062 | A$ 0.062 |
| Option exercise price (A$) | A$ 0.08 | A$ 0.08 |

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
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**17. SHARE-BASED PAYMENT PLANS (CONTINUED)**

**(g) Option pricing model: ESOP and Investor (continued)**

At year end, 623,000 options were unvested.

**iv)** On July 1, 2017, 1,110,000 options were granted to employee at an exercise price of A$0.08 expiring on December 31, 2018. The following table lists the inputs to the models used for the options granted to employees each year:

| | 2018 |
|---|---|
| Grant date | 07/01/2017 |
| Share price at date of grant | A$ 0.069 |
| Dividend yield (%) | 0% |
| Expected volatility (%) | 90% |
| Risk-free interest rate (%) | 1.5% |
| Expected life of option | 552 |
| Fair value at date of grant | A$ 0.031 |
| Option exercise price (A$) | A$ 0.08 |

At year end, 1,110,000 options were unvested.

v) On September 6, 2017, 4,000,000 options were granted to employee at an exercise price of A$0.063 expiring on September 6, 2027. The following table lists the inputs to the models used for the options granted to employees each year:

| | 2018 |
|---|---|
| Grant date | 09/06/2017 |
| Share price at date of grant | A$ 0.056 |
| Dividend yield (%) | 0% |
| Expected volatility (%) | 90% |
| Risk-free interest rate (%) | 1.5% |
| Expected life of option | 3,650 |
| Fair value at date of grant | A$ 0.052 |
| Option exercise price (A$) | A$ 0.063 |

At year end, 4,000,000 options were unvested.

vi) On January 3, 2018, 4,000,000 options were granted to employee at an exercise price of A$0.061 expiring on January 3, 2028. The following table lists the inputs to the models used for the options granted to employees each year:

| | 2018 |
|---|---|
| Grant date | 01/03/2018 |
| Share price at date of grant | A$ 0.061 |
| Dividend yield (%) | 0% |
| Expected volatility (%) | 90% |
| Risk-free interest rate (%) | 1.5% |
| Expected life of option | 3,650 |
| Fair value at date of grant | A$ 0.049 |
| Option exercise price (A$) | A$ 0.061 |

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
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## 17. SHARE-BASED PAYMENT PLANS (CONTINUED)

### (g) Option pricing model: ESOP and Investor (continued)

At year end, 4,000,000 options were unvested.

### (h) Long-term incentive rights

On November 30, 2017, 50,000,000 LTI's were issued to Dr. Michael Perry based on the following milestones:

1. Tenure – a total of 16,666,666 LTIs issued but to vest over the three-year period commencing July 1, 2017;
2. Company Share Price – a total of 16,666,666 LTIs issued but to vest in three equal tranches subject to the Volume Weighted Average Price (VWAP) of Company share price (as at close of trade on the ASX on relevant date) achieving multiples of 2x, 3x and 4x the Company's share price at the time of shareholder approval; and
3. Milestone performance – a total of 16,666,668 LTIs issued, but to vest in two equal tranches with one tranche to vest upon the achievement of the following milestones:
    a. FDA PMA approval of RECELL for burns
    b. Initial BARDA procurement under CLIN2 of the BARDA Contract

| | Tranche 1 | Tranche 2 | Tranche 3 | Tranche 4 |
|---|---|---|---|---|
| Grant date | 11/30/2017 | 11/30/2017 | 11/30/2017 | 11/30/2017 |
| Share price at date of grant | A$ 0.061 | A$ 0.061 | A$ 0.061 | A$ 0.061 |
| Exercise price | A$ nil | A$ nil | A$ nil | A$ nil |
| Vesting hurdle | n/a | n/a | n/a | A$ 0.122 |
| Expiry period | 11/30/2027 | 11/30/2027 | 11/30/2027 | 11/30/2027 |
| Dividend yield (%) | 0% | 0% | 0% | 0% |
| Expected volatility (%) | 70% | 70% | 70% | 70% |
| Risk-free interest rate (%) | 2.47% | 2.47% | 2.47% | 2.47% |

| | Tranche 5 | Tranche 6 | Tranche 7 | Tranche 8 |
|---|---|---|---|---|
| Grant date | 11/30/2017 | 11/30/2017 | 11/30/2017 | 11/30/2017 |
| Share price at date of grant | A$ 0.061 | A$ 0.061 | A$ 0.061 | A$ 0.061 |
| Exercise price | A$ nil | A$ nil | A$ nil | A$ nil |
| Vesting hurdle | A$ 0.183 | A$ 0.244 | n/a | n/a |
| Expiry period | 11/30/2027 | 11/30/2027 | 11/30/2027 | 11/30/2027 |
| Dividend yield (%) | 0% | 0% | 0% | 0% |
| Expected volatility (%) | 70% | 70% | 70% | 70% |
| Risk-free interest rate (%) | 2.47% | 2.47% | 2.47% | 2.47% |

## 18. SEGMENT INFORMATION

Operating segments are identified on the basis of internal reports about components of the Company that are regularly reviewed by the chief operating decision maker to allocate resources to the segment and to assess its performance. The Company's chief operating decision maker has been identified as the Chief Executive Officer.

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
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## 18. SEGMENT INFORMATION (CONTINUED)

The Chief Executive Officer reviews the financial and operating performance of the business primarily from a geographic perspective. On this basis, management have identified three reportable operating segments being the Asia Pacific, Europe and Americas including Canada. The Chief Executive Officer monitors the performance of all these segments separately. The Company does not operate in any other geographic segment.

The Asia Pacific operating segment derives its revenues from the sale of the RECELL System.

The Europe operating segment derives its revenues from the sale of the RECELL System.

The America operating segment derives its revenues primarily from fees received under its contracts with BARDA. The RECELL System was not approved for sale within the U.S. until subsequent to June 30, 2018, on September 20, 2018.

The Chief Executive Officer assesses the performance of the operating segments based on a measure of gross margin and net profit before tax.

*Unallocated*

The following items of income and expense and associated assets are not allocated to operating segments as they are not considered part of the core operations of any segment:

- Corporate revenue
- Corporate charges
- Amortization of intellectual property

The segment information provided to the Chief Executive Officer for the reportable segments for the year ended June 30, 2018 is as follows:

| | *Asia Pacific* | *EMEA* | *Americas* | *Total* |
|---|---|---|---|---|
| **Year ended June 30, 2018** | | | | |
| **Revenue** | | | | |
| Sale of goods | A$ 709,907 | A$ 488,955 | A$ — | A$ 1,198,862 |
| Other income from external customers | — | 2,961 | 10,104,082 | 10,107,043 |
| Interest received | 59,552 | 438 | 5,667 | 65,657 |
| **Total revenue and other income per consolidated statement of profit or loss and other comprehensive income** | **A$ 769,459** | **A$ 492,354** | **A$10,109,749** | **A$ 11,371,562** |
| Segment net loss before tax benefit | A$(1,341,200) | A$(2,181,622) | A$ (9,539,296) | A$(13,062,118) |
| **Reconciliation of segment net result before tax to loss before income tax:** | | | | |
| Corporate charges including share-based expenses | | | | (4,842,833) |
| **Loss before income tax benefit** | | | | **A$(17,904,951)** |

The Company's revenue in its Americas including Canada operating segment includes A$9,650,783 from BARDA, representing 85%.

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
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## 18. SEGMENT INFORMATION (CONTINUED)

Revenue is attributed to geographic location based on the location of the customers. The percentages of external revenues from external customers that are attributable to foreign countries are as shown below:

| | 2018 | 2017 | 2016 |
|---|---|---|---|
| Australia | 6.8% | 9.4% | 15.4% |
| Other | 93.2% | 90.6% | 84.6% |
| **Total revenue** | **100.0%** | **100.0%** | **100.0%** |

| | *Asia Pacific* | *EMEA* | *Americas* | *Total* |
|---|---|---|---|---|
| **Year ended June 30, 2018** | | | | |
| **Segment assets** | | | | |
| Segment operating assets | A$532,926 | A$579,081 | A$7,079,653 | A$18,191,660 |
| Segment non-current assets | 5,662 | 18,215 | 703,100 | 726,977 |
| Unallocated assets | — | — | — | 4,098,377 |
| **Total assets per the consolidated statement of financial position** | | | | **A$23,017,014** |
| **Segment liabilities** | | | | |
| Segment operating liabilities | A$189,531 | A$176,461 | A$3,314,423 | A$ 3,680,415 |
| Unallocated liabilities | — | — | — | 337,040 |
| **Total liabilities per the consolidated statement of financial position** | | | | **A$ 4,017,455** |

| | *Asia Pacific* | *EMEA* | *Americas* | *Total* |
|---|---|---|---|---|
| **Year ended June 30, 2017** | | | | |
| **Revenue** | | | | |
| Sale of goods | A$ 452,662 | A$ 448,714 | A$ — | A$ 901,376 |
| Other revenues from external customers | 197,488 | 23,537 | 6,886,236 | 7,107,261 |
| Interest received | 116,559 | 1,218 | 5,932 | 123,709 |
| **Total revenue and other income per consolidated statement of profit or loss and other comprehensive income** | **A$ 766,709** | **A$ 473,469** | **A$ 6,892,168** | **A$ 8,132,346** |
| Segment net operating loss before tax | A$(1,559,592) | A$(2,836,165) | A$(2,373,062) | A$ (6,768,819) |
| **Reconciliation of segment net result before tax to loss before income tax:** | | | | |
| Corporate charges including share-based expenses | | | | (5,790,442) |
| **Loss before income tax** | | | | **A$(12,559,261)** |

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(IN AUSTRALIAN DOLLARS)

## 18. SEGMENT INFORMATION (CONTINUED)

| | *Asia Pacific* | *EMEA* | *Americas* | *Total* |
|---|---|---|---|---|
| **Year ended June 30, 2017** | | | | |
| **Segment assets** | | | | |
| Segment operating assets | A$227,359 | A$1,166,946 | A$2,342,846 | A$3,737,150 |
| Segment non-current assets | 6,624 | 20,375 | 360,380 | 387,380 |
| Unallocated assets | — | — | — | 3,156,011 |
| **Total assets per the consolidated statement of financial position** | | | | **A$7,280,541** |
| **Segment liabilities** | | | | |
| Segment operating liabilities | A$153,502 | A$ 468,996 | A$1,743,657 | A$2,366,155 |
| Unallocated liabilities | — | — | — | 179,934 |
| **Total liabilities per the consolidated statement of financial position** | | | | **A$2,546,089** |

| | *Asia Pacific* | *EMEA* | *Americas* | *Total* |
|---|---|---|---|---|
| **Year ended June 30, 2016** | | | | |
| **Revenue** | | | | |
| Sale of goods | A$ 436,101 | A$ 565,906 | A$ — | A$ 1,002,007 |
| Other revenues from external customers | 2,358 | 474 | 2,431,321 | 2,434,153 |
| Interest received | 109,789 | 492 | 83 | 110,364 |
| **Total revenue and other income per consolidated statement of profit or loss and other comprehensive income** | **A$ 548,248** | **A$ 566,872** | **A$ 2,431,405** | **A$ 3,546,524** |
| Segment net operating loss before tax | A$(1,553,744) | A$(3,222,858) | A$(1,461,569) | A$ (6,238,171) |
| **Reconciliation of segment net result before tax to loss before income tax:** | | | | |
| Corporate charges | | | | (5,005,672) |
| **Loss before income tax** | | | | **A$(11,243,843)** |

| | *Continuing Operations* | | | |
|---|---|---|---|---|
| | *Asia Pacific* | *EMEA* | *Americas* | *Total* |
| **Year ended June 30, 2016** | | | | |
| **Segment assets** | | | | |
| Segment operating assets | A$254,672 | A$1,649,931 | A$2,746,915 | A$4,651,518 |
| Unallocated assets | — | — | — | 3,951,391 |
| **Total assets per the consolidated statement of financial position** | | | | **A$8,602,909** |
| **Segment liabilities** | | | | |
| Segment operating liabilities | A$163,992 | A$ 622,146 | A$ 727,167 | A$1,513,305 |
| Unallocated liabilities | — | — | — | 237,087 |
| **Total liabilities per the consolidated statement of financial position** | | | | **A$1,750,392** |

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 19. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Company's principal financial instruments comprise receivables, payables, cash and short-term deposits.

The Company manages its exposure to key financial risks, including interest rate and foreign currency risk in accordance with the Company's financial risk management policy. The objective of the policy is to support the delivery of the Company's financial targets whilst protecting future financial security.

The main risks arising from the Company's financial instruments are interest rate risk, foreign currency risk, credit risk and liquidity risk. The Company uses different methods to measure and manage different types of risk to which it is exposed. These include monitoring levels of exposure to interest rate and foreign exchange risk and assessments of market forecasts for interest rates and foreign exchange. Ageing analyses and monitoring of specific credit allowances are undertaken to manage credit risk, and liquidity risk is monitored through the development of future rolling cash flow forecasts. The Board reviews and agrees policies for managing each of these risks as summarized below.

Primary responsibility for identification and control of financial risks rests with the Finance Manager under the authority of the Board. The Board reviews and agrees policies for managing each of the risks identified below including foreign currency and interest rate risk, credit allowances and future cash flow forecast projections.

At the reporting date, the Company had the following financial assets and liabilities:

| | As of June 30, | |
|---|---|---|
| | 2018 | 2017 |
| **Financial Assets** | | |
| Cash and cash equivalents | A$14,825,532 | A$ 3,790,491 |
| Trade and other receivables | 5,437,357 | 2,070,534 |
| **Financial Liabilities** | | |
| Trade and other payables | (3,487,582) | (2,363,734) |
| Provisions | (395,535) | (182,355) |
| **Net** | **A$16,379,772** | **A$ 3,314,936** |

**Risk Exposures and Responses**

*Interest rate risk*

The Company's exposure to market interest rates relates primarily to short-term deposits with a floating interest rate. At reporting date, the Company had the following mix of financial assets exposed to Australian Variable interest rate risk:

| | As of June 30, | |
|---|---|---|
| | 2018 | 2017 |
| **Financial Assets** | | |
| Cash and cash equivalents | A$14,825,532 | A$3,790,491 |
| **Net exposure** | **A$14,825,532** | **A$3,790,491** |

The Company's policy is to manage its finance costs and revenue using a mix of fixed and variable interest rates depending on the forecast funding requirements of the Company. At June 30, 2018 and 2017, there were no cash and cash equivalents recorded at a fixed rate of interest.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 19. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONTINUED)

The following sensitivity analysis is based on the interest rate exposures in existence at the reporting date. The 1% sensitivity is based on reasonably possible changes over a financial year, using the observed range of historical rates for the preceding three-year period.

At June 30, 2018, if interest rates had moved, as illustrated in the table below, with all other variables held constant, post tax loss and equity would have been affected as follows:

| **Judgements of reasonably possible movements:** | **Post Tax Loss (Higher)/Lower** | | **Equity Higher/(Lower)** | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| +1% (100 basis points) | A$ 148,255 | A$ 37,905 | A$ 148,255 | A$ 37,905 |
| -1% (100 basis points) | (148,255) | (37,905) | (148,255) | (37,905) |

The movements in loss are due to higher/lower finance revenue from variable rate cash balances.

*Foreign currency risk*

The Company has investment operations in Europe and the United States. The Company's consolidated statement of financial position can be affected by movements in exchange rates and the Company does not currently hedge this exposure.

The Company also has transactional currency exposures. Such exposures arise from sales or purchases by an operating entity in currencies other than the functional currency.

Approximately 93% (2017: 94% and 2016: 87%) of the Company's sales are denominated in currencies other than the functional currency, whilst approximately 74% (2017: 60% and 2016: 51%) of costs are denominated in the functional currency.

At June 30, 2018, the Company had the following exposure to foreign currencies:

| | **As of June 30,** | |
|---|---|---|
| | **2018** | **2017** |
| **Financial assets** | | |
| Cash and cash equivalents | A$13,046,513 | A$ 1,726,568 |
| Trade and other receivables | 2,847,542 | 926,501 |
| | **15,894,055** | **2,653,069** |
| **Financial liabilities** | | |
| Trade and other payables | (3,356,546) | (1,209,902) |
| **Net exposure** | **A$12,537,509** | **A$ 1,443,167** |

The following sensitivity is based on the foreign currency risk exposures in existence at the reporting date. The percentage sensitivity is based on reasonably possible changes over a financial year, using the observed range of historical rates for the preceding two-year period.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 19. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONTINUED)

At June 30, 2018, had the Australian Dollar moved, as illustrated in the table below, with all other variables held constant, post tax loss and equity would have been affected as follows:

| Judgments of reasonably possible movements: | Post Tax Loss (Higher)/Lower | | | Equity Higher/(Lower) | | |
|---|---|---|---|---|---|---|
| | 2018 | 2017 | 2016 | 2018 | 2017 | 2016 |
| AUD/GBP + 10% | A$ 54,761 | A$(62,731) | A$(74,765) | A$ 54,761 | A$(62,731) | A$(74,765) |
| AUD/GBP – 5% | 27,380 | 31,366 | 37,383 | 27,380 | 31,366 | 37,383 |
| AUD/USD +10% | 1,827,003 | (67,791) | (70,732) | 1,827,003 | (67,791) | (70,732) |
| AUD/USD – 5% | 913,502 | 33,895 | 35,366 | 913,502 | 33,895 | 35,366 |
| AUD/EUR +10% | 8,663 | (13,795) | (22,151) | 8,663 | (13,795) | (22,151) |
| AUD/EUR – 5% | 4,332 | 6,897 | 11,076 | 4,332 | 6,897 | 11,076 |

Management believe the reporting date risk exposures are representative of the risk exposure inherent in the financial instruments. The Company has no processes and objectives for managing foreign exchange risks.

*Credit risk*

Credit risk arises from the financial assets of the Company, which comprise cash and cash equivalents and trade and other receivables. The Company's exposure to credit risk arises from potential default of the counter party, with a maximum exposure equal to the carrying amount of these instruments.

The Company does not hold any credit derivatives to offset its credit exposure.

The Company trades only with recognized, creditworthy third parties, and as such collateral is not requested nor is it the Company's policy to securitize its trade and other receivables.

It is the Company's policy that all customers who wish to trade on credit terms are subject to credit verification procedures including an assessment of their independent credit rating, financial position, past experience and industry reputation. Risk limits are set for each individual customer in accordance with parameters set by the Board. These risk limits are regularly monitored.

In addition, receivable balances are monitored on an on-going basis with the result that the Company's exposure to bad debts is not significant.

A significant balance of cash is held in National Australia Bank. This is a highly rated institution which effectively manages its risk profile and therefore the Company considers its cash balances to be secure.

There is no concentration of debt amongst the creditors.

*Liquidity risk*

The Company's objective is to maintain a balance between continuity of funding and flexibility through the use of bank overdrafts, bank loans and finance leases.

The table below reflects all contractually fixed pay-offs and receivables for settlement, repayments and interest resulting from recognized financial assets and liabilities. For all obligations, the respective undiscounted cash flows for the respective upcoming fiscal years are presented. Cash flows for financial assets and liabilities without fixed amount or timing are based on the conditions existing at June 30, 2018.

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(IN AUSTRALIAN DOLLARS)

## 19. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONTINUED)

The remaining contractual maturities of the Company's financial liabilities are:

| | As of June 30, 2018 | 2017 |
|---|---|---|
| 6 months or less | A$3,487,582 | A$2,363,734 |
| 6-12 months | — | — |
| 1-3 years | — | — |
| | **A$3,487,582** | **A$2,363,734** |

Maturity analysis of financial assets and liabilities are based on management's expectation.

The risk implied from the values shown in the table below, reflects a balanced view of cash inflows and outflows. Trade payables and other financial liabilities mainly originate from the financing of assets used in our on-going operations such as property, plant, equipment and investments in working capital including inventories and trade receivables. These assets are considered in the Company's overall liquidity risk.

| Year ended June 30, 2018 | < 6 months | 6-12 months | 1-5 years | Total |
|---|---|---|---|---|
| **Financial assets** | | | | |
| Cash and cash equivalents | A$14,825,532 | A$ — | A$ — | A$14,825,532 |
| Trade and other receivables | 5,437,357 | — | — | 5,437,357 |
| | **20,262,889** | **—** | **—** | **20,262,889** |
| **Financial liabilities** | | | | |
| Trade and other payables | (3,487,582) | — | — | (3,487,582) |
| **Net maturity** | **A$16,775,307** | **A$ —** | **A$ —** | **A$16,775,307** |

| Year ended June 30, 2017 | < 6 months | 6-12 months | 1-5 years | Total |
|---|---|---|---|---|
| **Financial assets** | | | | |
| Cash and cash equivalents | A$ 3,790,491 | A$ — | A$ — | A$ 3,790,491 |
| Trade and other receivables | 2,070,534 | — | — | 2,070,534 |
| | **5,861,025** | **—** | **—** | **5,861,025** |
| **Financial liabilities** | | | | |
| Trade and other payables | (2,363,734) | — | — | (2,363,734) |
| **Net maturity** | **A$ 3,497,291** | **A$ —** | **A$ —** | **A$ 3,497,291** |

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 20. COMMITMENTS AND CONTINGENCIES

**Finance leases as lessee**

The Company's furniture and IT equipment are held under lease arrangements. As of June 30, 2018, the net carrying amount of the furniture and IT equipment held under lease arrangements is A$159,043 (2017: A$66,408 and 2016: A$nil). The Company's finance lease liabilities, which are secured by the related assets held under finance leases, are classified as follows:

| | 2018 |
|---|---|
| **Finance lease liabilities** | |
| Current: | **A$ 86,883** |
| Non-current: | 72,160 |
| | A$159,043 |

| | Minimum Lease Payment Due | | | |
|---|---|---|---|---|
| | Within 1 Year | 1-5 Years | After 5 Years | Total |
| June 30, 2018 | | | | |
| Lease Payments | 114,650 | 92,515 | — | 207,165 |
| Finance charges | (27,767) | (20,355) | — | (48,122) |
| Net Present Values | 86,883 | 72,160 | — | 159,043 |

**Operating leases as lessee**

The Company leases space under operating leases. Future minimum lease payments as of June 30, 2018 are as follows:

| | Minimum Lease Payment Due | | | |
|---|---|---|---|---|
| | Within 1 Year | 1-5 Years | After 5 Years | Total |
| June 30, 2018 | 525,919 | 856,541 | — | 1,382,460 |
| June 30, 2017 | 344,431 | 879,079 | — | 1,223,509 |
| June 30, 2016 | 190,706 | 438,554 | — | 629,260 |

## 21. AUDITORS' REMUNERATION

The auditors of Avita Medical Limited and its subsidiaries are Grant Thornton Audit Pty Ltd.

| | Year ended June 30, | | |
|---|---|---|---|
| | 2018 | 2017 | 2016 |
| *Amounts received or due and receivable by Grant Thornton Audit Pty Ltd for:* | | | |
| An audit or review of the financial report of the Company and any other entity in the Company | A$182,440 | A$120,366 | A$131,586 |
| Other services in relation to the entity and any other entity in the Company - Taxation services | 46,811 | 62,635 | 30,397 |
| | **A$229,251** | **A$183,001** | **A$161,983** |

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 22. PARENT ENTITY INFORMATION

| Information relating to Avita Medical Limited: | As of June 30, 2018 | As of June 30, 2017 |
|---|---|---|
| Current assets | A$ 4,098,378 | A$ 3,156,011 |
| Total assets | 4,098,378 | 3,156,011 |
| Current liabilities | (337,040) | (179,934) |
| Total liabilities | (337,040) | (179,934) |
| **Net assets** | **A$ 3,761,338** | **A$ 2,976,077** |
| Issued capital | A$ 162,801,028 | A$ 134,806,022 |
| Accumulated losses | (163,541,196) | (135,034,498) |
| Share option reserves | 4,501,506 | 3,204,553 |
| **Total shareholders' equity** | **A$ 3,761,338** | **A$ 2,976,077** |
| Loss of parent entity after income tax | A$ (3,258,675) | A$ (4,741,808) |
| Total comprehensive loss of the parent entity | A$ (3,258,675) | A$ (4,741,808) |
| Details of any contingent liabilities of the parent entity | None | None |
| Details of any contractual commitments by the parent entity for the acquisition of property, plant and equipment | None | None |

During the period, the parent entity impaired A$21,368,073 (2017: A$5,983,551) of intercompany loans to subsidiaries and investments in subsidiaries. The impairment charges are eliminated on consolidation.

## 23. DEED OF CROSS GUARANTEE

The following entities are party to a deed of cross guarantee under which each company guarantees the debts of the others:

- Avita Medical Limited
- C3 Operations Pty Ltd
- Visiomed Group Pty Ltd
- Infamed Pty Limited

By entering into the deed, the wholly owned entities have been relieved from the requirement to prepare a financial report and Directors' Report under Australian Securities and Investments Commission ('ASIC') Corporations (Wholly-owned Companies) Instrument 2016/785. The above companies represent a 'Closed Group' for the purposes of the Class Order, and as there are no other parties to the Deed of Cross guarantee that are controlled by Avita Medical Limited, they also represent the 'Extended Closed Group'.

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(IN AUSTRALIAN DOLLARS)

## 23. DEED OF CROSS GUARANTEE (CONTINUED)

Set out below is a consolidated statement of profit or loss and other comprehensive income and consolidated statement of financial position of the 'Closed Group'.

| Continuing operations | Year ended June 30, 2018 | 2017 | 2016 |
|---|---|---|---|
| Sale of goods | A$ 709,907 | A$ 452,662 | A$ 436,101 |
| Other revenue | 59,552 | 129,958 | 109,789 |
| **Revenue** | **769,459** | **582,620** | **545,890** |
| Cost of sales | (331,244) | (243,708) | (210,200) |
| **Gross profit** | **438,215** | **338,912** | **335,690** |
| **Other income** | — | 184,088 | 2,226,911 |
| **Operating costs** | | | |
| Administrative expenses | (4,660,971) | (3,085,503) | (3,782,183) |
| Research and development expenses | (43,048) | (2,365,647) | (2,136,849) |
| Impairment of inter-company loans | (21,368,073) | (5,983,551) | (7,515,021) |
| Sales and marketing expenses | (1,250,976) | (834,600) | (978,429) |
| Finance costs | — | (41) | (3) |
| **Loss from continuing operations before income tax** | **(26,884,853)** | **(11,746,342)** | **(11,849,884)** |
| Profit from discontinued operations | — | — | 269,394 |
| Income tax benefit | 1,385,796 | 1,048,634 | 972,282 |
| **Total comprehensive loss for the period** | **A$(25,499,057)** | **A$(10,697,708)** | **A$(10,608,208)** |

AVITA MEDICAL LIMITED
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(IN AUSTRALIAN DOLLARS)

## 23. DEED OF CROSS GUARANTEE (CONTINUED)

| | As of June 30, 2018 | 2017 |
|---|---|---|
| **Current Assets** | | |
| Cash and cash equivalents | A$ 1,779,019 | A$ 2,063,923 |
| Trade and other receivables | 2,589,816 | 1,144,033 |
| Prepayments | 130,055 | 155,112 |
| Inventories | 132,414 | 26,925 |
| Investments | — | — |
| **Total Current Assets** | **4,631,304** | **3,389,993** |
| **Non-Current Assets** | | |
| Plant and equipment | 5,662 | 6,625 |
| **Total Non-Current Assets** | **5,662** | **6,625** |
| **TOTAL ASSETS** | **4,636,966** | **3,396,618** |
| **LIABILITIES** | | |
| **Current Liabilities** | | |
| Trade and other payables | 477,366 | 248,497 |
| Provisions | 49,205 | 84,938 |
| **Total Current Liabilities** | **526,571** | **333,435** |
| **TOTAL LIABILITIES** | **526,571** | **333,435** |
| **NET ASSETS** | **4,110,395** | **3,063,183** |
| **EQUITY** | | |
| Contributed equity | 162,801,028 | 134,806,022 |
| Accumulated losses | (163,194,156) | (134,977,180) |
| Reserves | 4,503,523 | 3,234,341 |
| **TOTAL EQUITY** | **A$ 4,110,395** | **A$ 3,063,183** |

## 24. INVESTMENTS

| | As of 30 June 2018 | 2017 | 2016 |
|---|---|---|---|
| Investment in MVP shares | $— | $— | $453,892 |
| Fair value gain on investment | — | — | 265,261 |
| **Carrying amount of investment** | **$—** | **$—** | **$719,153** |

The 2016 Investments of $719,153 was due to the holding in escrow of 117,894 shares of Medical Developments International Ltd (ASX: MVP) originating from the sale of Avita's Respiratory Business in February 2016. Consideration for the divestment was $2,029,478 in cash plus the MVP shares which were valued at $453,892 at the closing of the transaction on February 5, 2016. The statement of profit and loss reflects a fair value gain of $265,261 in other comprehensive income on these escrowed shares, as these shares had a fair value at the reporting date of $719,153.

**AVITA MEDICAL LIMITED**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**
**(IN AUSTRALIAN DOLLARS)**

## 24. INVESTMENTS (CONTINUED)

As of June 30, 2016, all MVP shares have been sold for proceeds amounting to $627,837 resulting in a loss of $91,316 which was recognised in administrative expenses.

## 25. EVENTS AFTER THE REPORTING DATE

On September 20, 2018, the U.S. Food and Drug Administration (FDA) approved the Company's application to market the RECELL System to treat patients with acute thermal burns in the U.S.

Subsequent to June 30, 2018 the Company completed a series of equity transactions in in which the Company received a total of A$45,014,900 in gross proceeds. During the year ended June 30, 2018 the Company completed an institutional placement of shares to international and Australian institutional and sophisticated investors. The institutional placement included a second tranche totaling A$3.250 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on July 23, 2018, and the net proceeds of A$3.041 million were received by the Company on July 26, 2018. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on July 23, 2018, and the Company issued 65 million shares at a price of A$0.050 per share and received gross proceeds of A$3,250,000 on July 26, 2018. Also subsequent to year end, on December 4, 2018 the Company completed the first tranche of an institutional placement of in which it issued 310,047,015 fully paid ordinary shares at a price of A$0.080 per share raising gross proceeds of A$24,803,761. The institutional placement included a second tranche totaling A$15.196 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on January 14, 2019, and the Company issued 189,952,985 shares at a price of A$0.080 per share and received gross proceeds of A$15,196,239 on January 14, 2019. In addition, on January 11, 2019 the Company complete a Share Purchase Plan under which it issued 22,061,250 shares of stock at a price of A$0.080 per share and received gross proceeds of A$1,764,900.

**AVITA MEDICAL LIMITED**
**CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS**
**AND OTHER COMPREHENSIVE LOSS**
**(IN AUSTRALIAN DOLLARS)**
**(UNAUDITED)**

| | Note | Half-year ended December 31, 2018 | 2017 |
|---|---|---|---|
| **Continuing operations** | | | |
| Sale of goods | 2 | A$ 1,813,195 | A$ 607,761 |
| Cost of sales | | (570,315) | (264,833) |
| **Gross profit** | | **1,242,880** | **342,928** |
| BARDA income | 2 | 5,009,137 | 3,856,716 |
| Other income | 2 | 103,626 | 37,595 |
| **Total other income** | | **5,112,763** | **3,894,311** |
| **Operating costs** | | | |
| Sales and marketing expenses | | (6,931,241) | (2,815,698) |
| Product development expenses | | (7,080,042) | (5,058,518) |
| Corporate and administrative expenses | | (6,865,250) | (2,873,511) |
| Share-based payment expense | | (1,043,694) | (726,856) |
| Finance costs | | (14,807) | (13,253) |
| Total operating costs | | (21,935,034) | (11,487,836) |
| Loss from continuing operations before income tax expense | | **(15,579,391)** | **(7,250,597)** |
| Income tax expense | | — | — |
| **Loss for the period** | | **(15,579,391)** | **(7,250,597)** |
| **Other comprehensive income (loss)** | | | |
| *Items that may be reclassified subsequently to profit or loss:* | | | |
| Foreign currency translation | | 1,374,144 | (55,390) |
| **Other comprehensive loss for the period, net of tax** | | **1,374,144** | **(55,390)** |
| **Total other comprehensive loss for the period** | | A$(14,205,247) | A$ (7,305,987) |
| Loss for the period attributable to owners of the parent | | (15,579,391) | (7,250,597) |
| **Total comprehensive loss attributable to owners of the parent** | | **A$(14,205,247)** | **A$ (7,305,987)** |
| **Earnings Per Share** | | | |
| **Basic and diluted loss per share from continuing operations** | | **A$(1.59) cents** | **A$(0.91) cents** |

The accompanying notes form part of the condensed consolidated financial statements.

**AVITA MEDICAL LIMITED**
**CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION**
**(IN AUSTRALIAN DOLLARS)**
**(UNAUDITED)**

| | Note | December 31, 2018 | June 30, 2018 |
|---|---|---|---|
| **ASSETS** | | | |
| **Current assets** | | | |
| Cash and cash equivalents | | A$ 30,342,360 | A$ 14,825,532 |
| Trade and other receivables | | 2,536,923 | 5,437,357 |
| Prepayments and other assets | | 931,431 | 855,716 |
| Inventories | | 1,143,062 | 1,155,826 |
| **Total current assets** | | **34,953,776** | **22,274,431** |
| **Non-current assets** | | | |
| Plant and equipment | | 1,299,831 | 742,583 |
| Intangible assets | | 93,775 | — |
| **Total non-current assets** | | **1,393,606** | **742,583** |
| **TOTAL ASSETS** | | **A$ 36,347,382** | **A$ 23,017,014** |
| **LIABILITIES** | | | |
| **Current liabilities** | | | |
| Trade and other payables | | 4,483,406 | 3,487,582 |
| Provisions | | 533,660 | 395,535 |
| **Total current liabilities** | | **5,017,066** | **3,883,117** |
| Finance lease | | 83,032 | 134,338 |
| **Total non-current liabilities** | | **83,032** | **134,338** |
| **TOTAL LIABILITIES** | | **5,100,098** | **4,017,455** |
| **NET ASSETS** | | **A$ 31,247,284** | **A$ 18,999,559** |
| **EQUITY** | | | |
| Equity attributable to equity holders of the parent: | | | |
| Contributed equity | 6 | 188,210,306 | 162,801,028 |
| Accumulated losses | | (164,172,270) | (148,592,879) |
| Reserves | | 7,209,248 | 4,791,410 |
| **TOTAL EQUITY** | | **A$ 31,247,284** | **A$ 18,999,559** |

The accompanying notes form part of the condensed consolidated financial statements.

**AVITA MEDICAL LIMITED**
**CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS**
**(IN AUSTRALIAN DOLLARS)**
**(UNAUDITED)**

| | Half-year ended December 31, 2018 | 2017 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Payments to suppliers and employees | A$(20,305,643) | A$(11,943,480) |
| Interest paid | — | (13,253) |
| BARDA receipts and other income received | 6,104,306 | 3,676,182 |
| Receipts from customers | 1,204,802 | 367,933 |
| R&D tax refunds received | 2,440,803 | — |
| Interest received | 97,253 | 37,593 |
| **Net cash flows used in operating activities** | **(10,458,479)** | **(7,875,025)** |
| **Cash flows from investing activities** | | |
| Payments for plant & equipment | (722,472) | (63,672) |
| **Net cash flows used in investing activities** | **(722,472)** | **(63,672)** |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of shares | 28,053,762 | 17,028,964 |
| Capital raising expenses | (2,689,423) | (1,048,359) |
| **Net cash flows provided by financing activities** | **25,364,339** | **15,980,605** |
| **Net increase in cash and cash equivalents** | **14,183,388** | **8,041,908** |
| Cash and cash equivalents at beginning of period | 14,825,532 | 3,790,491 |
| Impact of foreign exchange | 1,333,440 | (55,390) |
| **Cash and cash equivalents at end of period** | **A$ 30,342,360** | **A$ 11,777,009** |

For the purpose of the half-year Statement of Cash Flows, cash and cash equivalents are comprised of the following:

| | As of December 31, 2018 | 2017 |
|---|---|---|
| Cash at bank and in hand | A$29,084,452 | A$ 1,403,330 |
| Short-term deposits | 1,257,908 | 10,373,679 |
| **Total Cash and Cash Equivalents** | **A$30,342,360** | **A$11,777,009** |

The accompanying notes form part of the condensed consolidated financial statements.

**AVITA MEDICAL LIMITED**
**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**
**(IN AUSTRALIAN DOLLARS)**
**(UNAUDITED)**

| | Note | Contributed equity | Accumulated losses | Share-based payment reserve | Foreign currency translation reserve | Total |
|---|---|---|---|---|---|---|
| **As of July 1, 2018** | | **A$162,801,028** | **A$(148,592,879)** | **A$4,505,148** | **A$ 286,262** | **A$ 18,999,559** |
| Loss for the period | | — | (15,579,391) | — | — | (15,579,391) |
| Other comprehensive income | | — | — | — | 1,374,144 | 1,374,144 |
| **Total comprehensive loss for the period** | | **—** | **(15,579,391)** | **—** | **1,374,144** | **(14,205,247)** |
| *Transactions with owners in their capacity as owners:* | | | | | | |
| Share-based payments | | — | — | 1,043,694 | — | 1,043,694 |
| New shares | 6 | 28,098,701 | — | — | — | 28,098,701 |
| Cost of share placement | 6 | (2,689,423) | — | — | — | (2,689,423) |
| **Balance at December 31, 2018** | | **A$188,210,306** | **A$(164,172,270)** | **A$5,548,842** | **A$1,660,406** | **A$ 31,247,284** |

| | Contributed equity | Accumulated losses | Share-based payment reserve | Foreign currency translation reserve | Total |
|---|---|---|---|---|---|
| **As of July 1, 2017** | **A$134,806,022** | **$A(132,218,352)** | **A$2,811,179** | **A$(277,017)** | **A$ 5,121,832** |
| Loss for the period | — | (7,250,597) | — | — | (7,250,597) |
| Other comprehensive income | — | — | — | (55,390) | (55,390) |
| **Total comprehensive loss for the period** | **—** | **(7,250,597)** | **—** | **(55,390)** | **(7,305,987)** |
| *Transactions with owners in their capacity as owners:* | | | | | |
| Share-based payments | — | — | 726,855 | — | 726,855 |
| New shares | 17,028,964 | — | — | — | 17,028,964 |
| Cost of share placement | (1,048,359) | — | — | — | (1,048,359) |
| Transfer of expired options | — | 141,188 | (141,188) | — | — |
| **Balance at December 31, 2017** | **A$150,786,627** | **A$(139,327,761)** | **A$3,396,846** | **A$(332,407)** | **A$14,523,305** |

The accompanying notes form part of the condensed consolidated financial statements.

**AVITA MEDICAL LIMITED**
**NOTES TO THE HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**(IN AUSTRALIAN DOLLARS)**
**(UNAUDITED)**

## 1. BASIS OF PREPARATION AND ACCOUNTING POLICIES

### a) Basis of preparation

This general purpose condensed financial report for the half-year ended December 31, 2018 has been prepared in accordance with International Accounting Standards Board (IASB). The Company is a for-profit entity for financial reporting purposes under Australian Accounting Standards. The Parent Company's functional and presentation currency is AUD ($).

This half-year financial report does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide as full an understanding of the financial performance, financial position and financing and investing activities of the consolidated entity as the full financial report.

It is recommended that the half-year financial report be read in conjunction with the annual report for the year ended June 30, 2018 and considered together with any subsequent public announcements made by Avita Medical Limited in accordance with the continuous disclosure obligations of the *ASX listing rules*.

This financial report has been prepared on the going concern basis. The accounting policies have been applied consistently throughout the Company for the purposes of preparation of these interim financial statements. Certain items on the Consolidated Financial Statements and notes for the prior periods have been reclassified to conform to the current period presentation.

### b) Changes in accounting policy

The interim financial statements have been prepared in accordance with the same accounting policies adopted in the Company's last annual financial statements for the year ended June 30, 2018, except as described below. Note that the changes in accounting policies specified below only apply to the current period. The accounting policies included in the Company's last annual financial statements for the year ended June 30, 2018 are the relevant policies for the purposes of comparatives.

IFRS 15 Revenue from Contracts with Customers and IFRS 9 Financial Instruments (2014) became effective for periods beginning on or after January 1, 2018. Accordingly, the Company applied IFRS 15 and IFRS 9 for the interim period ended December 31, 2018. Changes to the Company's accounting policies arising from these standards are summarized below:

**IFRS 9 Financial Instruments**

IFRS 9 Financial Instruments replaces IAS 39 Financial Instruments: Recognition and Measurement requirements. It makes major changes to the previous guidance on the classification and measurement of financial assets and introduces an 'expected credit loss' model for impairment of financial assets.

The adoption of this standard has no impact on the current or previous reporting period and as such there have been no adjustments to the opening balance of retained earnings.

**IFRS 15 – Revenue from contracts with customers**

Revenue is comprised mainly from funding from BARDA and from the sale of goods. To determine whether to recognize revenue, the Company follows a five-step process:

1. Identifying the contract with a customer,

**AVITA MEDICAL LIMITED**
**NOTES TO THE HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**(IN AUSTRALIAN DOLLARS)**
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**1. BASIS OF PREPARATION AND ACCOUNTING POLICIES (CONTINUED)**

**b) Changes in accounting policy (continued)**

2. Identifying the performance obligations,
3. Determining the transaction price,
4. Allocating the transaction price to the performance obligation,
5. Recognizing revenue when performance obligation is satisfied.

Revenue from the sales of goods is recognized at a point in time, when the Company satisfies performance obligations by transferring the promised goods to its customers. The Company recognizes contract liabilities for consideration received in respect of unsatisfied performance obligations and reports these amounts as other liabilities in the statement of financial position. Similarly, if the Company satisfies a performance obligation before it receives the consideration, the Company recognizes either a contract asset or a receivable in its statement of financial position, depending on whether something other than the passage of time is required before the consideration is due.

The adoption of this standard has no impact on the current or previous reporting period and as such there have been no adjustments to the opening balance of retained earnings.

**Accounting Standards issued but not yet effective and not been adopted early by the Company**

**IFRS 16 Leases**

***IFRS 16:***

- replaces IAS 17 Leases and some lease-related Interpretations,
- requires all leases to be accounted for ‘on-balance sheet’ by lessees, other than short-term and low value asset leases,
- provides new guidance on the application of the definition of lease and on sale and lease back accounting,
- largely retains the existing lessor accounting requirements in IAS 17,
- requires new and different disclosures about leases.

A number of new and revised standards became effective for the first time to annual periods beginning on or after January 1, 2017. Information on the more significant standard is presented below.

Based on the entity’s assessment, it is expected that the first-time adoption of IFRS 16 for the year ending June 30, 2020 will have a material impact on the transactions and balances recognized in the financial statements, in particular:

- lease assets and financial liabilities on the balance sheet will increase by A$1,108,610 and A$1,195,801 respectively (based on the facts at the date of the assessment),
- there will be a reduction in the reported equity as the carrying amount of lease assets will reduce more quickly than the carrying amount of lease liabilities,

**AVITA MEDICAL LIMITED**
**NOTES TO THE HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
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**1. BASIS OF PREPARATION AND ACCOUNTING POLICIES (CONTINUED)**

**b) Changes in accounting policy (continued)**

- Loss for the period in the statement of profit or loss and other comprehensive income will be higher as the implicit interest in lease payments for former off-balance sheet leases will be presented as part of finance costs rather than being included in operating expenses,
- operating cash outflows will be lower and financing cash flows will be higher in the statement of cash flows as principal repayments on all lease liabilities will now be included in financing activities rather than operating activities. Interest can also be included within financing activities.

**c) Going concern**

These financial statements have been prepared on the basis of going concern, which contemplates the continuity of normal business activities and the realization of assets and settlement of liabilities in the ordinary course of business. During the half-year ended December 31, 2018, the Company has generated a loss for the period of A$15,579,391 (2017: A$7,250,597) and the Company has used cash in operations of A$10,458,479 (2017: A$7,875,025).

During the half-year ended December 31, 2018 and subsequent to that date, the Company completed a series of equity transactions totaling gross proceeds of A$45,014,900 which were used to fund operations. Of the total gross proceeds, A$28,073,761 was received in transactions completed during the half-year ended December 31, 2018, and A$16,961,139 was received in transactions completely subsequent to that date.

On June 6, 2018 the Company completed the first tranche of an institutional placement which included a second tranche totaling A$3.250 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on July 23, 2018, and the Company issued 65 million shares at a price of $0.050 per share and received gross proceeds of A$3,250,000 on July 26, 2018. On December 4, 2018 the Company completed the first tranche of an institutional placement of in which it issued 310,047,015 fully paid ordinary shares at a price of A$0.080 per share raising gross proceeds of A$24,803,761. The institutional placement included a second tranche totaling A$15.196 million of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on January 14, 2019, and subsequent to December 31, 2018 the Company issued 189,952,985 shares at a price of A$0.080 per share and received gross proceeds of A$15,196,239 on January 14, 2019. Also subsequent to December 31, 2018, on January 11, 2010 the Company completed a Share Purchase Plan under which it issued 22,061,250 shares of stock at a price of A$0.080 per share and received gross proceeds of A$1,764,900.

The Company benefits from cash inflows from the series of BARDA contracts, the first of which was awarded to the Company in September 2015. These payments from BARDA offset costs from various activities undertaken to support the FDA regulatory approval process for RECELL in the U.S., preparation for the planned commercial launch of RECELL in the U.S., and RECELL clinical programs in the U.S. With the U.S. FDA approval of RECELL for the treatment of burns in September 2018, and the U.S. market launch of the product in January 2019, sales of goods are expected to be an increasing source of revenue in the future. Another anticipated source of revenue for the Company is the BARDA contract line item covering the initial purchase, delivery and storage of the RECELL System in the amount of US$7,594,620 (~A$10m).

The Company expects to be utilizing cash reserves until U.S. and international sales of its products reach the level to fund ongoing operations. The Company has historically funded its research and development activities,

**AVITA MEDICAL LIMITED**
**NOTES TO THE HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
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## 1. BASIS OF PREPARATION AND ACCOUNTING POLICIES (CONTINUED)

### c) Going concern (continued)

and more recently its substantial investment in sales and marketing activities, through raising capital by issuing securities in the Company, and it is expected that similar funding will be obtained to provide working capital if and when required. If the Company is unable to raise capital in the future, the Company may need to curtail expenditures by scaling back certain research and development or other programs.

As a result of the above, the directors are satisfied that there is sufficient working capital to support the committed research and development programs and other activities over the next 12 months and the Company has the ability to realize its assets and pay its liabilities and commitments in the normal course of business. Accordingly, the directors have prepared the financial report on a going concern basis.

## 2. REVENUE

| | Half-year ended December 31, 2018 | 2017 |
|---|---|---|
| **Revenue** | | |
| Sale of goods | A$1,813,195 | A$ 607,761 |
| | **A$1,813,195** | **A$ 607,761** |
| **Other Income** | | |
| BARDA income | A$5,009,137 | A$3,856,716 |
| Other income | 103,626 | 37,595 |
| | **A$5,112,763** | **A$3,894,311** |

## 3. DIVIDENDS PAID OR PROVIDED FOR ON ORDINARY SHARES

No amounts have been paid, declared or recommended by Avita Medical Limited by way of dividend since the commencement of the half-year, and up to the date of this report.

## 4. OPERATING SEGMENTS

The Company's chief operating decision maker has been identified as the Chief Executive Officer.

The Chief Executive Officer reviews the financial and operating performance of the business primarily from a geographic perspective. On this basis, management have identified three reportable segments being the Asia Pacific, Europe and Americas including Canada. The Chief Executive Officer monitors the performance of all these segments separately. The Company does not operate in any other geographic segment.

The Chief Executive Officer assesses the performance of the operating segments based on a measure of gross margin and net profit before tax.

Unallocated

The following items of income and expense and associated assets are not allocated to operating segments as they are not considered part of the core operations of any segment:

- Corporate revenue
- Corporate charges

**AVITA MEDICAL LIMITED**
**NOTES TO THE HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
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## 4. OPERATING SEGMENTS (CONTINUED)

The segment information provided to the Chief Executive Officer for the reportable segments for the half-year ended December 31, 2018 is as follows:

| | *Continuing Operations* | | | |
|---|---|---|---|---|
| | *Asia Pacific* | *Europe* | *Americas* | *Total* |
| **Half-year ended December 31, 2018** | | | | |
| **Revenue** | | | | |
| Sales to external customers | A$ 457,571 | A$ 253,633 | A$ 1,101,991 | A$ 1,813,195 |
| **Total revenue per statement of profit of loss and other comprehensive income** | **457,571** | **253,633** | **1,101,991** | **1,813,195** |
| BARDA income and other income | 9,552 | 269 | 5,102,941 | 5,112,762 |
| Segment net loss before tax | A$(626,901) | A$(593,225) | A$(11,948,943) | A$(13,169,069) |
| **Reconciliation of segment net result before tax to loss before income tax** | | | | |
| Corporate charges | | | | (2,410,322) |
| **Loss before income tax** | | | | **A$(15,579,391)** |
| **Segment assets** | | | | |
| Segment operating assets | A$ 568,571 | A$ 401,546 | A$ 31,802,314 | 32,772,431 |
| Unallocated assets | | | | 3,574,951 |
| **Total assets per the statement of financial position** | | | | **A$ 36,347,382** |
| **Segment liabilities** | | | | |
| Segment operating liabilities | A$ 169,516 | A$ 151,248 | A$ 4,591,266 | A$ 4,912,030 |
| Unallocated liabilities | | | | 188,068 |
| **Total liabilities per the statement of financial position** | | | | **A$ 5,100,098** |

**AVITA MEDICAL LIMITED**
**NOTES TO THE HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
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## 4. OPERATING SEGMENTS (CONTINUED)

| | *Continuing Operations* | | | |
|---|---|---|---|---|
| | *Asia Pacific* | *Europe* | *Americas* | *Total* |
| **Half-year ended December 31, 2017** | | | | |
| **Revenue** | | | | |
| Sales to external customers | A$ 344,367 | A$ 263,394 | A$ — | A$ 607,761 |
| **Total revenue per statement of comprehensive income** | **344,367** | **263,394** | — | **607,761** |
| BARDA income and other income | 34,151 | 3,224 | 3,856,936 | 3,894,311 |
| Segment net loss before tax | A$(688,840) | A$(1,325,927) | A$(3,098,175) | A$ (5,112,942) |
| **Reconciliation of segment net result before tax to loss before income tax** | | | | |
| Corporate charges | | | | (2,137,655) |
| **Loss before income tax** | | | | **A$ (7,250,597)** |
| **Segment assets** | | | | |
| Segment operating assets | A$ 327,350 | A$ 692,388 | A$ 4,077,021 | A$ 5,096,759 |
| Unallocated assets | | | | 11,419,478 |
| **Total assets per the statement of financial position** | | | | **A$16,516,237** |
| **Segment liabilities** | | | | |
| Segment operating liabilities | A$ 119,882 | A$ 192,630 | A$ 1,526,727 | A$ 1,839,239 |
| Unallocated liabilities | | | | 153,693 |
| **Total liabilities per the statement of financial position** | | | | **A$ 1,992,932** |

## 4. COMMITMENTS AND CONTINGENCIES

There are no significant changes to the commitments and contingencies disclosed in the most recent annual financial report.

## 5. CONTRIBUTED EQUITY

| | **As of Dec 31, 2018** | **As of Jun 30, 2018** |
|---|---|---|
| *Ordinary shares* | | |
| Issued and fully paid | A$ 188,210,306 | A$ 162,801,028 |

| | **Number** | **A$** |
|---|---|---|
| *Movement in ordinary shares on issue:* | | |
| At July 1, 2018 | 1,277,378,325 | A$ 162,801,028 |
| Issue of shares | 375,047,015 | 28,098,701 |
| Capital raising costs | — | (2,689,423) |
| **At December 31, 2018** | **1,652,425,340** | **A$ 188,210,306** |

**AVITA MEDICAL LIMITED**
**NOTES TO THE HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
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## 5. CONTRIBUTED EQUITY (CONTINUED)

### (a) Recognized share-based payment expenses

The expense recognized for employee services received during the half-year is shown in the table below:

| | Half-year ended December 31, 2018 | 2017 |
|---|---|---|
| Expenses arising from equity-settled share-based payment transactions | A$1,043,694 | A$726,855 |
| **Total expense arising from share-based payment transactions** | **A$1,043,694** | **A$726,855** |

### (b) Option pricing model: ESOP and Investor

**Equity-settled transactions**

The fair value of the equity-settled share options granted under the ESOP is estimated at the date of grant using a Binomial Model taking into account the terms and conditions upon which the options were granted.

The options issued in the period have vesting criteria based on the following performance conditions:

- Tenure with the Company
- Revenue target
- FDA PMA approval of RECELL for burns
- Initial BARDA procurement under CLIN2 of the BARDA Contract
- US Quotation

i) On November 1, 2018, 2,000,000 options were granted to employee at an exercise price of A$0.056 expiring on November 1, 2028.

The following table lists the inputs to the models used for the options granted to employee each year:

| | |
|---|---|
| Grant date | 11/1/2018 |
| Share price at date of grant | A$ 0.093 |
| Dividend yield (%) | 0% |
| Expected volatility (%) | 90% |
| Risk-free interest rate (%) | 2.65% |
| Expected life of option (days) | 3,650 |
| Option exercise price (A$) | A$ 0.056 |

This represents tranches 2, 12-15, the fair value at date of grant for each tranche is as follows:

| | |
|---|---|
| Tranche 2 | A$0.0834 |
| Tranche 12 | A$0.0607 |
| Tranche 13 | A$0.0673 |
| Tranche 14 | A$0.0715 |
| Tranche 15 | A$0.0748 |

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**5. CONTRIBUTED EQUITY (CONTINUED)**

**(b) Option pricing model: ESOP and Investor (continued)**

ii) On November 1, 2018, 12,700,000 options were granted to employees at an exercise price of A$0.057 expiring on November 1, 2028.

The following table lists the inputs to the models used for the options granted to employees:

| | |
|---|---|
| Grant date | 11/1/2018 |
| Share price at date of grant | A$ 0.093 |
| Dividend yield (%) | 0% |
| Expected volatility (%) | 90% |
| Risk-free interest rate (%) | 2.65% |
| Expected life of option (days) | 3,650 |
| Option exercise price (A$) | A$ 0.057 |

This represents tranches 1, 4-11, 16-19, the fair value at date of grant for each tranche is as follows:

| | | | |
|---|---|---|---|
| Tranche 1 | A$0.0834 | Tranche 10 | A$0.0709 |
| Tranche 4 | A$0.0593 | Tranche 11 | A$0.0742 |
| Tranche 5 | A$0.0662 | Tranche 16 | A$0.0607 |
| Tranche 6 | A$0.0709 | Tranche 17 | A$0.0671 |
| Tranche 7 | A$0.0742 | Tranche 18 | A$0.0714 |
| Tranche 8 | A$0.0593 | Tranche 19 | A$0.0747 |
| Tranche 9 | A$0.0662 | | |

iii) On November 1, 2018, 3,000,000 options were granted to employees at an exercise price of A$0.059 expiring on November 1, 2028.

The following table lists the inputs to the models used for the options granted to employees:

| | |
|---|---|
| Grant date | 11/1/2018 |
| Share price at date of grant | A$ 0.093 |
| Dividend yield (%) | 0% |
| Expected volatility (%) | 90% |
| Risk-free interest rate (%) | 2.65% |
| Expected life of option (days) | 3,650 |
| Option exercise price (A$) | A$ 0.059 |

This represents tranches 3, 20-23, the fair value at date of grant for each tranche is as follows:

| | |
|---|---|
| Tranche 3 | A$0.0831 |
| Tranche 20 | A$0.0604 |
| Tranche 21 | A$0.0669 |
| Tranche 22 | A$0.0712 |
| Tranche 23 | A$0.0744 |

iv) On November 1, 2018, 17,200,000 options were granted to employees at an exercise price of A$0.089 expiring on November 1, 2028.

**AVITA MEDICAL LIMITED**
**NOTES TO THE HALF-YEAR CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
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**5. CONTRIBUTED EQUITY (CONTINUED)**

**(b) Option pricing model: ESOP and Investor (continued)**

The following table lists the inputs to the models used for the options granted to employees.

| | Tranche 1 | Tranche 2 | Tranche 3 | Tranche 4 |
|---|---|---|---|---|
| Grant date | 11/1/2018 | 11/1/2018 | 11/1/2018 | 11/1/2018 |
| Share price at date of grant | A$ 0.093 | A$ 0.093 | A$ 0.093 | A$ 0.093 |
| Dividend yield (%) | 0% | 0% | 0% | 0% |
| Expected volatility (%) | 90% | 90% | 90% | 90% |
| Risk-free interest rate (%) | 2.65% | 2.65% | 2.65% | 2.65% |
| Expected life of option (days) | 3,650 | 3,650 | 3,650 | 3,650 |
| Fair value at date of grant | A$ 0.0587 | A$ 0.0641 | A$ 0683 | A$ 0.0716 |
| Option exercise price (A$) | A$ 0.089 | A$ 0.089 | A$ 0.089 | A$ 0.089 |

v) On November 30, 2018, 24,851,250 options were granted to employees at an exercise price of A$0.082 expiring on November 30, 2028.

The following table lists the inputs to the models used for the options granted to employees.

| | Tranche 1 | Tranche 2 | Tranche 3 | Tranche 4 |
|---|---|---|---|---|
| Grant date | 11/1/2018 | 11/1/2018 | 11/1/2018 | 11/1/2018 |
| Share price at date of grant | A$ 0.082 | A$ 0.082 | A$ 0.082 | A$ 0.082 |
| Dividend yield (%) | 0% | 0% | 0% | 0% |
| Expected volatility (%) | 90% | 90% | 90% | 90% |
| Risk-free interest rate (%) | 2.65% | 2.65% | 2.65% | 2.65% |
| Expected life of option (days) | 3,650 | 3,650 | 3,650 | 3,650 |
| Fair value at date of grant | A$ 0.0514 | A$ 0.0561 | A$ 0.0599 | A$ 0.0628 |
| Option exercise price (A$) | A$ 0.082 | A$ 0.082 | A$ 0.082 | A$ 0.082 |

vi) On November 30, 2018, 15,000,000 options were granted to Dr. Michael Perry at an exercise price of A$0.082 expiring on November 20, 2028 based on the following milestones:

1. Tenure – a total of 7,499,999 options issued for immediate vesting and over thetwo-year period commencing July 1, 2017;

2. Company Share Price – a total of 5,000,001 options issued but to vest in three equal tranches subject to the Volume Weighted Average Price (VWAP) of Company share price (as at close of trade on the ASX on relevant date) achieving multiples of 2x, 3x and 4x the Company's share price at the time of shareholder approval; and

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## 5. CONTRIBUTED EQUITY (CONTINUED)

### (b) Option pricing model: ESOP and Investor (continued)

3. Milestone performance – a total of 2,500,000 options issued, but to vest upon the achievement of initial BARDA procurement under CLIN2 of the BARDA Contract.

| | Tranche 1 | Tranche 2 | Tranche 3 | Tranche 4 |
|---|---|---|---|---|
| Grant date | 11/30/2018 | 11/30/2018 | 11/30/2018 | 11/30/2018 |
| Share price at date of grant | A$ 0.082 | A$ 0.082 | A$ 0.082 | A$ 0.082 |
| Dividend yield (%) | 0% | 0% | 0% | 0% |
| Expected volatility (%) | 90% | 90% | 90% | 90% |
| Risk-free interest rate (%) | 2.59% | 2.59% | 2.59% | 2.59% |
| Expected life of option (days) | 3,650 | 3,650 | 3,650 | 3,650 |
| Fair value at date of grant | A$ 0.049 | A$ 0.054 | A$ 0.048 | A$ 0.052 |
| Option exercise price (A$) | A$ 0.082 | A$ 0.082 | A$ 0.082 | A$ 0.082 |

| | Tranche 5 | Tranche 6 | Tranche 7 |
|---|---|---|---|
| Grant date | 11/30/2018 | 11/30/2018 | 11/30/2018 |
| Share price at date of grant | A$ 0.082 | A$ 0.082 | A$ 0.082 |
| Dividend yield (%) | 0% | 0% | 0% |
| Expected volatility (%) | 90% | 90% | 90% |
| Risk-free interest rate (%) | 2.59% | 2.59% | 2.59% |
| Expected life of option (days) | 3,650 | 3,650 | 3,650 |
| Fair value at date of grant | A$ 0.058 | A$ 0.071 | A$ 0.048 |
| Option exercise price (A$) | A$ 0.082 | A$ 0.082 | A$ 0.082 |

## 7. RELATED PARTY DISCLOSURES

The total amount of transactions entered into with Key Management Personnel for the half-year ended December 31, 2018 were A$51,802 Consultancy fees (2017: A$124,156) paid under normal terms and conditions to Bioscience Managers Pty Ltd of which Mr. Curnock Cook is an officer and Dr. Michael Perry is a director.

Details of all related party transactions have been disclosed in the annual report for the year ended 30 June 2018. There have been no new significant related party transactions during the interim period.

## 8. SUBSEQUENT EVENTS

During the six months ended December 31, 2018, the Company completed an institutional placement of shares to institutional placements of shares to U.S., Australian and international institutional and sophisticated investors. The institutional placement included a second tranche contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on January 14, 2019, and subsequent to December 31, 2018 the Company issued 189,952,985 shares at a price of A$0.080 per share and received gross proceeds of A$15,196,239 on January 14, 2019. Also subsequent to December 31, 2018, on January 11, 2019 the Company completed a Share Purchase Plan under which it issued 22,061,250 shares of stock at a price of A$0.080 per share and received gross proceeds of A$1,764,900.

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Double asterisks denote omissions.

| **AWARD/CONTRACT** | 1. THIS CONTRACT IS A RATED ORDER. UNDER DPAS (15 CFR 700) | RATING PAGE OF PAGES 1 I 4 6 |
|---|---|---|

| 2. CONTRACT (Proc. Inst. Ident.) NO. | 3. EFFECTIVE DATE | 4. REQUISITION/PURCHASE REQUEST/PROJECT NO. |
|---|---|---|
| HHSO100201500028C | See Block 20C | OS164565 |

| 5. ISSUED BY | CODE ASPR—BARDA | 6. ADMINISTERED BY (If other than Item 5) | CODE ASPR—BARDA |
|---|---|---|---|
| ASPR-BARDA<br>200 Independence Ave., S.W.<br>Room 640-G<br>Washington DC 202016 | | See Block 5 | |

| 7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State end ZIP Code) | 8. DELIVERY<br>☐ FOB ORIGIN ☐ In OTHER (See below)9 |
|---|---|
| AVITA MEDICAL AMERICAS, LLC 1476585<br>9221 CORBIN AVE STE 220<br>NORTHRIDGE CA 91324 | 9. DISCOUNT FOR PROMPT PAYMENT |
| CODE 1476585 FACILITY CODE | 10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ▶ ITEM |

| 11. SHIP TO/MARK FOR | CODE HHS/OS/ASPR | 12. PAYMENT WILL BE MADE BY | CODE PSC |
|---|---|---|---|
| HHS/OS/ASPR<br>200 C SW<br>WASHINGTON DC 20201 | | PSC<br>Program Support Center<br>5600 Fishers Lane<br>Room 17--21<br>Rockville MD 20852 | |

| 13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: | 14. ACCOUNTING AND APPROPRIATION DATA |
|---|---|
| ☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 253(c) ( ) | 2015.1990002.26201 |

| 15A. ITEM NO | 15B. SUPPLIES/SERVICES | 15C. QUANTITY | 15D. UNIT | 15E. UNIT PRICE | 15F. AMOUNT |
|---|---|---|---|---|---|
| | Continued | | | | |
| | | | | 15G. TOTAL AMOUNT OF CONTRACT ▶ | $16,901,424.00 |

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| (x) | SEC | Description | Page(s) | (x) | SEC | Description | Page(s) |
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| | | PART I - THE SCHEDULE | | | | PART II - CONTRACT CLAUSES | |
| X | A | SOLICITATION/CONTRACT FORM . | 01 | X | I | CONTRACT CLAUSES | 39 |
| X | B | SUPPLIES OR SERVICES AND PRICES/COSTS | 03 | | | PART III -LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH. | |
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| X | O | PACKAGING AND MARKING | 11 | | | PART IV - REPRESENTATIONS AND INSTRUCTIONS | |
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| X | G | CONTRACT ADMINISTRATION DATA | 23 | | L | INSTRS., CONDS., AND NOTICES TO OFFERORS | |
| X | H | SPECIAL CONTRACT REQUIREMENTS | 27 | | M | EVALUATION FACTORS FOR AWARD | |

**CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18. (SEALED-BID PROCUREMENT) AS APPLICABLE**

| 17. ☐ CONTRACTOR'S AGREEMENT (Contractor is required to sign this document and return _____ copies to issuing office. Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents. (a) this award/contract, (b) the solicitation, if any, and (c) such problems, representations, certifications, and specifications as are attached or incorporated by reference herein. *(Attachments are listed herein)* | 18. ☐ SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents. (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 10 should be checked only when awarding a sealed-bid contract.) |
|---|---|

| 19A NAME AND TITLE OF SIGNE (Type or print) | 20A. NAME OF CONTRACTING OFFICER |
|---|---|

| 19B. NAME OF CONTRACTOR | 19C. DATE SIGNED | 20B. UNITED STATES OF AMERICA | 20C. DATE SIGNED |
|---|---|---|---|
| BY Timothy Rooney CFO/COO<br>/s/ Timothy Rooney<br>*(Signature of person authorized to sign)* | | BY Brooke Bernold<br>/s/ Brooke Bernold<br>*(Signature of the Contracting Officer)* | 29 Sept, 2015 |

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| AWARD/CONTRACT | 1. THIS CONTRACT IS A RATED ORDER. UNDER DPAS (15 CFR 700) | RATING | PAGE OF PAGES |
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| | | 1 | I 4 6 |

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| | 9. DISCOUNT FOR PROMPT PAYMENT | |
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|---|---|---|---|---|---|
| HHS/OS/ASPR<br>200 C SW<br>WASHINGTON DC 20201 | | | PSC<br>Program Support Center<br>5600 Fishers Lane<br>Room 17--21<br>Rockville MD 20852 | | |

| 13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: | 14. ACCOUNTING AND APPROPRIATION DATA |
|---|---|
| ☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 253(c) ( ) | 2015.1990002.26201 |

| 15A. ITEM NO | 15B. SUPPLIES/SERVICES | 15C. QUANTITY | 15D. UNIT | 15E. UNIT PRICE | 15F. AMOUNT |
|---|---|---|---|---|---|
| | Continued | | | | |
| | | | 15G. TOTAL AMOUNT OF CONTRACT ▶ | | $16,901,424.00 |

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17. ☐ CONTRACTOR'S AGREEMENT (Contractor is required to sign this document and return _____ copies to issuing office. Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents. (a) this award/contract, (b) the solicitation, if any, and (c) such problems, representations, certifications, and specifications as are attached or incorporated by reference herein. *(Attachments are listed herein)*

18. ☐ SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents. (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 10 should be checked only when awarding a sealed-bid contract.)

| 19A NAME AND TITLE OF SIGNE (Type or print) | 20A. NAME OF CONTRACTING OFFICER |
|---|---|
| | |

| 19B. NAME OF CONTRACTOR | 19C. DATE SIGNED | 20B. UNITED STATES OF AMERICA | 20C. DATE SIGNED |
|---|---|---|---|
| BY<br>(Signature of person authorized to sign) | | BY<br>(Signature of the Contracting Officer) | |

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NAME OF OFFEROR OR CONTRACTOR

AVITA MEDICAL AMERICAS, LLC 1476585

| ITEM NO. (A) | SUPPLIES/SERVICES (B) | QUANTITY (C) | UNIT (D) | UNIT PRICE (E) | AMOUNT (F) |
|---|---|---|---|---|---|
| | Tax ID Number: 20-2578762<br>DUNS Number: 026723570<br>Autograft-Sparing Products for Definitive Care of Burn Injuries<br>Appr. Yr.: 2015 CAN: 1990002 Object Class: 26201<br>FOB: Destination | | | | |
| 1 | ASPR-15-08829 — CLIN 0001 Advanced Development Studies for Licensure Approval of ReCell<br>POP: [**]/2015 – [**]/2020<br>Obligated Amount: [**] | | | | [**] |
| 2 | ASPR-15-08829 — CLIN 0002 Initial Purchase, Storage, and Delivery of ReCell Devices<br>POP: [**]/2015 – [**]/2020<br>Obligated Amount: [**] | | | | [**] |

**PART I – THE SCHEDULE**

**SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

**ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

Avita Medical is developing ReCell, a unique technology that enables clinicians to use a small sample of your skin to restore healthy, normal skin when treating partial thickness or full thickness burns. The product has the potential to greatly improve the patient's quality of life while reducing hospital stays and the need for reconstructive surgery. This product could find utility in day-to-day care, while simultaneously improving our capability to respond to mass casualty incidents.

Under the base period-of-performance, Avita Medical will further enhance their product to improve its commercial viability through the FDA approval process and potentially complete an initial purchase, storage, and delivery of product. The contract options may be exercised to perform follow-on studies as directed by the FDA, perform additional studies which further extend the ability to protect children and the elderly population, and purchase additional treatment courses.

The Research and Development (R&D) effort will progress in specific stages that cover the base performance segment and several options as specified in this contract. The period of performance for the base period is [**] months.

**ARTICLE B.2. BASE PERIOD**

| CLIN | Period of Performance | Supplies/ Services | Total Est. Cost | Fixed Fee (7%) | Total Cost Plus Fixed Fee |
|---|---|---|---|---|---|
| | | **COST REIMBURSEMENT** | | | |
| 0001 (Base) | [**]/2015 – [**]/2020 | Licensure, approval, and clearance of product through the FDA | [**] | [**] | [**] |
| | | **FIRM FIXED PRICE** | | | |
| **CLIN** | **Period of Performance** | **Supplies/ Services** | **Units (# of Product)** | **Unit Price ($)** | **Total ($)** |
| 0002 | [**]/2015 – [**]/2020 | Initial Purchase, storage, and delivery of product | [**] | [**] | [**] |
| **Total CLINS 1&2** | **[**]/2015 – [**]/2020** | **See Above Descriptions** | | | **[**]** |

**ARTICLE B.3. OPTION PRICES**

| CLIN | Period of Performance | Supplies/Services | Units (# of Product) | Unit Price ($) | Total ($) |
|---|---|---|---|---|---|
| | | **FIRM FIXED PRICE** | | | |
| 0003 (Option Quantity) | 36 Months | Phase IV post marketing commitments /Requirements (This is an option that may or may not be exercised during the base period as determined by the need and as established by the FDA) | N/A | N/A | [**] |
| | | **COST REIMBURSEMENT** | | | |
| 0004 (Option Quantity) | 60 Months | Pediatric Study (This is an option that may or may not be exercised during the base period for expansion of the label indication with guidance from the FDA) | [**] | [**] | [**] |
| | | **FIRM FIXED PRICE** | | | |
| 0005A (Option Quantity) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0005A (Option Quantity) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0005A (Option Quantity) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0005A (Option Quantity) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| **Total CLINs 3-5** | **60 Months** | **See Above Descriptions** | | | **[**]** |

**ARTICLE B.4. LIMITATIONS APPLICABLE TO DIRECT COSTS**

**a. Items Unallowable Unless Otherwise Provided**

Notwithstanding the clause FAR 52.216-7, Allowable Cost and Payment, incorporated in this contract, the costs of the following items or activities shall be unallowable as direct costs unless authorized in writing in advance by the Contracting Officer:

1. Acquisition, by purchase or lease, of any interest in real property;
2. Special rearrangement or alteration of facilities;

3. Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

4. Travel to attend general scientific meetings;

5. Unapproved foreign travel;

6. Consultant costs;

7. Subcontracts;

8. Patient care costs;

9. Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined as items of personal property, supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value.

10. Printing Costs (as defined in the Government Printing and Binding Regulations).

11. Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meeting, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

12. Meeting room or conference space used for face to face meetings with USG staff in the performance of this contract. Justification for why the meeting cannot be held at a government facility must be provided. COA requests must be made at least (2) two weeks prior to meeting date.

**b. Travel Costs**

1. Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred by the Prime Contractor in direct performance of this contract shall not exceed **[**]** without prior advance written approval by the Contracting Officer. Costs must be consistent with FAR 52.247-63 – Preference for U.S.-Flag Air Carriers.

2. The Contactor shall invoice and be reimbursed for all travel costs in accordance with FAR 31.703 and FAR31.205-46, Contracts with Commercial Organizations, Travel Costs.

3. Requests for foreign travel must be submitted at least six weeks in advance and shall contain the following:

   (i) Meeting(s) and place(s) to be visited, with costs and dates;

   (ii) Names(s) and title(s) of Contractor personnel to travel and their functions in the contract project;

   (iii) Contract purpose to be served by the travel;

   (iv) How travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of AMCG contract funds;

   (v) How such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and

   (vi) What additional functions may be performed by the travelers to accomplish other purpose of the contact and thus further benefit the project.

**ARTICLE B.5. ADVANCE UNDERSTANDINGS**

**a. Subcontracts and Consultants**

**Award of any FFP subcontract or FFP consulting agreement in excess of $150,000or any cost reimbursement subcontract or consulting agreement** shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter. COA letters will only be issued upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer within ten (10) days.

**b. Site Visits, Inspections and General Audits**

At the discretion of the USG and independent of activities conducted by the Contractor, with 48 hours' notice to the Contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis, including collection of product samples and intermediates held by the Contractor, or subcontractor. In case of subcontractor visits and inspections that are independent of activities conducted by the Contractor, the USG shall demonstrate cause for such visit and/or inspection. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs. The Contractor shall coordinate these visits and shall have the opportunity to accompany the USG on any such visits. Under time-sensitive or critical situations, the USG reserves the right to suspend the 48 hour notice to the Contractor. If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance.

- If issues are identified during the audit, Contractor shall submit an issues report to the CO and COR within 10 business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the issues report and provide a response to the Contractor within 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR within a time frame negotiated with the COR in writing after review of the issues report.

**c. QA Audits**

BARDA reserves the right to participate in QA audits performed by the Contractor. Upon completion of the QA audit the Contractor shall provide a report capturing the findings, results, and next steps in proceeding with any potential subcontractors. If action is requested for a subcontractor, detailed corrective and preventative plans for addressing areas of non-conformance to ICH and FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA for review and acceptance. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within 5 business days of report completion. The Contractor shall complete the report within 60 days of the audit/site visit, or as negotiated with the COR in writing dependent upon the audit findings.

**d. Man-in-Plant**

At the discretion of the Government and seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's facility, who shall be subject to the Contractor's policies and procedures regarding security and facility access at all times while in the Contractor's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor plant.

**e. Confidential Treatment of Sensitive Information**

The Contractor shall, to the extent permitted by law, guarantee strict confidentiality of the information/data that is provided by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

Notwithstanding the foregoing, such information/data shall not be deemed of a sensitive nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the Government that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/data belonging to the Government.

The Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction (b) otherwise required by law, (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information/data

**f. Emergency Use Authorization (EUA)**

The Contractor shall be responsible for generating the data to support the USG's filing of aPre-Emergency Use Authorization (Pre-EUA) package for use of the product prior to FDA licensure or approval during a declared emergency, declared potential emergency, or identification of material threat under an Emergency Use Authorization (EUA).

The Contractor commits to supporting the potential use of the product under a pre-EUA package as submitted by BARDA or the CDC/SNS. The Contractor shall supply BARDA or the CDC/SNS with the data needed to support such a submission, including expanded access INDs, right to hold product, right of reference to the Contractor's Investigational New Drug (IND), or other application that contains the supporting data. The Contractor shall address any FDA comments on all pre-EUA packages as applicable. The Contractor shall maintain and update, as required by the FDA, all required regulatory documentation (investigator brochure, regulatory binder, etc.), that will be used to support use under EUA and approval/licensure.

Any product which has not received FDA approval or licensure, but has completed submission of thePre-EUA package and has met the three (3) criteria listed below may be considered for procurement at the discretion of the USG. The Contractor would be required to demonstrate the three (3) essential criteria listed below for consideration of procurement of any unapproved products by seeking a COA. The COA shall include a product delivery schedule for consideration and documentation of the following:

- Substantial evidence, including a validated process, of the Contractor's ability to manufacture a product that would be identical to the commercial scale as required for product approval or licensure. A clear understanding of the outstanding risks, if any, for approval or licensure must be demonstrated through a risk register.
- Completion of pivotal clinical studies with substantial evidence of safety and efficacy for the indicated use. A list of outstanding activities and targets for completion, adverse events/safety profile which do not pose unusual risks or challenges for FDA approval or licensure shall be provided.
- Substantial evidence of product familiarity/acceptance for use in burn centers. The Contractor shall provide a list of burn centers familiar with the product, feedback received, and corrective actions required to address any concerns to ensure effective use of the product by burn care providers unfamiliar with the product. Evidence of the company's ability to educate such providers on the use of the product (as allowed within the constraints of law) will be useful.

A tentative delivery schedule of product delivery to the inventory (acceptable as in the Quality Agreement) shall be required as part of the COA. The delivery schedule shall be updated periodically as necessary.

For information concerning EUA, please consult http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127 and http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm

**g. Sharing of contract deliverables within United States Government (USG)**

In an effort to build a robust medical countermeasure pipeline through increased collaboration, BARDA may share technical deliverables with USG entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio's Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense and the National Institutes of Health, BARDA may share technical deliverables and data created in the performance of this contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize BARDA to share financial information outside HHS. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the Government's rights to deliverables submitted during performance as well as the Government's rights to data contained within those deliverables.

**h. Overtime Compensation**

No overtime (premium) compensation is authorized under the subject contract. Billing of actual hours should be limited to total productive hours in a month.

**i. Option CLINS**

The USG reserves the right to re-negotiate the option CLINS based availability of funds and feedback received from the FDA.

**j. Contract Number Designation**

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of the contract as follows:

HHSO100201500028C

**k. Quality Agreement**

The Quality Agreement shall define, establish, and document the responsibilities of both the Contractor and the USG (i.e. –CDC/SNS-Quality Control and BARDA) for event-driven and product shipping, receiving, acceptance into the inventory and/or custody by the USG. These documents shall be drafted, approved, and signed by all parties prior to the commencement of product procurement and acceptance, transport and custody of the product under the VMI/DMI or the CDC/SNS. The Contractor shall provide documentation and resolution for all concerns raised by USG and commits to cooperation in execution of this agreement.

## SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

### ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated September 29, 2015 set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

### ARTICLE C.2. REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

All reports required herein shall be submitted in electronic format. All paper/hardcopydocuments/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

### ARTICLE C.3. TWICE MONTHLY CONFERENCE CALLS

A conference call between the Contracting Officer's Representative (COR) and the Contractor's Project Leaders/delegates and designees shall occur twice-monthly or as directed by the Contracting Officer and Contracting Officer's Representative. During this call the Contractor's Project Leaders/delegates and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leaders/delegates may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative.

### ARTICLE C.4. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings with AMCG/BARDA in Washington, D.C. and at work sites of the Contractor. Such meetings may include, but are not limited to, meetings of the Contractor to discuss study designs, site visits to the Contractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the data rights provisions in this contract, the Contractor will provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Contracting Officer and Contracting Officer's Representative in order to facilitate review of contract activities.

**SECTION D - PACKAGING, MARKING AND SHIPPING**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the date, contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

**SECTION E - INSPECTION AND ACCEPTANCE**

The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this contract.

For the purpose of this SECTION E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance. The Contractor is advised to review FAR 52.243-1 Changes – Fixed Price Contracts Alternate V and FAR 52.243-2 Changes-Cost reimbursement contracts Alternative V, which is incorporated by reference into this contract in ARTICLE I.1.

Inspection and acceptance will be performed at:

Office of Acquisition Management, Contracts, and Grants (AMCG)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 C St. SW
Washington, D.C. 20024

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

The contract incorporates the following clause by reference with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

**FAR 52.246-4, Inspection of Services - Fixed Price (August 1996)**

**FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)**

**FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984)**

**FAR 52.246-16, Responsibility for Supplies (April 1984)**

## SECTION F - DELIVERIES OR PERFORMANCE

### ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance for this contract shall be from September 29, 2015 through September 28, 2020. The period of performance for the base period of this contract shall be consistent with the dates set forth in SECTION B. If the Government exercises option(s), the period of performance will be extended as described under in SECTION B of this contract.

### ARTICLE F.2. REPORTING REQUIREMENTS

In all cases the reports are intended to provide sufficient detail to understand the Contractor's approach and progress to addressing the technical requirements. The reports supplement, and do NOT replace, routine (i.e. daily) communication between the COR and project manager and/or their designee(s) regarding project plans and progress.

**A. Monthly Progress Report**

This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort.

SECTION II Part A: SUMMARY - A description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall include a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes). Please include all Quality Management System, Quality Control, and Quality Assurance updates as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall document the results of work completed and costs incurred during the period covered in relation to the proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES – This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as a rolling three (3) month forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT — This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

Invoices: Summary of any invoices submitted during the reporting period.

A Monthly Progress Report will not be required in the same months that Annual or Final Technical Progress Reports are due.

**B. Annual Progress Report**

This report shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The Contractor shall submit an Annual Progress Report on or before the 30th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort.

SECTION II Part A: SUMMARY - A description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE — This section shall include a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes). Please include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS — This section shall document the results of work completed and costs incurred during the period covered in relation to proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES — This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK — This section shall include a summary of work proposed as an annual forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT — This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

Invoices: Summary of any invoices submitted during the reporting period.

An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due.

**C. Draft Final Report and Final Report**

These reports are to include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Progress Report shall be due forty-five (45) calendar days prior to the expiration date of the contract and the Final Progress Report is due no later than 30 calendar days following the expiration date of the contract. The report shall conform to the following format:

Title Page: The title for these reports shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

SECTION II: RESULTS - A detailed description of the work performed and the results obtained including all expenses for the entire contract period of performance.

**D. FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions.**

**a.** Within five business days of any formal meeting with the FDA or other regulatory agency, the Contractor shall provide a formal contact report to BARDA. The Contractor shall forward the final minutes when available.

**b.** Within five business days of any informal meeting with the FDA or other regulatory agency, the Contractor shall forward the initial draft minutes to BARDA. The Contractor shall forward the final minutes when available and if applicable.

**c.** The Contractor shall forward the dates and times of any formal meeting with the FDA and other regulatory agencies to BARDA as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings.

**d.** The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Contractor shall provide BARDA with five (5) business days in which to review and provide comments back to the Contractor prior to the Contractor's submission to the FDA.

**e.** The Contractor shall forward Standard Operating Procedures (SOPs) upon request from COR.

**f.** The Contractor shall provide raw data and/or specific analysis of data generated with USG funds upon request from the COR.

**g.** The Contractor shall notify the Contracting Officer's Representative and Contracting Officer within 24 hours of all site visits/audits conducted by the FDA or any other regulatory agency. The Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the Contracting Officer's Representative and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

**E. Other Requirements/Deliverables**

**a. Integrated Master Project Plan**

The Contractor shall provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to annual deliverables and Work Breakdown Structure (WBS) elements. Attention shall be placed on providing sufficient turnaround time for the USG (BARDA, FDA, and CDC) for review of critical documentation. The Contractor shall integrate to demonstrate interdependencies among all CLINS. The Integrated Master Project Plan shall be incorporated into any potential contract and will be used to monitor performance of the contract. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

**i. Critical Path Milestones**

The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

**ii. Work Breakdown Structure**

The USG has provided a Contract Work Breakdown Structure (CWBS) template (See http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx) and the Contractor shall further delineate the CWBS to Level 5 as part of their Integrated Master Project Plan. The WBS shall be discernable and consistent. BARDA may require Contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

**iii. Risk Mitigation Plan/Matrix**

The Contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. The USG has provided a Risk Mitigation Matrix template (See **http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx)** to be completed by any prospective Contractor. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

**b. Technology Packages**

Technology packages developed under the contract that includes complete protocols must be submitted at the request of the BARDA Contracting Officer's Representative. See FAR clauses 52.227-11, Patent Rights-Ownership by the Contractor, and 52.227-14, Rights in Data. This report shall be due upon request from the COR or Alternate COR.

**c. Experimental Protocols**

The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for BARDA approval or upon request by the COR or Alternate COR when required.

**d. Annual/Final Invention Report**

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. An Annual Invention Report shall be due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report (see FAR 27.303 (b)(2)(ii)) shall be due on or before the expiration date of the contract. If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer.

**e. Publications**

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission. Reports of final submission for publication shall be due within 30 calendar days for manuscripts and 15 calendar days for abstracts.

**f. Press Releases**

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the Contracting Officer has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.

**g. Incident Security Report**

The Contractor shall report to the government any activity; or incident that is in violation of established security standards; or indicates the loss or theft of government products. Reports shall be due within 24 hours after occurrence of an activity or incident.

**i. Security Plan**

The Contractor shall submit a draft security plan within 90 days of contract award. A detailed security plan with any updates shall be submitted for approval at least three (3) months prior to the initiation of product procurement with proper documentation. The Contractor shall cooperate with USG representatives to develop a sustainable security plan to ensure continued security of the premises. Security plan updates are required when an incident security report has been filed.

**j. Quality Management System (QMS) Plan**

The Contractor shall provide a QMS plan within 90 days of contract award with updates at least three (3) months prior to initiation of product procurement and as directed by the COR or Alternate COR. The Contractor agrees to incorporate USG feedback and address concerns relating to QMS plans.

**k. Quality Agreement**

The Quality Agreement shall define, establish, and document the responsibilities of both the Contractor and the USG (i.e. – CDC/SNS-Quality Control and BARDA) for event-driven and product shipping, receiving, acceptance into the inventory and/or custody by the USG. These documents shall be drafted, approved, and signed by all parties prior to the commencement of product procurement and acceptance, transport and custody of the product under the VMI/DMI or the CDC/SNS. The Contractor shall provide documentation and resolution for all concerns raised by USG and commits to cooperation in execution of this agreement. Quality Agreement is due at least three (3) months prior to initiation of product procurement or as directed by the COR or Alternate COR.

**l. Vendor Managed Inventory (VMI) Plan**

The Contractor shall develop a plan to establish VMI in alignment with the Quality Agreement Report. Interim draft plans shall be submitted to USG as part of the development process. Draft submission for review is due upon completion of pre-EUA package. Final submission is required to initiate product procurement through a COA. Documents shall be updated as required by the COR or Co-COR. Developmental updates should be reported in the monthly reports as requested by the COR or Alternate COR.

A minimum of three (3) product deliveries from different manufacturing lots shall be delivered and accepted by USG to the inventory (considered as substantial delivery to the inventory) before the Contractor shall invoice for the product payment.

**F. Earned Value Management System Plan**

**a. Earned Value Management System Plan:**

Subject to the requirements under HHSAR Clause 352.234-3, the Contractor shall use principles of Earned Value Management System (EVMS) in the management of this contract (include this plan as part of the monthly, annual, and final reports). The Seven Principles are:

I. Plan all work scope for the program to completion.

II. Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.

III. Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control changes to the baseline.

IV. Use actual cost incurred and recorded in accomplishing the work performed.

V. Objectively assess accomplishments at the work performance level.

VI. Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.

VII. Use earned value information in the company's management processes.

VIII. Elements of EVMS shall be applied to all CLINs as part of the Integrated Master Project Plan, the Contractor shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements.

**b. Performance Measurement Baseline Review (PMBR):**

The Contractor shall submit a PMBR plan electronically via email to the CO and COR for a PMBR to occur within 90 days of contract award. At the PMBR, the Contractor and BARDA shall mutually agree upon the budget, schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout

the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. **The goals of the PMBR are as FOLLOWS:**

I. Jointly assess areas such as the Contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks.

II. Confirm the integrity of the Performance Measurement Baseline (PMB).

III. Foster the use of EVM as a means of communication.

IV. Provide confidence in the validity of Contractor reporting

V. Identify risks associated with the PMB.

VI. Present any revised PMBs for approval.

VII. Present an Integrated Master Schedule: The Contractor shall deliver an initial program level Integrated Master Schedule (IMS) that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR. DI-MGMT-81650 may be referenced as guidance in creation of the IMS (see http://www.acq.osd.mil/pm/).

VIII. Present the Risk Management Plan.

**c. Integrated Master Schedule**

The Contractor shall submit an IMS electronically via email as outlined in a format agreed upon by BARDA to the COR and the Contracting Officer for approval prior to the initiation of any activities of sufficient size and cost to require EVMS. The Integrated Master Schedule shall be incorporated into the contract, and shall be used to monitor performance of the contract. The Contractor shall include the key milestones and Go/No Go decision gates. The Contractor shall include BARDA Portfolio Management Milestones (See the AMCG Business Toolkit for a description and sample (http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx) in their IMS and provide monthly updates within their IMS. This IMS shall include the following fields at a minimum; baseline start and finish, forecast start and finish, actual start and finish, predecessor and/or successor. The Contractor shall deliver the Integrated Master Schedule, viewed at the work package level in MS Project file format

**d. Earned Value Contract Performance Report (EV-CPR)**

a. The Offeror shall deliver an Earned Value Contract Performance Report (CPR) on a monthly basis per the instruction in DI-MGMT-81466A (see http://www.acq.osd.mil/pm/). The Contractor shall provide Format 1, Format 3, and Format 5 only. Format 1 will be reported at the Work Breakdown Structure level agreed to by BARDA and the Contractor.

b. EV Variance thresholds will be negotiated with the Contractor post-award but for planning purposes will likely be (+/- 10%). In conjunction with the CPR, the Contractor shall provide a monthly update to the IMS with up to date performance data and shall include actual start/finish and projected start / finish dates.

c. The supplemental monthly CAP report shall contain, at the work package level, time phased budget (budgeted cost of work scheduled (BCWS)), earned value (budgeted cost of work performed (BCWP)), and actual costs of work performed (ACWP) as captured in the Contractor's EVM systems.

d. The Contractor and BARDA shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the COR. Such meetings may include, but are not limited to, site visits to the Contractor's and/or subcontractor's facilities, meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel and Government-contracted subject matter experts as required by the BARDA COR in order to facilitate review of contract activities.

e. The Contractor shall provide a list of individuals to serve as primary and secondary points of contact who will be available 24 hours a day, seven days a week, to be notified in case of a public health emergency.

**ARTICLE F.3. DELIVERIES**

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work dated September 29, 2015 set forth in SECTION J - List of Attachments of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule below:

| Item No. | Description | Addresses | Deliverable Schedule |
|---|---|---|---|
| 1 | Monthly Progress Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Reports are due on or before the 15th of each month following the end of each reporting period. |
| 2 | Annual Progress Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Reports are due on or before the 30th calendar day following the end of each reporting period. |
| 3 | Draft Final Progress Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Report is due 45 Calendar days prior to the expiration date of the contract. |

| | | | |
|---|---|---|---|
| 4 | Final Progress Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Report is due no later than 30 calendar days after the expiration date of the contract. |
| 5 | FDA/ Regulatory Agency Correspondence and Meeting Summaries | COR: (1) electronic copy | Reports are due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes from FDA/ regulatory agency, and upon request from the COR or Alternate COR. |
| 6 | Integrated Master Project Plan<br>-Critical Path Milestones<br>- Work Breakdown Structure<br>- Risk Mitigation Plan/Matrix | COR: (1) electronic copy | Report is due within 90 days of contract award. Updates are due as requested by the COR or Alternate COR. |
| 7 | Technology Packages | COR: (1) electronic copy | Upon request from the COR or Alternate COR. |
| 8 | Experimental Protocols for non- clinical animal studies or clinical studies | COR: (1) electronic copy | Upon request from the COR or Alternate COR. Written approval from the COR or Alternate COR is required prior to the execution of the study. |
| 9 | Annual/Final Invention Report | CO: (1) electronic copy<br>COR: (1) electronic copy | An Annual Invention Report is due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report is due on or before the expiration date of the contract. |
| 10 | Publications | COR: (1) electronic copy | Reports are due within 10 business days for manuscripts and 5 business days for abstracts. |
| 11 | Press Releases | COR: (1) electronic copy | Reports/Notices are due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release. |

| | | | |
|---|---|---|---|
| 12 | Incident Security Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Reports are due within 24 hours after occurrence of an activity or incident. |
| 13 | Security Plan | CO: (1) electronic copy<br>COR: (1) electronic copy | Draft report is due within 90 days of contract award. Updates are due at least 3 months prior to product procurement or as requested by the COR or Alternate COR. |
| 14 | Quality Management System (QMS) Plan | COR: (1) electronic copy | Draft report is due within 90 days of contract award. Updates are due at least 3 months prior to product procurement or as requested by the COR or Alternate COR. |
| 15 | Quality Agreement | COR: (1) electronic copy | Agreement is due at least 3 months prior to product procurement or as directed by the COR or Alternate COR. |
| 16 | VMI Plan | CO: (1) electronic copy<br>COR: (1) electronic copy | Plan is due upon completion of the Pre-EAU package. |
| 17 | Earned Value Management Requirements | CO: (1) electronic copy<br>COR: (1) electronic copy | As detailed in Section F.2 Reporting Requirements, subpart-F. |

Email Addresses: CO - [**]
COR - [**]

**ARTICLE F.4. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)**

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/far.

**FAR 52.242-15, Stop Work Order (August 1989)**
**FAR 52.242-15, Alternate 1 (April 1984) is applicable to this contract.**

## SECTION G - CONTRACT ADMINISTRATION DATA

### ARTICLE G.1. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

[**]
DHHS/OS/ASPR/AMCG
200 C St.
Washington, D.C. 20024

a. The Contracting Officer (CO) is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the CO can make any changes to the terms, conditions, general provisions, specifications or other requirements of this contract.

b. The Contracting Officer (CO) is the only person with authority to act as agent of the Government under this contract. Only the CO has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

c. No information, other than that which may be contained in an authorized modification to this contract duly issued by the CO, shall be considered grounds for deviation from this contract.

d. The Government may unilaterally change its CO designation.

### ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

[**]
Contracting Officer's Representative
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Service

[**]
[**]

Mailing Address:
200 C St.
Washington, D.C. 20024

Alternate COR:

[**]
Alternate Contracting Officer's Representative (COR)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Service

[**]
[**]
Mailing Address:
330 Independence Avenue, SW
Washington, D.C. 20201

The COR is responsible for:

a. Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;

b. Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;

c. Performing technical evaluation as required;

d. Performing technical inspections and assisting the Contracting Officer in acceptances of deliverables required by this contract; and

e. Assisting in the resolution of technical problems encountered during performance.

f. The Government may unilaterally change its COR designation(s).

**ARTICLE G.3. KEY PERSONNEL**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individuals are considered to be essential to the work being performed hereunder:

| Name | Title |
|---|---|
| [**] | [**] |
| [**] | [**] |
| [**] | [**] |
| [**] | [**] |

**ARTICLE G.4. INVOICE SUBMISSION**

a. The Contractor shall submit an electronic copy of contract monthly invoices/financial reports to the Contracting Officer as defined above, in ARTICLE G of this contract.

b. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests made a part of the contract at Section J, Attachments 2 & 3.

c. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

d. The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base period or any options for additional quantities (See estimated costs under Articles B.2 and B.3) and the reasons for the variance. Also refer to the requirements of FAR Clause 52.232-20, Limitation of Cost.

e. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

f. All invoice submissions shall be in accordance with FAR Clause52.232-25, Prompt Payment.

**ARTICLE G.5. INDIRECT COST RATES**

1. The following interim provisional indirect rates will be utilized for billing purposes during the period of performance: Fringe benefits at [**], and Overhead (G&A) at [**]. Final rate proposals must be sent to the Contracting Officer, within 6 months of the fiscal year end. See FAR Clause 52.216-7, Allowable Cost and Payment.

**ARTICLE G.6. REIMBURSEMENT OF COST**

1) The Government shall reimburse the Contractor those costs determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR 52.216-7, Allowable Cost and Payment and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

i. Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

ii. Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

iii. Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

iv. Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

**ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

1. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) will be prepared Annually as to coincide with the Anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

2. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure website for review and comment at the following:

http://cpars.gov

**ARTICLE G.8. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)**

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number HHSO100201500028C from Page 1 of the contract.

**ARTICLE G.9. GOVERNMENT PROPERTY**

1. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, “Contractor’s Guide for Control of Government Property,” which is incorporated into this contract by reference. This document can be accessed at:

   http://www.hhs.gov/hhsmanuals/ (HHS Logistics Management Manual)

   Among other issues, this publication provides a summary of the Contractor’s responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

2. Notwithstanding the provisions outlined in the HHS Publication, “Contractor’s Guide for Control of Government Property,” which is incorporated in this contract in paragraph 1. above, the Contractor shall use the form entitled, “Report of Government Owned, Contractor Held Property” for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

3. Title will vest in the Government for equipment purchased as a direct cost.

**SECTION H - Special Contract Requirements**

**ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)**

**a.** The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

**b.** The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

**c.** If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Human Subject Assurances.

**ARTICLE H.2. CLINICAL RESEARCH**

These Clinical Terms apply to all contracts that involve clinical research.

The Government shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by the Government under this contract, as defined in Rights in Data Clause in FAR 52.227-14. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form, to ensure the Government has the ability to review and distribute the deliverables, as the Government deems necessary.

**H.2.1 Safety and Monitoring Issues**

Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval Before award and then with Annual Progress Reports, the Contractor shall submit to the Government a copy of the current IRB or IEC approved informed consent document, documentation of continuing review and approval and the Office of Human Research Protections (OHRP) FWA number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide the Government initial and annual documentation of continuing review and approval, including the current approved informed consent document and FWA number.

The grantee institution must ensure that the applications as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the Government a summary explanation and copies of documents related to all major changes in the status of ongoing protocols, including the following:

1. All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
2. All changes in informed consent documents, identified by version number, date, or both and dates it is valid.
3. Termination or temporary suspension of patient accrual.
4. Termination or temporary suspension of the protocol.
5. Any change in IRB approval.
6. Any other problems or issues that could affect the participants in the studies.

Contractors must notify BARDA through the Contracting Officer's Representative (COR) and Contracting Officer (CO) of any of the above changes within 24 hours from the time the Contractor becomes aware of the change by email, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an Institutional Bio-safety Committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

**H.2.2. Data and Safety Monitoring Requirements**

The Contractor may be required to conduct independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trials of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform the Government of any upcoming site visits and/or audits of Contractor facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of Contractors and Subcontractors as the Government deems necessary. The type of monitoring to be used shall be mutually agreed upon between the Contractor and the Government before enrollment starts. Discussions with the responsible BARDA COR regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following:

1. **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

2. **Independent Monitoring Committee (IMC)** or **Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.

3. **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and curriculum vitae from all members must be submitted to and approved by the Government before enrollment starts.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the Government within 30 days of reviews or meetings.

**H.2.3. BARDA Protocol Review Process Before Patient Enrollment Begins**

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must provide the following (as applicable) for review and approval by the Government:

1. Clinical research protocol to be submitted for approval by the IRB identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria;

2. Informed consent document, identified by version number, date, or both and date it is valid;

3. Plans for the management of side effects;

4. Procedures for assessing and reporting adverse events;

5. Plans for data and safety monitoring (see B above) and monitoring of the clinical study site, pharmacy, and laboratory;

6. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

BARDA comments will be forwarded to the Contractor within two weeks (10 business days) of receipt of the above information. The Contractor must address in writing all study design, safety, regulatory, ethical, and conflict of interest concerns raised by the BARDA COR to the satisfaction of the Government before patient accrual or participant enrollment can begin. After the Government receives the corrected documentation, a written protocol approval will be provided by the COR to the Contractor. This written approval provides authorization to the Contractor to execute the specific clinical study funded in part or in whole by the Government.

Documentation of IRB approval, including OHRP FWA number, IRB registration number, and IRB and name, must be provided to the BARDA COR within 24 hours of receipt by the Contractor.

**H.2.4. Required Time-Sensitive Notification**

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA Contracting Officer's representative (COR) as follows:

1. Expedited safety report of unexpected or life-threatening experience or death – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted to the BARDA program officer or the Contracting Officer's Representative within 24 hours of FDA notification.
2. Expedited safety reports of serious and unexpected adverse experiences – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 calendar days after the IND sponsor's receipt of the information, must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.
3. IDE reports of unanticipated adverse device effect – A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.
4. Expedited safety reports – shall be sent to the BARDA COR concurrently with the report to FDA.
5. Other adverse events documented during the course of the trial shall be included in the annual IND or IDE report and reported to the BARDA annually.

In case of problems or issues, the BARDA COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

*Safety reporting for research not performed under an IND or IDE.*

Ongoing safety reporting requirements for research not performed under an IND or IDE shall be mutually agreed upon by the BARDA Contracting Officer's Representative and the Contractor.

**ARTICLE H.3. HUMAN MATERIALS**

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

**ARTICLE H.4. NEEDLE DISTRIBUTION**

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

**ARTICLE H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING**

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

**ARTICLE H.6. RESTRICTIONS ON ABORTIONS**

The Contractor shall not use funds for any abortion.

**ARTICLE H.7. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with the March 4, 1997 Presidential Memorandum entitled "Prohibition on Federal Funding for Cloning of Human Beings", federal funds may not be used for cloning of human beings.

**ARTICLE H.8. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

**ARTICLE H.9. OMB CLEARANCE**

In accordance with HHSAR 352.201-70, Paperwork Reduction Act of 1980 (44 U.S.C. section 3501), the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed.

**ARTICLE H.10. RESEARCH INVOLVING HUMAN FETAL TISSUE**

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

**ARTICLE H.11. REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

**ARTICLE H.12. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES**

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L.107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

**ARTICLE H.13. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS**

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

**ARTICLE H.14. CERTIFICATION OF FILING AND PAYMENT OF TAXES**

The Contractor must be in compliance with Section 518 of the Consolidated Appropriations Act of FY 2014.

**ARTICLE H.15. ELECTRONIC INFORMATION AND TECHNOLOGY ACCESSIBILITY NOTICE**

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. Accordingly, any Offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/sec508/standards.htm.

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, Offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows Offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://hhs.gov/web/508.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, Offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a Offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

**ARTICLE H.16. FULL EARNED VALUE MANAGEMENT SYSTEM, HHSAR 352.234-3 (October 2008) with ALTERNATE I (October 2008)**

a. The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the guidelines in ANSI/EIAStandard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS is not compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

b. If, at the time of award, the Contractor's EVM system is not in compliance with the EVMS guidelines in ANSI/EIAStandard-748 (current version at time of award), the Contractor shall:

a. Apply the current system to the contract; and

b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

c. HHS will not formally validate or accept the Contractor's EVMS with respect to this contract. The use of the Contractor's EVMS for this contract does not imply HHS acceptance of the Contractor's EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

d. HHS will conduct a Performance Measurement Baseline Review (PMBR). If a pre-award PMBR has not been conducted, a post-award PMBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require a PMBR as part of the exercise of an option or the incorporation of a major modification.

e. The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform to the requirements referenced in paragraph (a) of this clause.

f. The Contractor shall require the subcontractors specified below to comply with the requirements of the clause:

**ARTICLE H.17. CONFIDENTIALITY OF INFORMATION**

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

**ARTICLE H.18. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR CONFLICTS OF INTERESTS**

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site:
http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

    2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

    3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

    Significant financial interests do not include the following:

    1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

    2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any BARDA funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the BARDA funded research.

d. Require that each Investigator who is planning to participate in the BARDA funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for BARDA funded research. Require that each Investigator who is participating in the BARDA funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to BARDA funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to BARDA funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the BARDA funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the BARDA funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the BARDA funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

**ARTICLE H.19. PUBLICATION AND PUBLICITY**

The Contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201500028C"

Press Releases:

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non-Governmental sources.

**ARTICLE H.20. ACCESS TO DOCUMENTATION/DATA**

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance, all data generated, all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Contractor commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence with the FDA within 24 hours of receipt. The Government shall acquire unlimited rights to all data funded under a contract awarded in response to this RFP in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

**ARTICLE H.21. DISSEMINATION OF INFORMATION**

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

**ARTICLE H.22. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

**ARTICLE H.23. IDENTIFICATION AND DISPOSITION OF DATA**

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (HHS). HHS reserves the right to review any other data generated under this contract and determined by HHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

**ARTICLE H.24. CONFLICT OF INTEREST**

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

**ARTICLE H.25. IN-PROCESS REVIEW**

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables may be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or unilaterally institute changes to the work segment, or terminate the work segment.

IPRs may be scheduled at the discretion of the Government to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 days prior to the IPR. The Contractor shall provide a draft presentation to the Contracting Officer at least 10 days prior to the IPR.

**ARTICLE H.26. PRIVACY ACT APPLICABILITY**

1) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at http://www.gpoaccess.gov/cfr/index.html

2) The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

**ARTICLE H.27. QA AUDIT REPORTS**

BARDA reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications. The Contractor shall notify the CO and COR reasonably in advance of upcoming QA audit so that Government personnel may participate in person at BARDA's discretion.
- Contractor shall notify the COR and CO within 5 business days of report completion.

**ARTICLE H.28. BARDA AUDITS**

Contractor shall accommodate periodic or ad hoc site visits by the Government. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

**ARTICLE H.29. SECURITY REPORTING REQUIREMENT**

Violations of established security protocols shall be reported to the CO and COR upon discovery within 24 hours of its receipt of any compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system has been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. The CO in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the CO.

**PART II - CONTRACT CLAUSES**

**SECTION I - CONTRACT CLAUSES**

**ARTICLE I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at these addresses: https://www.acquisition.gov/FAR/ HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html

**General Clauses for Cost-Reimbursement/Fixed Price Research and Development Contract**

**(1) FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:**

| Reg | Clause | Date | Clause Title |
|---|---|---|---|
| FAR | 52.202-1 | Nov 2013 | Definitions |
| FAR | 52.203-3 | Apr 1984 | Gratuities |
| FAR | 52.203-5 | May 2014 | Covenant Against Contingent Fees |
| FAR | 52.203-6 | Sep 2006 | Restrictions on Subcontractor Sales to the Government |
| FAR | 52.203-7 | May 2014 | Anti-Kickback Procedures |
| FAR | 52.203-8 | May 2014 | Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity |
| FAR | 52.203-10 | May 2014 | Price or Fee Adjustment for Illegal or Improper Activity |
| FAR | 52.203-12 | Oct 2010 | Limitation on Payments to Influence Certain Federal Transactions |
| FAR | 52.203-13 | Apr 2010 | Contractor Code of Business Ethics and Conduct |
| FAR | 52.203-14 | Dec 2007 | Display of Hotline Poster(s) |
| FAR | 52.203-17 | Apr 2014 | Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights |
| FAR | 52.204-4 | May 2011 | Printed or Copied Double-Sided on Postconsumer Fiber Content Paper |
| FAR | 52.204-7 | Jul 2013 | System for Award Management |
| FAR | 52.204-10 | Jul 2013 | Reporting Executive Compensation and First-Tier Subcontract Awards |
| FAR | 52.204-13 | Jul 2013 | System for Award Management Maintenance |
| FAR | 52.209-6 | Aug 2013 | Protecting the Government’s Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment |
| FAR | 52.209-10 | Dec 2014 | Prohibition on Contracting with Inverted Domestic Corporations |
| FAR | 52.210-1 | Apr 2011 | Market Research |
| FAR | 52.215-2 | Oct 2010 | Audit and Records – Negotiation |
| FAR | 52.215-8 | Oct 1997 | Order of Precedence - Uniform Contract Format |
| FAR | 52.215-10 | Aug 2011 | Price Reduction for Defective Cost or Pricing Data |
| FAR | 52.215-11 | Aug 2011 | Price Reduction for Defective Certified Cost or Pricing Data—Modifications. |
| FAR | 52.215-12 | Oct 2010 | Subcontractor Certified Cost or Pricing Data |
| FAR | 52.215-13 | Oct 2010 | Subcontractor Certified Cost or Pricing Data—Modifications |
| FAR | 52.215-15 | Oct 2010 | Pension Adjustments and Asset Reversions |
| FAR | 52.215-18 | Jul 2005 | Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions |
| FAR | 52.215-19 | Oct 1997 | Notification of Ownership Changes |
| FAR | 52.215-21 | Oct 2010 | Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications |
| FAR | 52.215-23 | Oct 2009 | Limitations on Pass-Through Charges |
| FAR | 52.216-7 | Jun 2013 | Allowable Cost and Payment |
| FAR | 52.216-8 | Jun 2011 | Fixed Fee |
| FAR | 52.219-8 | Oct 2014 | Utilization of Small Business Concerns |
| FAR | 52.219-28 | July 2013 | Post-Award Small Business Program Representation |

| | | | |
|---|---|---|---|
| FAR | 52.222-1 | Feb 1997 | Notice to the Government of Labor Disputes |
| FAR | 52.222-2 | Jul 1990 | Payment for Overtime Premiums |
| FAR | 52.222-3 | Jun 2003 | Convict Labor |
| FAR | 52.222-21 | Apr 2015 | Prohibition of Segregated Facilities |
| FAR | 52.222-26 | Apr 2015 | Equal Opportunity |
| FAR | 52.222-35 | Jul 2014 | Equal Opportunity for Veterans |
| FAR | 52.222-36 | Jul 2014 | Equal Opportunity for Workers with Disabilities |
| FAR | 52.222-37 | Jul 2014 | Employment Reports on Veterans |
| FAR | 52.222-40 | Dec 2010 | Notification of Employee Rights Under the National Labor Relations Act |
| FAR | 52.222-43 | May 2014 | Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (Multiple Year and Option Contracts) |
| FAR | 52.222-50 | Mar 2015 | Combating Trafficking in Persons |
| FAR | 52.222-54 | Aug 2013 | Employment Eligibility Verification |
| FAR | 52.223-6 | May 2001 | Drug-Free Workplace |
| FAR | 52.223-18 | Aug 2011 | Encouraging Contractor Policy to Ban Text Messaging While Driving |
| FAR | 52.224-1 | April 1984 | Privacy Act Notification |
| FAR | 52.224-2 | April 1984 | Privacy Act |
| FAR | 52.225-13 | Jun 2008 | Restrictions on Certain Foreign Purchases |
| FAR | 52.227-1 | Dec 2007 | Authorization and Consent, Alternate 1 (APR 1984) |
| FAR | 52.227-2 | Dec 2007 | Notice and Assistance Regarding Patent and Copyright Infringement |
| FAR | 52.227-3 | Apr 1984 | Patent Indemnity |
| FAR | 52.227-11 | May 2014 | Patent Rights – Ownership by the Contractor |
| FAR | 52.227-14 | May 2014 | Rights in Data – General |
| FAR | 52.228-7 | Mar 1996 | Insurance – Liability to Third Persons |
| FAR | 52.229-3 | Feb 2013 | Federal, State and Local Taxes |
| FAR | 52.230-2 | May 2014 | Cost Accounting Standards |
| FAR | 52.230-6 | June 2010 | Administration of Cost Accounting Standards |
| FAR | 52.232-1 | Apr 1984 | Payments |
| FAR | 52.232-2 | Apr 1984 | Payments under Fixed-Price Research and Development Contracts |
| FAR | 52.232-8 | Feb 2002 | Discounts for Prompt Payment |
| FAR | 52.232-9 | Apr 1984 | Limitation on Withholding of Payments |
| FAR | 52.232-11 | Apr 1984 | Extras |
| FAR | 52.232-17 | May 2014 | Interest |
| FAR | 52.232-20 | Apr 1984 | Limitation of Cost |
| FAR | 52.232-23 | May 2014 | Assignment of Claims |
| FAR | 52.232-25 | Jul 2013 | Prompt Payment |
| FAR | 52.232-33 | Jul 2013 | Payment by Electronic Funds Transfer—System for Award Management |
| FAR | 52.233-1 | May 2014 | Disputes |
| FAR | 52.233-3 | Aug 1996 | Protest After Award, Alternate I |
| FAR | 52.233-4 | Oct 2004 | Applicable Law for Breach of Contract Claim |
| FAR | 52.242-1 | Apr 1984 | Notice of Intent to Disallow Costs |
| FAR | 52.242-3 | May 2014 | Penalties for Unallowable Costs |
| FAR | 52.242-4 | Jan 1997 | Certification of Final Indirect Costs |
| FAR | 52.242-13 | Jul 1995 | Bankruptcy |
| FAR | 52.242-15 | Aug 1989 | Stop Work Order, Alternate I (Aug 1984) |
| FAR | 52.243-1 | Aug 1987 | Changes—Fixed-Price Alternate V (Apr 1984). |
| FAR | 52.243-2 | Aug 1987 | Changes—Cost-Reimbursement Alternate V (Apr 1984). |
| FAR | 52.243-7 | Apr 1984 | Notification of Changes |
| FAR | 52.244-2 | Oct 2010 | Subcontracts, Alternate 1 (Jun 2007) |
| FAR | 52.244-5 | Dec 1996 | Competition in Subcontracting |
| FAR | 52.244-6 | Apr 2015 | Subcontracts for Commercial Items |
| FAR | 52.245-1 | Apr 2012 | Government Property |
| FAR | 52.245-9 | Apr 2012 | Use and Charges |

| | | | |
|---|---|---|---|
| FAR | 52.246-23 | Feb 1997 | Limitation of Liability. |
| FAR | 52.246-25 | Feb 1997 | Limitation of Liability—Services |
| FAR | 52.248-1 | October 2010 | Value Engineering |
| FAR | 52.249-2 | Apr 2012 | Termination for the Convenience of the Government (Fixed-Price) |
| FAR | 52.249-6 | May 2004 | Termination (Cost-Reimbursement) |
| FAR | 52.249-8 | Apr 1984 | Default (Fixed-Price Supply and Service) |
| FAR | 52.249-9 | Apr 1984 | Default (Fixed-Price Research and Development) |
| FAR | 52.249-14 | Apr 1984 | Excusable Delays |
| FAR | 52.253-1 | Jan 1991 | Computer Generated Forms |

**(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:**

| | | | |
|---|---|---|---|
| HHSAR | 352.202-1 | Jan 2006 | Definitions - with Alternate paragraph (h) |
| HHSAR | 352.203-70 | Mar 2012 | Anti-Lobbying |
| HHSAR | 352.216-70 | Jan 2006 | Additional Cost Principles |
| HHSAR | 352.222-70 | Jan 2010 | Contractor Cooperation in Equal Employment Opportunity Investigations |
| HHSAR | 352.223-70 | Sept 2010 | Safety and Health |
| HHSAR | 352.227-70 | Jan 2006 | Publications and Publicity |
| HHSAR | 352.228-7 | Dec 1991 | Insurance - Liability to Third Persons |
| HHSAR | 352.231-70 | Jan 2006 | Salary Rate Limitation |
| HHSAR | 352.231-71 | Jan 2001 | Pricing of Adjustments |
| HHSAR | 352.233-71 | Jan 2006 | Litigation and Claims |
| HHSAR | 352.242-70 | Jan 2006 | Key Personnel |
| HHSAR | 352.242-73 | Jan 2006 | Withholding of Contract Payments |
| HHSAR | 352.242-74 | Apr 1984 | Final Decisions on Audit Findings |

**ARTICLE I.2. ADDITIONAL CONTRACT CLAUSES**

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

**a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES**

1. FAR 52.215-17, Waiver of Facilities Capital Cost of Money (October 1997).
2. FAR 52.227-16, Additional Data Requirements (June 1987).

**ARTICLE I.3. ADDITIONAL HHSAR CLAUSES – IN FULL TEXT**

**352.231-70 Salary rate limitation (August 2012)**

1. Pursuant to the current and applicable prior HHS appropriations acts, the Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date an expense is incurred.
2. For purposes of the salary rate limitation, the terms “direct salary,” “salary”, and “institutional base salary”, have the same meaning and are collectively referred to as “direct salary”, in this clause. An individual’s direct salary is the annual compensation that the Contractor pays for an individual’s direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

**Note:** The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.

1. The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract or order funding.

2. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

**ARTICLE I.4. ADDITIONAL FAR CLAUSES INCLUDED IN FULL TEXT**

**FAR 52.217-7 Option for Increased Quantity-Separately Priced Line Item (Mar 1989)**

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

**FAR 52.217-9 Option to Extend the Term of the Contract (Mar 2000)**

**a. The Government may extend the term of this contract by written notice to the Contractor within 30 Days provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.**

**b. If the Government exercises this option, the extended contract shall be considered to include this option clause.**

**c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed 8 years.**

**FAR 52.219-1 Small Business Program Representations (Oct 2014)**

1. The North American Industry Classification System (NAICS) code for this acquisition is 541711.

2. The small business size standard is 500 employees.

3. The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

**b. Representations.**

1. The Offeror represents as part of its offer that it [X] is, [__] is not a small business concern.

2. Complete only if the Offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The Offeror represents, for general statistical purposes, that it [__] is, [X] is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

3. [Complete only if the Offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The Offeror represents as part of its offer that it [ ] is, [X] is not a women-owned small business concern.

4. Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the Offeror represented itself as a women-owned small business concern in paragraph (b)(3) of this provision.] The Offeror represents as part of its offer that—

   (i) It [__] is, [X] is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

   (ii) It [__] is, [X] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(4)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: .] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

5. Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (b)(4) of this provision.] The Offeror represents as part of its offer that—

   (i) It [__] is, [X] is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

   (ii) It [__] is, [X] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(5)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [The Offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

6. [Complete only if the Offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The Offeror represents as part of its offer that it [__] is, [X] is not a veteran-owned small business concern.

7. [Complete only if the Offeror represented itself as a veteran-owned small business concern in paragraph (b)(6) of this provision.] The Offeror represents as part of its offer that is [__] is, [__] is not a service-disabled veteran-owned small business concern.

8. [Complete only if the Offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The Offeror represents, as part of its offer, that –

(i) It [__] is, [X] is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR part 126; and

(ii) It [__] is, [X] is not a HUBZone joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(8)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

**c. Definitions. As used in this provision—**

"Economically disadvantaged women-owned small business (EDWOSB) concern" means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program. "Service-disabled veteran-owned small business concern"—

1. Means a small business concern—

   (i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

   (ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

2. Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern," means a concern, including its affiliates that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

"Veteran-owned small business concern" means a small business concern—

1. Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

2. The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern," means a small business concern –

1. That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

2. Whose management and daily business operations are controlled by one or more women.

"Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127)," means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

**d. Notice.**

1. If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

2. Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15, 31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall –

   (i) Be punished by imposition of fine, imprisonment, or both;

   (ii) Be subject to administrative remedies, including suspension and debarment; and

   (iii) Be ineligible for participation in programs conducted under the authority of the Act.

**FAR 52.232-40, Providing Accelerated Payment to Small Business Subcontractors (Dec 2013)**

**a.** Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

**b.** The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

**c.** Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

**PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS**

**SECTION J - LIST OF ATTACHMENTS**

The following documents are attached and incorporated in this contract:

1. Statement of Work, dated September 29, 2015, 18 pages
2. Invoice/Financing Instructions for Cost-Reimbursement Type Contracts
3. Invoice Instructions for Fixed-Priced Type Contracts
4. Sample Invoice Form
5. Research Patient Care Costs
6. Report of Government Owned, Contractor Held Property, 1 page.
7. Form SF-LLL, Disclosure of Lobbying Activities, 2 pages
8. Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page

**Attachment 1 - Statement of Work (SOW)**

*Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to support this acquisition.*

**Avita Medical BASE SOW**

Summary Table

| CLIN | WBS 1st Level Element | Title | Objectives |
|---|---|---|---|
| 0001 | 1 | Project Management | • Establish project management infrastructure<br>• Establish EVM systems<br>• Finalize IMPP<br>• Technical and financial reporting |
| | 2 | Non-Clinical Objectives | • Close gaps in non-clinical data required for PMA module 1 of 3, including biocompatibility, human factors, packaging testing to generate ISO design dossier as an FDA-compliant design history file.<br>• Establish appropriate training for use of ReCell in mass casualty setting.<br>• Achieve 4-year stability |
| | 3 | Clinical Objectives | • Complete pivotal trials (-5 and -6 protocols) and clinical study reports for PMA module 3 of 3. |
| | 4 | Regulatory Objectives | • Fulfill Pre-EUA requirements<br>• Modular PMA Submission<br>• Secure Pre-Market Approval (PMA) |
| | 5 | Product Development for Mass Casualty/VMI | • Gather requirements for Mass Casualty and VMI<br>• Redesign ReCell packaging and any other subcomponents in order to meet requirements for more efficient VMI and deployment<br>• Complete V&V |
| | 6 | QSR Objectives | • Perform QSR Gap remediation (address all gaps identified) for PMA module 2 of 3.<br>• Scale up manufacturing process for ReCell to support USG acquisition and US Market introduction<br>• Qualify alternate suppliers, for sustainability |
| 0002 | 7 | Procurement (Initial) | • Execute acquisition contract<br>• Establish VMI<br>• Manage inventory |

**Overview**

Avita's initial primary objective with the proposed effort is to secure FDA approval for the ReCell device. In order to accomplish this we need (1) a documented design (with documentation and supporting testing -e.g. biocompatibility- done to FDA standards rather than ISO standards), for which the work is done in WBS 2.1.2, 2.1.3, and 2.1.4; (2) an FDA-compliant quality system and documentation of GMP manufacturing: WBS 6.1; and (3) Pivotal Clinical Data: WBS 3.1.

The above-mentioned work is delivered to FDA via PMA modules 1, 2 and 3, respectively (WBS 4.2.2). The PMA modules will require organizing and assembling reports into a standardized format, setting context and drawing overall conclusions. In addition to submission of the PMA modules, Avita will also draft (and get FDA-approval of) a Conditions of Approval study protocol (WBS 3.3.1.1, 4.2.2.4.2), and pass through a panel (of experts) review (WBS 4.2.2.5). Avita will need favorable reviews of the PMA modules, CoA protocol approval, and panel review to get the product approved.

Concurrent with the FDA approval process, there is an Emergency Use pathway, activated in the event of a mass casualty, which would enable FDA to authorize use of an investigational (unapproved) product for life-saving measures. There is "pre-emergency" work that can be done to facilitate a future potential Authorization. (WBS 4.1)

Once there is confidence in EUA status or there is PMA approval, base procurement (WBS 7.1.1) is triggered.

There are several other items that are part of the program in order to ensure success in stockpiling, distributing, and using ReCell during an emergency event:

1. Training of medics for use of ReCell in mass casualty events (WBS 2.1.1).
2. Increased shelf-life, with a target of up to 4 years (as supported by stability testing) (WBS 2.3)
3. VMI planning/implementation (WBS 7.2, 7.3, 7.4)
4. Optimize product packaging more for palletized storage and VMI, (WBS 5)
5. Qualifying second sources for key components and for product final assembly (i.e. alternative/supplementary sources for enzyme and a supplement/alternative to Parker) (WBS 6.2.2).

**CLIN 0001 - Base Period**

1.0 Program Management

1.1 Internal Project Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.1.5 Integrated Master Project Plan | Upon delivery to and acceptance by BARDA | All required elements of this plan as listed in the RFP |

1.1.5 Title: Integrated Master Project Plan

Objective/Description of Work: Avita will compile all necessary materials and finalize all aspects of the project related to preparing the Integrated Master Project Plan. This will include finalizing critical path milestones, Work Breakdown Structure (WBS), and Risk Mitigation Plan. The final deliverable of the IMPP will represent the finalization and approval of all project elements between Avita and BARDA.

Milestones:

1.1.5.1 Critical Path Milestones – The critical path milestones are finalized and submitted, reviewed, and approved by BARDA.

1.1.5.2 Work Breakdown Structure – The WBS is finalized and submitted, reviewed, and approved by BARDA for all project activities.

1.1.5.3 Risk Mitigation Plan/Matrix – Any additional elements of risk are identified and all elements of risk are finalized and submitted, reviewed, and approved by BARDA. Risk management plans for each risk are finalized and submitted, reviewed, and approved by BARDA.

Deliverables:

1.1.5 Integrated Master Project Plan – Containing all required elements as listed in the RFP and/or requested by BARDA.

1.1.5.1 Critical Path Milestones – An updated and finalized critical path milestone document.

1.1.5.2 Work Breakdown Schedule – An updated and finalized WBS document.

1.1.5.3 Risk Mitigation Plan/Matrix – An updated and finalized risk mitigation plan/matrix.

1.2 Contract Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.2.2 Reporting | Upon delivery to and acceptance by BARDA | All required reports as listed in the RFP and requested by BARDA |
| 1.2.3 Meetings | BARDA Kick-Off Meeting | Meeting Presentation Materials |

1.2.2 Title: Reporting

Objective/Description of Work: Avita will comply with all reporting requirements as outlined and formatted in the RFP and as requested by BARDA. Reporting will include at a minimum monthly progress reports, annual progress reports, annual invention reports, draft final report, and final report. Additional deliverables such as technology packages, experimental protocols, publication, press releases, security reports, or other reports will be provided to BARDA for review prior to initiation of a corresponding work element, deliverable, or FDA submission.

Milestones:

1.2.2.1 Monthly Progress Report – Delivery to and acceptance by BARDA.

1.2.2.2 Annual Progress Report – Delivery to and acceptance by BARDA.

1.2.2.3 Invention Reports – Delivery to and acceptance by BARDA.

1.2.2.4 Draft Final and Final Progress Reports – Delivery to and acceptance by BARDA.

Deliverables:

1.2.2.1 Monthly Progress Report – A report detailing the prior month's activities and activities planned for the following month. Report will be delivered prior to the 15th of the month following the reporting period.

1.2.2.2 Annual Progress Report – A report summarizing the activities of the period of performance and the activities planned for the upcoming period. Report will be delivered prior to the 30th of the month following the reporting period.

1.2.2.3 Annual/Final Invention Report – A report detailing any intellectual property developed as a result of the work performed during each period of performance and the entire contract period. Report will be delivered in conjunction with the annual progress report.

1.2.2.4 Draft Final and Final Progress Report – The Final Progress Report will include a complete summary of all work performed during the entire contract period of performance. A Draft Final Progress Report will be delivered 45 days prior to contract expiration for BARDA review and comments. A Final Progress Report will be delivered prior to 30 days following contract expiration.

1.2.3 Title: Meetings

Objective/Description of Work: Avita and BARDA will engage in regular meetings to coordinate and review project activities. Meetings will be both face-to-face and teleconference/video conference. The first official meeting will be theface-to-face kick-off meeting, followed by status update meetings on a biweekly/monthly basis, ad hoc teleconferences and site visits, and annual meetings to report on the period of performance activities.

Milestones:

1.2.3.1 Kickoff Meeting with BARDA – The contract is awarded and aface-to face kickoff meeting is conducted within 30 days of award date.

Deliverables:

1.2.3.2 Kickoff Meeting Presentation Materials – Avita will prepare all necessary presentation materials for the kickoff meeting.

1.4 IMS and EVM

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.4.2 Performance Measurement Baseline | Performance Measurement Baseline Review (PMBR) | All required components for the PMBR |
| 1.4.3 Integrated Master Schedule | PMBR | Integrated Master Schedule |
| 1.4.4 Monthly Earned Value Performance Report | Delivery to and acceptance by BARDA | Monthly Earned Value Performance Report |
| 1.4.5 Supplemental monthly CAP report | Delivery to and acceptance by BARDA | Supplemental monthly CAP report |

1.4.2 Title: Performance Measurement Baseline

Objective/Description of Work: The Performance Measurement Baseline will provide a master schedule of deliverables, costs, and milestones in order to completely cover all items in the SOW. All required components will be submitted to BARDA within 90 days of contract award. BARDA and Avita will mutually agree on the budget, schedule and technical plan baselines as a result of the PMBR.

Milestones:

1.4.2 Performance Measurement Baseline Review – The PMBR plan is submitted and reviewed by BARDA.

Deliverables:

1.4.2 Performance Measurement Baseline Review Plan and Required Components – A plan detailing a schedule of deliverables, costs, milestones, and risks that will serve as the basis for measuring project progress.

1.4.3 Title: Integrated Master Schedule (IMS)

Objective/Description of Work: The IMS will be used to monitor performance of the contract. Avita will develop an IMS in a format approved by BARDA in order to track key milestones, Go/No Go decision gates. The IMS will contain baseline start and finish, forecast start and finish, actual start and finish, predecessor and/or successor. Avita will provide a baseline IMS for the PMBR and monthly updates thereafter.

Milestones:

1.4.2 Integrated Master Schedule is approved by BARDA.

Deliverables:

1.4.3 Integrated Master Schedule – Provided for the PMBR and monthly in order to monitor performance of the contract. The IMS shall be provided at the work package level in MS Project file format.

1.4.4 Title: Monthly Earned Value Performance Report

Objective/Description of Work: The Monthly Earned Value Performance Report will be generated from Avita's EVMS in order to track any project variances against the baseline. The report will contain technical, schedule, and cost status information in order to identify any issues that may impact project progress and/or cost.

Milestones:

1.4.4 Monthly Earned Value Performance Report – Delivery to and acceptance by BARDA.

Deliverables:

1.4.4 Monthly Earned Value Performance Report – Provided monthly to track project progress according to WBS and EV variance.

1.4.5 Title: Supplemental Monthly CAP Report

Objective/Description of Work: The Supplemental Monthly CAP Report will be generated from Avita's EVMS and will contain cost information to report on the time phased budget, earned value, and actual costs of work performed. The report will be submitted monthly to BARDA for review.

Milestones:

1.4.5 Supplemental Monthly CAP Report – Delivery to and acceptance by BARDA.

Deliverables:

1.4.5 Supplemental Monthly CAP Report – Provided monthly to detail time phased budget, earned value, and actual costs of work performed as captured by Avita's EVM systems.

## 2 Non-Clinical Objectives

### 2.1 Efficacy and Safety

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 2.1.1.1 Updated training resources for mass casualty | Effective training for mass casualty event. | Updated user training documentation |
| 2.1.2 Biocompatibility review | Biocompatibility review complete | Biocompatibility Review Report |
| 2.1.3 Human Factors | FDA requests human factors studies | Human factors studies submitted to FDA |
| 2.1.4 FDA-compliant design documentation | Completion of backup documentation for PMA module 1. | QSR-mandated design control documents and supporting lab test results |

2.1.1.1 Title: Updated training resources for mass casualty

Objective/Description of Work: Existing training manuals for use of the ReCell device are designed for a clinical/surgical setting by experienced clinicians. Led by the Director of Education, with support from the Education Specialist, Avita will develop a new training protocol sufficient for a mass casualty event for ReCell to be used by minimally trained personnel that may or may not have burn surgery experience. Target goal will be a one-hour training session to personnel at a trained medic level or higher. New training materials will be submitted to BARDA for review/feedback and then finalized.

Milestones:

2.1.1 Creation of training materials, including video, workshop/online course materials, reference guides, as determined in collaboration with BARDA

Deliverables:

2.1.1.1 Training materials as determined in collaboration with BARDA.

2.1.2 Title: Biocompatibility review complete

Objective/Description of Work: Full biocompatibility is demonstrated for EU and Australia, to ISO standards. The testing work needs to be done to US FDA standards. Results of biocompatibility review will be submitted to BARDA for review/feedback.

Milestones:

2.1.2 Biocompatibility submitted to FDA

Deliverables:

2.1.2 Biocompatibility Review Report draft and final report submitted to BARDA and final report submitted to FDA

2.1.3 Title: Human Factors

Objective/Description of Work: Avita will conduct an evaluation to ensure that the ReCell devices meet usability guidelines when used by the intended user population. Avita will conduct all required studies and submit the results to BARDA for review and feedback. Upon BARDA approval, Avita will submit report to FDA.

Milestones:

2.1.3 Requested data/report submitted to FDA

Deliverables:

2.1.3 As requested by FDA, human factors draft and final reports submitted to BARDA and final data and report submitted to FDA

2.1.4 Title: FDA-Compliant Design Documentation

Objective/Description of Work: Avita's recent gap analysis for PMA module 1 readiness indicates that in addition to biocompatibility testing Avita will need to create an FDA QSR-compliant design control document package, including backup lab test data and reports, including packaging testing. Avita will provide the various reports to BARDA, as requested, for review and approval prior to sending to FDA.

Milestones:

2.1.4.1 Functional Testing Complete

2.1.4.2 Packaging/Shipping Testing Complete

2.1.4.3 EMI/EMC Testing Complete

2.2 Non-clinical data sufficient for PMA module 1 of 1

Deliverables:

2.1.4 QSR-mandated design control documents and supporting lab test results – Avita will generate a design control document package that will meet current FDA requirements, in support of PMA module 1 of 1

2.3 Stability and Review of Extended Shelf Life

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 2.3.1 Stability Plan | Expiration limiting components identified and plan developed to extend to 4-year target | Stability Plan |
| 2.3.6 Stability Report (accelerated aging) | Accelerated aging testing results complete | Stability report |
| 2.3.7 Stability report (real- time aging) | Real-time aging testing results complete | Stability report |
| 2.3.8 Review of extended shelf life | New expiry limits determined | Results report submitted to BARDA |
| 2.3.9 Revisions to labeling | Stability extension submission | Shelf life report and revised labeling submitted to FDA |

2.3.1 Title: S0tability Plan

Objective/Description of Work: Avita will develop a stability plan that will outline the testing necessary to extend the shelf life of the ReCell unit to 4 years in order to minimize product losses due to expiry. Avita will focus on specific expiration-limiting components (enzyme and buffer, RPU, and nozzle). Avita will design and execute on a stability testing plan to verify stability for extension of shelf life. Reports will be submitted to BARDA detailing the shelf life of ReCell units. Labeling will be modified based on new expiries and submitted to FDA to approval.

Milestones:

2.3.1 Expiration limiting components are identified and a plan is developed to extend ReCell unit to a target of4-year expiry.

Deliverables:

2.3.1 Stability plan outlining all necessary real-time and accelerated aging testing required to justify expiry.

2.3.6 Title: Stability Report (accelerated aging)

2.3.7

Objective/Description of Work: Following accelerated aging testing, a report will be prepared outlining the product performance. The report will detail whether expiry targets were achieved. If targets were not achieved, a plan will be provided detailing further modifications or a plan for acceptance of a new expiry target. Avita will submit to BARDA for review and comments.

Milestones:

2.3.6 Stability testing results complete.

Deliverables:

2.3.6 Stability report detailing product performance for ReCell components after aging

2.3.7 Title: Stability Report (real-time aging)

Objective/Description of Work: Following real-time aging testing, a report will be prepared outlining the product performance. The report will detail whether expiry targets were achieved. If targets were not achieved, a plan will be provided detailing further modifications or a plan for acceptance of a new expiry target. Avita will submit to BARDA for review and comments.

Milestones:

2.3.7 Stability testing results complete.

Deliverables:

2.3.7 Stability report detailing aged performance for ReCell components

2.3.8 Title: Review of extended shelf life

Objective/Description of Work: Avita will prepare a report for BARDA detailing the changes product shelf life. Avita will report on the plan for accordingly revised product labeling to be submitted to FDA.

Milestones:

2.3.8 Delivery of report of extended shelf life

Deliverables:

2.3.8 Shelf life report delivered to BARDA for review, followed by a report detailing plans for FDA submission, and implications for the VMI.

2.3.9 Title: Revisions to labeling

Objective/Description of Work: Avita will revised the product labeling to reflect new shelf life parameters, and will submit to FDA.

Milestones:

2.3.9 FDA approval of revised product labeling

Deliverables:

2.3.9 New product labeling and FDA submission for review/approval of new product labeling.

**3 Clinical**

3.1 Pivotal Clinical Trials

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.1.1.4 Clinical Study Report | CTP001-5 Clinical Study Report (CSR), review complete | CTP001-5 Clinical Study Report (CSR), review/submit to FDA |
| 3.1.2.6.1 Statistical Analysis (9mo) | Statistical analysis complete | CTP001-6 Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.1.2.6.2 Clinical Study Report (9mo) | CTP001-6 Initial (9-months) CSR complete | CTP001-6 Initial (9-months) CSR, review (PMA module 3 of 3) |
| 3.1.2.6.4 Statistical Analysis (12mo) | Statistical analysis complete | CTP001-6 Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.1.2.6.5 Clinical Study Report (12mo) | CTP001-6 Final (12-months) CSR complete | CTP001-6 Final (12-months) CSR, review |

3.1.2.8 Title: Final CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Pivotal Clinical Trials encompass two ongoing clinical protocols:CTP001-5 (deep partial-thickness) and CTP001-6 (mixed depth including full-thickness). Both studies show definitive closure using less donor skin with ReCell as compared to standard care, and are also looking at long-term scar outcomes. The clinical study report (CSR) from CTP001-6 is the primary component of PMA module 3 of 3. All CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.1.1.1 Last subject last visit forCTP001-5 (complete)

3.1.1.4 Clinical Study Report complete forCTP001-5

3.1.2.1.1 FDA Statistical Analysis Plan submitted and approved by FDA forCTP001-6 (complete)

3.1.2.3.2 Last subject last visit forCTP001-6

3.1.2.6.4 CRO completes 9-month statistical analysis for PMA module 3 of 3.

3.1.2.8 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.1.1.4 CTP001-5 Clinical Study Report (CSR)

3.1.2.6.1 CTP001-6 9-month Tables, Listings & Figures (i.e. Statistical analysis output)

3.1.2.6.2 CTP001-6 Initial (9-months) CSR (for PMA module 3 of 3)

3.1.2.6.4 CTP001-6 12-month Tables, Listings & Figures (i.e. Statistical analysis output)

3.1.2.6.5 CTP001-6 Final (12-months) CSR

**4 Regulatory**

4.1 Pre-Emergency Use Authorization

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 4.1 Pre-Emergency Use Authorization | Avita completes all submissions needed for EUA | All data requested by BARDA to obtain pre-EUA |

4.1 Title: Pre-Emergency Use Authorization

Objective/Description of Work: Avita will support BARDA/HHS in obtaining a Pre-Emergency Use Authorization for the ReCell device. All required studies, reviews, reports, and analyses will be provided as requested.

Milestones:

4.1 Avita completes all submissions needed for EUA

Deliverables:

4.1 Submission to BARDA/HHS of all required materials needed for Pre-EUA.

4.2 Premarket Approval (PMA

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 4.2.2.1.4 Module 1 Submission | Module 1 package assembled | Module 1 package to FDA |
| 4.2.2.2.4 Module 2 Submission | Module 2 package assembled | Module 2 package to FDA |
| 4.2.2.3.4 Module 3 Submission | Module 3 package assembled | Module 3 package to FDA |
| 4.2.2.5.3 Create action plan to address panel recommendations | FDA Panel Meeting | Action Plan |

4.2.2.1.4 Title: Module 1 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package with modular submissions for FDA review and approval. The PMA package will consist of three PMA modules. Module 1 will focus on non-clinical data.

Milestones:

4.2.2.1.4 Module 1 package assembled

Deliverables:

4.2.2.1.4 Module 1 submission to FDA – Module 1 includes biocompatibility, human factors, shipping/packaging validation, EMI/EMC, and all other required non-clinical data.

4.2.2.2.4 Title: Module 2 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package for FDA approval. The PMA package will consist of three PMA modules. Module 2 will focus on manufacturing data.

Milestones:

4.2.2.2.4 Module 2 package assembled

Deliverables:

4.2.2.2.4 Module 2 submission to FDA – Submission will include the principles of operation, quality system and manufacturing documentation, sterilization, shelf-life information, and packaging information.

4.2.2.3.4 Title: Module 3 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package for FDA approval. The PMA package will consist of three PMA modules. Module 3 will focus on clinical data. Module 3 will be submitted to BARDA for review and approval, followed by submission to FDA.

Milestone:

4.2.2.3.4 Module 3 package assembled and approved by BARDA

Deliverables:

4.2.2.3.4 Module 3 submission to FDA – Submission will include theCTP001-6 clinical data labels and manuals, draft post-marketing plan (CoA study protocol) and bibliography.

**5 Product Development for mass casualty/VMI**

5.1 Requirement Gathering, 5.2 Product Design, 5.3 Systems Requirements and Design Review, and 5.4 CDC Quality Agreement

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 5.3 Systems Requirements (VMI optimization) and Design Review | Review of VMI optimized product design package complete | Product optimized for VMI Design Package |
| 5.4 CDC Quality Agreement | Executed CDC Quality Agreement | CDC Quality Agreement |

5.3, 5.4 Title: Systems Requirements (VMI optimization) and Design Review

Objective/Description of Work: In order to develop a product ready for manufacturing and stockpiling, Avita will work with BARDA to first gather the requirements for DFM/DFA, inventory management and any other requirements. Based on the requirements, Avita will initiate Product Design to all ensure the product will meet specifications. This includes design and review for any changed or affected part: Components, Subassembly, Product System, and Packaging Design. Document package will be sent to BARDA for review. Avita will work with CDC to establish a quality agreement, if required.

Milestones:

5.1 Requirements document compiled from BARDA

5.2.1.2 Component Design Review complete

5.2.2.2 Subassembly Design Review complete

5.2.3.2 Product System Design Review complete

5.2.4.2 Packaging Design Review complete

5.3 Full systems requirements and design review complete and approved by BARDA

5.4 If required, establish quality agreement with CDC for supporting VMI

Deliverables:

5.3 System Requirements and Design Review – A system requirements and design review report will be submitted to BARDA containing the requirements and the design changes made to meet those requirements.

5.4 Agreed upon CDC quality agreement for supporting VMI (if required)

5.5 Verification and Validation

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 5.5 Verification and Validation Report | V&V verifies product meets specifications and requirements | V&V Report |

5.5 Title: Verification and Validation Report

Objective/Description of Work: Verification & Validation are used to verify that the product meets the specifications and requirements and address the intended purpose. Verification demonstrates that the product meets specification and Validation demonstrates fitness of use for the intended purpose. Once V&V results are positive, the product is ready to release to manufacturing. Avita will submit a report to BARDA detailing the results of the V&V analysis.

Milestones:

5.5 Testing and analysis indicate that the product meets specification and intended purpose.

Deliverables:

5.5 V&V Report - Avita will submit a report to BARDA detailing the results of the V&V analysis.

6 QSR

6.1 Quality System Preparedness

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 6.1.3 3rd Party Audit | Audit completed | QSR Audit Report |

6.1.3 Title: 3rd Party Audit

Objective/Description of Work: The US FDA Quality System Regulation (QSR) describes the environment under which medical device firms must operate. This task involves preparing the Avita quality systems for FDA review and inspection, and verifying compliance with FDA requirements. Avita hired an external 3rd party auditor to complete a QSR gap analysis. Following the audit a gap assessment was prepared and presented to Avita from the 3rd party auditor. Avita will develop a Gap Corrective Action plan to address any gaps identified. This will support PMA submission. Once the corrective action plan has been implemented and changes are in place a mock audit will be performed by a 3rd party auditor in preparation for an expected FDA inspection during PMA review.

Milestones:

6.1.1 Gap Assessment

6.1.2 Gap corrective action performed and all systems brought into compliance

6.1.3 Mock QSR audit

Deliverables:

6.1.3 QSR 3rd Party Audit Report - Avita will submit a report to BARDA detailing the results of the final QSR audit.

6.2 Commercial Manufacturing

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 6.2.1 Commercialization Plan and Gap Analysis | Completion of commercialization plans | Final Commercialization Plan |
| 6.2.2.4 Validation Report | IQ/OQ/PQ process validations complete | Validation Report |

6.2.1 Title: Commercialization Plan and Gap Analysis

Objective/Description of Work: Perform a gap analysis to assess commercialization readiness and draft a commercialization plan in support of market entry. Tasks include, as necessary, establishing SKU#, Supply chain and vendor qualifications, raw material inventory, sterilization, packaging, and labeling, and lot release.

Milestones:

6.2.1.1 Commercialization Gap Assessment completed

6.2.1.2 Commercialization Plan Draft created, reviewed with BARDA

6.2.1.3 Commercialization Plan finalized.

Deliverables:

6.2.1.1 Commercialization Gap Assessment Report

6.2.1.2 Commercialization Plan draft and final versions reviewed and submitted to BARDA.

6.2.2.4 Title: Validation Report

Objective/Description of Work: Process validation involves the collection and evaluation of data from the processes used to produce the product. Avita's commercial manufacturer will lead the effort in manufacturing, under close supervision and collaboration with Avita. Sterile packaging will be a primary focus of the validation effort to ensure repeatable package integrity and valid sterilization processes. Process validations will include IQ/OQ/PQ and final validation. Avita will present a final report detailing the results of the validation analysis.

Milestones:

6.2.2.1 IQ, Installation Qualification complete

6.2.2.2 OQ, Operation Qualification complete

6.2.2.3 PQ, Process Qualification complete

Deliverables:

6.2.2.4 Validation Report - Avita will submit a report to BARDA detailing the results of the process validation analysis.

**CLIN 0002 – Base Period**

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.1.1.2 Product Manufacturing | Order Received | Initial Product |
| 7.1.1.3 Deploy product to VMI sites | Product shipped to sites | Product deployed |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: Upon authorization from BARDA, Avita will cause the production and delivery of ReCell devices. Upon receiving the order Avita will authorize the manufacturer to procure supplies for the manufacture of the devices and preparing designated inventory locations.

Milestones:

7.1.1.1 Order Received

7.1.1.2 Delivery of specified quantity of units to VMI.

Deliverables:

7.1.1.2 Initial Product – Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices.

7.1.1.3 Product integrated into VMI and available for deployment

7.2 VMI Remote inventory management system

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.2.1 - Gather VMI Requirements | All VMI requirements agreed upon with BARDA | VMI Requirements Document |

7.2.1 Title: Gather VMI Requirements

Objective/Description of Work: Avita will work with USG to identify all VMI requirements, and prepare a document detailing the requirements.

Milestones:

7.2.1 All VMI requirements agreed upon with BARDA

Deliverables:

7.2.1 VMI Requirements Document – Report detailing the agreed upon requirements for VMI.

7.3 Sustainment/Stockpile Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.4.1 Inventory Management | Quarterly inventory reports | Inventory Management Report |

7.3.1 Title: Inventory Management

Objective/Description of Work: Inventory management encompasses activities that occur after the inventory is on site and the inventory system is in operation. The purpose is to ensure ongoing compliance with the stockpiling requirements, and manage replenishment to ensure unit availability in emergency situations. Site environments will continue to be monitored through the lifetime of the contract for compliance with environmental requirements, and inventory controls will be followed. Site performance will be monitored periodically, supplemented by BARDA site visits. Plans will be executed to replenish expiring goods and units will be reworked as needed to maintain currency. Avita will present to BARDA Inventory Management Reports detailing the status and activities at all VMI locations at a frequency determined appropriate by BARDA and Avita.

Milestones:

7.3.1 Quarterly inventory reports

Deliverables:

7.3.1 Inventory Management Report

Summary Table

| CLIN | WBS 1st Level Element | Title | Objectives |
|---|---|---|---|
| **0003** | 3 | CoA Study | • Complete Post-Approval (conditions of approval) study, as required by FDA |
| **0004** | 3, 4 | Pediatric Studies | • Complete pediatric clinical trials per FDA requirements and BARDA guidance |
| **0005** | 7 | Procurement (Surge) | • Execute acquisition contract<br>• Expand VMI as necessary<br>• Manage inventory |

**Overview**

Avita has defined three option periods covering the Conditions of Approval (CoA) study after FDA approval of the ReCell Device (CLIN 0003), a Pediatric study to expand the indications for ReCell for a broader pediatric demographic, if necessary, for ReCell (CLIN 0004), and for the procurement of additional ReCell devices beyond the initial acquisition (CLIN0005). **Note: Updated SOW(s) will be provided to BARDA based on FDA feedback to support the execution of each CLIN**. The accompanying budget(s) will also be updated to align with the revised SOW(s).

The purpose of the CoA, CLIN 0003, is to provide longer-term evaluation of the ReCell device after FDA approval, in order to track and confirm that any post-market commitments are addressed by Avita.

The purpose of the Pediatric Study, CLIN 0004, is to expand the approved range of patients for ReCell, specifically for pediatric patients, beyond those originally approved during the PMA process. The specific study design and objectives will be based on the PMA approval outcomes as well as consultation with BARDA, and will be intended to expand the range of patients able to be treated by ReCell.

Surge acquisition, CLIN 0005, will support additional acquisition of ReCell devices by BARDA, CDC, or other stakeholders.

**CLIN 0003 – Option – CoA Study**

**3 Clinical**

3.3 Post approval (Condition of Approval Stud

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.3.1.2 Submit protocol to BARDA for review | Protocol developed | Study Protocol |
| 3.3.6.1 Statistical analysis | Statistical analysis complete | Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.3.6.2 Clinical study report | CSR complete | CSR, review/submit to FDA |

3.3.6.4 Title: Final CoA CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Post approval (COA study) will be carried out if an additional study is required by FDA as a condition of PMA approval. If a COA study is required, a new clinical study will need to be prepared and approved, including protocol with inclusion and exclusion criteria, endpoints, and IDE application written and submitted, FDA approval of the IDE, local IRB approval, clinical study site agreements, and local ethics approvals. The study protocol and all CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.3.1.1 Protocol developed

3.3.2.2 Last subject last visit

3.3.6.1 CRO completes statistical analysis

3.3.6.2 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.3.1.2 Study Protocol submitted to BARDA

3.3.6.1 Tables, Listings & Figures (i.e. Statistical analysis output)

3.3.6.2 CSR, review/submit to FDA

**CLIN 0004 – Option – Pediatric Study**

**3 Clinical**

3.2 Pediatric Study for Expanded Labeling

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.2.1.2 Submit protocol to BARDA for review | Protocol developed | Study protocol |
| 3.2.6.1 Statistical Analysis | Statistical analysis complete | Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.2.6.2 Clinical Study Report | CSR complete | CSR, review/submit to FDA |

3.2.8 Title: Final Pediatric CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Pediatric study for expanded labeling will be carried out if requested by the BARDA to study younger children. If a pediatric study is required, a new clinical study will need to be prepared and approved, including protocol with inclusion and exclusion criteria, endpoints, and IDE application written and submitted, FDA approval of the IDE, local IRB approval, clinical study site agreements, and local ethics approvals. The study protocol and all CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.2.1.1 Protocol developed

3.2.3.1 Last subject last visit

3.2.6.1 CRO completes statistical analysis

3.2.6.2 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.2.1.2 Clinical Study Protocol

3.2.6.1 Tables, Listings & Figures (i.e. Statistical analysis output)

3.2.6.2 Clinical Study Report (CSR)

**4 Regulatory**

4.2.5 Pediatric Indication

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 4.2.5.1 Pediatric IDE | FDA approval of pediatric IDE | Pediatric IDE application |
| 4.2.5.3 Pediatric PMA supplement | FDA approval of expanded indication for pediatrics | Submission for Pediatric label expansion |

4.2.5 Title: Pediatric Indication

Objective/Description of Work: Avita will make the regulatory filings with FDA for both a pediatric IDE clinical trial and a PMA supplement for expansion of labeling for pediatric indication.

Milestones:

4.2.5.2 FDA approval of pediatric IDE study

4.2.5.4 FDA approval of pediatric indication

Deliverables:

4.1.5.1 Pediatric IDE application.

4.2.5.3 PMA supplement for pediatric indication

**CLIN 0005 – Procurement (Surge)**

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.1.2.2 Product Manufacturing | Order Received | Additional product to meet surge capacity |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: BARDA would authorize the surge procurement order to acquire additional ReCell devices beyond the initial order. Upon receiving the order Avita would authorize the manufacturer to begin acquiring supplies for the manufacture of the additional devices.

Milestones:

7.1.2.1 Order Received

Deliverables:

7.1.2.2 Surge Capacity Product – Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices according to the additional products required to meet surge capacity. Product will be deployed to designated VMI locations.

**ATTACHMENT #2**

**INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS**

**Format**: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

**Number of Copies**: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

**Frequency**: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

**Cost Incurrence Period**: Costs incurred must be within the contract performance period or covered bypre-contract cost provisions.

**Billing of Costs Incurred**: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

**Contractor's Fiscal Year**: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

**Currency**: All BARDA contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

**Costs Requiring Prior Approval**: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

**Invoice/Financing Request Identification**: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice**: The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice**: A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

**Preparation and Itemization of the Invoice/Financing Request**: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address**: Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number**: Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number**: Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared**: Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable)**: Insert the contract number and order number (if applicable).

(f) **Effective Date**: Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order**: Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee**: Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

(i) **Two-Way/Three-Way Match**: Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions**: Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution**: Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period**: Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period**: Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative**: Insert the cumulative amounts claimed by major cost element, including any adjustments andfixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs**: Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor**: Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits**: List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property**: Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS Contractor's Guide for Control of Government Property)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

-Item number for the specific piece of equipment listed in the Property Schedule, and

-COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies**: Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay**: List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee**: List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel**: Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs**: List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other**: Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM)**: Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(q) **Indirect Costs**: Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee**: Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed**: Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments**: Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation**: If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

**ATTACHMENT #3**

**INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS**

General The Contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form l034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form l035, Public Voucher for Purchases and Services Other than Personal—Continuation Sheet, and the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies: As indicated in the contract.

Frequency Invoices submitted in accordance with the Payment Clause shall be submitted monthly upon delivery of goods or services unless otherwise authorized by the Contracting Officer.

Preparation and Itemization of the Invoice The invoice shall be prepared as follows:

(a) Designated Billing Office and address:

HHS/ASPR/BARDA

330 Independence Ave, Room G640

Washington DC 20201

ATTN: Contracting Officer

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.

(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)

(h) Equipment - If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency: Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

**ATTACHMENT #4 - SAMPLE INVOICE FORM**

Company Name

**Designated Billing Office Name and Address:**

DHHS/OS/ASPR/AMCG
Attn: Contracting Officer
200 C St., S.W.

Washington, D.C. 20201

**Contractor's Address and Contact Information:**

POC: Name of accountant or COO or signatory authority for invoice
Title:
Phone:
E-Mail:

**TIN:**
**DUNS #:**

**Invoice/Finance Number:**

**Date Invoice Prepared:**

**Contract No. and Title:**

**Effective Date & Period of Performance:**

**Total Estimated Cost of Order:**

**Office of Acquisitions:**

Contracting Officer (insert name here)
Office of Acquisitions Management, Contracts, and Grants (AMCG)

**Central Point of Distribution:**

This invoice represents reimbursable costs for the period from

| | | Amount Billed | | |
|---|---|---|---|---|
| **Expenditure Category** | | **Current** | **Cumulative** | **Contract** |
| **Direct Costs:** | | | | |
| Direct Labor | | | | |
| Fringe Benefits | **0.00%** | | | |
| **Total Labor Costs:** | | | | |
| **Overhead** | **0.00%** | | | |
| Travel | | | | |
| Subcontracts | | | | |
| Consultant Fees | | | | |
| Materials and Supplies | | | | |
| Other | | | | |
| **Total Direct Costs** | | | | |
| G&A Rate | **0.00%** | | | |
| Subtotal: | | | | |
| Fixed Fee | **0.0** | | | |
| Total Amount Claimed | | | | |
| Adjustments | | | | |
| **Grand Total** | | **$ —** | | |

I Certify that all payments are for appropriate purposes and in accordance with the contract.

_____

Name/signature of signatory authority for invoicing

**ATTACHMENT #5**

**RESEARCH PATIENT CARE COSTS**

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the Contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The Contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

Attachment 6

**REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY**

**CONTRACTOR:**

**ADDRESS:**

ADDRESS1:

ADDRESS2:

CITY:

STATE:

ZIP:

**CONTRACT NUMBER:**

**REPORT DATE:**

**FISCAL YEAR:**

| | **BEGINNING OF PERIOD** | | **ADJUSTMENTS** | | | **END OF PERIOD** | |
|---|---|---|---|---|---|---|---|
| **CLASSIFICATION** | #ITEMS | VALUE | GFP ADDED | CAP ADDED | DELETIONS | #ITEMS | VALUE |
| LAND >=$25K | | | | | | | |
| LAND <$25K | | | | | | | |
| OTHER REAL >=$25K | | | | | | | |
| OTHER REAL <$25K | | | | | | | |
| PROPERTY UNDER CONST >=$25K | | | | | | | |
| PROPERTY UNDER CONST <$25K | | | | | | | |
| PLANT EQUIP >=$25K | | | | | | | |
| PLANT EQUIP <$25K | | | | | | | |
| SPECIAL TOOLING >=$25K | | | | | | | |
| SPECIAL TOOLING <$25K | | | | | | | |
| SPECIAL TEST EQUIP >=$25K | | | | | | | |
| SPECIAL TEST EQUIP <$25K | | | | | | | |
| AGENCY PECULIAR >=$25K | | | | | | | |
| AGENCY PECULIAR <$25K | | | | | | | |
| MATERIAL >=$25K (CUMULATIVE) | | | | | | | |
| PROPERTY UNDER MFR >=$25K | | | | | | | |
| PROPERTY UNDER MFR <$25K | | | | | | | |

**SIGNED BY:**

SIGNATURE _____ DATE SIGNED: _____

NAME PRINTED _____ Email _____

TITLE _____ TELEPHONE _____

Attachment 7

**DISCLOSURE OF LOBBYING ACTIVITIES** **Approved by OMB**

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352 0348-0046

(See reverse for public burden disclosure.)

**1. Type of Federal Action:**
a. contract
b. grant
c. cooperative agreement
d. loan
e. loan guarantee
f. loan insurance

**2. Status of Federal Action:**
a. bid/offer/application
b. initial award
c. post-award

**3. Report Type:**
a. initial filing
b. material change
**For Material Change Only:**
year _____ quarter _____
date of last report _____

**4. Name and Address of Reporting Entity:**
☐ Prime ☐ Subawardee
Tier _____, *if known*:

**Congressional District**, *if known*:

**5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:**

**Congressional District**, *if known*:

**6. Federal Department/Agency:**

**7. Federal Program Name/Description:**

CFDA Number, *if applicable*: _____

**8. Federal Action Number,** *if known***:**

**9. Award Amount,** *if known*:
$ _____

***10.*a. Name and Address of Lobbying Registrant**
(*if individual, last name, first name, MI*):

**b. Individuals Performing Services (***including address if different from No. 10a***)**
**(***last name, first name, MI***):**

**11.** Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____

Print Name: _____

Title: _____

Telephone No.: _____ Date: _____

**Federal Use Only:**

Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

PRINT

**INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES**

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks “Subawardee,” then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., “RFP-DE-90-001.”

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

**Cumulative Inclusion Enrollment Report**

**This report format should NOT be used for collecting data from study participants.**

**Study Title:** _____

**Comments:** _____

| Racial Categories | Ethnic Categories: Not Hispanic or Latino | | | Hispanic or Latino | | | Unknown/Not Reported Ethnicity | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| | Female | Male | Unknown/ Not Reported | Female | Male | Unknown/ Not Reported | Female | Male | Unknown/ Not Reported | |
| American Indian/Alaska Native | | | | | | | | | | |
| Asian | | | | | | | | | | |
| Native Hawaiian or Other Pacific Islander | | | | | | | | | | |
| Black or African American | | | | | | | | | | |
| White | | | | | | | | | | |
| More Than One Race | | | | | | | | | | |
| Unknown or Not Reported | | | | | | | | | | |
| **Total** | | | | | | | | | | |

**Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.**

| **AWARD/CONTRACT** | 1. THIS CONTRACT IS A RATED ORDER. UNDER DPAS (15 CFR 700) | RATING 1 | PAGE OF PAGES I 4 6 |
|---|---|---|---|

| 2. CONTRACT (Proc. Inst. Ident.) NO. | 3. EFFECTIVE DATE | 4. REQUISITION/PURCHASE REQUEST/PROJECT NO. |
|---|---|---|
| HHSO100201500028C | See Block 20C | OS164565 |

| 5. ISSUED BY | CODE ASPR—BARDA | 6. ADMINISTERED BY (If other than Item 5) | CODE ASPR—BARDA |
|---|---|---|---|
| ASPR-BARDA<br>200 Independence Ave., S.W.<br>Room 640-G<br>Washington DC 202016 | | See Block 5 | |

| 7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code) | 8. DELIVERY<br>☐ FOB ORIGIN ☒ In OTHER (See below)9 |
|---|---|
| AVITA MEDICAL AMERICAS, LLC 1476585<br>9221 CORBIN AVE STE 220<br>NORTHRIDGE CA 91324 | 9. DISCOUNT FOR PROMPT PAYMENT |
| CODE 1476585 FACILITY CODE | 10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ▶ ITEM |

| 11. SHIP TO/MARK FOR | CODE HHS/OS/ASPR | 12. PAYMENT WILL BE MADE BY | CODE PSC |
|---|---|---|---|
| HHS/OS/ASPR<br>200 C ST SW<br>WASHINGTON DC 20201 | | PSC<br>Program Support Center<br>5600 Fishers Lane<br>Room 17--21<br>Rockville MD 20852 | |

| 13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: | 14. ACCOUNTING AND APPROPRIATION DATA |
|---|---|
| ☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 253(c) ( ) | 2015.1990002.26201 |

| 15A. ITEM NO | 15B. SUPPLIES/SERVICES | 15C. QUANTITY | 15D. UNIT | 15E. UNIT PRICE | 15F. AMOUNT |
|---|---|---|---|---|---|
| | Continued | | | | |
| | | | | 15G. TOTAL AMOUNT OF CONTRACT ▶ | $16,901,424.00 |

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| (x) | SEC | Description | Page(s) | (x) | SEC | Description | Page(s) |
|---|---|---|---|---|---|---|---|
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**CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18. (SEALED-BID PROCUREMENT) AS APPLICABLE**

17. ☒CONTRACTOR'S AGREEMENT (Contractor is required to sign this document and return ____2____ copies to issuing office. Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents. (a) this award/contract, (b) the solicitation, if any, and (c) such problems, representations, certifications, and specifications as are attached or incorporated by reference herein. *(Attachments are listed herein)*

18. ☐ SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents. (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 10 should be checked only when awarding a sealed-bid contract.)

| 19A NAME AND TITLE OF SIGNE (Type or print) | 20A. NAME OF CONTRACTING OFFICER |
|---|---|
| Timothy Rooney CFO/COO | Brooke Bernold |

| 19B. NAME OF CONTRACTOR | 19C. DATE SIGNED | 20B. UNITED STATES OF AMERICA | 20C. DATE SIGNED |
|---|---|---|---|
| BY<br>/s/ Timothy Rooney<br>*(Signature of person authorized to sign)* | 29 Sep 2015 | BY<br>/s/ Brooke Bernold<br>*(Signature of the Contracting Officer)* | 29 Sept 2015 |

**AUTHORIZED FOR REPRODUCTION**
**Previous edition is NOT usable**

**AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT**

| 1. CONTRACT ID CODE | PAGE OF PAGES | |
|---|---|---|
| N/A | 1 | 3 |

| 2. AMENDMENT/MODIFICATION NO. | 3. EFFECTIVE DATE | 4. REQUISITION/PURCHASE REQ. NO. | 5. PROJECT NO. (*If applicable*) |
|---|---|---|---|
| Modification 01 | See Block 16C | N/A | N/A |

| 6. ISSUED BY | CODE | None | 7. ADMINISTERED BY (*If other then item 6*) | CODE | N/A |
|---|---|---|---|---|---|
| DCHHS/ASPR/AMCG<br>200 C Street, S.W.<br>Washington, DC 20024 | | | See Block 6 | | |

| 8. NAME AND ADDRESS OF CONTRACTOR (*No., street. county. State and ZIP Code*) | | 9A. AMENDMENT OF SOLICITATION NO. |
|---|---|---|
| AVITA MEDICAL AMERICAS, LLC 1476585<br>9221 CORBIN AVE STE 220<br>NORTHRIDGE, CA 91324 | (x) | 9B. DATED (*SEE ITEM 11*) |
| | X | 10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201500028C |
| CODE N/A FACILITY CODE N/A | | 10B. DATED (SEE ITEM 13) 09/29/2015 |

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and dale specified for receipt of Offers ☐ is extended. ☐ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified M the solicitation or as amended by one of the following methods: (a) By completing Items B and 15, and returning _____ copies of the amendment (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate teller or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER If try virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and Is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*) N/A
CAN# N/A

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

| CHECK ONE | |
|---|---|
| | THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| X | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14. PURSUANT TO THE AUTHORITY OF FAR43.103(b). |
| | **C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:** |
| | **D. OTHER (Specify type of modification and authority)** |

**E. IMPORTANT**: Contractor ☐ is not. ☒ is required to sign this document and return 2 copies to the issuing office.

**14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)**

PURPOSE: To add option CLINs 003, 004, and 0005A into PRISM as an administrative modification.

Funds Obligated Prior to this Modification: $16,901,424
Funds Obligated with mod #04: $0
Total Funds Obligated to Date: $16,901,424
PSC Code: 6505

Expiration date: September 28, 2020 (Unchanged)

**Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged arid in lull farce and affect.**

| 15A. NAME AND TITLE OF SIGNER (Type or print) | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) |
|---|---|
| Timothy Rooney, CFO/COO | Brooke Bernold |

| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
|---|---|---|---|
| *(Signature of person authorized to sign)* | 5 Oct 2015 | *(Signature of Contracting Officer)* | 10/7/15 |



NAME OF OFFEROR OR CONTRACTOR

AVITA MEDICAL AMERICAS, LLC 1476585

| ITEM NO. (A) | SUPPLIES/SERVICES (B) | QUANTITY (C) | UNIT (D) | UNIT PRICE (E) | AMOUNT (F) |
|---|---|---|---|---|---|
| | Tax ID Number: 20-2578762<br>DUNS Number: 026723570<br>Autograft-Sparing Products for Definitive Care of Burn Injuries<br>Appr. Yr.: 2015 CAN: 1990002 Object Class: 26201<br>FOB: Destination<br>Period of Performance: [**]/2015 to [**]/2020 | | | | |
| 1 | ASPR-15-08829 — CLIN 0001 Advanced Development Studies for Licensure Approval of ReCell<br>POP: [**]/2015 – [**]/2020<br>Obligated Amount: [**] | | | | [**] |
| 2 | ASPR-15-08829 — CLIN 0002 Initial Purchase, Storage, and Delivery of ReCell Devices<br>POP: [**]/2015 – [**]/2020<br>Obligated Amount: [**] | | | | [**] |

NAME OF OFFEROR OR CONTRACTOR

AVITA MEDICAL AMERICAS, LLC 1476585

| ITEM NO. (A) | SUPPLIES/SERVICES (B) | QUANTITY (C) | UNIT (D) | UNIT PRICE (E) | AMOUNT (F) |
|---|---|---|---|---|---|
| | Add Item 3 as follows: | | | | |
| 3 | CLIN 0003 Phase IV post marketing Commitments/Requirements<br>Amount: [**] (Option Line Item) | | | | 0.00 |
| | Add Item 4 as follows: | | | | |
| 4 | CLIN 0004 Pediatric Study<br>Amount: [**] (Option Line Item) | | | | 0.00 |
| | Add Item 5 as follows: | | | | |
| 5 | CLIN 0005A Additional Surge Capacity Less Than [**] Units<br>Amount: [**] (Option Line Item) | | | | 0.00 |
| | Add Item 6 as follows: | | | | |
| 6 | CLIN 0005A Additional Surge Capacity [**] Units<br>Amount: [**] (Option Line Item) | | | | 0.00 |
| | Add Item 7 as follows: | | | | |
| 7 | CLIN 0005A Additional Surge Capacity [**] Units<br>Amount: [**] (Option Line Item) | | | | 0.00 |
| | Add Item 8 as follows: | | | | |
| 8 | CLIN 0005A Additional Surge Capacity [**] Units<br>Amount: [**] (Option Line Item) | | | | 0.00 |

**PART I – THE SCHEDULE**

**SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS**

**ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

Avita Medical is developing ReCell, a unique technology that enables clinicians to use a small sample of your skin to restore healthy, normal skin when treating partial thickness or full thickness burns. The product has the potential to greatly improve the patient's quality of life while reducing hospital stays and the need for reconstructive surgery. This product could find utility in day-to-day care, while simultaneously improving our capability to respond to mass casualty incidents.

Under the base period-of-performance, Avita Medical will further enhance their product to improve its commercial viability through the FDA approval process and potentially complete an initial purchase, storage, and delivery of product. The contract options may be exercised to perform follow-on studies as directed by the FDA, perform additional studies which further extend the ability to protect children and the elderly population, and purchase additional treatment courses.

The Research and Development (R&D) effort will progress in specific stages that cover the base performance segment and several options as specified in this contract. The period of performance for the base period is 60 months.

**ARTICLE B.2. BASE PERIOD**

| CLIN | Period of Performance | Supplies/ Services | Total Est. Cost | Fixed Fee (7%) | Total Cost Plus Fixed Fee |
|---|---|---|---|---|---|
| | | **COST REIMBURSEMENT** | | | |
| 0001 (Base) | [**]/2015 – [**]/2020 | Licensure, approval, and clearance of product through the FDA | [**] | [**] | [**] |
| | | **FIRM FIXED PRICE** | | | |
| **CLIN** | **Period of Performance** | **Supplies/ Services** | **Units (# of Product)** | **Unit Price ($)** | **Total ($)** |
| 0002 | [**]/2015 – [**]/2020 | Initial Purchase, storage, and delivery of product | [**] | [**] | [**] |
| **Total CLINS 1&2** | **[**]/2015 – [**]/2020** | **See Above Descriptions** | | | **[**]** |

**ARTICLE B.3. OPTION PRICES**

| CLIN | Period of Performance | Supplies/ Services | Units (# of Product) | Unit Price ($) | Total ($) |
|---|---|---|---|---|---|
| | | **FIRM FIXED PRICE** | | | |
| 0003 (Option Quantity) | 36 Months | Phase IV post marketing commitments /Requirements (This is an option that may or may not be exercised during the base period as determined by the need and as established by the FDA) | N/A | N/A | [**] |
| | | **COST REIMBURSEMENT** | | | |
| 0004 (Option Quantity) | 60 Months | Pediatric Study (This is an option that may or may not be exercised during the base period for expansion of the label indication with guidance from the FDA) | [**] | [**] | [**] |
| | | **FIRM FIXED PRICE** | | | |
| 0005A (Option Quantity) | 36 Months | Additional Surge Capacity | Less than [**] | [**] | [**] |
| 0005A (Option Quantity) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0005A (Option Quantity) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0005A (Option Quantity) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| **Total CLINs 3-5** | **60 Months** | **See Above Descriptions** | | | **[**]** |

**ARTICLE B.4. LIMITATIONS APPLICABLE TO DIRECT COSTS**

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clause FAR 52.216-7, Allowable Cost and Payment, incorporated in this contract, the costs of the following items or activities shall be unallowable as direct costs unless authorized in writing in advance by the Contracting Officer:

1. Acquisition, by purchase or lease, of any interest in real property;

2. Special rearrangement or alteration of facilities;

3. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

4. Travel to attend general scientific meetings;

5. Unapproved foreign travel;

6. Consultant costs;

7. Subcontracts;

8. Patient care costs;

9. Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined as items of personal property, supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value.

10. Printing Costs (as defined in the Government Printing and Binding Regulations).

11. Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meeting, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

12. Meeting room or conference space used for face to face meetings with USG staff in the performance of this contract. Justification for why the meeting cannot be held at a government facility must be provided. COA requests must be made at least (2) two weeks prior to meeting date.

b. Travel Costs

1. Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred by the Prime Contractor in direct performance of this contract shall not exceed **[**]** without prior advance written approval by the Contracting Officer. Costs must be consistent with FAR 52.247-63 – Preference for U.S.-Flag Air Carriers.

2. The Contactor shall invoice and be reimbursed for all travel costs in accordance with FAR 31.703 and FAR31.205-46, Contracts with Commercial Organizations, Travel Costs.

3. Requests for foreign travel must be submitted at least six weeks in advance and shall contain the following:

(i) Meeting(s) and place(s) to be visited, with costs and dates;

(ii) Names(s) and title(s) of Contractor personnel to travel and their functions in the contract project;

(iii) Contract purpose to be served by the travel;

(iv) How travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of AMCG contract funds;

(v) How such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and

(vi) What additional functions may be performed by the travelers to accomplish other purpose of the contact and thus further benefit the project.

**ARTICLE B.5. ADVANCE UNDERSTANDINGS**

a. Subcontracts and Consultants

Award of **any FFP subcontract or FFP consulting agreement in excess of $150,000 or any cost reimbursement subcontract or consulting agreement** shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter. COA letters will only be issued upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer within ten (10) days.

b. **Site Visits, Inspections and General Audits**

At the discretion of the USG and independent of activities conducted by the Contractor, with 48 hours' notice to the Contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis, including collection of product samples and intermediates held by the Contractor, or subcontractor. In case of subcontractor visits and inspections that are independent of activities conducted by the Contractor, the USG shall demonstrate cause for such visit and/or inspection. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs. The Contractor shall coordinate these visits and shall have the opportunity to accompany the USG on any such visits. Under time-sensitive or critical situations, the USG reserves the right to suspend the 48 hour notice to the Contractor.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance.

- If issues are identified during the audit, Contractor shall submit an issues report to the CO and COR within 10 business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the issues report and provide a response to the Contractor within 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR within a time frame negotiated with the COR in writing after review of the issues report.

c. QA Audits

BARDA reserves the right to participate in QA audits performed by the Contractor. Upon completion of the QA audit the Contractor shall provide a report capturing the findings, results, and next steps in proceeding with any potential subcontractors. If action is requested for a subcontractor, detailed corrective and preventative plans for addressing areas of non-conformance to ICH and FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA for review and acceptance. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within 5 business days of report completion. The Contractor shall complete the report within 60 days of the audit/site visit, or as negotiated with the COR in writing dependent upon the audit findings.

d. **Man-in-Plant**

At the discretion of the Government and seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's facility, who shall be subject to the Contractor's policies and procedures regarding security and facility access at all times while in the Contractor's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor plant.

e. **Confidential Treatment of Sensitive Information**

The Contractor shall, to the extent permitted by law, guarantee strict confidentiality of the information/data that is provided by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

Notwithstanding the foregoing, such information/data shall not be deemed of a sensitive nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the Government that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/data belonging to the Government.

The Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction (b) otherwise required by law, (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information/data

f. **Emergency Use Authorization (EUA)**

The Contractor shall be responsible for generating the data to support the USG's filing of aPre-Emergency Use Authorization (Pre-EUA) package for use of the product prior to FDA licensure or approval during a declared emergency, declared potential emergency, or identification of material threat under an Emergency Use Authorization (EUA).

The Contractor commits to supporting the potential use of the product under apre-EUA package as submitted by BARDA or the CDC/SNS. The Contractor shall supply BARDA or the CDC/SNS with the data needed to support such a submission, including expanded access INDs, right to hold product, right of reference to the Contractor's Investigational New Drug (IND), or other application that contains the supporting data. The Contractor shall address any FDA comments on all pre-EUA packages as applicable. The Contractor shall maintain and update, as required by the FDA, all required regulatory documentation (investigator brochure, regulatory binder, etc.), that will be used to support use under EUA and approval/licensure.

Any product which has not received FDA approval or licensure, but has completed submission of thePre-EUA package and has met the three (3) criteria listed below may be considered for procurement at the discretion of the USG. The Contractor would be required to demonstrate the three (3) essential criteria listed below for consideration of procurement of any unapproved products by seeking a COA. The COA shall include a product delivery schedule for consideration and documentation of the following:

- Substantial evidence, including a validated process, of the Contractor's ability to manufacture a product that would be identical to the commercial scale as required for product approval or licensure. A clear understanding of the outstanding risks, if any, for approval or licensure must be demonstrated through a risk register.
- Completion of pivotal clinical studies with substantial evidence of safety and efficacy for the indicated use. A list of outstanding activities and targets for completion, adverse events/safety profile which do not pose unusual risks or challenges for FDA approval or licensure shall be provided.
- Substantial evidence of product familiarity/acceptance for use in burn centers. The Contractor shall provide a list of burn centers familiar with the product, feedback received, and corrective actions required to address any concerns to ensure effective use of the product by burn care providers unfamiliar with the product. Evidence of the company's ability to educate such providers on the use of the product (as allowed within the constraints of law) will be useful.

A tentative delivery schedule of product delivery to the inventory (acceptable as in the Quality Agreement) shall be required as part of the COA. The delivery schedule shall be updated periodically as necessary.

For information concerning EUA, please consult
http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127 and
http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/
MCMLegalRegulatoryandPolicyFramework/ucm182568.htm

g. **Sharing of contract deliverables within United States Government (USG)**

In an effort to build a robust medical countermeasure pipeline through increased collaboration, BARDA may share technical deliverables with USG entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio's Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense and the National Institutes of Health, BARDA may share technical deliverables and data created in the performance of this contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize BARDA to share financial information outside HHS. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the Government's rights to deliverables submitted during performance as well as the Government's rights to data contained within those deliverables.

h. **Overtime Compensation**

No overtime (premium) compensation is authorized under the subject contract. Billing of actual hours should be limited to total productive hours in a month.

i. **Option CLINS**

The USG reserves the right to re-negotiate the option CLINS based availability of funds and feedback received from the FDA.

j. **Contract Number Designation**

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of the contract as follows:

HHSO100201500028C

**h. Quality Agreement**

The Quality Agreement shall define, establish, and document the responsibilities of both the Contractor and the USG (i.e. –CDC/SNS-Quality Control and BARDA) for event-driven and product shipping, receiving, acceptance into the inventory and/or custody by the USG. These documents shall be drafted, approved, and signed by all parties prior to the commencement of product procurement and acceptance, transport and custody of the product under the VMI/DMI or the CDC/SNS. The Contractor shall provide documentation and resolution for all concerns raised by USG and commits to cooperation in execution of this agreement.

## SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

### ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated [**], 2015 set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

### ARTICLE C.2. REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

All reports required herein shall be submitted in electronic format. All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

### ARTICLE C.3. TWICE MONTHLY CONFERENCE CALLS

A conference call between the Contracting Officer's Representative (COR) and the Contractor's Project Leaders/delegates and designees shall occur twice-monthly or as directed by the Contracting Officer and Contracting Officer's Representative. During this call the Contractor's Project Leaders/delegates and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leaders/delegates may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative.

### ARTICLE C.4. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings with AMCG/BARDA in Washington, D.C. and at work sites of the Contractor. Such meetings may include, but are not limited to, meetings of the Contractor to discuss study designs, site visits to the Contractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the data rights provisions in this contract, the Contractor will provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Contracting Officer and Contracting Officer's Representative in order to facilitate review of contract activities.

**SECTION D – PACKAGING, MARKING AND SHIPPING**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the date, contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

**SECTION E – INSPECTION AND ACCEPTANCE**

The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this contract.

For the purpose of this SECTION E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance. The Contractor is advised to review FAR 52.243-1 Changes – Fixed Price Contracts Alternate V and FAR 52.243-2 Changes-Cost reimbursement contracts Alternative V, which is incorporated by reference into this contract in ARTICLE I.1.

Inspection and acceptance will be performed at:

Office of Acquisition Management, Contracts, and Grants (AMCG)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 C St. SW
Washington, D.C. 20024

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

The contract incorporates the following clause by reference with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

**FAR 52.246-4, Inspection of Services - Fixed Price (August 1996)**

**FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)**

**FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984)**

**FAR 52.246-16, Responsibility for Supplies (April 1984)**

**SECTION F – DELIVERIES OR PERFORMANCE**

**ARTICLE F.1. PERIOD OF PERFORMANCE**

The period of performance for this contract shall be from [**], 2015 through [**], 2020. The period of performance for the base period of this contract shall be consistent with the dates set forth in SECTION B. If the Government exercises option(s), the period of performance will be extended as described under in SECTION B of this contract.

**ARTICLE F.2. REPORTING REQUIREMENTS**

In all cases the reports are intended to provide sufficient detail to understand the Contractor's approach and progress to addressing the technical requirements. The reports supplement, and do NOT replace, routine (i.e. daily) communication between the COR and project manager and/or their designee(s) regarding project plans and progress.

**A. Monthly Progress Report**

This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort.

SECTION II Part A: SUMMARY - A description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall include a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes). Please include all Quality Management System, Quality Control, and Quality Assurance updates as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall document the results of work completed and costs incurred during the period covered in relation to the proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES – This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as a rolling three (3) month forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT — This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

Invoices: Summary of any invoices submitted during the reporting period.

A Monthly Progress Report will not be required in the same months that Annual or Final Technical Progress Reports are due.

**B. Annual Progress Report**

This report shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The Contractor shall submit an Annual Progress Report on or before the 30th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort.

SECTION II Part A: SUMMARY - A description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE — This section shall include a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes). Please include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS — This section shall document the results of work completed and costs incurred during the period covered in relation to proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES — This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK — This section shall include a summary of work proposed as an annual forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT — This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

Invoices: Summary of any invoices submitted during the reporting period.

An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due.

**C. Draft Final Report and Final Report**

These reports are to include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Progress Report shall be due forty-five (45) calendar days prior to the expiration date of the contract and the Final Progress Report is due no later than 30 calendar days following the expiration date of the contract. The report shall conform to the following format:

Title Page: The title for these reports shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

SECTION II: RESULTS - A detailed description of the work performed and the results obtained including all expenses for the entire contract period of performance.

**D. FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions.**

a. Within five business days of any formal meeting with the FDA or other regulatory agency, the Contractor shall provide a formal contact report to BARDA. The Contractor shall forward the final minutes when available.

b. Within five business days of any informal meeting with the FDA or other regulatory agency, the Contractor shall forward the initial draft minutes to BARDA. The Contractor shall forward the final minutes when available and if applicable.

c. The Contractor shall forward the dates and times of any formal meeting with the FDA and other regulatory agencies to BARDA as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings.

d. The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Contractor shall provide BARDA with five (5) business days in which to review and provide comments back to the Contractor prior to the Contractor's submission to the FDA.

e. The Contractor shall forward Standard Operating Procedures (SOPs) upon request from COR.

f. The Contractor shall provide raw data and/or specific analysis of data generated with USG funds upon request from the COR.

g. The Contractor shall notify the Contracting Officer's Representative and Contracting Officer within 24 hours of all site visits/audits conducted by the FDA or any other regulatory agency. The Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the Contracting Officer's Representative and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

**E. Other Requirements/Deliverables**

a. **Integrated Master Project Plan**

The Contractor shall provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to annual deliverables and Work Breakdown Structure (WBS) elements. Attention shall be placed on providing sufficient turnaround time for the USG (BARDA, FDA, and CDC) for review of critical documentation. The Contractor shall integrate to

demonstrate interdependencies among all CLINS. The Integrated Master Project Plan shall be incorporated into any potential contract and will be used to monitor performance of the contract. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

**i. Critical Path Milestones**

The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

**ii. Work Breakdown Structure**

The USG has provided a Contract Work Breakdown Structure (CWBS) template (See http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx) and the Contractor shall further delineate the CWBS to Level 5 as part of their Integrated Master Project Plan. The WBS shall be discernable and consistent. BARDA may require Contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

**iii. Risk Mitigation Plan/Matrix**

The Contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. The USG has provided a Risk Mitigation Matrix template (See **http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx)** to be completed by any prospective Contractor. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR or Alternate COR.

b. **Technology Packages**

Technology packages developed under the contract that includes complete protocols must be submitted at the request of the BARDA Contracting Officer's Representative. See FAR clauses 52.227-11, Patent Rights-Ownership by the Contractor, and 52.227-14, Rights in Data. This report shall be due upon request from the COR or Alternate COR.

c. **Experimental Protocols**

The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for BARDA approval or upon request by the COR or Alternate COR when required.

d. **Annual/Final Invention Report**

All reports and documentation required by FAR Clause52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. An Annual Invention Report shall be due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report (see FAR 27.303 (b)(2)(ii)) shall be due on or before the expiration date of the contract. If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer.

e. **Publications**

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission. Reports of final submission for publication shall be due within 30 calendar days for manuscripts and 15 calendar days for abstracts.

f. **Press Releases**

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the Contracting Officer has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.

g. **Incident Security Report**

The Contractor shall report to the government any activity; or incident that is in violation of established security standards; or indicates the loss or theft of government products. Reports shall be due within 24 hours after occurrence of an activity or incident.

i. **Security Plan**

The Contractor shall submit a draft security plan within 90 days of contract award. A detailed security plan with any updates shall be submitted for approval at least three (3) months prior to the initiation of product procurement with proper documentation. The Contractor shall cooperate with USG representatives to develop a sustainable security plan to ensure continued security of the premises. Security plan updates are required when an incident security report has been filed.

j. **Quality Management System (QMS) Plan**

The Contractor shall provide a QMS plan within 90 days of contract award with updates at least three (3) months prior to initiation of product procurement and as directed by the COR or Alternate COR. The Contractor agrees to incorporate USG feedback and address concerns relating to QMS plans.

k. **Quality Agreement**

The Quality Agreement shall define, establish, and document the responsibilities of both the Contractor and the USG (i.e. – CDC/SNS-Quality Control and BARDA) for event-driven and product shipping, receiving, acceptance into the inventory and/or custody by the USG. These documents shall be drafted, approved, and signed by all parties prior to the commencement of product procurement and acceptance, transport and custody of the product under the VMI/DMI or the CDC/SNS. The Contractor shall provide documentation and resolution for all concerns raised by USG and commits to cooperation in execution of this agreement. Quality Agreement is due at least three (3) months prior to initiation of product procurement or as directed by the COR or Alternate COR.

l. Vendor Managed Inventory (VMI) Plan

The Contractor shall develop a plan to establish VMI in alignment with the Quality Agreement Report. Interim draft plans shall be submitted to USG as part of the development process. Draft submission for review is due upon completion of pre-EUA package. Final submission is required to initiate product procurement through a COA. Documents shall be updated as required by the COR or Co-COR. Developmental updates should be reported in the monthly reports as requested by the COR or Alternate COR.

A minimum of three (3) product deliveries from different manufacturing lots shall be delivered and accepted by USG to the inventory (considered as substantial delivery to the inventory) before the Contractor shall invoice for the product payment.

**F. Earned Value Management System Plan**

a. **Earned Value Management System Plan:**

Subject to the requirements under HHSAR Clause 352.234-3, the Contractor shall use principles of Earned Value Management System (EVMS) in the management of this contract (include this plan as part of the monthly, annual, and final reports). The Seven Principles are:

i. Plan all work scope for the program to completion.

ii. Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.

iii. Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control changes to the baseline.

iv. Use actual cost incurred and recorded in accomplishing the work performed.

v. Objectively assess accomplishments at the work performance level.

vi. Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.

vii. Use earned value information in the company's management processes.

viii. Elements of EVMS shall be applied to all CLINs as part of the Integrated Master Project Plan, the Contractor shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements.

**b. Performance Measurement Baseline Review (PMBR):**

The Contractor shall submit a PMBR plan electronically via email to the CO and COR for a PMBR to occur within 90 days of contract award. At the PMBR, the Contractor and BARDA shall mutually agree upon the budget, schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. **The goals of the PMBR are as FOLLOWS**:

i. Jointly assess areas such as the Contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks.

ii. Confirm the integrity of the Performance Measurement Baseline (PMB).

iii. Foster the use of EVM as a means of communication.

iv. Provide confidence in the validity of Contractor reporting

v. Identify risks associated with the PMB.

vi. Present any revised PMBs for approval.

vii. Present an Integrated Master Schedule: The Contractor shall deliver an initial program level Integrated Master Schedule (IMS) that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR. DI-MGMT-81650 may be referenced as guidance in creation of the IMS (see http://www.acq.osd.mil/pm/).

viii. Present the Risk Management Plan.

c. **Integrated Master Schedule**

The Contractor shall submit an IMS electronically via email as outlined in a format agreed upon by BARDA to the COR and the Contracting Officer for approval prior to the initiation of any activities of sufficient size and cost to require EVMS. The Integrated Master Schedule shall be incorporated into the contract, and shall be used to monitor performance of the contract. The Contractor shall include the key milestones and Go/No Go decision gates. The Contractor shall include BARDA Portfolio Management Milestones (See the AMCG Business Toolkit for a description and sample (http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx) in their IMS and provide monthly updates within their IMS. This IMS shall include the following fields at a minimum; baseline start and finish, forecast start and finish, actual start and finish, predecessor and/or successor. The Contractor shall deliver the Integrated Master Schedule, viewed at the work package level in MS Project file format.

d. **Earned Value Contract Performance Report (EV-CPR)**

a. The Offeror shall deliver an Earned Value Contract Performance Report (CPR) on a monthly basis per the instruction in DI-MGMT-81466A (see http://www.acq.osd.mil/pm/). The Contractor shall provide Format 1, Format 3, and Format 5 only. Format 1 will be reported at the Work Breakdown Structure level agreed to by BARDA and the Contractor.

b. EV Variance thresholds will be negotiated with the Contractor post-award but for planning purposes will likely be (+/- 10%). In conjunction with the CPR, the Contractor shall provide a monthly update to the IMS with up to date performance data and shall include actual start/finish and projected start / finish dates.

c. The supplemental monthly CAP report shall contain, at the work package level, time phased budget (budgeted cost of work scheduled (BCWS)), earned value (budgeted cost of work performed (BCWP)), and actual costs of work performed (ACWP) as captured in the Contractor's EVM systems.

d. The Contractor and BARDA shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the COR. Such meetings may include, but are not limited to, site visits to the Contractor's and/or subcontractor's facilities, meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel and Government-contracted subject matter experts as required by the BARDA COR in order to facilitate review of contract activities.

e. The Contractor shall provide a list of individuals to serve as primary and secondary points of contact who will be available 24 hours a day, seven days a week, to be notified in case of a public health emergency.

**ARTICLE F.3. DELIVERIES**

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work dated September 29, 2015 set forth in SECTION J - List of Attachments of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule below:

| Item No. | Description | Addresses | Deliverable Schedule |
|---|---|---|---|
| 1 | Monthly Progress Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Reports are due on or before the 15th of each month following the end of each reporting period. |
| 2 | Annual Progress Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Reports are due on or before the 30th calendar day following the end of each reporting period. |
| 3 | Draft Final Progress Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Report is due 45 Calendar days prior to the expiration date of the contract. |
| 4 | Final Progress Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Report is due no later than 30 calendar days after the expiration date of the contract. |
| 5 | FDA/ Regulatory Agency Correspondence and Meeting Summaries | COR: (1) electronic copy | Reports are due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes from FDA/regulatory agency, and upon request from the COR or Alternate COR. |
| 6 | Integrated Master Project Plan<br>- Critical Path Milestones<br>- Work Breakdown Structure<br>- Risk Mitigation Plan/Matrix | COR: (1) electronic copy | Report is due within 90 days of contract award. Updates are due as requested by the COR or Alternate COR. |
| 7 | Technology Packages | COR: (1) electronic copy | Upon request from the COR or Alternate COR. |
| 8 | Experimental Protocols for non- clinical animal studies or clinical studies | COR: (1) electronic copy | Upon request from the COR or Alternate COR. Written approval from the COR or Alternate COR is required prior to the execution of the study. |

| Item No. | Description | Addresses | Deliverable Schedule |
|---|---|---|---|
| 9 | Annual/Final Invention Report | CO: (1) electronic copy<br>COR: (1) electronic copy | An Annual Invention Report is due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report is due on or before the expiration date of the contract. |
| 10 | Publications | COR: (1) electronic copy | Reports are due within 10 business days for manuscripts and 5 business days for abstracts. |
| 11 | Press Releases | COR: (1) electronic copy | Reports/Notices are due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release. |
| 12 | Incident Security Report | CO: (1) electronic copy<br>COR: (1) electronic copy | Reports are due within 24 hours after occurrence of an activity or incident. |
| 13 | Security Plan | CO: (1) electronic copy<br>COR: (1) electronic copy | Draft report is due within 90 days of contract award. Updates are due at least 3 months prior to product procurement or as requested by the COR or Alternate COR. |
| 14 | Quality Management System (QMS) Plan | COR: (1) electronic copy | Draft report is due within 90 days of contract award. Updates are due at least 3 months prior to product procurement or as requested by the COR or Alternate COR. |
| 15 | Quality Agreement | COR: (1) electronic copy | Agreement is due at least 3 months prior to product procurement or as directed by the COR or Alternate COR. |
| 16 | VMI Plan | CO: (1) electronic copy<br>COR: (1) electronic copy | Plan is due upon completion of the Pre-EAU package. |
| 17 | Earned Value Management Requirements | CO: (1) electronic copy<br>COR: (1) electronic copy | Agreement is due at least 3 months prior to product procurement or as directed by the COR or Alternate COR. |

Email Addresses: CO – [**]
COR – [**]

**ARTICLE F.4. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)**

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/far.

**FAR 52.242-15, Stop Work Order (August 1989)**

**FAR 52.242-15, Alternate 1 (April 1984) is applicable to this contract.**

## SECTION G - CONTRACT ADMINISTRATION DATA

### ARTICLE G.1. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Christopher Scott, CO
DHHS/OS/ASPR/AMCG
200 C St.
Washington, D.C. 20024

a. The Contracting Officer (CO) is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the CO can make any changes to the terms, conditions, general provisions, specifications or other requirements of this contract.

b. The Contracting Officer (CO) is the only person with authority to act as agent of the Government under this contract. Only the CO has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

c. No information, other than that which may be contained in an authorized modification to this contract duly issued by the CO, shall be considered grounds for deviation from this contract.

d. The Government may unilaterally change its CO designation.

### ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

[**]
Contracting Officer's Representative
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
[**]
[**]

Mailing Address:
200 C St.
Washington, D.C. 20024

Alternate COR:

[**]
Alternate Contracting Officer's Representative (COR)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
[**]
[**]

Mailing Address:
330 Independence Avenue, SW
Washington, D.C. 20201

The COR is responsible for:

a. Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;

b. Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;

c. Performing technical evaluation as required;

d. Performing technical inspections and assisting the Contracting Officer in acceptances of deliverables required by this contract; and

e. Assisting in the resolution of technical problems encountered during performance.

f. The Government may unilaterally change its COR designation(s).

**ARTICLE G.3. KEY PERSONNEL**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individuals are considered to be essential to the work being performed hereunder:

| Name | Title |
|---|---|
| [**] | [**] |
| [**] | [**] |
| [**] | [**] |
| [**] | [**] |

**ARTICLE G.4. INVOICE SUBMISSION**

a. The Contractor shall submit an electronic copy of contract monthly invoices/financial reports to the Contracting Officer as defined above, in ARTICLE G of this contract.

b. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests made a part of the contract at Section J, Attachments 2 & 3.

c. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

d. The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base period or any options for additional quantities (See estimated costs under Articles B.2 and B.3) and the reasons for the variance. Also refer to the requirements of FAR Clause 52.232-20, Limitation of Cost.

e. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

f. All invoice submissions shall be in accordance with FAR Clause52.232-25, Prompt Payment.

**ARTICLE G.5. INDIRECT COST RATES**

1) The following interim provisional indirect rates will be utilized for billing purposes during the period of performance: Fringe benefits at [**], and Overhead (G&A) at [**]. Final rate proposals must be sent to the Contracting Officer, within 6 months of the fiscal year end. See FAR Clause 52.216-7, Allowable Cost and Payment.

**ARTICLE G.6. REIMBURSEMENT OF COST**

1) The Government shall reimburse the Contractor those costs determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR 52.216-7, Allowable Cost and Payment and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

   a) All direct materials and supplies that are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.

   b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

   c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

i. Air travel shall be by the most direct route using “air coach” or “air tourist” (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

ii. Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

iii. Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

iv. Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

**ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

1. **Contractor Performance Evaluations**

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) will be prepared Annually as to coincide with the Anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

2. **Electronic Access to Contractor Performance Evaluations**

Contractors may access evaluations through a secure website for review and comment at the following:

http://cpars.gov

**ARTICLE G.8. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)**

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number HHSO100201500028C from Page 1 of the contract.

**ARTICLE G.9. GOVERNMENT PROPERTY**

1. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

   http://www.hhs.gov/hhsmanuals/ (HHS Logistics Management Manual)

   Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

2. Notwithstanding the provisions outlined in the HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated in this contract in paragraph 1. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

3. Title will vest in the Government for equipment purchased as a direct cost.

**SECTION H - Special Contract Requirements**

**ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)**

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Human Subject Assurances.

**ARTICLE H.2. CLINICAL RESEARCH**

These Clinical Terms apply to all contracts that involve clinical research.

The Government shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by the Government under this contract, as defined in Rights in Data Clause in FAR 52.227-14. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form, to ensure the Government has the ability to review and distribute the deliverables, as the Government deems necessary.

**H.2.1 Safety and Monitoring Issues**

Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval

Before award and then with Annual Progress Reports, the Contractor shall submit to the Government a copy of the current IRB or IEC approved informed consent document, documentation of continuing review and approval and the Office of Human Research Protections (OHRP) FWA number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide the Government initial and annual documentation of continuing review and approval, including the current approved informed consent document and FWA number.

The grantee institution must ensure that the applications as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the Government a summary explanation and copies of documents related to all major changes in the status of ongoing protocols, including the following:

1. All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
2. All changes in informed consent documents, identified by version number, date, or both and dates it is valid.
3. Termination or temporary suspension of patient accrual.
4. Termination or temporary suspension of the protocol.
5. Any change in IRB approval.
6. Any other problems or issues that could affect the participants in the studies.

Contractors must notify BARDA through the Contracting Officer's Representative (COR) and Contracting Officer (CO) of any of the above changes within 24 hours from the time the Contractor becomes aware of the change by email, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an Institutional Bio-safety Committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

**H.2.2. Data and Safety Monitoring Requirements**

The Contractor may be required to conduct independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trials of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform the Government of any upcoming site visits and/or audits of Contractor facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of Contractors and Subcontractors as the Government deems necessary. The type of monitoring to be used shall be mutually agreed upon between the Contractor and the Government before enrollment starts. Discussions with the responsible BARDA COR regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following:

1. **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

2. **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)**– a small group of independent investigators and biostatisticians who review data from a particular study.

3. **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the Government before enrollment starts.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the Government within 30 days of reviews or meetings.

**H.2.3. BARDA Protocol Review Process Before Patient Enrollment Begins**

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must provide the following (as applicable) for review and approval by the Government:

1. Clinical research protocol to be submitted for approval by the IRB identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria;
2. Informed consent document, identified by version number, date, or both and date it is valid;
3. Plans for the management of side effects;
4. Procedures for assessing and reporting adverse events;
5. Plans for data and safety monitoring (see B above) and monitoring of the clinical study site, pharmacy, and laboratory;
6. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

BARDA comments will be forwarded to the Contractor within two weeks (10 business days) of receipt of the above information. The Contractor must address in writing all study design, safety, regulatory, ethical, and conflict of interest concerns raised by the BARDA COR to the satisfaction of the Government before patient accrual or participant enrollment can begin. After the Government receives the corrected documentation, a written protocol approval will be provided by the COR to the Contractor. This written approval provides authorization to the Contractor to execute the specific clinical study funded in part or in whole by the Government.

Documentation of IRB approval, including OHRP FWA number, IRB registration number, and IRB and name, must be provided to the BARDA COR within 24 hours of receipt by the Contractor.

**H.2.4. Required Time-Sensitive Notification**

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA Contracting Officer's representative (COR) as follows:

1. *Expedited safety report of unexpected or life-threatening experience or death*– A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted to the BARDA program officer or the Contracting Officer's Representative within 24 hours of FDA notification.

2. *Expedited safety reports of serious and unexpected adverse experiences*– A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 calendar days after the IND sponsor's receipt of the information, must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.

3. *IDE reports of unanticipated adverse device effect*– A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the BARDA Contracting Officer's Representative within 24 hours of FDA notification.

4. *Expedited safety reports* – shall be sent to the BARDA COR concurrently with the report to FDA.

5. Other adverse events documented during the course of the trial shall be included in the annual IND or IDE report and reported to the BARDA annually.

In case of problems or issues, the BARDA COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

*Safety reporting for research not performed under an IND or IDE.*

Ongoing safety reporting requirements for research not performed under an IND or IDE shall be mutually agreed upon by the BARDA Contracting Officer's Representative and the Contractor.

**ARTICLE H.3. HUMAN MATERIALS**

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

**ARTICLE H.4. NEEDLE DISTRIBUTION**

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

**ARTICLE H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING**

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

**ARTICLE H.6. RESTRICTIONS ON ABORTIONS**

The Contractor shall not use funds for any abortion.

**ARTICLE H.7. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with the March 4, 1997 Presidential Memorandum entitled "Prohibition on Federal Funding for Cloning of Human Beings", federal funds may not be used for cloning of human beings.

**ARTICLE H.8. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

**ARTICLE H.9. OMB CLEARANCE**

In accordance with HHSAR 352.201-70, Paperwork Reduction Act of 1980 (44 U.S.C. section 3501), the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed.

**ARTICLE H.10. RESEARCH INVOLVING HUMAN FETAL TISSUE**

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

**ARTICLE H.11. REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

**ARTICLE H.12. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES**

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L.107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

**ARTICLE H.13. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS**

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

**ARTICLE H.14. CERTIFICATION OF FILING AND PAYMENT OF TAXES**

The Contractor must be in compliance with Section 518 of the Consolidated Appropriations Act of FY 2014.

**ARTICLE H.15. ELECTRONIC INFORMATION AND TECHNOLOGY ACCESSIBILITY NOTICE**

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. Accordingly, any Offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/sec508/standards.htm.

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, Offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows Offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://hhs.gov/web/508.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, Offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a Offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

**ARTICLE H.16. FULL EARNED VALUE MANAGEMENT SYSTEM, HHSAR 352.234-3 (October 2008) with ALTERNATE I (October 2008)**

a. The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the guidelines in ANSI/EIAStandard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS is not compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

b. If, at the time of award, the Contractor's EVM system is not in compliance with the EVMS guidelines in ANSI/EIAStandard-748 (current version at time of award), the Contractor shall:

a. Apply the current system to the contract; and

b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

c. HHS will not formally validate or accept the Contractor's EVMS with respect to this contract. The use of the Contractor's EVMS for this contract does not imply HHS acceptance of the Contractor's EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

d. HHS will conduct a Performance Measurement Baseline Review (PMBR). If a pre-award PMBR has not been conducted, a post-award PMBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require a PMBR as part of the exercise of an option or the incorporation of a major modification.

e. The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform to the requirements referenced in paragraph (a) of this clause.

f. The Contractor shall require the subcontractors specified below to comply with the requirements of the clause:

**ARTICLE H.17. CONFIDENTIALITY OF INFORMATION**

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

**ARTICLE H.18. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR CONFLICTS OF INTERESTS**

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site:
http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51 &idno=45

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

   1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

   2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

   3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

   1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

   2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any BARDA funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the BARDA funded research.

d. Require that each Investigator who is planning to participate in the BARDA funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for BARDA funded research. Require that each Investigator who is participating in the BARDA funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to BARDA funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to BARDA funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the BARDA funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the BARDA funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the BARDA funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

**ARTICLE H.19. PUBLICATION AND PUBLICITY**

The Contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201500028C*"*

Press Releases:

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non-Governmental sources.

**ARTICLE H.20. ACCESS TO DOCUMENTATION/DATA**

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance, all data generated, all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Contractor commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence with the FDA within 24 hours of receipt. The Government shall acquire unlimited rights to all data funded under a contract awarded in response to this RFP in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

**ARTICLE H.21. DISSEMINATION OF INFORMATION**

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

**ARTICLE H.22. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

**ARTICLE H.23. IDENTIFICATION AND DISPOSITION OF DATA**

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (HHS). HHS reserves the right to review any other data generated under this contract and determined by HHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

**ARTICLE H.24. CONFLICT OF INTEREST**

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

**ARTICLE H.25. IN-PROCESS REVIEW**

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables may be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or unilaterally institute changes to the work segment, or terminate the work segment.

IPRs may be scheduled at the discretion of the Government to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 days prior to the IPR. The Contractor shall provide a draft presentation to the Contracting Officer at least 10 days prior to the IPR.

**ARTICLE H.26. PRIVACY ACT APPLICABILITY**

1) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at http://www.gpoaccess.gov/cfr/index.html

2) The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

**ARTICLE H.27. QA AUDIT REPORTS**

BARDA reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications. The Contractor shall notify the CO and COR reasonably in advance of upcoming QA audit so that Government personnel may participate in person at BARDA's discretion.
- Contractor shall notify the COR and CO within 5 business days of report completion.

**ARTICLE H.28. BARDA AUDITS**

Contractor shall accommodate periodic or ad hoc site visits by the Government. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

**ARTICLE H.29. SECURITY REPORTING REQUIREMENT**

Violations of established security protocols shall be reported to the CO and COR upon discovery within 24 hours of its receipt of any compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system has been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. The CO in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the CO.

**PART II - CONTRACT CLAUSES**

**SECTION I - CONTRACT CLAUSES**

**ARTICLE I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at these addresses: https://www.acquisition.gov/FAR/ . HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

**General Clauses for Cost-Reimbursement/Fixed Price Research and Development Contract**

**(1) FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:**

| Reg | Clause | Date | Clause Title |
|---|---|---|---|
| FAR | 52.202-1 | Nov 2013 | Definitions |
| FAR | 52.203-3 | Apr 1984 | Gratuities |
| FAR | 52.203-5 | May 2014 | Covenant Against Contingent Fees |
| FAR | 52.203-6 | Sep 2006 | Restrictions on Subcontractor Sales to the Government |
| FAR | 52.203-7 | May 2014 | Anti-Kickback Procedures |
| FAR | 52.203-8 | May 2014 | Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity |
| FAR | 52.203-10 | May 2014 | Price or Fee Adjustment for Illegal or Improper Activity |
| FAR | 52.203-12 | Oct 2010 | Limitation on Payments to Influence Certain Federal Transactions |
| FAR | 52.203-13 | Apr 2010 | Contractor Code of Business Ethics and Conduct |
| FAR | 52.203-14 | Dec 2007 | Display of Hotline Poster(s) |
| FAR | 52.203-17 | Apr 2014 | Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights |
| FAR | 52.204-4 | May 2011 | Printed or Copied Double-Sided on Postconsumer Fiber Content Paper |
| FAR | 52.204-7 | Jul 2013 | System for Award Management |
| FAR | 52.204-10 | Jul 2013 | Reporting Executive Compensation and First-Tier Subcontract Awards |
| FAR | 52.204-13 | Jul 2013 | System for Award Management Maintenance |
| FAR | 52.209-6 | Aug 2013 | Protecting the Government’s Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment |
| FAR | 52.209-10 | Dec 2014 | Prohibition on Contracting with Inverted Domestic Corporations |
| FAR | 52.210-1 | Apr 2011 | Market Research |
| FAR | 52.215-2 | Oct 2010 | Audit and Records – Negotiation |
| FAR | 52.215-8 | Oct 1997 | Order of Precedence - Uniform Contract Format |
| FAR | 52.215-10 | Aug 2011 | Price Reduction for Defective Cost or Pricing Data |
| FAR | 52.215-11 | Aug 2011 | Price Reduction for Defective Certified Cost or Pricing Data—Modifications. |
| FAR | 52.215-12 | Oct 2010 | Subcontractor Certified Cost or Pricing Data |
| FAR | 52.215-13 | Oct 2010 | Subcontractor Certified Cost or Pricing Data—Modifications |
| FAR | 52.215-15 | Oct 2010 | Pension Adjustments and Asset Reversions |

| Reg | Clause | Date | Clause Title |
|---|---|---|---|
| FAR | 52.215-18 | Jul 2005 | Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions |
| FAR | 52.215-19 | Oct 1997 | Notification of Ownership Changes |
| FAR | 52.215-21 | Oct 2010 | Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications |
| FAR | 52.215-23 | Oct 2009 | Limitations on Pass-Through Charges |
| FAR | 52.216-7 | Jun 2013 | Allowable Cost and Payment |
| FAR | 52.216-8 | Jun 2011 | Fixed Fee |
| FAR | 52.219-8 | Oct 2014 | Utilization of Small Business Concerns |
| FAR | 52.219-28 | July 2013 | Post-Award Small Business Program Representation |
| FAR | 52.222-1 | Feb 1997 | Notice to the Government of Labor Disputes |
| FAR | 52.222-2 | Jul 1990 | Payment for Overtime Premiums |
| FAR | 52.222-3 | Jun 2003 | Convict Labor |
| FAR | 52.222-21 | Apr 2015 | Prohibition of Segregated Facilities |
| FAR | 52.222-26 | Apr 2015 | Equal Opportunity |
| FAR | 52.222-35 | Jul 2014 | Equal Opportunity for Veterans |
| FAR | 52.222-36 | Jul 2014 | Equal Opportunity for Workers with Disabilities |
| FAR | 52.222-37 | Jul 2014 | Employment Reports on Veterans |
| FAR | 52.222-40 | Dec 2010 | Notification of Employee Rights Under the National Labor Relations Act |
| FAR | 52.222-43 | May 2014 | Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (Multiple Year and Option Contracts) |
| FAR | 52.222-50 | Mar 2015 | Combating Trafficking in Persons |
| FAR | 52.222-54 | Aug 2013 | Employment Eligibility Verification |
| FAR | 52.223-6 | May 2001 | Drug-Free Workplace |
| FAR | 52.223-18 | Aug 2011 | Encouraging Contractor Policy to Ban Text Messaging While Driving |
| FAR | 52.224-1 | April 1984 | Privacy Act Notification |
| FAR | 52.224-2 | April 1984 | Privacy Act |
| FAR | 52.225-13 | Jun 2008 | Restrictions on Certain Foreign Purchases |
| FAR | 52.227-1 | Dec 2007 | Authorization and Consent, Alternate 1 (APR 1984) |
| FAR | 52.227-2 | Dec 2007 | Notice and Assistance Regarding Patent and Copyright Infringement |
| FAR | 52.227-3 | Apr 1984 | Patent Indemnity |
| FAR | 52.227-11 | May 2014 | Patent Rights – Ownership by the Contractor |
| FAR | 52.227-14 | May 2014 | Rights in Data - General |
| FAR | 52.228-7 | Mar 1996 | Insurance – Liability to Third Persons |
| FAR | 52.229-3 | Feb 2013 | Federal, State and Local Taxes |
| FAR | 52.230-2 | May 2014 | Cost Accounting Standards |
| FAR | 52.230-6 | June 2010 | Administration of Cost Accounting Standards |
| FAR | 52.232-1 | Apr 1984 | Payments |
| FAR | 52.232-2 | Apr 1984 | Payments under Fixed-Price Research and Development Contracts |
| FAR | 52.232-8 | Feb 2002 | Discounts for Prompt Payment |
| FAR | 52.232-9 | Apr 1984 | Limitation on Withholding of Payments |
| FAR | 52.232-11 | Apr 1984 | Extras |
| FAR | 52.232-17 | May 2014 | Interest |
| FAR | 52.232-20 | Apr 1984 | Limitation of Cost |
| FAR | 52.232-23 | May 2014 | Assignment of Claims |
| FAR | 52.232-25 | Jul 2013 | Prompt Payment |
| FAR | 52.232-33 | Jul 2013 | Payment by Electronic Funds Transfer—System for Award Management |

| Reg | Clause | Date | Clause Title |
|---|---|---|---|
| FAR | 52.233-1 | May 2014 | Disputes |
| FAR | 52.233-3 | Aug 1996 | Protest After Award, Alternate I |
| FAR | 52.233-4 | Oct 2004 | Applicable Law for Breach of Contract Claim |
| FAR | 52.242-1 | Apr 1984 | Notice of Intent to Disallow Costs |
| FAR | 52.242-3 | May 2014 | Penalties for Unallowable Costs |
| FAR | 52.242-4 | Jan 1997 | Certification of Final Indirect Costs |
| FAR | 52.242-13 | Jul 1995 | Bankruptcy |
| FAR | 52.242-15 | Aug 1989 | Stop Work Order, Alternate I (Aug 1984) |
| FAR | 52.243-1 | Aug 1987 | Changes - Fixed-Price Alternate V (Apr 1984). |
| FAR | 52.243-2 | Aug 1987 | Changes—Cost-Reimbursement Alternate V (Apr 1984). |
| FAR | 52.243-7 | Apr 1984 | Notification of Changes |
| FAR | 52.244-2 | Oct 2010 | Subcontracts, Alternate 1 (Jun 2007) |
| FAR | 52.244-5 | Dec 1996 | Competition in Subcontracting |
| FAR | 52.244-6 | Apr 2015 | Subcontracts for Commercial Items |
| FAR | 52.245-1 | Apr 2012 | Government Property |
| FAR | 52.245-9 | Apr 2012 | Use and Charges |
| FAR | 52.246-23 | Feb 1997 | Limitation of Liability. |
| FAR | 52.246-25 | Feb 1997 | Limitation of Liability—Services |
| FAR | 52.248-1 | Oct 2010 | Value Engineering |
| FAR | 52.249-2 | Apr 2012 | Termination for the Convenience of the Government (Fixed-Price) |
| FAR | 52.249-6 | May 2004 | Termination (Cost-Reimbursement) |
| FAR | 52.249-8 | Apr 1984 | Default (Fixed-Price Supply and Service) |
| FAR | 52.249-9 | Apr 1984 | Default (Fixed-Price Research and Development) |
| FAR | 52.249-14 | Apr 1984 | Excusable Delays |
| FAR | 52.253-1 | Jan 1991 | Computer Generated Forms |

**(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:**

| Reg | Clause | Date | Clause Title |
|---|---|---|---|
| HHSAR | 352.202-1 | Jan 2006 | Definitions - with Alternate paragraph (h) |
| HHSAR | 352.203-70 | Mar 2012 | Anti-Lobbying |
| HHSAR | 352.216-70 | Jan 2006 | Additional Cost Principles |
| HHSAR | 352.222-70 | Jan 2010 | Contractor Cooperation in Equal Employment Opportunity Investigations |
| HHSAR | 352.223-70 | Sept 2010 | Safety and Health |
| HHSAR | 352.227-70 | Jan 2006 | Publications and Publicity |
| HHSAR | 352.228-7 | Dec 1991 | Insurance - Liability to Third Persons |
| HHSAR | 352.231-70 | Jan 2006 | Salary Rate Limitation |
| HHSAR | 352.231-71 | Jan 2001 | Pricing of Adjustments |
| HHSAR | 352.233-71 | Jan 2006 | Litigation and Claims |
| HHSAR | 352.242-70 | Jan 2006 | Key Personnel |
| HHSAR | 352.242-73 | Jan 2006 | Withholding of Contract Payments |
| HHSAR | 352.242-74 | Apr 1984 | Final Decisions on Audit Findings |

**ARTICLE I.2. ADDITIONAL CONTRACT CLAUSES**

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. **FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES**

1. FAR 52.215-17, Waiver of Facilities Capital Cost of Money (October 1997).

2. FAR 52.227-16, Additional Data Requirements (June 1987).

**ARTICLE I.3. ADDITIONAL HHSAR CLAUSES – IN FULL TEXT**

**352.231-70 Salary rate limitation (August 2012)**

1. Pursuant to the current and applicable prior HHS appropriations acts, the Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date an expense is incurred.

2. For purposes of the salary rate limitation, the terms “direct salary,” “salary”, and “institutional base salary”, have the same meaning and are collectively referred to as “direct salary”, in this clause. An individual’s direct salary is the annual compensation that the Contractor pays for an individual’s direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

**Note:** The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.

1. The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract or order funding.

2. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

**ARTICLE I.4. ADDITIONAL FAR CLAUSES INCLUDED IN FULL TEXT**

**FAR 52.217-7 Option for Increased Quantity-Separately Priced Line Item (Mar 1989)**

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

**FAR 52.217-9 Option to Extend the Term of the Contract (Mar 2000)**

a. The Government may extend the term of this contract by written notice to the Contractor within 30 Days provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

b. If the Government exercises this option, the extended contract shall be considered to include this option clause.

c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed 8 years.

**FAR 52.219-1 Small Business Program Representations (Oct 2014)**

a. 1. The North American Industry Classification System (NAICS) code for this acquisition is541711.

2. The small business size standard is 500 employees.

3. The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

b. *Representations*.

1. The Offeror represents as part of its offer that it [X] is, [_] is not a small business concern.

2. [*Complete only if the Offeror represented itself as a small business concern in paragraph (b)(1) of this provision*] The Offeror represents, for general statistical purposes, that it [_] is, [X] is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

3. [*Complete only if the Offeror represented itself as a small business concern in paragraph (b)(1) of this provision*] The Offeror represents as part of its offer that it [ ] is, [X] is not a women-owned small business concern.

4. Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the Offeror represented itself as a women-owned small business concern in paragraph (b)(3) of this provision.] The Offeror represents as part of its offer that—

(i) It [_] is, [X] is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) (ii) It [_] is, [X] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(4)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

5. Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (b)(4) of this provision.] The Offeror represents as part of its offer that—

   (i) It [_] is, [X] is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

   (ii) It [_] is, [X] is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (b)(5)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [The Offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

6. [*Complete only if the Offeror represented itself as a small business concern in paragraph (b)(1) of this provision*] The Offeror represents as part of its offer that it [_] is, [X] is not a veteran-owned small business concern.

7. [Complete only if the Offeror represented itself as a veteran-owned small business concern in paragraph (b)(6) of this provision.] The Offeror represents as part of its offer that is [_] is, [_] is not a service-disabled veteran-owned small business concern.

8. [Complete only if the Offeror represented itself as a small business concern in paragraph (b)(1) of this provision.] The Offeror represents, as part of its offer, that –

   (i) It [_] is, [X] is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR part 126; and

   (ii) It [_] is, [X] is not a HUBZone joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(8)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [*The offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture:* _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

c. *Definitions*. As used in this provision—

"Economically disadvantaged women-owned small business (EDWOSB) concern" means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program. "Service-disabled veteran-owned small business concern"—

1. Means a small business concern—

   (i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

   (ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

2. Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

"Small business concern," means a concern, including its affiliates that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

"Veteran-owned small business concern" means a small business concern—

1. Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

2. The management and daily business operations of which are controlled by one or more veterans.

"Women-owned small business concern," means a small business concern –

1. That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

2. Whose management and daily business operations are controlled by one or more women.

"Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127)," means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States.

d. *Notice.*

1. If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

2. Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15, 31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall –

   (i) Be punished by imposition of fine, imprisonment, or both;

   (ii) Be subject to administrative remedies, including suspension and debarment; and

   (iii) Be ineligible for participation in programs conducted under the authority of the Act.

**FAR 52.232-40, Providing Accelerated Payment to Small Business Subcontractors (Dec 2013)**

a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b. The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

c. Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

**PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS**

**SECTION J - LIST OF ATTACHMENTS**

**The following documents are attached and incorporated in this contract:**

1. Statement of Work, dated September 29, 2015, 18 pages
2. Invoice/Financing Instructions for Cost-Reimbursement Type Contracts
3. Invoice Instructions for Fixed-Priced Type Contracts
4. Sample Invoice Form
5. Research Patient Care Costs
6. Report of Government Owned, Contractor Held Property, 1 page.
7. Form SF-LLL, Disclosure of Lobbying Activities, 2 pages
8. Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page

**Attachment 1 - Statement of Work (SOW)**

*Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to support this acquisition.*

**Avita Medical BASE SOW**

Summary Table

| CLIN | WBS1st Level Element | Title | Objectives |
|---|---|---|---|
| 0001 | 1 | Project Management | • Establish project management infrastructure<br>• Establish EVM systems<br>• Finalize IMPP<br>• Technical and financial reporting |
| | 2 | Non-Clinical Objectives | • Close gaps in non-clinical data required for PMA module 1 of 3, including biocompatibility, human factors, packaging testing to generate ISO design dossier as an FDA-compliant design history file.<br>• Establish appropriate training for use of ReCell in mass casualty setting.<br>• Achieve 4-year stability |
| | 3 | Clinical Objectives | • Complete pivotal trials (-5 and -6 protocols) and clinical study reports for PMA module 3 of 3. |
| | 4 | Regulatory Objectives | • Fulfill Pre-EUA requirements<br>• Modular PMA Submission<br>• Secure Pre-Market Approval (PMA) |
| | 5 | Product Development for Mass Casualty/VMI | • Gather requirements for Mass Casualty and VMI<br>• Redesign ReCell packaging and any other subcomponents in order to meet requirements for more efficient VMI and deployment<br>• Complete V&V |
| | 6 | QSR Objectives | • Perform QSR Gap remediation (address all gaps identified) for PMA module 2 of 3.<br>• Scale up manufacturing process for ReCell to support USG acquisition and US Market introduction<br>• Qualify alternate suppliers, for sustainability |
| 0002 | 7 | Procurement (Initial) | • Execute acquisition contract<br>• Establish VMI<br>• Manage inventory |

**Overview**

Avita's initial primary objective with the proposed effort is to secure FDA approval for the ReCell device. In order to accomplish this we need (1) a documented design (with documentation and supporting testing -e.g. biocompatibility- done to FDA standards rather than ISO standards), for which the work is done in WBS 2.1.2, 2.1.3, and 2.1.4; (2) an FDA-compliant quality system and documentation of GMP manufacturing: WBS 6.1; and (3) Pivotal Clinical Data: WBS 3.1.

The above-mentioned work is delivered to FDA via PMA modules 1, 2 and 3, respectively (WBS 4.2.2). The PMA modules will require organizing and assembling reports into a standardized format, setting context and drawing overall conclusions. In addition to submission of the PMA modules, Avita will also draft (and get FDA-approval of) a Conditions of Approval study protocol (WBS 3.3.1.1, 4.2.2.4.2), and pass through a panel (of experts) review (WBS 4.2.2.5). Avita will need favorable reviews of the PMA modules, CoA protocol approval, and panel review to get the product approved.

Concurrent with the FDA approval process, there is an Emergency Use pathway, activated in the event of a mass casualty, which would enable FDA to authorize use of an investigational (unapproved) product for life-saving measures. There is "pre-emergency" work that can be done to facilitate a future potential Authorization. (WBS 4.1)

Once there is confidence in EUA status or there is PMA approval, base procurement (WBS 7.1.1) is triggered.

There are several other items that are part of the program in order to ensure success in stockpiling, distributing, and using ReCell during an emergency event:

1. Training of medics for use of ReCell in mass casualty events (WBS 2.1.1).
2. Increased shelf-life, with a target of up to 4 years (as supported by stability testing) (WBS 2.3)
3. VMI planning/implementation (WBS 7.2, 7.3, 7.4)
4. Optimize product packaging more for palletized storage and VMI, (WBS 5)
5. Qualifying second sources for key components and for product final assembly (i.e. alternative/supplementary sources for enzyme and a supplement/alternative to Parker) (WBS 6.2.2).

**CLIN 0001 - Base Period**

**1.0 Program Management**

1.1 Internal Project Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.1.5 Integrated Master Project Plan | Upon delivery to and acceptance by BARDA | All required elements of this plan as listed in the RFP |

1.1.5 Title: Integrated Master Project Plan

Objective/Description of Work: Avita will compile all necessary materials and finalize all aspects of the project related to preparing the Integrated Master Project Plan. This will include finalizing critical path milestones, Work Breakdown Structure (WBS), and Risk Mitigation Plan. The final deliverable of the IMPP will represent the finalization and approval of all project elements between Avita and BARDA.

Milestones:

1.1.5.1 Critical Path Milestones – The critical path milestones are finalized and submitted, reviewed, and approved by BARDA.

1.1.5.2 Work Breakdown Structure – The WBS is finalized and submitted, reviewed, and approved by BARDA for all project activities.

1.1.5.3 Risk Mitigation Plan/Matrix – Any additional elements of risk are identified and all elements of risk are finalized and submitted, reviewed, and approved by BARDA. Risk management plans for each risk are finalized and submitted, reviewed, and approved by BARDA.

Deliverables:

1.1.5 Integrated Master Project Plan – Containing all required elements as listed in the RFP and/or requested by BARDA.

1.1.5.1 Critical Path Milestones – An updated and finalized critical path milestone document.

1.1.5.2 Work Breakdown Schedule – An updated and finalized WBS document. 1.1.5.3 Risk Mitigation Plan/Matrix – An updated and finalized risk mitigation plan/matrix.

1.2 Contract Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.2.2 Reporting | Upon delivery to and acceptance by BARDA | All required reports as listed in the RFP and requested by BARDA |
| 1.2.3 Meetings | BARDA Kick-Off Meeting | Meeting Presentation Materials |

1.2.2 Title: Reporting

Objective/Description of Work: Avita will comply with all reporting requirements as outlined and formatted in the RFP and as requested by BARDA. Reporting will include at a minimum monthly progress reports, annual progress reports, annual invention reports, draft final report, and final report. Additional deliverables such as technology packages, experimental protocols, publication, press releases, security reports, or other reports will be provided to BARDA for review prior to initiation of a corresponding work element, deliverable, or FDA submission.

Milestones:

1.2.2.1 Monthly Progress Report – Delivery to and acceptance by BARDA.

1.2.2.2 Annual Progress Report – Delivery to and acceptance by BARDA.

1.2.2.3 Invention Reports – Delivery to and acceptance by BARDA.

1.2.2.4 Draft Final and Final Progress Reports – Delivery to and acceptance by BARDA.

Deliverables:

1.2.2.1 Monthly Progress Report – A report detailing the prior month's activities and activities planned for the following month. Report will be delivered prior to the 15th of the month following the reporting period.

1.2.2.2 Annual Progress Report – A report summarizing the activities of the period of performance and the activities planned for the upcoming period. Report will be delivered prior to the 30th of the month following the reporting period.

1.2.2.3 Annual/Final Invention Report – A report detailing any intellectual property developed as a result of the work performed during each period of performance and the entire contract period. Report will be delivered in conjunction with the annual progress report.

1.2.2.4 Draft Final and Final Progress Report – The Final Progress Report will include a complete summary of all work performed during the entire contract period of performance. A Draft Final Progress Report will be delivered 45 days prior to contract expiration for BARDA review and comments. A Final Progress Report will be delivered prior to 30 days following contract expiration.

1.2.3 Title: Meetings

Objective/Description of Work: Avita and BARDA will engage in regular meetings to coordinate and review project activities. Meetings will be both face-to-face and teleconference/video conference. The first official meeting will be theface-to-face kick-off meeting, followed by status update meetings on a biweekly/monthly basis, ad hoc teleconferences and site visits, and annual meetings to report on the period of performance activities.

Milestones:

1.2.3.1 Kickoff Meeting with BARDA – The contract is awarded and aface-to- face kickoff meeting is conducted within 30 days of award date.

Deliverables:

1.2.3.2 Kickoff Meeting Presentation Materials – Avita will prepare all necessary presentation materials for the kickoff meeting.

1.4 IMS and EVM

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.4.2 Performance Measurement Baseline | Performance Measurement Baseline Review (PMBR) | All required components for the PMBR |
| 1.4.3 Integrated Master Schedule | PMBR | Integrated Master Schedule |
| 1.4.4 Monthly Earned Value Performance Report | Delivery to and acceptance by BARDA | Monthly Earned Value Performance Report |
| 1.4.5 Supplemental monthly CAP report | Delivery to and acceptance by BARDA | Supplemental monthly CAP report |

1.4.2 Title: Performance Measurement Baseline

Objective/Description of Work: The Performance Measurement Baseline will provide a master schedule of deliverables, costs, and milestones in order to completely cover all items in the SOW. All required components will be submitted to BARDA within 90 days of contract award. BARDA and Avita will mutually agree on the budget, schedule and technical plan baselines as a result of the PMBR.

Milestones:

1.4.2 Performance Measurement Baseline Review – The PMBR plan is submitted and reviewed by BARDA.

Deliverables:

1.4.2 Performance Measurement Baseline Review Plan and Required Components – A plan detailing a schedule of deliverables, costs, milestones, and risks that will serve as the basis for measuring project progress.

1.4.3 Title: Integrated Master Schedule (IMS)

Objective/Description of Work: The IMS will be used to monitor performance of the contract. Avita will develop an IMS in a format approved by BARDA in order to track key milestones, Go/No Go decision gates. The IMS will contain baseline start and finish, forecast start and finish, actual start and finish, predecessor and/or successor. Avita will provide a baseline IMS for the PMBR and monthly updates thereafter.

Milestones:

1.4.2 Integrated Master Schedule is approved by BARDA.

Deliverables:

1.4.3 Integrated Master Schedule – Provided for the PMBR and monthly in order to monitor performance of the contract. The IMS shall be provided at the work package level in MS Project file format.

1.4.4 Title: Monthly Earned Value Performance Report

Objective/Description of Work: The Monthly Earned Value Performance Report will be generated from Avita's EVMS in order to track any project variances against the baseline. The report will contain technical, schedule, and cost status information in order to identify any issues that may impact project progress and/or cost.

Milestones:

1.4.4 Monthly Earned Value Performance Report – Delivery to and acceptance by BARDA.

Deliverables:

1.4.4 Monthly Earned Value Performance Report – Provided monthly to track project progress according to WBS and EV variance.

1.4.5 Title: Supplemental Monthly CAP Report

Objective/Description of Work: The Supplemental Monthly CAP Report will be generated from Avita's EVMS and will contain cost information to report on the time phased budget, earned value, and actual costs of work performed. The report will be submitted monthly to BARDA for review.

Milestones:

1.4.5 Supplemental Monthly CAP Report – Delivery to and acceptance by BARDA.

Deliverables:

1.4.5 Supplemental Monthly CAP Report – Provided monthly to detail time phased budget, earned value, and actual costs of work performed as captured by Avita's EVM systems.

**2 Non-Clinical Objectives**

2.1 Efficacy and Safet

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 2.1.1.1 Updated training resources for mass casualty | Effective training for mass casualty event. | Updated user training documentation |
| 2.1.2 Biocompatibility review | Biocompatibility review complete | Biocompatibility Review Report |
| 2.1.3 Human Factors | FDA requests human factors studies | Human factors studies submitted to FDA |
| 2.1.4 FDA-compliant design documentation | Completion of backup documentation for PMA module 1. | QSR-mandated design control documents and supporting lab test results |

2.1.1.1 Title: Updated training resources for mass casualty

Objective/Description of Work: Existing training manuals for use of the ReCell device are designed for a clinical/surgical setting by experienced clinicians. Led by the Director of Education, with support from the Education Specialist, Avita will develop a new training protocol sufficient for a mass casualty event for ReCell to be used by minimally trained personnel that may or may not have burn surgery experience. Target goal will be a one-hour training session to personnel at a trained medic level or higher. New training materials will be submitted to BARDA for review/feedback and then finalized.

Milestones:

2.1.1 Creation of training materials, including video, workshop/online course materials, reference guides, as determined in collaboration with BARDA

Deliverables:

2.1.1.1 Training materials as determined in collaboration with BARDA.

2.1.2 Title: Biocompatibility review complete

Objective/Description of Work: Full biocompatibility is demonstrated for EU and Australia, to ISO standards. The testing work needs to be done to US FDA standards. Results of biocompatibility review will be submitted to BARDA for review/feedback.

Milestones:

2.1.2 Biocompatibility submitted to FDA

Deliverables:

2.1.2 Biocompatibility Review Report draft and final report submitted to BARDA and final report submitted to FDA

2.1.3 Title: Human Factors

Objective/Description of Work: Avita will conduct an evaluation to ensure that the ReCell devices meet usability guidelines when used by the intended user population. Avita will conduct all required studies and submit the results to BARDA for review and feedback. Upon BARDA approval, Avita will submit report to FDA.

Milestones:

2.1.3 Requested data/report submitted to FDA

Deliverables:

2.1.3 As requested by FDA, human factors draft and final reports submitted to BARDA and final data and report submitted to FDA

2.1.4 Title: FDA-Compliant Design Documentation

Objective/Description of Work: Avita's recent gap analysis for PMA module 1 readiness indicates that in addition to biocompatibility testing Avita will need to create an FDA QSR-compliant design control document package, including backup lab test data and reports, including packaging testing. Avita will provide the various reports to BARDA, as requested, for review and approval prior to sending to FDA.

Milestones:

2.1.4.1 Functional Testing Complete

2.1.4.2 Packaging/Shipping Testing Complete

2.1.4.3 EMI/EMC Testing Complete

2.2 Non-clinical data sufficient for PMA module 1 of 1

Deliverables:

2.1.4 QSR-mandated design control documents and supporting lab test results – Avita will generate a design control document package that will meet current FDA requirements, in support of PMA module 1 of 1

2.3 Stability and Review of Extended Shelf Life

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 2.3.1 Stability Plan | Expiration limiting components identified and plan developed to extend to 4-year target | Stability Plan |
| 2.3.6 Stability Report (accelerated aging) | Accelerated aging testing results complete | Stability report |
| 2.3.7 Stability report (real- time aging) | Real-time aging testing results complete | Stability report |
| 2.3.8 Review of extended shelf life | New expiry limits determined | Results report submitted to BARDA |
| 2.3.9 Revisions to labeling | Stability extension submission | Shelf life report and revised labeling submitted to FDA |

2.3.1 Title: Stability Plan

Objective/Description of Work: Avita will develop a stability plan that will outline the testing necessary to extend the shelf life of the ReCell unit to 4 years in order to minimize product losses due to expiry. Avita will focus on specific expiration-limiting components (enzyme and buffer, RPU, and nozzle). Avita will design and execute on a stability testing plan to verify stability for extension of shelf life. Reports will be submitted to BARDA detailing the shelf life of ReCell units. Labeling will be modified based on new expiries and submitted to FDA to approval.

Milestones:

2.3.1 Expiration limiting components are identified and a plan is developed to extend ReCell unit to a target of4-year expiry.

Deliverables:

2.3.1 Stability plan outlining all necessary real-time and accelerated aging testing required to justify expiry.

2.3.6 Title: Stability Report (accelerated aging)

Objective/Description of Work: Following accelerated aging testing, a report will be prepared outlining the product performance. The report will detail whether expiry targets were achieved. If targets were not achieved, a plan will be provided detailing further modifications or a plan for acceptance of a new expiry target. Avita will submit to BARDA for review and comments.

Milestones:

2.3.6 Stability testing results complete.

Deliverables:

2.3.6 Stability report detailing product performance for ReCell components after aging

2.3.7 Title: Stability Report (real-time aging)

Objective/Description of Work: Following real-time aging testing, a report will be prepared outlining the product performance. The report will detail whether expiry targets were achieved. If targets were not achieved, a plan will be provided detailing further modifications or a plan for acceptance of a new expiry target. Avita will submit to BARDA for review and comments.

Milestones:

2.3.7 Stability testing results complete.

Deliverables:

2.3.7 Stability report detailing aged performance for ReCell components

2.3.8 Title: Review of extended shelf life

Objective/Description of Work: Avita will prepare a report for BARDA detailing the changes product shelf life. Avita will report on the plan for accordingly revised product labeling to be submitted to FDA.

Milestones:

2.3.8 Delivery of report of extended shelf life

Deliverables:

2.3.8 Shelf life report delivered to BARDA for review, followed by a report detailing plans for FDA submission, and implications for the VMI.

2.3.9 Title: Revisions to labeling

Objective/Description of Work: Avita will revised the product labeling to reflect new shelf life parameters, and will submit to FDA.

Milestones:

2.3.9 FDA approval of revised product labeling

Deliverables:

2.3.9 New product labeling and FDA submission for review/approval of new product labeling.

**3 Clinical**

3.1 Pivotal Clinical Trials

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.1.1.4 Clinical Study Report | CTP001-5 Clinical Study Report (CSR), review complete | CTP001-5 Clinical Study Report (CSR), review/submit to FDA |
| 3.1.2.6.1 Statistical Analysis (9mo) | Statistical analysis complete | CTP001-6 Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.1.2.6.2 Clinical Study Report (9mo) | CTP001-6 Initial (9-months) CSR complete | CTP001-6 Initial (9-months) CSR, review (PMA module 3 of 3) |
| 3.1.2.6.4 Statistical Analysis (12mo) | Statistical analysis complete | CTP001-6 Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.1.2.6.5 Clinical Study Report (12mo) | CTP001-6 Final (12-months) CSR complete | CTP001-6 Final (12-months) CSR, review |

3.1.2.8 Title: Final CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Pivotal Clinical Trials encompass two ongoing clinical protocols:CTP001-5 (deep partial-thickness) and CTP001-6 (mixed depth including full-thickness). Both studies show definitive closure using less donor skin with ReCell as compared to standard care, and are also looking at long-term scar outcomes. The clinical study report (CSR) from CTP001-6 is the primary component of PMA module 3 of 3. All CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.1.1.1 Last subject last visit forCTP001-5 (complete)

3.1.1.4 Clinical Study Report complete forCTP001-5

3.1.2.1.1 FDA Statistical Analysis Plan submitted and approved by FDA forCTP001-6 (complete)

3.1.2.3.2 Last subject last visit for CTP001-6

3.1.2.6.4 CRO completes 9-month statistical analysis for PMA module 3 of 3.

3.1.2.8 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.1.1.4 CTP001-5 Clinical Study Report (CSR)

3.1.2.6.1 CTP001-6 9-month Tables, Listings & Figures (i.e. Statistical analysis output)

3.1.2.6.2 CTP001-6 Initial (9-months) CSR (for PMA module 3 of 3)

3.1.2.6.4 CTP001-6 12-month Tables, Listings & Figures (i.e. Statistical analysis output)

3.1.2.6.5 CTP001-6 Final (12-months) CSR

**4 Regulatory**

4.1 Pre-Emergency Use Authorization

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 4.1 Pre-Emergency Use Authorization | Avita completes all submissions needed for EUA | All data requested by BARDA to obtain pre-EUA |

4.1 Title: Pre-Emergency Use Authorization

Objective/Description of Work: Avita will support BARDA/HHS in obtaining a Pre-Emergency Use Authorization for the ReCell device. All required studies, reviews, reports, and analyses will be provided as requested.

Milestones:

4.1 Avita completes all submissions needed for EUA

Deliverables:

4.1 Submission to BARDA/HHS of all required materials needed for Pre-EUA.

4.2 Premarket Approval (PMA)

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 4.2.2.1.4 Module 1 Submission | Module 1 package assembled | Module 1 package to FDA |
| 4.2.2.2.4 Module 2 Submission | Module 2 package assembled | Module 2 package to FDA |
| 4.2.2.3.4 Module 3 Submission | Module 3 package assembled | Module 3 package to FDA |
| 4.2.2.5.3 Create action plan to address panel recommendations | FDA Panel Meeting | Action Plan |

4.2.2.1.4 Title: Module 1 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package with modular submissions for FDA review and approval. The PMA package will consist of three PMA modules. Module 1 will focus on non-clinical data.

Milestones:

4.2.2.1.4 Module 1 package assembled

Deliverables:

4.2.2.1.4 Module 1 submission to FDA – Module 1 includes biocompatibility, human factors, shipping/packaging validation, EMI/EMC, and all other required non-clinical data.

4.2.2.2.4 Title: Module 2 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package for FDA approval. The PMA package will consist of three PMA modules. Module 2 will focus on manufacturing data.

Milestones:

4.2.2.2.4 Module 2 package assembled

Deliverables:

4.2.2.2.4 Module 2 submission to FDA – Submission will include the principles of operation, quality system and manufacturing documentation, sterilization, shelf-life information, and packaging information.

4.2.2.3.4 Title: Module 3 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package for FDA approval. The PMA package will consist of three PMA modules. Module 3 will focus on clinical data. Module 3 will be submitted to BARDA for review and approval, followed by submission to FDA.

Milestone:

4.2.2.3.4 Module 3 package assembled and approved by BARDA

Deliverables:

4.2.2.3.4 Module 3 submission to FDA – Submission will include theCTP001-6 clinical data labels and manuals, draft post-marketing plan (CoA study protocol) and bibliography.

**5 Product Development for mass casualty/VMI**

5.1 Requirement Gathering, 5.2 Product Design, 5.3 Systems Requirements and Design Review, and 5.4 CDC Quality Agreement

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 5.3 Systems Requirements (VMI optimization) and Design Review | Review of VMI optimized product design package complete | Product optimized for VMI Design Package |
| 5.4 CDC Quality Agreement | Executed CDC Quality Agreement | CDC Quality Agreement |

5.3, 5.4 Title: Systems Requirements (VMI optimization) and Design Review

Objective/Description of Work: In order to develop a product ready for manufacturing and stockpiling, Avita will work with BARDA to first gather the requirements for DFM/DFA, inventory management and any other requirements. Based on the requirements, Avita will initiate Product Design to all ensure the product will meet specifications. This includes design and review for any changed or affected part: Components, Subassembly, Product System, and Packaging Design. Document package will be sent to BARDA for review. Avita will work with CDC to establish a quality agreement, if required.

Milestones:

5.1 Requirements document compiled from BARDA

5.2.1.2 Component Design Review complete

5.2.2.2 Subassembly Design Review complete

5.2.3.2 Product System Design Review complete

5.2.4.2 Packaging Design Review complete

5.3 Full systems requirements and design review complete and approved by BARDA

5.4 If required, establish quality agreement with CDC for supporting VMI

Deliverables:

5.3 System Requirements and Design Review – A system requirements and design review report will be submitted to BARDA containing the requirements and the design changes made to meet those requirements.

5.4 Agreed upon CDC quality agreement for supporting VMI (if required)

5.5 Verification and Validation

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 5.5 Verification and Validation Report | V&V verifies product meets specifications and requirements | V&V Report |

5.5 Title: Verification and Validation Report

Objective/Description of Work: Verification & Validation are used to verify that the product meets the specifications and requirements and address the intended purpose. Verification demonstrates that the product meets specification and Validation demonstrates fitness of use for the intended purpose. Once V&V results are positive, the product is ready to release to manufacturing. Avita will submit a report to BARDA detailing the results of the V&V analysis.

Milestones:

5.5 Testing and analysis indicate that the product meets specification and intended purpose.

Deliverables:

5.5 V&V Report - Avita will submit a report to BARDA detailing the results of the V&V analysis.

**6 QSR**

6.1 Quality System Preparedness

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 6.1.3 3rd Party Audit | Audit completed | QSR Audit Report |

6.1.3 Title: 3rd Party Audit

Objective/Description of Work: The US FDA Quality System Regulation (QSR) describes the environment under which medical device firms must operate. This task involves preparing the Avita quality systems for FDA review and inspection, and verifying compliance with FDA requirements. Avita hired an external 3rd party auditor to complete a QSR gap analysis. Following the audit a gap assessment was prepared and presented to Avita from the 3rd party auditor. Avita will develop a Gap Corrective Action plan to address any gaps identified. This will support PMA submission. Once the corrective action plan has been implemented and changes are in place a mock audit will be performed by a 3rd party auditor in preparation for an expected FDA inspection during PMA review.

Milestones:

6.1.1 Gap Assessment

6.1.2 Gap corrective action performed and all systems brought into compliance

6.1.3 Mock QSR audit

Deliverables:

6.1.3 QSR 3rd Party Audit Report - Avita will submit a report to BARDA detailing the results of the final QSR audit.

6.2 Commercial Manufacturin

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 6.2.1 Commercialization Plan and Gap Analysis | Completion of commercialization plans | Final Commercialization Plan |
| 6.2.2.4 Validation Report | IQ/OQ/PQ process validations complete | Validation Report |

6.2.1 Title: Commercialization Plan and Gap Analysis

Objective/Description of Work: Perform a gap analysis to assess commercialization readiness and draft a commercialization plan in support of market entry. Tasks include, as necessary, establishing SKU#, Supply chain and vendor qualifications, raw material inventory, sterilization, packaging, and labeling, and lot release.

Milestones:

6.2.1.1 Commercialization Gap Assessment completed

6.2.1.2 Commercialization Plan Draft created, reviewed with BARDA

6.2.1.3 Commercialization Plan finalized.

Deliverables:

6.2.1.1 Commercialization Gap Assessment Report

6.2.1.2 Commercialization Plan draft and final versions reviewed and submitted to BARDA.

6.2.2.4 Title: Validation Report

Objective/Description of Work: Process validation involves the collection and evaluation of data from the processes used to produce the product. Avita's commercial manufacturer will lead the effort in manufacturing, under close supervision and collaboration with Avita. Sterile packaging will be a primary focus of the validation effort to ensure repeatable package integrity and valid sterilization processes. Process validations will include IQ/OQ/PQ and final validation. Avita will present a final report detailing the results of the validation analysis.

Milestones:

6.2.2.1 IQ, Installation Qualification complete

6.2.2.2 OQ, Operation Qualification complete

6.2.2.3 PQ, Process Qualification complete

Deliverables:

6.2.2.4 Validation Report - Avita will submit a report to BARDA detailing the results of the process validation analysis.

**CLIN 0002 – Base Period**

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.1.1.2 Product Manufacturing | Order Received | Initial Product |
| 7.1.1.3 Deploy product to VMI sites | Product shipped to sites | Product deployed |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: Upon authorization from BARDA, Avita will cause the production and delivery of ReCell devices. Upon receiving the order Avita will authorize the manufacturer to procure supplies for the manufacture of the devices and preparing designated inventory locations.

Milestones:

7.1.1.1 Order Received

7.1.1.2 Delivery of specified quantity of units to VMI.

Deliverables:

7.1.1.2 Initial Product – Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices.

7.1.1.3 Product integrated into VMI and available for deployment

7.2 VMI Remote inventory management system

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.2.1 - Gather VMI Requirements | All VMI requirements agreed upon with BARDA | VMI Requirements Document |

7.2.1 Title: Gather VMI Requirements

Objective/Description of Work: Avita will work with USG to identify all VMI requirements, and prepare a document detailing the requirements.

Milestones:

7.2.1 All VMI requirements agreed upon with BARDA

Deliverables:

7.2.1 VMI Requirements Document – Report detailing the agreed upon requirements for VMI.

7.3 Sustainment/Stockpile Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.4.1 Inventory Management | Quarterly inventory reports | Inventory Management Report |

7.3.1 Title: Inventory Management

Objective/Description of Work: Inventory management encompasses activities that occur after the inventory is on site and the inventory system is in operation. The purpose is to ensure ongoing compliance with the stockpiling requirements, and manage replenishment to ensure unit availability in emergency situations. Site environments will continue to be monitored through the lifetime of the contract for compliance with environmental requirements, and inventory controls will be followed. Site performance will be monitored periodically, supplemented by BARDA site visits. Plans will be executed to replenish expiring goods and units will be reworked as needed to maintain currency. Avita will present to BARDA Inventory Management Reports detailing the status and activities at all VMI locations at a frequency determined appropriate by BARDA and Avita.

Milestones:

7.3.1 Quarterly inventory reports

Deliverables:

7.3.1 Inventory Management Report

Summary Table

| CLIN | WBS 1st Level Element | Title | Objectives |
|---|---|---|---|
| **0003** | 3 | CoA Study | • Complete Post-Approval (conditions of approval) study, as required by FDA |
| **0004** | 3, 4 | Pediatric Studies | • Complete pediatric clinical trials per FDA requirements and BARDA guidance |
| **0005** | 7 | Procurement (Surge) | • Execute acquisition contract<br>• Expand VMI as necessary |

**Overview**

Avita has defined three option periods covering the Conditions of Approval (CoA) study after FDA approval of the ReCell Device (CLIN 0003), a Pediatric study to expand the indications for ReCell for a broader pediatric demographic, if necessary, for ReCell (CLIN 0004), and for the procurement of additional ReCell devices beyond the initial acquisition (CLIN0005). **Note: Updated SOW(s) will be provided to BARDA based on FDA feedback to support the execution of each CLIN.** The accompanying budget(s) will also be updated to align with the revised SOW(s).

The purpose of the CoA, CLIN 0003, is to provide longer-term evaluation of the ReCell device after FDA approval, in order to track and confirm that any post-market commitments are addressed by Avita.

The purpose of the Pediatric Study, CLIN 0004, is to expand the approved range of patients for ReCell, specifically for pediatric patients, beyond those originally approved during the PMA process. The specific study design and objectives will be based on the PMA approval outcomes as well as consultation with BARDA, and will be intended to expand the range of patients able to be treated by ReCell.

Surge acquisition, CLIN 0005, will support additional acquisition of ReCell devices by BARDA, CDC, or other stakeholders.

**CLIN 0003 – Option – CoA Study**

**3 Clinical**

3.3 Post approval (Condition of Approval Stud

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.3.1.2 Submit protocol to BARDA for review | Protocol developed | Study Protocol |
| 3.3.6.1 Statistical analysis | Statistical analysis complete | Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.3.6.2 Clinical study report | CSR complete | CSR, review/submit to FDA |

3.3.6.4 Title: Final CoA CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Post approval (COA study) will be carried out if an additional study is required by FDA as a condition of PMA approval. If a COA study is required, a new clinical study will need to be prepared and approved, including protocol with inclusion and exclusion criteria, endpoints, and IDE application written and submitted, FDA approval of the IDE, local IRB approval, clinical study site agreements, and local ethics approvals. The study protocol and all CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.3.1.1 Protocol developed

3.3.2.2 Last subject last visit

3.3.6.1 CRO completes statistical analysis

3.3.6.2 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.3.1.2 Study Protocol submitted to BARDA

3.3.6.1 Tables, Listings & Figures (i.e. Statistical analysis output)

3.3.6.2 CSR, review/submit to FDA

**CLIN 0004 – Option – Pediatric Study**

**3 Clinical**

3.2 Pediatric Study for Expanded Labelin

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.2.1.2 Submit protocol to BARDA for review | Protocol developed | Study protocol |
| 3.2.6.1 Statistical Analysis | Statistical analysis complete | Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.2.6.2 Clinical Study Report | CSR complete | CSR, review/submit to FDA |

3.2.8 Title: Final Pediatric CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Pediatric study for expanded labeling will be carried out if requested by the BARDA to study younger children. If a pediatric study is required, a new clinical study will need to be prepared and approved, including protocol with inclusion and exclusion criteria, endpoints, and IDE application written and submitted, FDA approval of the IDE, local IRB approval, clinical study site agreements, and local ethics approvals. The study protocol and all CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.2.1.1 Protocol developed

3.2.3.1 Last subject last visit

3.2.6.1 CRO completes statistical analysis

3.2.6.2 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.2.1.2 Clinical Study Protocol

3.2.6.1 Tables, Listings & Figures (i.e. Statistical analysis output)

3.2.6.2 Clinical Study Report (CSR)

**4 Regulatory**

4.2.5 Pediatric Indication

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 4.2.5.1 Pediatric IDE | FDA approval of pediatric IDE | Pediatric IDE application |
| 4.2.5.3 Pediatric PMA supplement | FDA approval of expanded indication for pediatrics | Submission for Pediatric label expansion |

4.2.5 Title: Pediatric Indication

Objective/Description of Work: Avita will make the regulatory filings with FDA for both a pediatric IDE clinical trial and a PMA supplement for expansion of labeling for pediatric indication.

Milestones:

4.2.5.2 FDA approval of pediatric IDE study

4.2.5.4 FDA approval of pediatric indication

Deliverables:

4.1.5.1 Pediatric IDE application.

4.2.5.3 PMA supplement for pediatric indication

**CLIN 0005 – Procurement (Surge)**

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.1.2.2 Product Manufacturing | Order Received | Additional product to meet surge capacity |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: BARDA would authorize the surge procurement order to acquire additional ReCell devices beyond the initial order. Upon receiving the order Avita would authorize the manufacturer to begin acquiring supplies for the manufacture of the additional devices.

Milestones:

7.1.2.1 Order Received

Deliverables:

7.1.2.2 Surge Capacity Product – Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices according to the additional products required to meet surge capacity. Product will be deployed to designated VMI locations.

**ATTACHMENT #2**

**INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS**

**Format:** Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

**Number of Copies:** Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

**Frequency:** Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

**Cost Incurrence Period:** Costs incurred must be within the contract performance period or covered bypre-contract cost provisions.

**Billing of Costs Incurred:** If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

**Contractor's Fiscal Year:** Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

**Currency:** All BARDA contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

**Costs Requiring Prior Approval:** Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

**Invoice/Financing Request Identification:** Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

**Preparation and Itemization of the Invoice/Financing Request:** The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(j) **Office of Acquisitions**: Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- Item number for the specific piece of equipment listed in the Property Schedule, and
- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

**ATTACHMENT #3**

**INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS**

General The Contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form l034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form l035, Public Voucher for Purchases and Services Other than Personal—Continuation Sheet, and the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies: As indicated in the contract.

Frequency Invoices submitted in accordance with the Payment Clause shall be submitted monthly upon delivery of goods or services unless otherwise authorized by the Contracting Officer.

Preparation and Itemization of the Invoice The invoice shall be prepared as follows:

(a) Designated Billing Office and address:

HHS/ASPR/BARDA

330 Independence Ave, Room G640

Washington DC 20201

ATTN: Contracting Officer

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.

(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)

(h) Equipment - If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency: Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

**ATTACHMENT #4 - SAMPLE INVOICE FORM**

Company Name

**Designated Billing Office Name and Address:**

DHHS/OS/ASPR/AMCG
Attn: Contracting Officer
200 C St., S.W.

Washington, D.C. 20201

**Contractor's Address and Contact Information:**

POC: Name of accountant or COO or signatory authority for invoice
Title:
Phone:
E-Mail:

**TIN:**
**DUNS #:**

**Invoice/Finance Number:**

**Date Invoice Prepared:**

**Contract No. and Title:**

**Effective Date & Period of Performance:**

**Total Estimated Cost of Order:**

**Office of Acquisitions:**

Contracting Officer (insert name here)
Office of Acquisitions Management, Contracts, and Grants (AMCG)

**Central Point of Distribution:**

This invoice represents reimbursable costs for the period from

| Expenditure Category | | Amount Billed | | |
|---|---|---|---|---|
| | | Current | Cumulative | Contract Value |
| **Direct Costs:** | | | | |
| Direct Labor | | | | |
| Fringe Benefits | **0.00%** | | | |
| **Total Labor Costs:** | | | | |
| **Overhead** | **0.00%** | | | |
| Travel | | | | |
| Subcontracts | | | | |
| Consultant Fees | | | | |
| Materials and Supplies | | | | |
| Other | | | | |
| **Total Direct Costs** | | | | |
| G&A Rate | **0.00%** | | | |
| Subtotal: | | | | |
| Fixed Fee | **0.0** | | | |
| Total Amount Claimed | | | | |
| Adjustments | | | | |
| **Grand Total** | | **$ —** | | |

I Certify that all payments are for appropriate purposes and in accordance with the contract.

Name/signature of signatory authority for invoicing

**ATTACHMENT #5**

**RESEARCH PATIENT CARE COSTS**

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the Contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The Contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

Attachment 6

**REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY**

**CONTRACTOR:**

**ADDRESS:**
ADDRESS1:
ADDRESS2:
CITY:
STATE:
ZIP:

**CONTRACT NUMBER:**

**REPORT DATE:**

**FISCAL YEAR:**

| | BEGINNING OF PERIOD | | ADJUSTMENTS | | | END OF PERIOD | |
|---|---|---|---|---|---|---|---|
| **CLASSIFICATION** | #ITEMS | VALUE | GFP ADDED | CAP ADDED | DELETIONS | #ITEMS | VALUE |
| LAND >=$25K | | | | | | | |
| LAND <$25K | | | | | | | |
| OTHER REAL >=$25K | | | | | | | |
| OTHER REAL <$25K | | | | | | | |
| PROPERTY UNDER CONST >=$25K | | | | | | | |
| PROPERTY UNDER CONST <$25K | | | | | | | |
| PLANT EQUIP >=$25K | | | | | | | |
| PLANT EQUIP <$25K | | | | | | | |
| SPECIAL TOOLING >=$25K | | | | | | | |
| SPECIAL TOOLING <$25K | | | | | | | |
| SPECIAL TEST EQUIP >=$25K | | | | | | | |
| SPECIAL TEST EQUIP <$25K | | | | | | | |
| AGENCY PECULIAR >=$25K | | | | | | | |
| AGENCY PECULIAR <$25K | | | | | | | |
| MATERIAL >=$25K (CUMULATIVE) | | | | | | | |
| PROPERTY UNDER MFR >=$25K | | | | | | | |
| PROPERTY UNDER MFR <$25K | | | | | | | |

**SIGNED BY:**

SIGNATURE _____ DATE SIGNED: _____

NAME PRINTED _____ Email _____

TITLE _____ TELEPHONE _____

Report of Government Owned, Contractor Held Property (Rev 10/2014)

**Attachment 7**

**DISCLOSURE OF LOBBYING ACTIVITIES Approved by OMB**

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352 0348-0046 (See reverse for public burden disclosure.)

**1. Type of Federal Action:**
a. contract
b. grant
c. cooperative agreement
d. loan
e. loan guarantee
f. loan insurance

**2. Status of Federal Action:**
a. bid/offer/application
____b. initial award
c. post-award

**3. Report Type:**
a. initial filing
b. material change
**For Material Change Only:**
year _____ quarter _____
date of last report _____

**4. Name and Address of Reporting Entity:**
☐ **Prime** ☐ **Subawardee**
Tier _____, *if known*:

**Congressional District**, *if known*:

**5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:**

**Congressional District**, *if known*:

**6. Federal Department/Agency:**

**7. Federal Program Name/Description:**

CFDA Number, *if applicable*:_____

**8. Federal Action Number,** *if known*:

**9. Award Amount,** *if known*:
$_____

***10.*a. Name and Address of Lobbying Registrant**
(*if individual, last name, first name, MI*):

**b. Individuals Performing Services** (*including address if different from No. 10a*)
(*last name, first name, MI*):

**11.** Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Signature: _____
Print Name: _____
Title: _____
Telephone No.: _____ Date: _____

**Federal Use Only:**

Authorized for Local Reproduction
Standard Form LLL (Rev. 7-97)

PRINT

**INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES**

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreementto make payment to any lobbying entity for influencing or attempting to influence an officer or employeeof any agency, a Member of Congress, an officer or employee of Congress, or an employeeof a Memberof Congress in connection with a covered Federal action. Complete all items that applyfor both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks “Subawardee,” then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., “RFP-DE-90-001.”

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

**Cumulative Inclusion Enrollment Report**

**This report format should NOT be used for collecting data from study participants.**

**Study Title:** _____

**Comments:** _____

| | Ethnic Categories | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Not Hispanic or Latino | | | Hispanic or Latino | | | Unknown/Not Reported Ethnicity | | | |
| **Racial Categories** | **Female** | **Male** | **Unknown/ Not Reported** | **Female** | **Male** | **Unknown/ Not Reported** | **Female** | **Male** | **Unknown/ Not Reported** | **Total** |
| American Indian/Alaska Native | | | | | | | | | | |
| Asian | | | | | | | | | | |
| Native Hawaiian or Other Pacific Islander | | | | | | | | | | |
| Black or African American | | | | | | | | | | |
| White | | | | | | | | | | |
| More Than One Race | | | | | | | | | | |
| Unknown or Not Reported | | | | | | | | | | |
| **Total** | | | | | | | | | | |

**Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.**

**AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT**

| 1. CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 of 4 |

| 2. AMENDMENT/MODIFICATION NO. | 3. EFFECTIVE DATE | 4. REQUISITION/PURCHASE REQ. NO. | 5. PROJECT NO. (*If applicable*) |
|---|---|---|---|
| 0002 | See Block 16C | OS176812 | |

**6. ISSUED BY** CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

**7. ADMINISTERED BY** (*If other than item 6*) **CODE** ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 638-G
Washington DC 20201

**8. NAME AND ADDRESS OF CONTRACTOR** (*No., street, county, State and ZIP Code*)

AVITA MEDICAL AMERICAS,LLC 1476585
AVITA MEDICAL AMERICAS, LLC 92
28159 Avenue Stanford
Suite 220
Valencia CA 91355

CODE 1476585 FACILITY CODE

(x) **9A. AMENDMENT OF SOLICITATION NO.**

**9B. DATED** (***SEE ITEM 11***)

X **10A. MODIFICATION OF CONTRACT/ORDER NO.**
HHS0100201500028C

**10B. DATED (SEE ITEM 13)**
09/29/2015

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*) Net Increase: $24,317,466.00

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

| CHECK ONE | |
|---|---|
| | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.*) SET FORTH IN ITEM 14. PURSUANT TO THE AUTHORITY OF FAR43.103(b). |
| | **C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:** |
| X | **D. OTHER** (***Specify type of modification and authority***) FAR 52.243-2 Changes-Cost Reimbursement |

**E. IMPORTANT**: Contractor ☐ is not. ☒ is required to sign this document and return 2 copies to the issuing office.

**14. DESCRIPTION OF AMENDMENT/MODIFICATION** (*Organized by UCF section headings, including solicitation/contract subject matter where feasible.*)

Tax ID Number: 20-2578762
DUNS Number: 026723570
To modify ARTICLES B.2. BASE PERIOD, C.1. STATEMENT OF WORK, G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR), G.3 KEY PERSONNEL, G.4. INVOICE SUBMISSION, and section j List of Attachments.

The COR is now [**]. The previous COR was [**].
Funds Obligated Prior to this Modification: $16,901,414
Continued . . .

**Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.**

| 15A. NAME AND TITLE OF SIGNER (*Type or print*) | | 16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*) | |
|---|---|---|---|
| Timothy J. Rooney, CFO | | Christopher Scott | |
| **15B. CONTRACTOR/OFFEROR** | **15C. DATE SIGNED** | **16B. UNITED STATES OF AMERICA** | **16C. DATE SIGNED** |
| /s/ Timothy J. Rooney<br>(*Signature of person authorized to sign*) | | /s/ Christopher Scott<br>(*Signature of Contracting Officer*) | 6/24/16 |

NSN 7540-01-152-8070
Previous Edition Unusable

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

| ITEM NO. (A) | SUPPLIES/SERVICES (B) | QUANTITY (C) | UNIT (D) | UNIT PRICE (E) | AMOUNT (F) |
|---|---|---|---|---|---|
| | Funds Obligated with mod #02: [**] | | | | |
| | Total Funds Obligated to Date : [**]<br>PSC Code: 6505 | | | | |
| | Expiration date: September 28, 2020 (Unchanged) | | | | |
| | Delivery: 06/24/2016<br>Delivery Location Code: HHS/OS/ASPR<br>HHS/OS/ASPR<br>200 C St SW<br>WASHINGTON DC 20201 US | | | | |
| | Appr. Yr.: 2016 CAN: 1992016 Object Class: 25103<br>FOB: Destination | | | | |
| 4 | Period of Performance: [**]/2015 to [**]/2020 | | | | 7,958,654.00 |
| | Add Item 9 as follows: | | | | |
| | ASPR-16-01488 — CLINOOOlA Compassionate use, continued access to patients, and mock audit<br>POP: [**]/2016 – [**]/2020<br>Obligated Amount: [**] | | | | |

**ARTICLE B.2. BASE PERIOD is hereby modified as follows:**

| CLIN | Period of Performance | Supplies/ Services | Total Est. Cost | Fixed Fee (7%) | Total Cost Plus Fixed Fee |
|---|---|---|---|---|---|
| | | **COST REIMBURSEMENT** | | | |
| 0001 (Base) | [**] /2015 – [**] /2020 | Licensure, approval and clearance of product through the FDA | [**] | [**] | [**] |
| 0001A | [**] /2016 – [**] /2020 | Compassionate use, continued access to patients, and mock audit | [**] | [**] | [**] |

**FIRM FIXED PRICED**

| CLIN | Period of Performance | Supplies/ Services | Units (# of Product) | Unit Price ($) | Total ($) |
|---|---|---|---|---|---|
| 0002 | [**]/2015 – [**]/2020 | Initial Purchase, storage, and delivery of product | 5614 | [**] | [**] |
| **Total CLINS 1&2** | **[**]/2015 – [**]/2020** | **See Above Descriptions** | | | **$24,860,078 (Funded)** |

**ARTICLE C.1. STATEMENT OF WORK is hereby modified as follows:**

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated June 24, 2016 set forth in SECTION J—List of Attachments, attached hereto and made a part of the contract.

**ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR) is hereby modified as follows:**

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

[**]
Contracting Officer's Representative
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
[**]
[**]
Mailing Address:
200 C Street
Washington, D.C. 20024

**ARTICLE G.3. KEY PERSONNEL is hereby modified as follows:**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the

Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individuals are considered to be essential to the work being performed hereunder:

| Name | Title |
|---|---|
| [**] | [**] |
| [**] | [**] |
| [**] | [**] |
| [**] | [**] |

**ARTICLE G.4. INVOICE SUBMISSION paragraph g is hereby added as follows:**

g. Invoices shall be delivered electronically to the Contracting Officer (CO), the Contracting Officer's Representative (COR), PSC, and e-Room electronically. Unless otherwise specified by the Contracting Officer, all deliverables, invoices, and reports furnished to the Government under the resultant contract shall be addressed as follows:

[**]
Contracting Officer
HHS/ASPR/AMCG
200 C Street, S.W.
Washington, DC 20024
Email: [**]

[**]
Contracting Officer Representative
HHS/ASPR/BARDA
200 C Street, S.W.
Washington, DC 20024
Email: [**]

Email invoices to:

PSC Invoices@psc.hhs.gov

e-Room

**SECTION J — LIST OF ATTACHMENTS: Attachment 1 is hereby modified as follows:**

1. Statement of Work, dated June 24, 2016, 29 pages

**All other terms and conditions of this contract remain unchanged.**

**End of Modification #2**

Advance Understandings

The following scope of work is submitted by Avita Medical Americas LLC in compliance with the advanced understandings listed in ARTICLE B of this contract, including invoicing, publications and press releases, protection of human subjects, communication with BARDA, export control, manufacturing standards, contact prohibitions, subcontracting, data handling, confidentiality, compensation, and security reporting.

Avita Medical BASE SOW

Summary Table

| CLIN | WBS 15t Level Element | Title | Objectives |
|---|---|---|---|
| **0001/*0001A*** | 1 | Project Management | • Establish project management infrastructure<br>• Establish EVM systems<br>• Finalize IMPP<br>• Technical and financial reporting |
| | 2 | Non-Clinical Objectives | • Close gaps in non-clinical data required for PMA module 1 of 3, including biocompatibility, human factors, packaging testing to generate ISO design dossier as an FDA-compliant design history file.<br>• Establish appropriate training for use of ReCell in mass casualty setting.<br>• Achieve 4-year stability<br>• *Expand Compassionate Use IDE 15945 (0001A)*<br>• *Extend Continued Access IDE 13053 (0001A)*<br>• *Incorporate Reimbursement Methods (0001A)*<br>• *Model the Economic Benefits of Medical Countermeasures (0001A*) |
| | 3 | Clinical Objectives | • Complete pivotal trials (-5 and -6 protocols) and clinical study reports for PMA module 3 of 3. |
| | 4 | Regulatory Objectives | • Fulfill Pre-EIJA requirements<br>• Modular PMA Submission<br>• Secure Pre-Market Approval (PMA)<br>• *BIMO Mock Audit (0001A)*<br>• *Enhanced in-house support of the PMA Pathway (0001A)* |

| CLIN | WBS 15t Level Element | Title | Objectives |
|---|---|---|---|
| | **5** | Product Development for Mass Casualty/VMI | • Gather requirements for Mass Casualty and VMI<br>• Redesign ReCell packaging and any other subcomponents in order to meet requirements for more efficient VMI and deployment<br>• Complete V&V |
| | 6 | QSR Objectives | • Perform QSR Gap remediation (address all gaps identified) for PMA module 2 of 3.<br>• Scale up manufacturing process for ReCell to support USG acquisition and US Market introduction<br>• Qualify alternate suppliers, for sustainability |
| **0002** | 7 | Procurement (Initial) | • Execute acquisition contract<br>• Establish VMI<br>• Manage inventory |

CLIN 0001 Overview

Avita's initial primary objective with the proposed effort is to secure FDA approval for the ReCell device. In order to accomplish this we need (1) a documented design (with documentation and supporting testing -e.g. biocompatibility- done to FDA standards rather than ISO standards), for which the work is done in WBS 2.1.2, 2.1.3, and 2.1.4; (2) an FDA-compliant quality system and documentation of GMP manufacturing: WBS 6.1; and (3) Pivotal Clinical Data: WBS 3.1.

The above-mentioned work is delivered to FDA via PMA modules 1, 2 and 3, respectively (WBS 4.2.2). The PMA modules will require organizing and assembling reports into a standardized format, setting context and drawing overall conclusions. In addition to submission of the PMA modules, Avita will also draft (and get FDA-approval of) a Conditions of Approval study protocol (WBS 3.3.1.1, 4.2.2.4.2), and pass through a panel (of experts) review (WBS 4.2.2.5). Avita will need favorable reviews of the PMA modules, CoA protocol approval, and panel review to get the product approved.

Concurrent with the FDA approval process, there is an Emergency Use pathway, activated in the event of a mass casualty, which would enable FDA to authorize use of an investigational (unapproved) product for life-saving measures. There is "pre-emergency" work that can be done to facilitate a future potential Authorization. (WBS 4.1)

Once there is confidence in EUA status or there is PMA approval, base procurement (WBS 7.1.1) is triggered.

There are several other items that are part of the program in order to ensure success in stockpiling, distributing, and using ReCell during an emergency event:

1. Training of medics for use of ReCell in mass casualty events (WBS 2.1.1).
2. Increased shelf-life, with a target of up to 4 years (as supported by stability testing) (WBS 2.3)
3. VMI planning/implementation (WBS 7.2, 7.3, 7.4)

4. Optimize product packaging more for palletized storage and VW, (WBS 5)

5. Qualifying second sources for key components and for product final assembly (i.e. alternative/supplementary sources for enzyme and a supplement/alternative to [**]) (WBS 6.2.2).

CLIN 0001A Overview

The objectives of CLIN 0001a are to facilitate the overarching objective of preparedness for effective treatment of burn injuries secondary to detonation of a nuclear device. In addition to ensuring FDA approval of the ReCell device, the work put forward in this SOW further bolsters efforts for development of familiarity and acceptance of the autograft-sparing product within U.S. Burn Centers by expanding Compassionate Use (WBS 2.1.5), extending Continued Access (WBS 2.1.6), incorporating Reimbursement training (WBS 2.1.6) and Modeling the Economic Benefits of Medical Countermeasures (WBS 2.1.8).

Additionally, this SOW includes scope to ensure successful navigation of the PMA Pathway by adding a BIMO Mock Audit and addingin-house technical and regulatory expertise for overall support to de-risk the program (4.3.1)

CLIN 0001/0001A- Base Period

**1.0 Program Management**

1.1 Internal Project Management

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 1.1.5 Integrated Master Project Plan | Upon delivery to and acceptance by BARDA | All required elements of this plan as listed in the RFP |

1.1.5 Title: Integrated Master Project Plan

Objective/Description of Work: Avita will compile all necessary materials and finalize all aspects of the project related to preparing the Integrated Master Project Plan. This will include finalizing critical path milestones, Work Breakdown Structure (WBS), and Risk Mitigation Plan. The final deliverable of the IMPP will represent the finalization and approval of all project elements between Avita and BARDA.

Milestones:

1.1.5.1 Critical Path Milestones — The critical path milestones are finalized and submitted, reviewed, and approved by BARDA.

1.1.5.2 Work Breakdown Structure—The WBS is finalized and submitted, reviewed, and approved by BARDA for all project activities.

1.1.5.3 Risk Mitigation Plan/Matrix — Any additional elements of risk are identified and all elements of risk are finalized and submitted, reviewed, and approved by BARDA. Risk management plans for each risk are finalized and submitted, reviewed, and approved by BARDA.

Deliverables:

1.1.5 Integrated Master Project Plan Containing all required elements as listed in the RFP and/or requested by BARDA.

1.1.5.1 Critical Path Milestones—An updated and finalized critical path milestone document.

1.1.5.2 Work Breakdown Schedule —An updated and finalized WBS document.

1.1.5.3 Risk Mitigation Plan/Matrix—An updated and finalized risk mitigation plan/matrix.

1.2 Contract Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN001 | | |
| 1.2.2 Reporting | Upon delivery to and acceptance by BARDA | All required reports as listed in the RFP and requested by BARDA |
| 1.2.3 Meetings | BARDA Kick-Off Meeting | Material Presentation Materials |

1.2.2 Title: Reporting

Objective/Description of Work: Avita will comply with all reporting requirements as outlined and formatted in the REP and as requested by BARDA. Reporting will include at a minimum monthly progress reports, annual progress reports, annual invention reports, draft final report, and final report. Additional deliverables such as technology packages, experimental protocols, publication, press releases, security reports, or other reports will be provided to BARDA for review prior to initiation of a corresponding work element, deliverable, or FDA submission.

Milestones:

1.2.2.1 Monthly Progress Report — Delivery to and acceptance by BARDA.

1.2.2.2 Annual Progress Report — Delivery to and acceptance by BARDA.

1.2.2.3 Invention Reports — Delivery to and acceptance by BARDA.

1.2.2.4 Draft Final and Final Progress Reports — Delivery to and acceptance by BARDA.

Deliverables:

1.2.2.1 Monthly Progress Report — A report detailing the prior month's activities and activities planned for the following month. Report will be delivered prior to the 15th of the month following the reporting period.

1.2.2.2 Annual Progress Report — A report summarizing the activities of the period of performance and the activities planned for the upcoming period. Report will be delivered prior to the 30th of the month following the reporting period.

1.2.2.3 Annual/Final Invention Report — A report detailing any intellectual property developed as a result of the work performed during each period of performance and the entire contract period. Report will be delivered in conjunction with the annual progress report.

1.2.2.4 Draft Final and Final Progress Report—The Final Progress Report will include a complete summary of all work performed during the entire contract period of performance. A Draft Final Progress Report will be delivered 45 days prior to contract expiration for BARDA review and comments. A Final Progress Report will be delivered prior to 30 days following contract expiration.

1.2.3 Title: Meetings

Objective/Description of Work: Avita and BARDA will engage in regular meetings to coordinate and review project activities. Meetings will be both face-to-face and teleconference/video conference. The first official meeting will be theface-to-face kick-off meeting, followed by status update meetings on a biweekly/monthly basis, ad hoc teleconferences and site visits, and annual meetings to report on the period of performance activities.

Milestones:

1.2.3.1 Kickoff Meeting with BARDA — The contract is awarded and aface-to-face kickoff meeting is conducted within 30 days of award date.

Deliverables:

1.2.3.2 Kickoff Meeting Presentation Materials — Avita will prepare all necessary presentation materials for the kickoff meeting.

1.4 IMS and EVM

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.4.2 Performance Measurement Baseline | Performance Measurement Baseline Review (PMBR) | All required components for the PMBR |
| 1.4.3 Integrated Master Schedule | PMBR | Integrated Master Schedule |
| 1.4.4 Monthly Earned Value Performance Report | Delivery to and acceptance by BARDA | Monthly Earned Value Performance Report |
| 1.4.5 Supplemental monthly CAP report | Delivery to and acceptance by BARDA | Supplemental monthly CAP report |

1.4.2 Title: Performance Measurement Baseline

Objective/Description of Work: The Performance Measurement Baseline will provide a master schedule of deliverables, costs, and milestones in order to completely cover all items in the SOW. All required components will be submitted to BARDA within 90 days of contract award. BARDA and Avita will mutually agree on the budget, schedule and technical plan baselines as a result of the PM BR.

Milestones:

1.4.2 Performance Measurement Baseline Review — The PMBR plan is submitted and reviewed by BARDA.

Deliverables:

1.4.2 Performance Measurement Baseline Review Plan and Required Components — A plan detailing a schedule of deliverables, costs, milestones, and risks that will serve as the basis for measuring project progress.

1.4.3 Title: Integrated Master Schedule (IMS)

Objective/Description of Work: The IMS will be used to monitor performance of the contract. Avita will develop an IMS in a format approved by BARDA in order to track key milestones, Go/No Go decision gates. The IMS will contain baseline start and finish, forecast start and finish, actual start and finish, predecessor and/or successor. Avita will provide a baseline IMS for the PMBR and monthly updates thereafter.

Milestones:

1.4.2 Integrated Master Schedule is approved by BARDA.

Deliverables:

1.4.3 Integrated Master Schedule — Provided for the PMBR and monthly in order to monitor performance of the contract. The IMS shall be provided at the work package level in MS Project file format.

1.4.4 Title: Monthly Earned Value Performance Report

Objective/Description of Work: The Monthly Earned Value Performance Report will be generated from Avita's EVMS in order to track any project variances against the baseline. The report will contain technical, schedule, and cost status information in order to identify any issues that may impact project progress and/or cost.

Milestones:

1.4.4 Monthly Earned Value Performance Report — Delivery to and acceptance by BARDA.

Deliverables:

1.4.4 Monthly Earned Value Performance Report — Provided monthly to track project progress according to WBS and EV variance.

1.4.5 Title: Supplemental Monthly CAP Report

Objective/Description of Work: The Supplemental Monthly CAP Report will be generated from Avita's EVMS and will contain cost information to report on the time phased budget, earned value, and actual costs of work performed. The report will be submitted monthly to BARDA for review.

Milestones:

1.4.5 Supplemental Monthly CAP Report — Delivery to and acceptance by BARDA.

Deliverables:

1.4.5 Supplemental Monthly CAP Report — Provided monthly to detail time phased budget, earned value, and actual costs of work performed as captured by Avita's EVM systems.

**Non-Clinical Objectives**

**2.1 Efficacy and Safety**

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 2.1.1.1 Updated training resources for mass casualty | Effective training for mass casualty event. | Updated user training documentation |
| 2.1.2 Biocompatibility review | Biocompatibility review complete | Biocompatibility Review Report |
| 2.1.3 Human Factors | FDA requests human factors studies | Human factors studies submitted to FDA |
| 2.1.4 FDA-compliant design documentation | Completion of backup documentation for PMA module 1. | QSR-mandated design control documents and supporting lab test results |
| 2.1.5 Compassionate Use IDE | Deliver to BARDA the annual IDE report on Compassionate Use. | Annual IDE report on Compassionate Use. |
| 2.1.6.1 Continued Access IDE 13053 | Deliver to BARDA the clinical trial protocol (CTP) on Continued Access. | Clinical trial protocol (CTP) on Continued Access. |
| 2.1.6.2 Annual IDE Report | Deliver to BARDA the Annual IDE reports | Annual IDE reports |
| 2.1.6.3 Final Clinical Study Report | Deliver to BARDA the Final Clinical Study Report | Final Clinical Study Report |
| 2.1.7 Burn Center Reimbursement educational materials | Deliver to BARDA the Guidance materials on reimbursement. | Guidance materials on reimbursement. |
| 2.1.8.1 Kick-off Meeting & Project Management | Complete Kick-off Meeting | MS PowerPoint presentation outlining understanding of goals, objectives, anticipated approach, and project deliverables, milestones, and timeline. |
| 2.1.8.2 Targeted Literature Search | Complete Literature Search | Draft and final literature review search strategy in MS Word |
| 2.1.8.3 Focusing goals | Complete Briefing which defines focus of goals | A brief MS PowerPoint presentation outlining options for the model framework |
| 2.1.8.4 Model Storyboard | Completion of Model Storyboard | Draft and revised model storyboards (MS PowerPoint). |

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 2.1.8.5 KOL Engagement | Complete Recruitment of KOL's | KOL recruitment and management (for [**] KOLs), draft and final KOL summary feedback (Word) for all KOL meetings, final storyboard (MS PowerPoint). KOL's to be approved by BARDA. |
| 2.1.8.6 Preliminary Model Programming and Results | Complete Preliminary Model | Preliminary model (MS Excel 2013 file for PC) and a presentation of preliminary findings in a MS PowerPoint slide deck to be shared with BARDA via WebEx or during an in-person meeting. |
| 2.1.8.7 Final Model | Complete Final Model | Final model version (in MS Excel) and final results slides (in MS PowerPoint); quality assurance documentation (MS Word) can be made available upon request. |
| 2.1.8.8 Technical Reporting | Complete Final Technical Report | Two drafts and a final version of a written technical report (MS Word). |

2.1.1.1 Title: Updated training resources for mass casualty

Objective/Description of Work: Existing training manuals for use of the ReCell device are designed for a clinical/surgical setting by experienced clinicians. Led by the Director of Education, with support from the Education Specialist, Avita will develop a new training protocol sufficient for a mass casualty event for ReCell to be used by minimally trained personnel that may or may not have burn surgery experience. Target goal will be a one-hour training session to personnel at a trained medic level or higher. New training materials will be submitted to BARDA for review/feedback and then finalized.

Milestones:

2.1.1 Creation of training materials, including video, workshop/online course materials, reference guides, as determined in collaboration with BARDA

Deliverables:

2.1.1.1 Training materials as determined in collaboration with BARDA.

2.1.2 Title: Biocompatibility review complete

Objective/Description of Work: Full biocompatibility is demonstrated for EU and Australia, to ISO standards. The testing work needs to be done to US FDA standards. Results of biocompatibility review will be submitted to BARDA for review/feedback.

Milestones:

2.1.2 Biocompatibility submitted to FDA

Deliverables:

2.1.2 Biocompatibility Review Report draft and final report submitted to BARDA and final report submitted to FDA

2.1.3 Title: Human Factors

Objective/Description of Work: Avita will conduct an evaluation to ensure that the ReCell devices meet usability guidelines when used by the intended user population. Avita will conduct all required studies and submit the results to BARDA for review and feedback. Upon BARDA approval, Avita will submit report to FDA.

Milestones:

2.1.3 Requested data/report submitted to FDA

Deliverables:

2.1.3 As requested by FDA, human factors draft and final reports submitted to BARDA and final data and report submitted to FDA

2.1.4 Title: FDA-Compliant Design Documentation

Objective/Description of Work: Avita's recent gap analysis for PMA module 1 readiness indicates that in addition to biocompatibility testing Avita will need to create an FDA QSR-compliant design control document package, including backup lab test data and reports, including packaging testing. Avita will provide the various reports to BARDA, as requested, for review and approval prior to sending to FDA.

Milestones:

2.1.4.1 Functional Testing Complete

2.1.4.2 Packaging/Shipping Testing Complete

2.1.4.3 EMI/EMC Testing Complete

2.2 Non-clinical data sufficient for PMA module 1 of 1

Deliverables:

2.1.4 QSR-mandated design control documents and supporting lab test results — Avita will generate a design control document package that will meet current FDA requirements, in support of PMA module 1 of 1

2.1.5 Title: Compassionate Use IDE 15945

Objective/Description of Work: Avita's Compassionate Use IDE provides a mechanism for surgeon access to ReCell as an investigational device, for patients presenting with life-threatening injuries for which there is insufficient donor skin for conventional autograft treatment. Requests, along with a letter of support, are evaluated for suitability and patients are approved by Avita on a case by case basis. Surgeons may request Compassionate Use regardless of their prior experience with ReCell and independent from their site's participation in IDE 13053 (for the study of burns). The Compassionate Use IDE provides for further experience in the use of ReCell, toward fulfilment of BARDA's objective of familiarity/acceptance in US burn centers. Avita personnel travel to support these surgeries, and a 3`d-party CRO and an independent consultant are contracted to perform clinical monitoring for compliance with Good Clinical Practice. In-house regulatory personnel will draft associated regulatory submissions.

Milestones:

2.1.5 Deliver to BARDA the annual IDE report on Compassionate Use.

Deliverables:

2.1.5 Annual IDE report on Compassionate Use.

2.1.6 Title: Continued Access IDE 13053

Objective/Description of Work: FDA may allow continued enrollment of subjects after the controlled clinical trial under an IDE has been completed in order to allow access to the investigational medical device while the marketing application is being prepared by the sponsor or reviewed by FDA. Under this policy, a sponsor may propose to conduct an "extended" clinical trial if: 1) there is a public health need for the device and 2) there is preliminary evidence that the device is likely to be effective and no significant safety concerns have been identified for the proposed indication. Avita will submit CTP001-7 to the FDA to allow Continued Access of ReCell at up to 15 clinical sites for treatment of up to an additional 100 patients. As with Compassionate Use, this positions the US burn centers to be more effective in the event of a mass casualty. Onsite training of burn centers will be required, and a 3rd-party CRO will be contracted for clinical project management, clinical data management and clinical monitoring, for compliance with IDE requirements.

Milestones:

2.1.6.1 Continued Access IDE 13053 — Delivered to BARDA

2.1.6.2 Annual IDE Report — Delivered to BARDA

2.1.6.3 Final Clinical Study Report—Delivered to BARDA

Deliverables:

2.1.6.1 Continued Access IDE 13053 Report

2.1.6.2 Annual IDE Report

2.1.6.3 Final Clinical Study Report

2.1.7 Title: Reimbursement

| WBS# and Title<br>CLIN0001A | Deliverable |
|---|---|
| 2.1.7 Burn Center Reimbursement educational materials | Guidance materials on reimbursement |

Objective/Description of Work: Reimbursement coding is central to establishing familiarity and acceptance of a new product in healthcare. Avita will hire a Reimbursement Manager to establish coding mechanism(s) for ReCell, and this information will be integrated into the educational material provided to burn centers. The support of expert consulting is also anticipated.

Milestones:

2.1.7 Guidance materials on reimbursement—Delivered to BARDA

Deliverables:

2.1.7 Guidance materials on reimbursement

2.1.8 Title: Modeling the Economic Benefits of Medical Countermeasures

Objective/Description of Work: Avita will work with a Subject Matter expert to develop a generic model for cost and economic impact in burn care with introduction of ReCell technology as a candidate for evaluation, both at the single-center level, and a multi-center (commercial) use. The model (aka tool) will allow for evaluation of cost impact on burn care from use of specific products as well as broader economic impact. The tool is expected to be self-standing and include access to other required information such as databases necessary for full functionality and use of the software. Other features of the model will include:

a. A comprehensive review of parameters which influence the integrated cost impact on burn care (and broader economic impact) both directly or indirectly would be identified and evaluated. Such parameters may include but are not limited to impact of resources (surgical and non-surgical) personnel time, material resources as well tangible changes to the clinical outcomes (example, length of hospital stay or ICU days). Impact of product launch pricing models and potential market share over time may also be included in the tool.

b. The tool will be designed to predict costs and benefits associated with the care of burn patients based on (i) specifiable characteristics of a hypothetical group of patients (e.g. in terms of burn severity, number of patients, etc) and (ii) modeled changes to fundamental cost drivers associated with particular changes in practice as a result of introduction of the new product and associated downstream impact. As such, the financial and economic impact of introduction of medical countermeasures, alone and in combination, may become predictable.

c. Avita will test the tool with available data and assumptions and iteratively develop in consultation with the experts to refine the model using ReCell data as well as to ensure the generic nature of the cost and economic Impact tool.

d. For this effort it is recognized that definitive burn care is typically provided over time and that care treatments/procedures change as burn etiology evolves. This has allowed for identification of distinct treatment areas within the definitive care continuum. New products (such as Avita's ReCell) directed at such treatment targets are expected to have an impact on the cost effectiveness of burn care, which represents the over-arching scope of this effort.

e. For the sake of comprehensive analysis under this effort, an exhaustive list of parameters (preferably ranked) shall be identified and qualified to be measurable within the following treatment targets in the continuum of definitive care: (1) debridement, (2) application of skin substitutes (which eliminate autografting), (3) autograft sparing technology, and (4) adjuncts to enhance/accelerate healing.

f. The overall capability of the tool is to capture the key parameters across this continuum wherein impact of any new products altering these key parameters within a treatment area, objectively demonstrates a clear, measurable value proposition (or a lack thereof) in the overall cost effectiveness and other attributes. The tool would also feature an ability to be customized either by turning on or off the key parameters or add a user chosen parameter, based on relevance to target area.

g. Based upon a competitive selection process between three potential SME's, IMS Health is the primary candidate for this project. A designated panel of experts should be accessible.

2.1.8.1 Title: Kick-off Meeting & Project Management

Objective/Description of Work: A Kick-off meeting will be conducted to:

- Introduce the project team members
- Discuss KOL selection process;
- Review and confirm the goals of the project;
- Finalize the approach to the project phases; and
- Review anticipated project deliverables, milestones and timelines (Gantt chart).

Milestones:

2.1.8.1 Complete Kick-off Meeting

Deliverable:

2.1.8.1 MS PowerPoint presentation outlining understanding of goals, objectives, anticipated approach, and project deliverables, milestones, and timeline.

2.1.8.2 Title: Targeted Literature Search

Objective/Description of Work: Develop literature search strategy and obtain agreement with BARDA. Perform literature search and report on results.

Milestones:

2.1.8.2 Complete Literature Search

Deliverable:

2.1.8.2 Draft and final literature review search strategy in MS Word.

2.1.8.3 Title: Focusing goals

Objective/Description of Work: Compile a preliminary burn care model structure and identify any key points that may require discussion and agreement between project participants. Develop a discussion deck (in MS PPT) that outlines options for the model framework, including a detailed proposed structure. The deck will be used to facilitate an interactive discussion with BARDA.

Milestones:

2.1.8.3 Complete Briefing which defines focus of goals

Deliverable:

2.1.8.3 A brief MS PowerPoint presentation outlining options for the model framework and structure to facilitate discussion; appended summary of action items.

2.1.8.4 Title: Model Storyboard

Objective/Description of Work: Develop a Model Storyboard, which is a detailed plan for the model, intended to provide an opportunity for discussion and agreement with BARDA, prior to programming. This storyboard will include the model structure to facilitate cost effectiveness and budget impact assessments, detailed parameter types (including all clinical inputs and costs), with referenced default values for all variables, as well as model user-functionality and model outputs.

Although this model will be developed to have a generic structure, the storyboard and model development will be performed to permit evaluation of Avita's ReCell technology. One primary comparator (e.g. a standard autograft procedure) will serve as the base case for the cost-effectiveness evaluation, and will focus the storyboard accordingly with detailed input values around ReCell and the base case comparator. The model will be developed to include up to three (3) dummy comparators to permit exploration of additional interventions at points along the burn care pathway, but data specific to these hypothetical interventions will not be included in the storyboard or analyses. Because the US model may be used in discussions with different types of stakeholders, it is anticipated that the storyboard will include information to inform different perspectives, including hospital perspective, payer perspective, and at BARDA's option, societal perspective. Differences between these may include time horizon (shorter term for hospital perspective) and cost inputs. It is assumed that budget impact calculations will rely on the same underlying structure and inputs as are used for the cost- effectiveness model, and thus gain efficiencies between the two analysis types. However, pricing predictions, market uptake assumptions and market share distribution will be required from marketing research. Any additional detailed clinical and cost input values not available from other sources may be solicited from KOLs (e.g. likely resource use assumptions); based on discussion with KOLs, however, a survey or database analysis Optional Task may be desired to obtain the best possible data.

After presentation of the storyboard to BARDA, comments received during this meeting and any additional consolidated comments received in the following week will be incorporated into a storyboard revision. Input from all internal stakeholders at this phase will ensure the model contains the appropriate elements and addresses key considerations. This revision will serve as the platform for the first KOL engagement.

Milestones:

2.1.8.4 Completion of Model Storyboard

Deliverable:

2.1.8.4 Draft and revised model storyboards (MS PowerPoint).

2.1.8.5 Title: KOL Engagement

Objective/Description of Work: Engage three KOLs for the following:

- One hour each for a meeting to collect feedback on the proposed model storyboard;
- One additional hour each to help fill any key model data gaps (e.g. providing resource use assumptions);
- A two-hour advisory panel (joint meeting) for a discussion of the preliminary model and results. (At Avita's option, this may be redefined as a half-day advisory board with KOLs and all project participants. Please see Optional Tasks.)

Engage with the KOLs via teleconference, utilizing presentation materials generated during other project tasks, including the storyboard and preliminary model results presentation. Provide a short written summary of meeting minutes and implications for analysis following ach discussion. Following one round of review, the summary of feedback (meeting minutes) document will be considered final, and details will be incorporated into a final version of the storyboard.

The budget assumes [**] US-based KOLs. Payment of honoraria will be contracted in accordance with Avita governance procedures. Any fees paid by will be considered as pass-through costs to BARDA and will be clearly reported and documented.

Milestones:

2.1.8.5 Complete Recruitment of KOL's

Deliverable:

2.1.8.5 KOL recruitment and management (for [**] KOLs), draft and final KOL summary feedback (Word) for all KOL meetings, final storyboard (MS PowerPoint). KOL's to be approved by BARDA

2.1.8.6 Title: Preliminary Model Programming and Results

Objective/Description of Work: Initiate programming the model for use on a PC platform with MS Excel 2013. Populate the model with parameter estimates, and use the model to generate preliminary estimates of the cost- effectiveness of using ReCell technology vs a chosen appropriate comparator available perspectives (e.g. hospital, payer, and (optional) US society), and of the budget impact of adding ReCell to the available burn care therapies. Include up to three (3) dummy comparators into the model (one for each phase of the burn care pathway) to permit evaluation of the impact of other therapeutic options. Model programming will also include a univariate sensitivity analysis function to identify the most sensitive parameters in the model, displayed as a tornado diagram for convenient interpretation and reporting.

At this stage, Avita will outline preliminary model results, and will present the draft results to BARDA to obtain internal feedback, and also deliver the preliminary model to ensure transparency.

After collecting initial feedback from BARDA, engage the [**] KOLs in a single2-hour meeting for collective review and validation.

Milestones:

2.1.8.6 Complete Preliminary Model

Deliverable:

2.1.8.6 Preliminary model (MS Excel 2013 file for PC) and a presentation of preliminary findings in a MS PowerPoint slide deck to be shared with Avita via WebEx or during an in-person meeting.

2.1.8.7 Title: Final Model

Objective/Description of Work: Develop the final version of the model and update the preliminary results slides with final results to be shared with BARDA via WebEx or during an in-person meeting. The model will be developed for two US perspectives, and at BARDA's option, may include a third. The scope of work assumes that the costing model will contain two perspectives (hospital, payer), and one primary comparator to ReCell (e.g. standard of care autografting), with dummy structure for three (3) additional comparators (i.e. intervention-specific data will not be prepopulated for these dummies).

Milestones:

2.1.8.7 Complete Final Model

Deliverable:

2.1.8.7 Final model version (in MS Excel) and final results slides (in MS PowerPoint); quality assurance documentation (MS Word) can be made available upon request.

2.1.8.8 Title: Technical Reporting

Objective/Description of Work: Prepare a written report which includes a description of the project objectives, methods (including structure, referenced parameter values, and analytic outcomes), results, and concluding summary of the results ( 520 pages).

Milestones:

2.1.8.8 Complete Final Technical Report

Deliverable:

2.1.8.8 Two drafts and a final version of a written technical report (MS Word).

2.1.8.9 Title: Optional Supplemental Project Tasks

Objective/Description of Work: The following is a list of representative tasks that may be required. This task list may be modified and/or supplemented in accordance with written direction and approval from BARDA.

- Option 1: Abstract and poster
- Option 2: Scientific manuscript
- Option 3: Adding societal perspective to the model
- Option 4: Expert survey to obtain missing data
- Option 5: Database analysis to obtain missing data
- Option 6: Half-Day advisory board to review and discuss preliminary model
- Option 7: Dynamic summary report
- Option 8: iPad tool adaptation
- Option 9: Bank of Hours to Support Scope Amendments
- Option 10: Detailed Analysis of Patient Level Data:
    - Analysis will include ICD codes (such as under ICD9, 10 ),HCPCS code-Level data, CPT code-Level data, Revenue code-Level data and other data sources such as the Healthcare Blue Book. These data can be used to assess data provided by providers on resource use (hospital LOS, frequency of dressing changes, use of diagnostics and disposables, blood transfusions, escharotomies, autografting, etc.) at each stage in the treatment timeline (debridement, autografting, etc.)

2.3 Stability and Review of Extended Shelf Life

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 2.3.1 Stability Plan | Expiration limiting components identified and plan developed to extend to [**] year target | Stability Plan |
| 2.3.6 Stability Report (accelerated aging) | Accelerated aging testing results complete | Stability report |
| 2.3.7 Stability report (real- time aging) | Real-time aging testing results complete | Stability report |
| 2.3.8 Review of extended shelf life | New expiry limits determined | Results report submitted to BARDA |
| 2.3.9 Revisions to labeling | Stability extension submission | Shelf life report and revised labeling submitted to FDA |

2.3.1 Title: Stability Plan

Objective/Description of Work: Avita will develop a stability plan that will outline the testing necessary to extend the shelf life of the ReCell unit to [**] years in order to minimize product losses due to expiry. Avita will focus on specific expiration-limiting components (enzyme and buffer, RPU, and nozzle). Avita will design and execute on a stability testing plan to verify stability for extension of shelf life. Reports will be submitted to BARDA detailing the shelf life of ReCell units. Labeling will be modified based on new expiries and submitted to FDA to approval.

Milestones:

2.3.1 Expiration limiting components are identified and a plan is developed to extend ReCell unit to a target of [**]-year expiry.

Deliverables:

2.3.1 Stability plan outlining all necessary real-time and accelerated aging testing required to justify expiry.

2.3.6 Title: Stability Report (accelerated aging)

Objective/Description of Work: Following accelerated aging testing, a report will be prepared outlining the product performance. The report will detail whether expiry targets were achieved. If targets were not achieved, a plan will be provided detailing further modifications or a plan for acceptance of a new expiry target. Avita will submit to BARDA for review and comments.

Milestones:

2.3.6 Stability testing results complete.

Deliverables:

2.3.6 Stability report detailing product performance for ReCell components after aging

2.3.7 Title: Stability Report (real-time aging)

Objective/Description of Work: Following real-time aging testing, a report will be prepared outlining the product performance. The report will detail whether expiry targets were achieved. If targets were not achieved, a plan will be provided detailing further modifications or a plan for acceptance of a new expiry target. Avita will submit to BARDA for review and comments.

Milestones:

2.3.7 Stability testing results complete.

Deliverables:

2.3.7 Stability report detailing aged performance for ReCell components

2.3.8 Title: Review of extended shelf life

Objective/Description of Work: Avita will prepare a report for BARDA detailing the changes product shelf life. Avita will report on the plan for accordingly revised product labeling to be submitted to FDA.

Milestones:

2.3.8 Delivery of report of extended shelf life

Deliverables:

2.3.8 Shelf life report delivered to BARDA for review, followed by a report detailing plans for FDA submission, and implications for the VMI.

2.3.9 Title: Revisions to labeling

Objective/Description of Work: Avita will revised the product labeling to reflect new shelf life parameters, and will submit to FDA.

Milestones:

2.3.9 FDA approval of revised product labeling

Deliverables:

2.3.9 New product labeling and FDA submission for review/approval of new product labeling.

**2 Clinical**

3.1 Pivotal Clinical Trials

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 3.1.1.4 Clinical Study Report | CTP001-5 Clinical Study Report (CSR) complete, review | CTP001-5 Clinical Study Report (CSR), review/submit to FDA |
| 3.1.2.6.1 Statistical Analysis (9mo) | Statistical analysis complete | CTP001-6 Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.1.2.6.2 Clinical Study Report (9mo) | CTP001-6 Initial (9- months) CSR complete | CTP001-6 Initial (9 months) CSR, review (PMA module 3 of 3) |
| 3.1.2.6.4 Statistical Analysis (12mo) | Statistical analysis complete | CTP001-6 Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.1.2.6.5 Clinical Study Report (12mo) | CTP001-6 Final (12- months) CSR complete | CTP001-6 Final (12 months) CSR, review |

3.1.2.8 Title: Final CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Pivotal Clinical Trials encompass two ongoing clinical protocols:CTP001-5 (deep partial-thickness) and CTP001-6 (mixed depth including full-thickness). Both studies show definitive closure using less donor skin with ReCell as compared to standard care, and are also looking at long-term scar outcomes. The clinical study report (CSR) from CTP001-6 is the primary component of PMA module 3 of 3. All CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.1.1.1 Last subject last visit forCTP001-5 (complete)

3.1.1.4 Clinical Study Report complete forCTP001-5

3.1.2.1.1 FDA Statistical Analysis Plan submitted and approved by FDA forCTP001-6 (complete)

3.1.2.3.2 Last subject last visit forCTP001-6

3.1.2.6.4 CRO completes 9-month statistical analysis for PMA module 3 of 3. 3.1.2.8 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.1.1.4 CTP001-5 Clinical Study Report (CSR)

3.1.2.6.1 CTP001-6 9-month Tables, Listings & Figures (i.e. Statistical analysis output)

3.1.2.6.2 CTP001-6 Initial (9-months) CSR (for PMA module 3 of 3)

3.1.2.6.4 CTP001-6 12-month Tables, Listings & Figures (i.e. Statistical analysis output)

3.1.2.6.5 CTP001-6 Final (12-months) CSR

**3 Regulatory**

4.1 Pre-Emergency Use Authorization

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 4.1 Pre-Emergency Use Authorization | Avita completes all submissions needed for EUA | All data requested by BARDA to obtain pre-EUA |

4.1 Title: Pre-Emergency Use Authorization

Objective/Description of Work: Avita will support BARDA/HHS in obtaining a Pre-Emergency Use Authorization for the ReCell device. All required studies, reviews, reports, and analyses will be provided as requested.

Milestones:

4.1 Avita completes all submissions needed for EUA

Deliverables:

4.1 Submission to BARDA/HHS of all required materials needed for Pre-EUA.

4.2 Premarket Approval (PMA)

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 4.2.2.1.4 Module 1 Submission | Module 1 package assembled | Module 1 package to FDA |
| 4.2.2.2.4 Module 2 Submission | Module 2 package assembled | Module 2 package to FDA |
| 4.2.2.3.4 Module 3 Submission | Module 3 package assembled | Module 3 package to FDA |
| 4.2.2.5.3 Create action plan to address panel recommendations | FDA Panel Meeting | Action Plan |

4.2.2.1.4 Title: Module 1 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package with modular submissions for FDA review and approval. The PMA package will consist of three PMA modules. Module 1 will focus on non-clinical data.

Milestones:

4.2.2.1.4 Module I package assembled

Deliverables:

4.2.2.1.4 Module 1 submission to FDA — Module 1 includes biocompatibility, human factors, shipping/packaging validation, EMI/EMC, and all other required non-clinical data.

4.2.2.2.4 Title: Module 2 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package for FDA approval. The PMA package will consist of three PMA modules. Module 2 will focus on manufacturing data.

Milestones:

4.2.2.2.4 Module 2 package assembled

Deliverables:

4.2.2.2.4 Module 2 submission to FDA — Submission will include the principles of operation, quality system and manufacturing documentation, sterilization, shelf-life information, and packaging information.

4.2.2.3.4 Title: Module 3 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package for FDA approval. The PMA package will consist of three PMA modules. Module 3 will focus on clinical data. Module 3 will be submitted to BARDA for review and approval, followed by submission to FDA.

Milestone:

4.2.2.3.4 Module 3 package assembled and approved by BARDA

Deliverables:

4.2.2.3.4 Module 3 submission to FDA — Submission will include theCTP001-6 clinical data labels and manuals, draft post-marketing plan (CoA study protocol) and bibliography.

4.3 Title: BIMO Mock Audit and Enhanced in-house support of the PMA Pathway

| WBS# and Title<br>CLIN0001A | Milestone | Deliverable |
|---|---|---|
| 4.3.1 | Complete Remediation of Trial Master Files | Submit BIMO Mock Audit Report and remedial action plan. |

Objective/Description of Work: Prepare for and execute a BIMO Mock Audit to review the Trial Master Files (TMF) at Avita and to audit the site files of [**] selected burn centers participating in IDE 13053. Avita will subsequently prepare a remedial action plan, and then correct deficiencies as identified by the mock auditing. The status of the remediation activity will be reported in Avita's monthly progress report to BARDA. Ensure availability of in-house regulatory, quality, engineering and manufacturing subject matter experts to respond to the following:

- Clinical and non-clinical data questions, findings, deficiencies & remediation.

- Technical and regulatory questions from BARDA and FDA in response to Avita's submission of documents and reports.
- Implementation of design and manufacturing change requests and process improvements as a result of review and feedback.

Milestone:

4.3.1 Complete Remediation of Trial Master Files

Deliverables:

4.3.1 Submit BIMO Mock Audit Report and remedial action plan.

**4 Product Development for mass casualty/VMI**

5.1 Requirement Gathering, 5.2 Product Design, 5.3 Systems Requirements and Design Review, and 5.4 CDC Quality Agreement

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 5.3 Systems Requirements (VMI optimization) and Design Review | Review of VMI optimized product design package complete | Product optimized for VMI Design Package |
| 5.4 CDC Quality Agreement | Executed CDC Quality Agreement | CDC Quality Agreement |

5.3 5.4 Title: Systems Requirements (VMI optimization) and Design Review

Objective/Description of Work: In order to develop a product ready for manufacturing and stockpiling, Avita will work with BARDA to first gather the requirements for DFM/DFA, inventory management and any other requirements. Based on the requirements, Avita will initiate Product Design to all ensure the product will meet specifications. This includes design and review for any changed or affected part: Components, Subassembly, Product System, and Packaging Design. Document package will be sent to BARDA for review. Avita will work with CDC to establish a quality agreement, if required.

Milestones:

5.1 Requirements document compiled from BARDA

5.2.1.2 Component Design Review complete

5.2.2.2 Subassembly Design Review complete

5.2.3.2 Product System Design Review complete

5.2.4.2 Packaging Design Review complete

5.3 Full systems requirements and design review complete and approved by BARDA

5.4 If required, establish quality agreement with CDC for supporting VMI

Deliverables:

5.3 System Requirements and Design Review — A system requirements and design review report will be submitted to BARDA containing the requirements and the design changes made to meet those requirements.

5.4 Agreed upon CDC quality agreement for supporting VMI (if required)

5.5 Verification and Validation

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 5.5 Verification and Validation Report | V&V verifies product meets specifications and requirements | V&V Report |

5.5 Title: Verification and Validation Report

Objective/Description of Work: Verification & Validation are used to verify that the product meets the specifications and requirements and address the intended purpose. Verification demonstrates that the product meets specification and Validation demonstrates fitness of use for the intended purpose. Once V&V results are positive, the product is ready to release to manufacturing. Avita will submit a report to BARDA detailing the results of the V&V analysis.

Milestones:

5.5 Testing and analysis indicate that the product meets specification and intended purpose.

Deliverables:

5.5 V&V Report — Avita will submit a report to BARDA detailing the results of the V&V analysis.

**5 QSR**

6.1 Quality System Preparedness

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 6.1.3 3rd Party Audit | Audit completed | QSR Audit Report |

6.1.3 Title: 3rd Party Audit

Objective/Description of Work: The US FDA Quality System Regulation (QSR) describes the environment under which medical device firms must operate. This task involves preparing the Avita quality systems for FDA review and inspection, and verifying compliance with FDA requirements. Avita hired an external 3rd party auditor to complete a QSR gap analysis. Following the audit a gap assessment was prepared and presented to Avita from the 3rd party auditor. Avita will develop a Gap Corrective Action plan to address any gaps identified. This will support PMA submission. Once the corrective action plan has been implemented and changes are in place a mock audit will be performed by a 3rd party auditor in preparation for an expected FDA inspection during PMA review.

Milestones:

6.1.1 Gap Assessment

6.1.2 Gap corrective action performed and all systems brought into compliance

6.1.3 Mock QSR audit

Deliverables:

6.1.3 QSR 3rd Party Audit Report - Avita will submit a report to BARDA detailing the results of the final QSR audit.

6.2 Commercial Manufacturing

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 6.2.1 Commercialization Plan and Gap Analysis | Completion of commercialization plans | Final Commercialization Plan |
| 6.2.2.4 Validation Report | 10/0Q/PQ process validations complete | Validation Report |

6.2.1 Title: Commercialization Plan and Gap Analysis

Objective/Description of Work: Perform a gap analysis to assess commercialization readiness and draft a commercialization plan in support of market entry. Tasks include, as necessary, establishing SKU#, Supply chain and vendor qualifications, raw material inventory, sterilization, packaging, and labeling, and lot release.

Milestones:

6.2.1.1 Commercialization Gap Assessment completed

6.2.1.2 Commercialization Plan Draft created, reviewed with BARDA

6.2.1.3 Commercialization Plan finalized.

Deliverables:

6.2.1.1 Commercialization Gap Assessment Report

6.2.1.2 Commercialization Plan draft and final versions reviewed and submitted to BARDA.

6.2.2.4 Title: Validation Report

Objective/Description of Work: Process validation involves the collection and evaluation of data from the processes used to produce the product. Avita's commercial manufacturer will lead the effort in manufacturing, under close supervision and collaboration with Avita. Sterile packaging will be a primary focus of the validation effort to ensure repeatable package integrity and valid sterilization processes. Process validations will include 1Q/0Q/PQ and final validation. Avita will present a final report detailing the results of the validation analysis.

Milestones:

6.2.2.1 IQ, Installation Qualification complete

6.2.2.2 00, Operation Qualification complete

6.2.2.3 PO, Process Qualification complete

Deliverables:

6.2.2.4 Validation Report - Avita will submit a report to BARDA detailing the results of the process validation analysis.

CLIN 0002 — Base Period

**6 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 7.1.1.2 Product Manufacturing | Order Received | Initial Product |
| 7.1.1.3 Deploy product to VMI sites | Product shipped to sites | Product deployed |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: Upon authorization from BARDA, Avita will cause the production and delivery of ReCell devices. Upon receiving the order Avita will authorize the manufacturer to procure supplies for the manufacture of the devices and preparing designated inventory locations.

Milestones:

7.1.1.1 Order Received

7.1.1.2 Delivery of specified quantity of units to VMI.

Deliverables:

7.1.1.2 Initial Product — Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices.

7.1.1.3 Product integrated into VMI and available for deployment

7.2 VMI Remote inventory management system

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN001 | | |
| 7.2.1 - Gather VMI Requirements | All VMI requirements agreed upon with BARDA | VMI Requirements Document |

7.2.1 Title: Gather VMI Requirements

Objective/Description of Work: Avita will work with USG to identify all VMI requirements, and prepare a document detailing the requirements.

Milestones:

7.2.1 All VMI requirements agreed upon with BARDA

Deliverables:

7.2.1 VMI Requirements Document—Report detailing the agreed upon requirements for VMI.

7.4 Sustainment/Stockpile Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 7.4.1 Inventory Management | Quarterly inventory reports | Inventory Management Report |



Summary Table

| CLIN | WBS 1st Level Element | Title | Objectives |
|---|---|---|---|
| **0003** | 3 | CoA Study | • Complete Post-Approval (conditions of approval) study, as required by FDA |
| **0004** | 3, 4 | Pediatric Studies | • Complete pediatric clinical trials per FDA requirements and BARDA guidance |
| **0005** | 7 | Procurement (Surge) | • Execute acquisition contract<br>• Expand VMI as necessary<br>• Manage inventory |

Overview

Avita has defined three option periods covering the Conditions of Approval (CoA) study after FDA approval of the ReCell Device (CLIN 0003), a Pediatric study to expand the indications for ReCell for a broader pediatric demographic, if necessary, for ReCell (CLIN 0004), and for the procurement of additional ReCell devices beyond the initial acquisition (CLIN0005). **Note: Updated SOW(s) will be provided to BARDA based on FDA feedback to support the execution of each CLIN.** The accompanying budget(s) will also be updated to align with the revised SOW(s).

The purpose of the CoA, CLIN 0003, is to provide longer-term evaluation of the ReCell device after FDA approval, in order to track and confirm that any post-market commitments are addressed by Avita.

The purpose of the Pediatric Study, CLIN 0004, is to expand the approved range of patients for ReCell, specifically for pediatric patients, beyond those originally approved during the PMA process. The specific study design and objectives will be based on the PMA approval outcomes as well as consultation with BARDA, and will be intended to expand the range of patients able to be treated by ReCell.

Surge acquisition, CLIN 0005, will support additional acquisition of ReCell devices by BARDA, CDC, or other stakeholders.

CLIN 0003 — Option — CoA Study

**3 Clinical**

3.3 Post approval (Condition of Approval Study)

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.3.1.2 Submit protocol to BARDA for review | Protocol developed | Study Protocol |
| 3.3.6.1 Statistical analysis | Statistical analysis complete | Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.3.6.2 Clinical study report | CSR complete | CSR, review/submit to FDA |

3.3.6.4 Title: Final CoA CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Post approval (COA study) will be carried out if an additional study is required by FDA as a condition of PMA approval. If a COA study is required, a new clinical study will need to be prepared and approved, including protocol with inclusion and exclusion criteria, endpoints, and IDE application written and submitted, FDA approval of the IDE, local IRB approval, clinical study site agreements, and local ethics approvals. The study protocol and all CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.3.1.1 Protocol developed

3.3.2.2 Last subject last visit

3.3.6.1 CRO completes statistical analysis

3.3.6.2 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.3.1.2 Study Protocol submitted to BARDA

3.3.6.1 Tables, Listings & Figures (i.e. Statistical analysis output)

3.3.6.2 CSR, review/submit to FDA

CLIN 0004 — Option — Pediatric Study

**3 Clinical**

3.2 Pediatric Study for Expanded Labeling

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.2.1.2 Submit protocol to BARDA for review | Protocol developed | Study protocol |
| 3.2.6.1 Statistical Analysis | Statistical analysis complete | Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.2.6.2 Clinical Study Report | CSR complete | CSR, review/submit to FDA |

3.2.8 Title: Final Pediatric CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Pediatric study for expanded labeling will be carried out if requested by the BARDA to study younger children. If a pediatric study is required, a new clinical study will need to be prepared and approved, including protocol with inclusion and exclusion criteria, endpoints, and IDE application written and submitted, FDA approval of the IDE, local IRB approval, clinical study site agreements, and local ethics approvals. The study protocol and all CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.2.1.1 Protocol developed

3.2.3.1 Last subject last visit

3.2.6.1 CRO completes statistical analysis

3.2.6.2 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.2.1.2 Clinical Study Protocol

3.2.6.1 Tables, Listings & Figures (i.e. Statistical analysis output)

3.2.6.2 Clinical Study Report (CSR)

**4 Regulatory**

4.2.5 Pediatric Indication

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 4.2.5.1 Pediatric IDE | FDA approval of pediatric IDE | Pediatric IDE application |
| 4.2.5.3 Pediatric PMA supplement | FDA approval of expanded indication for pediatrics | Submission for Pediatric label expansion |

4.2.5 Title: Pediatric Indication

Objective/Description of Work: Avita will make the regulatory filings with FDA for both a pediatric IDE clinical trial and a PMA supplement for expansion of labeling for pediatric indication.

Milestones:

4.2.5.2 FDA approval of pediatric IDE study

4.2.5.4 FDA approval of pediatric indication

Deliverables:

4.1.5.1 Pediatric IDE application.

4.2.5.3 PMA supplement for pediatric indication

CLIN 0005 — Procurement (Surge)

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.1.2.2 Product Manufacturing | Order Received | Additional product to meet surge capacity |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: BARDA would authorize the surge procurement order to acquire additional ReCell devices beyond the initial order. Upon receiving the order Avita would authorize the manufacturer to begin acquiring supplies for the manufacture of the additional devices.

Milestones:

7.1.2.1 Order Received

Deliverables:

7.1.2.2 Surge Capacity Product — Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices according to the additional products required to meet surge capacity. Product will be deployed to designated VMI locations.

**Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.**

**AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT**

| 1. CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 \| 4 |

| 2. AMENDMENT/MODIFICATION NO. | 3. EFFECTIVE DATE | 4. REQUISITION/PURCHASE REQ. NO. | 5. PROJECT NO. (*If applicable*) |
|---|---|---|---|
| 0003 | See Block 16C | OS206970 | |

**6. ISSUED BY** CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

**7. ADMINISTERED BY** (*If other than item 6*) **CODE** ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 638-G
Washington DC 20201

**8. NAME AND ADDRESS OF CONTRACTOR** (*No., street, county, State and ZIP Code*)

AVITA MEDICAL AMERICAS,LLC 1476585
AVITA MEDICAL AMERICAS, LLC 92
28159 Avenue Stanford
Suite 220
Valencia CA 91355

CODE 1476585 FACILITY CODE

(x) **9A. AMENDMENT OF SOLICITATION NO.**

**9B. DATED** (***SEE ITEM 11***)

X **10A. MODIFICATION OF CONTRACT/ORDER NO.**
HHS0100201500028C

**10B. DATED (SEE ITEM 13)**
09/29/2015

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*) Net Increase: [**]
2017.1990008.26402

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

| CHECK ONE | |
|---|---|
| | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14. PURSUANT TO THE AUTHORITY OF FAR43.103(b). |
| | **C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:** |
| X | **D. OTHER** (***Specify type of modification and authority***) 52.217-9 Option To Extend the Term of the Contract |

**E. IMPORTANT**: Contractor ☐ is not. ☒ is required to sign this document and return 2 copies to the issuing office.

**14. DESCRIPTION OF AMENDMENT/MODIFICATION** (*Organized by UCF section headings, including solicitation/contract subject matter where feasible.*)

Tax ID Number: 20-2578762
DUNS Number: 026723570
To modify ARTICLES B.3 OPTION PRICES, C.1. STATEMENT OF WORK, F.1. PERIOD of PERFORMANCE, and SECTION J List of Attachments.

Funds Obligated Prior to this Modification: [**]
Funds Obligated with mod #03: [**]
Total Funds Obligated to Date: [**]
PSC Code: 6505
Continued . . .

**Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.**

| 15A. NAME AND TITLE OF SIGNER (*Type or print*) | | 16A. NAME AND TITLE OF CONTRACTING OFFICER (*Type or print*) | |
|---|---|---|---|
| Timothy J. Rooney CFO | | Christopher Scott | |
| **15B. CONTRACTOR/OFFEROR** | **15C. DATE SIGNED** | **16B. UNITED STATES OF AMERICA** | **16C. DATE SIGNED** |
| /s/ Timothy J. Rooney<br>(*Signature of person authorized to sign*) | 9/18/17 | /s/ Christopher Scott<br>(*Signature of Contracting Officer*) | 9/18/17 |

NSN 7540-01-152-8070
Previous Edition Unusable

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

**NAME OF OFFEROR OR CONTRACTOR**
AVITA MEDICAL AMERICAS, LLC 1476585

| ITEM NO. (A) | SUPPLIES/SERVICES (B) | QUANTITY (C) | UNIT (D) | UNIT PRICE (E) | AMOUNT (F) |
|---|---|---|---|---|---|
| | Expiration date: [**], 2022 (Changed) | | | | |
| | Delivery Location Code: HHS<br>HHS<br>200 Independence Avenue, SW<br>WASHINGTON DC 20201 US | | | | |
| | Appr. Yr.: 2017 CAN: 1990008 Object Class: 26402<br>FOB: Destination<br>Period of Performance: [**]/2015 to [**]/2022 | | | | |
| | Change Item 4 to read as follows (Amount Shown is the obligated amount): | | | | |
| 4 | CLIN 0004 Pediatric Study<br>Obligated Amount: [**] | | | | [**] |

**ARTICLE B.3. OPTION PRICES is hereby modified as follows:**

| CLIN | Period of Performance | Supplies/ Services | Units (# of Product) | Unit Price ($) | Total ($) |
|---|---|---|---|---|---|
| | | **FIRM FIXED PRICE** | | | |
| 0003 (Option) | [**] Months | Phase IV post marketing commitments /Requirements (This is an option that may or may not be exercised during the base period as determined by the need and as established by the FDA) | N/A | N/A | [**] |
| | | **COST REIMBURSEMENT** | | | |
| **0004 (Option)** | **[**]/17 – [**]/22** | **Pediatric Study (This is an option that may or may not be exercised during the base period for expansion of the label indication with guidance from the FDA)** | [**] | [**] | [**] |
| | | **FIRM FIXED PRICE** | | | |
| 0005 (Option) | 36 Months | Additional Surge Capacity | Less than 2,000 | [**] | [**] |
| 0006 (Option) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0007 (Option) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0008 (Option) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| **Total Unfunded Option CLINs 3, 5-8** | **60 Months** | **See Above Descriptions** | | | **[**]** |

*** Option CLIN 0004 is exercised with this modification**

**ARTICLE C.1. STATEMENT OF WORK is hereby modified as follows:**

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work dated **[**], 2017** set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

**ARTICLE F.1. PERIOD OF PERFORMANCE is hereby modified as follows:**

The period of performance for this contract shall be from [**], 2015 through [**], 2022. The period of performance for the base period of this contract shall be consistent with the dates set forth in SECTION B. If the Government exercises option(s), the period of performance will be extended as described under in SECTION B of this contract.

**SECTION J – LIST OF ATTACHMENTS: Attachment 1 is hereby modified as follows:**

1. Statement of Work, dated September 18, 2017, 44 pages

**All other terms and conditions of this contract remain unchanged.**

**End of Modification #3**

**Avita Medical SOW**

Advance Understandings

The following scope of work is submitted by Avita Medical Americas LLC in compliance with the advanced understandings listed in ARTICLE B of this contract, including invoicing, publications and press releases, protection of human subjects, communication with BARDA, export control, manufacturing standards, contact prohibitions, subcontracting, data handling, confidentiality, compensation, and security reporting.

Avita Medical BASE SOW

Summary Table

| CLIN | WBS 1st Level Element | Title | Objectives |
|---|---|---|---|
| **0001/0001A** | 1 | Project Management | • Establish project management infrastructure |
| | | | • Establish EVM systems |
| | | | • Finalize IMPP |
| | | | • Technical and financial reporting |
| | 2 | Non-Clinical Objectives | • Close gaps in non-clinical data required for PMA module 1 of 3, including biocompatibility, human factors, packaging testing to generate ISO design dossier as an FDA-compliant design history file. |
| | | | • Establish appropriate training for use of ReCell in mass casualty setting. |
| | | | • Achieve 4-year stability |
| | | | • *Expand Compassionate Use IDE 15945 (0001A)* |
| | | | • *Extend Continued Access IDE 13053 (0001A)* |
| | | | • *Incorporate Reimbursement Methods (0001A)* |
| | | | • *Model the Economic Benefits of Medical Countermeasures (0001A)* |
| | 3 | Clinical Objectives | • Complete pivotal trials (-5 and -6 protocols) and clinical study reports for PMA module 3 of 3. |
| | 4 | Regulatory Objectives | • Fulfill Pre-EUA requirements |
| | | | • Modular PMA Submission |
| | | | • Secure Pre-Market Approval (PMA) |
| | | | • *BIMO Mock Audit (0001A)* |
| | | | • *Enhanced in-house support of the PMA Pathway (0001A)* |
| | 5 | Product Development for Mass Casualty/VMI | • Gather requirements for Mass Casualty and VMI |
| | | | • Redesign ReCell packaging and any other subcomponents in order to meet requirements for more efficient VMI and deployment |
| | | | • Complete V&V |

| CLIN | WBS 1st Level Element | Title | Objectives |
|---|---|---|---|
| | 6 | QSR Objectives | • Perform QSR Gap remediation (address all gaps identified) for PMA module 2 of 3.<br>• Scale up manufacturing process for ReCell to support USG acquisition and US Market introduction<br>• Qualify alternate suppliers, for sustainability |
| 0002 | 7 | Procurement (Initial) | • Execute acquisition contract<br>• Establish VMI<br>• Manage inventory |

CLIN 0001 Overview

Avita's initial primary objective with the proposed effort is to secure FDA approval for the ReCell device. In order to accomplish this we need (1) a documented design (with documentation and supporting testing ¬e.g. biocompatibility- done to FDA standards rather than ISO standards), for which the work is done in WBS 2.1.2, 2,1.3, and 2.1.4; (2) an FDA-compliant quality system and documentation of GMP manufacturing: WBS 6.1; and (3) Pivotal Clinical Data: WBS 3.1.

The above-mentioned work is delivered to FDA via PMA modules 1, 2 and 3, respectively (WBS 4.2.2). The PMA modules will require organizing and assembling reports into a standardized format, setting context and drawing overall conclusions. In addition to submission of the PMA modules, Avita will also draft (and get FDA-approval of) a Conditions of Approval study protocol (WBS 3.3.1.1, 4.2.2.4.2), and pass through a panel (of experts) review (WBS 4.2.2.5). Avita will need favorable reviews of the PMA modules, CoA protocol approval, and panel review to get the product approved.

Concurrent with the FDA approval process, there is an Emergency Use pathway, activated in the event of a mass casualty, which would enable FDA to authorize use of an investigational (unapproved) product for life-saving measures. There is "pre-emergency" work that can be done to facilitate a future potential Authorization. (WBS 4.1)

Once there is confidence in EUA status or there is PMA approval, base procurement (WBS 7.1.1) is triggered.

There are several other items that are part of the program in order to ensure success in stockpiling, distributing, and using ReCell during an emergency event:

1. Training of medics for use of ReCell in mass casualty events (WBS 2.1.1).
2. Increased shelf-life, with a target of up to 4 years (as supported by stability testing) (WBS 2.3)
3. VMI planning/implementation (WBS 7.2, 7.3, 7.4)
4. Optimize product packaging more for palletized storage and VMI, (WBS 5)
5. Qualifying second sources for key components and for product final assembly (i.e. alternative/supplementary sources for enzyme and a supplement/alternative to Parker) (WBS 6.2.2).

CLIN 0001A Overview

The objectives of CLIN 0001a are to facilitate the overarching objective of preparedness for effective treatment of burn injuries secondary to detonation of a nuclear device. In addition to ensuring FDA approval of the ReCell device, the work put forward in this SOW further bolsters efforts for development of familiarity and acceptance of the autograft-sparing product within U.S. Burn Centers by expanding Compassionate Use (WBS 2.1.5), extending Continued Access (WBS 2.1.6), incorporating Reimbursement training (WBS 2.1.6) and Modeling the Economic Benefits of Medical Countermeasures (WBS 2.1.8).

Additionally, this SOW includes scope to ensure successful navigation of the PMA Pathway by adding a BIMO Mock Audit and addingin-house technical and regulatory expertise for overall support to de-risk the program (4.3.1)

CLIN 0001/0001A- Base Period

**1.0 Program Management**

1.1 Internal Project Management

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 1.1.5 Integrated Master Project Plan | Upon delivery to and acceptance by BARDA | All required elements of this plan as listed in the RFP |

1.1.5 Title: Integrated Master Project Plan

Objective/Description of Work: Avita will compile all necessary materials and finalize all aspects of the project related to preparing the Integrated Master Project Plan. This will include finalizing critical path milestones, Work Breakdown Structure (WBS), and Risk Mitigation Plan. The final deliverable of the IMPP will represent the finalization and approval of all project elements between Avita and BARDA.

Milestones:

1.1.5.1 Critical Path Milestones –The critical path milestones are finalized and submitted, reviewed, and approved by BARDA.

1.1.5.2 Work Breakdown Structure –The WBS is finalized and submitted, reviewed, and approved by BARDA for all project activities.

1.1.5.3 Risk Mitigation Plan/Matrix – Any additional elements of risk are identified and all elements of risk are finalized and submitted, reviewed, and approved by BARDA. Risk management plans for each risk are finalized and submitted, reviewed, and approved by BARDA.

Deliverables:

1.1.5 Integrated Master Project Plan – Containing all required elements as listed in the RFP and/or requested by BARDA.

1.1.5.1 Critical Path Milestones – An updated and finalized critical path milestone document.

1.1.5.2 Work Breakdown Schedule – An updated and finalized WBS document.

1.1.5.3 Risk Mitigation Plan/Matrix – An updated and finalized risk mitigation plan/matrix.

1.2 Contract Management

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 1.2.2 Reporting | Upon delivery to and acceptance by BARDA | All required reports as listed in the RFP and requested by BARDA |
| 1.2.3 Meetings | BARDA Kick-Off Meeting | Meeting Presentation Materials |

1.2.2 Title: Reporting

Objective/Description of Work: Avita will comply with all reporting requirements as outlined and formatted in the RFP and as requested by BARDA. Reporting will include at a minimum monthly progress reports, annual progress reports, annual invention reports, draft final report, and final report. Additional deliverables such as technology packages, experimental protocols, publication, press releases, security reports, or other reports will be provided to BARDA for review prior to initiation of a corresponding work element, deliverable, or FDA submission.

Milestones:

1.2.2.1 Monthly Progress Report – Delivery to and acceptance by BARDA.

1.2.2.2 Annual Progress Report – Delivery to and acceptance by BARDA.

1.2.2.3 Invention Reports – Delivery to and acceptance by BARDA.

1.2.2.4 Draft Final and Final Progress Reports – Delivery to and acceptance by BARDA.

Deliverables:

1.2.2.1 Monthly Progress Report –A report detailing the prior month's activities and activities planned for the following month. Report will be delivered prior to the 15th of the month following the reporting period.

1.2.2.2 Annual Progress Report –A report summarizing the activities of the period of performance and the activities planned for the upcoming period. Report will be delivered prior to the 30th of the month following the reporting period.

1.2.2.3 Annual/Final Invention Report A report detailing any intellectual property developed as a result of the work performed during each period of performance and the entire contract period. Report will be delivered in conjunction with the annual progress report.

1.2.2.4 Draft Final and Final Progress Report – The Final Progress Report will include a complete summary of all work performed during the entire contract period of performance. A Draft Final Progress Report will be delivered 45 days prior to contract expiration for BARDA review and comments. A Final Progress Report will be delivered prior to 30 days following contract expiration.

1.2.3 Title: Meetings

Objective/Description of Work: Avita and BARDA will engage in regular meetings to coordinate and review project activities. Meetings will be both face-to-face and teleconference/video conference. The first official meeting will be theface-to-face kick-off meeting, followed by status update meetings on a biweekly/monthly basis, ad hoc teleconferences and site visits, and annual meetings to report on the period of performance activities.

Milestones:

1.2.3.1 Kickoff Meeting with BARDA – The contract is awarded and aface-to-face kickoff meeting is conducted within 30 days of award date.

Deliverables:

1.2.3.2 Kickoff Meeting Presentation Materials –Avita will prepare all necessary presentation materials for the kickoff meeting.

1.4 IMS and EVM

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.4.2 Performance Measurement Baseline | Performance Measurement Baseline Review (PMBR) | All required components for the PMBR |
| 1.4.3 Integrated Master Schedule | PMBR | Integrated Master Schedule |
| 1.4.4 Monthly Earned Value Performance Report | Delivery to and acceptance by BARDA | Monthly Earned Value Performance Report |
| 1.4.5 Supplemental monthly CAP report | Delivery to and acceptance by BARDA | Supplemental monthly CAP report |

1.4.2 Title: Performance Measurement Baseline

Objective/Description of Work: The Performance Measurement Baseline will provide a master schedule of deliverables, costs, and milestones in order to completely cover all items in the SOW. All required components will be submitted to BARDA within 90 days of contract award. BARDA and Avita will mutually agree on the budget, schedule and technical plan baselines as a result of the PMBR.

Milestones:

1.4.2 Performance Measurement Baseline Review – The PMBR plan is submitted and reviewed by BARDA.

Deliverables:

1.4.2 Performance Measurement Baseline Review Plan and Required Components – A plan detailing a schedule of deliverables, costs, milestones, and risks that will serve as the basis for measuring project progress.

1.4.3 Title: Integrated Master Schedule (IMS)

Objective/Description of Work: The NS will be used to monitor performance of the contract. Avita will develop an IMS in a format approved by BARDA in order to track key milestones, Go/No Go decision gates. The IMS will contain baseline start and finish, forecast start and finish, actual start and finish, predecessor and/or successor. Avita will provide a baseline IMS for the PMBR and monthly updates thereafter.

Milestones:

1.4.2 Integrated Master Schedule is approved by BARDA.

Deliverables:

1.4.3 Integrated Master Schedule – Provided for the PMBR and monthly in order to monitor performance of the contract. The IMS shall be provided at the work package level in MS Project file format.

1.4.4 Title: Monthly Earned Value Performance Report

Objective/Description of Work: The Monthly Earned Value Performance Report will be generated from Avita's EVMS in order to track any project variances against the baseline. The report will contain technical, schedule, and cost status information in order to identify any issues that may impact project progress and/or cost.

Milestones:

1.4.4 Monthly Earned Value Performance Report – Delivery to and acceptance by BARDA.

Deliverables:

1.4.4 Monthly Earned Value Performance Report – Provided monthly to track project progress according to WBS and EV variance.

1.4.5 Title: Supplemental Monthly CAP Report

Objective/Description of Work: The Supplemental Monthly CAP Report will be generated from Avita's EVMS and will contain cost information to report on the time phased budget, earned value, and actual costs of work performed. The report will be submitted monthly to BARDA for review.

Milestones:

1.4.5 Supplemental Monthly CAP Report – Delivery to and acceptance by BARDA.

Deliverables:

1.4.5 Supplemental Monthly CAP Report – Provided monthly to detail time phased budget, earned value, and actual costs of work performed as captured by Avita's EVM systems.

**2. Non-Clinical Objectives**

**2.1 Efficacy and Safety**

| WBS# and Title<br>CLIN0001A | Milestone | Deliverable |
|---|---|---|
| 2.1.1.1 Updated training resources for mass casualty | Effective training for mass casualty event. | Updated user training documentation |
| 2.1.2 Biocompatibility review | Biocompatibility review complete | Biocompatibility Review Report |
| 2.1.3 Human Factors | FDA requests human factors studies | Human factors studies submitted to FDA |
| 2.1.4 FDA-compliant design documentation | Completion of backup documentation for PMA module 1. | QSR-mandated design control documents and supporting lab test results |
| 2.1.5 Compassionate Use IDE | Deliver to BARDA the annual IDE report on Compassionate Use. | Annual IDE report on Compassionate Use. |

| WBS# and Title<br>CLIN0001A | Milestone | Deliverable |
|---|---|---|
| 2.1.6.1 Continued Access IDE 13053 | Deliver to BARDA the clinical trial protocol (CTP) on Continued Access. | Clinical trial protocol (CTP) on Continued Access. |
| 2.1.6.2 Annual IDE Report | Deliver to BARDA the Annual IDE reports | Annual IDE reports |
| 2.1.6.3 Final Clinical Study Report | Deliver to BARDA the Final Clinical Study Report | Final Clinical Study Report |
| 2.1.7 Burn Center Reimbursement educational materials | Deliver to BARDA the Guidance materials on reimbursement. | Guidance materials on reimbursement. |
| 2.1.8.1 Kick-off Meeting & Project Management | Complete Kick-off Meeting | MS PowerPoint presentation outlining understanding of goals, objectives, anticipated approach, and project deliverables, milestones, and timeline. |
| 2.1.8.2 Targeted Literature Search | Complete Literature Search | Draft and final literature review search strategy in MS Word |
| 2.1.8.3 Focusing goals | Complete Briefing which defines focus of goals | A brief MS PowerPoint presentation outlining options for the model framework |
| 2.1.8.4 Model Storyboard | Completion of Model Storyboard | Draft and revised model storyboards (MS PowerPoint). |
| 2.1.8.5 KOL Engagement | Complete Recruitment of KOL's | KOL recruitment and management (for 3 KOLs), draft and final KOL summary feedback (Word) for all KOL meetings, final storyboard (MS PowerPoint). KOL's to be approved by BARDA. |
| 2.1.8.6 Preliminary Model Programming and Results | Complete Preliminary Model | Preliminary model (MS Excel 2013 file for PC) and a presentation of preliminary findings in a MS PowerPoint slide deck to be shared with BARDA via WebEx or during an in-person meeting. |
| 2.1.8.7 Final Model | Complete Final Model | Final model version (in MS Excel) and final results slides (in MS PowerPoint); quality assurance documentation (MS Word) can be made available upon request. |
| 2.1.8.8 Technical Reporting | Complete Final Technical Report | Two drafts and a final version of a written technical report (MS Word). |

2.1.1.1 Title: Updated training resources for mass casualty

Objective/Description of Work: Existing training manuals for use of the ReCell device are designed for a clinical/surgical setting by experienced clinicians. Led by the Director of Education, with support from the Education Specialist, Avita will develop a new training protocol sufficient for a mass casualty event for ReCell to be used by minimally trained personnel that may or may not have burn surgery experience. Target goal will be a one-hour training session to personnel at a trained medic level or higher. New training materials will be submitted to BARDA for review/feedback and then finalized.

Milestones:

2.1.1 Creation of training materials, including video, workshop/online course materials, reference guides, as determined in collaboration with BARDA

Deliverables:

2.1.1.1 Training materials as determined in collaboration with BARDA.

2.1.2 Title: Biocompatibility review complete

Objective/Description of Work: Full biocompatibility is demonstrated for EU and Australia, to ISO standards. The testing work needs to be done to US FDA standards. Results of biocompatibility review will be submitted to BARDA for review/feedback.

Milestones:

2.1.2 Biocompatibility submitted to FDA

Deliverables:

2.1.2 Biocompatibility Review Report draft and final report submitted. to BARDA and final report submitted to FDA

2.1.3 Title: Human Factors

Objective/Description of Work: Avita will conduct an evaluation to ensure that the ReCell devices meet usability guidelines when used by the intended user population. Avita will conduct all required studies and submit the results to BARDA for review and feedback. Upon BARDA approval, Avita will submit report to FDA.

Milestones:

2.1.3 Requested data/report submitted to FDA

Deliverables:

2.1.3 As requested by FDA, human factors draft and final reports submitted to BARDA and final data and report submitted to FDA

2.1.4 Title: FDA-Compliant Design Documentation

Objective/Description of Work: Avita's recent gap analysis for PMA module 1 readiness indicates that in addition to biocompatibility testing Avita will need to create an FDA QSR-compliant design control document package, including backup lab test data and reports, including packaging testing. Avita will provide the various reports to BARDA, as requested, for review and approval prior to sending to FDA.

Milestones:

2.1.4.1 Functional Testing Complete

2.1.4.2 Packaging/Shipping Testing Complete

2.1.4.3 EMI/EMC Testing Complete

2.2 Non-clinical data sufficient for PMA module 1 of 1

Deliverables:

2.1.4 QSR-mandated design control documents and supporting lab test results –Avita will generate a design control document package that will meet current FDA requirements, in support of PMA module 1 of 1

2.1.5 Title: Compassionate Use IDE 15945

Objective/Description of Work: Avita's Compassionate Use IDE provides a mechanism for surgeon access to ReCell as an investigational device, for patients presenting with life-threatening injuries for which there is insufficient donor skin for conventional autograft treatment. Requests, along with a letter of support, are evaluated for suitability and patients are approved by Avita on a case by case basis. Surgeons may request Compassionate Use regardless of their prior experience with ReCell and independent from their site's participation in IDE 13053 for the study of burns). The Compassionate Use IDE provides for further experience in the use of ReCell, toward fulfilment of BARDA's objective of familiarity/acceptance in US burn centers. Avita personnel travel to support these surgeries, and a 3`d-party CRO and an independent consultant are contracted to perform clinical monitoring for compliance with Good Clinical Practice. In-house regulatory personnel will draft associated regulatory submissions.

Milestones:

2.1.5 Deliver to BARDA the annual IDE report on Compassionate Use.

Deliverables:

2.1.5 Annual IDE report on Compassionate Use.

2.1.6 Title: Continued Access IDE 13053

Objective/Description of Work: FDA may allow continued enrollment of subjects after the controlled clinical trial under an IDE has been completed in order to allow access to the investigational medical device while the marketing application is being prepared by the sponsor or reviewed by FDA. Under this policy, a sponsor may propose to conduct an "extended" clinical trial if: 1) there is a public health need for the device and 2) there is preliminary evidence that the device is likely to be effective and no significant safety concerns have been identified for the proposed indication. Avita will submit CTP001-7 to the FDA to allow Continued Access of ReCell at up to 15 clinical sites for treatment of up to an additional 100 patients. As with Compassionate Use, this positions the US burn centers to be more effective in the event of a mass casualty. Onsite training of burn centers will be required, and a 3rd-party CRO will be contracted for clinical project management, clinical data management and clinical monitoring, for compliance with IDE requirements.

Milestones:

2.1.6.1 Continued Access IDE 13053 – Delivered to BARDA

2.1.6.2 Annual IDE Report Delivered to BARDA

2.1.6.3 Final Clinical Study Report – Delivered to BARDA

Deliverables:

2.1.6.1 Continued Access IDE 13053 Report

2.1.6.2 Annual IDE Report

2.1.6.3 Final Clinical Study Report

2.1.7 Title: Reimbursement

| WBS# and Title<br>CLIN0001A | Deliverable |
|---|---|
| 2.1.7 Burn Center Reimbursement educational materials | Guidance materials on reimbursement. |

Objective/Description of Work: Reimbursement coding is central to establishing familiarity and acceptance of a new product in healthcare. Avita will hire a Reimbursement Manager to establish coding mechanism(s) for ReCell, and this information will be integrated into the educational material provided to burn centers. The support of expert consulting is also anticipated.

Milestones:

2.1.7 Guidance materials on reimbursement – Delivered to BARDA

Deliverables:

2.1.7 Guidance materials on reimbursement

2.1.8 Title: Modeling the Economic Benefits of Medical Countermeasures

Objective/Description of Work: Avita will work with a Subject Matter expert to develop a generic model for cost and economic impact in burn care with introduction of ReCell technology as a candidate for evaluation, both at the single-center level, and a multi-center (commercial) use. The model (aka tool) will allow for evaluation of cost impact on burn care from use of specific products as well as broader economic impact. The tool is expected to be self-standing and include access to other required information such as databases necessary for full functionality and use of the software. Other features of the model will include:

a. A comprehensive review of parameters which influence the integrated cost impact on burn care (and broader economic impact) both directly or indirectly would be identified and evaluated. Such parameters may include but are not limited to impact of resources (surgical and non-surgical) personnel time, material resources as well tangible changes to the clinical outcomes (example, length of hospital stay or ICU days). Impact of product launch pricing models and potential market share over time may also be included in the tool.

b. The tool will be designed to predict costs and benefits associated with the care of burn patients based on (i) specifiable characteristics of a hypothetical group of patients (e.g. in terms of burn severity, number of patients, etc) and (ii) modeled changes to fundamental cost drivers associated with particular changes in practice as a result of introduction of the new product and associated downstream impact. As such, the financial and economic impact of introduction of medical countermeasures, alone and in combination, may become predictable.

c. Avita will test the tool with available data and assumptions and iteratively develop in consultation with the experts to refine the model using ReCell data as well as to ensure the generic nature of the cost and economic Impact tool.

d. For this effort it is recognized that definitive burn care is typically provided over time and that care treatments/procedures change as burn etiology evolves. This has allowed for identification of distinct treatment areas within the definitive care continuum. New products (such as Avita's ReCell) directed at such treatment targets are expected to have an impact on the cost effectiveness of burn care, which represents the over-arching scope of this effort.

e. For the sake of comprehensive analysis under this effort, an exhaustive list of parameters (preferably ranked) shall be identified and qualified to be measurable within the following treatment targets in the continuum of definitive care: (1) debridement, (2) application of skin substitutes (which eliminate autografting), (3) autograft sparing technology, and (4) adjuncts to enhance/accelerate healing.

f. The overall capability of the tool is to capture the key parameters across this continuum wherein impact of any new products altering these key parameters within a treatment area, objectively demonstrates a clear, measurable value proposition (or a lack thereof) in the overall cost effectiveness and other attributes. The tool would also feature an ability to be customized either by turning on or off the key parameters or add a user chosen parameter, based on relevance to target area.

g. Based upon a competitive selection process between three potential SME's, [**] is the primary candidate for this project. A designated panel of experts should be accessible.

2.1.8.1 Title: Kick-off Meeting & Project Management

Objective/Description of Work: A Kick-off meeting will be conducted to:

- Introduce the project team members
- Discuss KOL selection process;
- Review and confirm the goals of the project;
- Finalize the approach to the project phases; and
- Review anticipated project deliverables, milestones and timelines (Gantt chart).

Milestones:

2.1.8.1 Complete Kick-off Meeting

Deliverable:

2.1.8.1 MS PowerPoint presentation outlining understanding of goals, objectives, anticipated approach, and project deliverables, milestones, and timeline.

2.1.8.2 Title: Targeted Literature Search

Objective/Description of Work: Develop literature search strategy and obtain agreement with BARDA. Perform literature search and report on results.

Milestones:

2.1.8.2 Complete Literature Search

Deliverable:

2.1.8.2 Draft and final literature review search strategy in MS Word.

2.1.8.3 Title: Focusing goals

Objective/Description of Work: Compile a preliminary burn care model structure and identify any key points that may require discussion and agreement between project participants. Develop a discussion deck (in MS PPT) that outlines options for the model framework, including a detailed proposed structure. The deck will be used to facilitate an interactive discussion with BARDA.

Milestones:

2.1.8.3 Complete Briefing which defines focus of goals

Deliverable:

2.1.8.3 A brief MS PowerPoint presentation outlining options for the model framework and structure to facilitate discussion; appended summary of action items.

2.1.8.4 Title: Model Storyboard

Objective/Description of Work: Develop a Model Storyboard, which is a detailed plan for the model, intended to provide an opportunity for discussion and agreement with BARDA, prior to programming. This storyboard will include the model structure to facilitate cost-effectiveness and budget impact assessments, detailed parameter types (including all clinical inputs and costs), with referenced default values for all variables, as well as model user-functionality and model outputs.

Although this model will be developed to have a generic structure, the storyboard and model development will be performed to permit evaluation of Avita's ReCell technology. One primary comparator (e.g. a standard autograft procedure) will serve as the base case for the cost-effectiveness evaluation, and will focus the storyboard accordingly with detailed input values around ReCell and the base case comparator. The model will be developed to include up to three (3) dummy comparators to permit exploration of additional interventions at points along the burn care pathway, but data specific to these hypothetical interventions will not be included in the storyboard or analyses. Because the US model may be used in discussions with different types of stakeholders, it is anticipated that the storyboard will include information to inform different perspectives, including hospital perspective, payer perspective, and at BARDA's option, societal perspective. Differences between these may include time horizon (shorter term for hospital perspective) and cost inputs. It is assumed that budget impact calculations will rely on the same underlying structure and inputs as are used for the cost- effectiveness model, and thus gain efficiencies between the two analysis types. However, pricing predictions, market uptake assumptions and market share distribution will be required from marketing research. Any additional detailed clinical and cost input values not available from other sources may be solicited from KOLs (e.g. likely resource use assumptions); based on discussion with KOLs, however, a survey or database analysis Optional Task may be desired to obtain the best possible data.

After presentation of the storyboard to BARDA, comments received during this meeting and any additional consolidated comments received in the following week will be incorporated into a storyboard revision. Input from all internal stakeholders at this phase will ensure the model contains the appropriate elements and addresses key considerations. This revision will serve as the platform for the first KOL engagement.

Milestones:

2.1.8.4 Completion of Model Storyboard

Deliverable:

2.1.8.4 Draft and revised model storyboards (MS PowerPoint).

2.1.8.5 Title: KOL Engagement

Objective/Description of Work: Engage three KOLs for the following:

- One hour each for a meeting to collect feedback on the proposed model storyboard;
- One additional hour each to help fill any key model data gaps (e.g. providing resource use assumptions);
- A two-hour advisory panel (joint meeting) for a discussion of the preliminary model and results. (At Avita's option, this may be redefined as a half-day advisory board with KOLs and all project participants. Please see Optional Tasks.)

Engage with the KOLs via teleconference, utilizing presentation materials generated during other project tasks, including the storyboard and preliminary model results presentation. Provide a short written summary of meeting minutes and implications for analysis following ach discussion. Following one round of review, the summary of feedback (meeting minutes) document will be considered final, and details will be incorporated into a final version of the storyboard.

The budget assumes [**]US-based KOLs. Payment of honoraria will be contracted in accordance with Avita governance procedures. Any fees paid by will be considered as pass-through costs to BARDA and will be clearly reported and documented.

Milestones:

2.1.8.5 Complete Recruitment of KOL's

Deliverable:

2.1.8.5 KOL recruitment and management (for [**] KOLs), draft and final KOL summary feedback (Word) for all KOL meetings, final storyboard (MS PowerPoint). KOL's to be approved by BARDA

2.1.8.6 Title: Preliminary Model Programming and Results

Objective/Description of Work: Initiate programming the model for use on a PC platform with MS Excel 2013. Populate the model with parameter estimates, and use the model to generate preliminary estimates of the cost- effectiveness of using ReCell technology vs a chosen appropriate comparator available perspectives (e.g. hospital, payer, and

(optional) US society), and of the budget impact of adding ReCell to the available burn care therapies. Include up to [**] dummy comparators into the model (one for each phase of the burn care pathway) to permit evaluation of the impact of other therapeutic options. Model programming will also include a univariate sensitivity analysis function to identify the most sensitive parameters in the model, displayed as a tornado diagram for convenient interpretation and reporting.

At this stage, Avita will outline preliminary model results, and will present the draft results to BARDA to obtain internal feedback, and also deliver the preliminary model to ensure transparency.

After collecting initial feedback from BARDA, engage the [**] KOLs in a single2-hour meeting for collective review and validation.

Milestones:

2.1.8.6 Complete Preliminary Model

Deliverable:

2.1.8.6 Preliminary model (MS Excel 2013 file for PC) and a presentation of preliminary findings in a MS PowerPoint slide deck to be shared with Avita via WebEx or during an in-person meeting.

2.1.8.7 Title: Final Model

Objective/Description of Work: Develop the final version of the model and update the preliminary results slides with final results to be shared with BARDA via WebEx or during an in-person meeting. The model will be developed for two US perspectives, and at BARDA's option, may include a third. The scope of work assumes that the costing model will contain two perspectives (hospital, payer), and one primary comparator to ReCell (e.g. standard of care autografting), with dummy structure for [**] additional comparators (i.e. intervention-specific data will not be prepopulated for these dummies).

Milestones:

2.1.8.7 Complete Final Model

Deliverable:

2.1.8.7 Final model version (in MS Excel) and final results slides (in MS PowerPoint); quality assurance documentation (MS Word) can be made available upon request.

2.1.8.8 Title: Technical Reporting

Objective/Description of Work: Prepare a written report which includes a description of the project objectives, methods (including structure, referenced parameter values, and analytic outcomes), results, and concluding summary of the results (520 pages).

Milestones:

2.1.8.8 Complete Final Technical Report

Deliverable:

2.1.8.8 Two drafts and a final version of a written technical report (MS Word).

2.1.8.9 Title: Optional Supplemental Project Tasks

Objective/Description of Work: The following is a list of representative tasks that may be required. This task list may be modified and/or supplemented in accordance with written direction and approval from BARDA.

- Option 1: Abstract and poster
- Option 2: Scientific manuscript
- Option 3: Adding societal perspective to the model
- Option 4: Expert survey to obtain missing data
- Option 5: Database analysis to obtain missing data
- Option 6: Half-Day advisory board to review and discuss preliminary model
- Option 7: Dynamic summary report
- Option 8: iPad tool adaptation
- Option 9: Bank of Hours to Support Scope Amendments
- Option 10: Detailed Analysis of Patient Level Data:
    - Analysis will include ICD codes (such as under ICD9, 10 ),HCPCS code-Level data, CPT code-Level data, Revenue code-Level data and other data sources such as the Healthcare Blue Book. These data can be used to assess data provided by providers on resource use (hospital LOS, frequency of dressing changes, use of diagnostics and disposables, blood transfusions, escharotomies, autografting, etc.) at each stage in the treatment timeline (debridement, autografting, etc.)

2.3 Stability and Review of Extended Shelf Life

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 2.3.1 Stability Plan | Expiration limiting components identified and plan developed to extend to 4-year target | Stability Plan |
| 2.3.6 Stability Report (accelerated aging) | Accelerated aging testing results complete | Stability report |
| 2.3.7 Stability report (real- time aging) | Real-time aging testing results complete | Stability report |
| 2.3.8 Review of extended shelf life | New expiry limits determined | Results report submitted to BARDA |
| 2.3.9 Revisions to labeling | Stability extension submission | Shelf life report and revised labeling submitted to FDA |

2.3.1 Title: Stability Plan

Objective/Description of Work: Avita will develop a stability plan that will outline the testing necessary to extend the shelf life of the ReCell unit to 4 years in order to minimize product losses due to expiry. Avita will focus on specific expiration-limiting components (enzyme and buffer, RPU, and nozzle). Avita will design and execute on a stability testing plan to verify stability for extension of shelf life. Reports will be submitted to BARDA detailing the shelf life of ReCell units. Labeling will be modified based on new expiries and submitted to FDA to approval.

Milestones:

2.3.1 Expiration limiting components are identified and a plan is developed to extend ReCell unit to a target of4-year expiry.

Deliverables:

2.3.1 Stability plan outlining all necessary real-time and accelerated aging testing required to justify expiry.

2.3.6 Title: Stability Report (accelerated aging)

Objective/Description of Work: Following accelerated aging testing, a report will be prepared outlining the product performance. The report will detail whether expiry targets were achieved. If targets were not achieved, a plan will be provided detailing further modifications or a plan for acceptance of a new expiry target. Avita will submit to BARDA for review and comments.

Milestones:

2.3.6 Stability testing results complete.

Deliverables:

2.3.6 Stability report detailing product performance for ReCell components after aging

2.3.7 Title: Stability Report (real-time aging)

Objective/Description of Work: Following real-time aging testing, a report will be prepared outlining the product performance. The report will detail whether expiry targets were achieved. If targets were not achieved, a plan will be provided detailing further modifications or a plan for acceptance of a new expiry target. Avita will submit to BARDA for review and comments.

Milestones:

2.3.7 Stability testing results complete.

Deliverables:

2.3.7 Stability report detailing aged performance for ReCell components

2.3.8 Title: Review of extended shelf life

Objective/Description of Work: Avita will prepare a report for BARDA detailing the changes product shelf life. Avita will report on the plan for accordingly revised product labeling to be submitted to FDA.

Milestones:

2.3.8 Delivery of report of extended shelf life

Deliverables:

2.3.8 Shelf life report delivered to BARDA for review, followed by a report detailing plans for FDA submission, and implications for the VMI.

2.3.9 Title: Revisions to labeling

Objective/Description of Work: Avita will revised the product labeling to reflect new shelf life parameters, and will submit to FDA.

Milestones:

2.3.9 FDA approval of revised product labeling

Deliverables:

2.3.9 New product labeling and FDA submission for review/approval of new product labeling.

**3 Clinical**

3.1 Pivotal Clinical Trials

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 3.1.1.4 Clinical Study Report | CTP001-5 Clinical Study Report (CSR), review complete | CTP001-5 Clinical Study Report (CSR), review/submit to FDA |
| 3.1.2.6.1 Statistical Analysis (9mo) | Statistical analysis complete | CTP001-6 Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.1.2.6.2 Clinical Study Report (9mo) | CTP001-6 Initial (9- months) CSR complete | CTP001-6 Initial (9-months) CSR, review (PMA module 3 of 3) |
| 3.1.2.6.4 Statistical Analysis (12mo) | Statistical analysis complete | CTP001-6 Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.1.2.6.5 Clinical Study Report (12mo) | CTP001-6 Final (12- months) CSR complete | CTP001-6 Final (12-months) CSR, review |

3.1.2.8 Title: Final CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Pivotal Clinical Trials encompass two ongoing clinical protocols:CTP001-5 (deep partial-thickness) and CTP001-6 (mixed depth including full-thickness). Both studies show definitive closure using less donor skin with ReCell as compared to standard care, and are also looking at long-term scar outcomes. The clinical study report (CSR) from CTP001-6 is the primary component of PMA module 3 of 3. All CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.1.1.1 Last subject last visit forCTP001-5 (complete)

3.1.1.4 Clinical Study Report complete forCTP001-5

3.1.2.1.1 FDA Statistical Analysis Plan submitted and approved by FDA forCTP001-6 (complete)

3.1.2.3.2 Last subject last visit forCTP001-6

3.1.2.6.4 CRO completes 9-month statistical analysis for PMA module 3 of 3.

3.1.2.8 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.1.1.4 CTP001-5 Clinical Study Report (CSR)

3.1.2.6.1 CTP001-6 9-month Tables, Listings & Figures (i.e. Statistical analysis output)

3.1.2.6.2 CTP001-6 Initial (9-months) CSR (for PMA module 3 of 3)

3.1.2.6.4 CTP001-6 12-month Tables, Listings & Figures (i.e. Statistical analysis output)

3.1.2.6.5 CTP001-6 Final (12-months) CSR

## 4 Regulatory

### 4.1 Pre-Emergency Use Authorization

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 4.1 Pre-Emergency Use Authorization | Avita completes all submissions needed for EUA | All data requested by BARDA to obtain pre-EUA |

4.1 Title: Pre-Emergency Use Authorization

Objective/Description of Work: Avita will support BARDA/HHS in obtaining a Pre-Emergency Use Authorization for the ReCell device. All required studies, reviews, reports, and analyses will be provided as requested.

Milestones:

4.1 Avita completes all submissions needed for EUA

Deliverables:

4.1 Submission to BARDA/HHS of all required materials needed for Pre-EUA.

### 4.2 Premarket Approval (PMA)

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 4.2.2.1.4 Module 1 Submission | Module 1 package assembled | Module 1 package to FDA |
| 4.2.2.2.4 Module 2 Submission | Module 2 package assembled | Module 2 package to FDA |
| 4.2.2.3.4 Module 3 Submission | Module 3 package assembled | Module 3 package to FDA |
| 4.2.2.5.3 Create action plan to address panel recommendations | FDA Panel Meeting | Action Plan |

4.2.2.1.4 Title: Module 1 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package with modular submissions for FDA review and approval. The PMA package will consist of three PMA modules. Module 1 will focus on non-clinical data.

Milestones:

4.2.2.1.4 Module 1 package assembled

Deliverables:

4.2.2.1.4 Module 1 submission to FDA – Module 1 includes biocompatibility, human factors, shipping/packaging validation, EMI/EMC, and all other required non-clinical data.

4.2.2.2.4 Title: Module 2 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package for FDA approval. The PMA package will consist of three PMA modules. Module 2 will focus on manufacturing data.

Milestones:

4.2.2.2.4 Module 2 package assembled

Deliverables:

4.2.2.2.4 Module 2 submission to FDA – Submission will include the principles of operation, quality system and manufacturing documentation, sterilization, shelf-life information, and packaging information.

4.2.2.3.4 Title: Module 3 PMA Submission

Objective/Description of Work: Avita will prepare a complete PMA package for FDA approval. The PMA package will consist of three PMA modules. Module 3 will focus on clinical data. Module 3 will be submitted to BARDA for review and approval, followed by submission to FDA.

Milestone:

4.2.2.3.4 Module 3 package assembled and approved by BARDA

Deliverables:

4.2.2.3.4 Module 3 submission to FDA – Submission will include theCTP001-6 clinical data labels and manuals, draft post-marketing plan (CoA study protocol) and bibliography.

4.3 Title: BIMO Mock Audit and Enhanced in-house support of the PMA Pathway

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 4.3.1 | Complete Remediation of Trial Master Files | Submit BIMO Mock Audit Report and remedial action plan. |

Objective/Description of Work: Prepare for and execute a BIMO Mock Audit to review the Trial Master Files (TMF) at Avita and to audit the site files of three selected burn centers participating in IDE 13053. Avita will subsequently prepare a remedial action plan, and then correct deficiencies as identified by the mock auditing. The status of the remediation activity will be reported in Avita's monthly progress report to BARDA. Ensure availability of in-house regulatory, quality, engineering and manufacturing subject matter experts to respond to the following:

- Clinical and non-clinical data questions, findings, deficiencies & remediation.
- Technical and regulatory questions from BARDA and FDA in response to Avita's submission of documents and reports.
- Implementation of design and manufacturing change requests and process improvements as a result of review and feedback.

Milestone:

4.3.1 Complete Remediation of Trial Master Files

Deliverables:

4.3.1 Submit BIMO Mock Audit Report and remedial action plan.

**5 Product Development for mass casualty/VMI**

5.1 Requirement Gathering, 5.2 Product Design, 5.3 Systems Requirements and Design Review, and 5.4 CDC Quality Agreement

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 5.3 Systems Requirements (VMI optimization) and Design Review | Review of VMI optimized product design package complete | Product optimized for VMI Design Package |
| 5.4 CDC Quality Agreement | Executed CDC Quality Agreement | CDC Quality Agreement |

5.3, 5.4 Title: Systems Requirements (VMI optimization) and Design Review

Objective/Description of Work: In order to develop a product ready for manufacturing and stockpiling, Avita will work with BARDA to first gather the requirements for DFM/DFA, inventory management and any other requirements. Based on the requirements, Avita will initiate Product Design to all ensure the product will meet specifications. This includes design and review for any changed or affected part: Components, Subassembly, Product System, and Packaging Design. Document package will be sent to BARDA for review. Avita will work with CDC to establish a quality agreement, if required.

Milestones:

5.1 Requirements document compiled from BARDA

5.2.1.2 Component Design Review complete

5.2.2.2 Subassembly Design Review complete

5.2.3.2 Product System Design Review complete

5.2.4.2 Packaging Design Review complete

5.3 Full systems requirements and design review complete and approved by BARDA

5.4 If required, establish quality agreement with CDC for supporting VMI

Deliverables:

5.3 System Requirements and Design Review – A system requirements and design review report will be submitted to BARDA containing the requirements and the design changes made to meet those requirements.

5.4 Agreed upon CDC quality agreement for supporting VMI (if required)

5.5 Verification and Validation

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0001 | | |
| 5.5 Verification and Validation Report | V&V verifies product meets specifications and requirements | V&V Report |

5.5 Title: Verification and Validation Report

Objective/Description of Work: Verification & Validation are used to verify that the product meets the specifications and requirements and address the intended purpose. Verification demonstrates that the product meets specification and Validation demonstrates fitness of use for the intended purpose. Once V&V results are positive, the product is ready to release to manufacturing. Avita will submit a report to BARDA detailing the results of the V&V analysis.

Milestones:

5.5 Testing and analysis indicate that the product meets specification and intended purpose.

Deliverables:

5.5 V&V Report - Avita will submit a report to BARDA detailing the results of the V&V analysis.

**6 QSR**

6.1 Quality System Preparedness

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 6.1.3 3rd Party Audit | Audit completed | QSR Audit Report |

6.1.3 Title: 3rd Party Audit

Objective/Description of Work: The US FDA Quality System Regulation (QSR) describes the environment under which medical device firms must operate. This task involves preparing the Avita quality systems for FDA review and inspection, and verifying compliance with FDA requirements. Avita hired an external 3rd party auditor to complete a QSR gap analysis. Following the audit a gap assessment was prepared and presented to Avita from the 3rd party auditor. Avita will develop a Gap Corrective Action plan to address any gaps identified. This will support PMA submission. Once the corrective action plan has been implemented and changes are in place a mock audit will be performed by a 3rd party auditor in preparation for an expected FDA inspection during PMA review.

Milestones:

6.1.1 Gap Assessment

6.1.2 Gap corrective action performed and all systems brought into compliance

6.1.3 Mock QSR audit

Deliverables:

6.1.3 QSR 3rd Party Audit Report - Avita will submit a report to BARDA detailing the results of the final QSR audit.

6.2 Commercial Manufacturing

| WBS# and Title<br>CLIN0001 | Milestone | Deliverable |
|---|---|---|
| 6.2.1. Commercialization Plan and Gap Analysis | Completion of commercialization plans | Final Commercialization Plan |
| 6.2.2.4 Validation Report | IQ/OQ/PQ process validations complete | Validation Report |

6.2.1 Title: Commercialization Plan and Gap Analysis

Objective/Description of Work: Perform a gap analysis to assess commercialization readiness and draft a commercialization plan in support of market entry. Tasks include, as necessary, establishing SKU#, Supply chain and vendor qualifications, raw material inventory, sterilization, packaging, and labeling, and lot release.

Milestones:

6.2.1.1 Commercialization Gap Assessment completed

6.2.1.2 Commercialization Plan Draft created, reviewed with BARDA

6.2.1.3 Commercialization Plan finalized.

Deliverables:

6.2.1.1 Commercialization Gap Assessment Report

6.2.1.2 Commercialization Plan draft and final versions reviewed and submitted to BARDA.

6.2.2.4 Title: Validation Report

Objective/Description of Work: Process validation involves the collection and evaluation of data from the processes used to produce the product. Avita's commercial manufacturer will lead the effort in manufacturing, under close supervision and collaboration with Avita. Sterile packaging will be a primary focus of the validation effort to ensure repeatable package integrity and valid sterilization processes. Process validations will include 10/0Q/PQ and final validation. Avita will present a final report detailing the results of the validation analysis.

Milestones:

6.2.2.1 IQ, Installation Qualification complete

6.2.2.2 OQ, Operation Qualification complete

6.2.2.3 PQ, Process Qualification complete

Deliverables:

6.2.2.4 Validation Report - Avita will submit a report to BARDA detailing the results of the process validation analysis.

CLIN 0002 – Base Period

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0002 | | |
| 7.1.1.2 Product Manufacturing | Order Received | Initial Product |
| 7.1.1.3 Deploy product to VMI sites | Product shipped to sites | Product deployed |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: Upon authorization from BARDA, Avita will cause the production and delivery of ReCell devices. Upon receiving the order Avita will authorize the manufacturer to procure supplies for the manufacture of the devices and preparing designated inventory locations.

Milestones:

7.1.1.1 Order Received

7.1.1.2 Delivery of specified quantity of units to VMI.

Deliverables:

7.1.1.2 Initial Product Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices.

7.1.1.3 Product integrated into VMI and available for deployment

7.2.1 Title: Gather VMI Requirements

Objective/Description of Work: Avita will work with USG to identify all VMI requirements, and prepare a document detailing the requirements.

Milestones:

7.2.1 All VMI requirements agreed upon with BARDA

Deliverables:

7.2.1 VMI Requirements Document – Report detailing the agreed upon requirements for VMI.

7.4 Sustainment/Stockpile Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| CLIN0002 | | |
| 7.4.1 Inventory Management | Quarterly inventory reports | Inventory Management Report |

7.4.1 Title: inventory Management

Objective/Description of Work: Inventory management encompasses activities that occur after the inventory is on site and the inventory system is in operation. The purpose is to ensure ongoing compliance with the stockpiling requirements, and manage replenishment to ensure unit availability in emergency situations. Site environments will continue to be monitored through the lifetime of the contract for compliance with environmental requirements, and inventory controls will be followed. Site performance will be monitored periodically, supplemented by BARDA site visits. Plans will be executed to replenish expiring goods and units will be reworked as needed to maintain currency. Avita will present to BARDA Inventory Management Reports detailing the status and activities at all VMI locations at a frequency determined appropriate by BARDA and Avita.

Milestones:

7.4.1 Quarterly inventory reports

Deliverables:

7.4.1 Inventory Management Report

Summary Table

| CLIN | WBS 1st Level Element | Title | Objectives |
|---|---|---|---|
| **0003** | 3 | CoA Study | • Complete Post-Approval (conditions of approval) study, as required by FDA |
| **0004** | 3, 4 | Pediatric Studies | • Complete pediatric clinical trials per FDA requirements and BARDA guidance |
| **0005** | 7 | Procurement (Surge) | • Execute acquisition contact<br>• Expand VMI as necessary<br>• Manage inventory |
| **0006** | 7 | Procurement (Surge) | • Execute acquisition contact<br>• Expand VMI as necessary<br>• Manage inventory |
| **0007** | 7 | Procurement (Surge) | • Execute acquisition contact<br>• Expand VMI as necessary<br>• Manage inventory |
| **0008** | 7 | Procurement (Surge) | • Execute acquisition contact<br>• Expand VMI as necessary<br>• Manage inventory |

Overview

Avita has defined three option periods covering the Conditions of Approval (CoA) study after FDA approval of the ReCell Device (CLIN 0003), a Pediatric study to expand the indications for ReCell for a broader pediatric demographic, if necessary, for ReCell (CLIN 0004), and for the procurement of additional ReCell devices beyond the initial acquisition (CLIN0005). **Note: Updated SOW(s) will be provided to BARDA based on FDA feedback to support the execution of each CLIN**. The accompanying budget(s) will also be updated to align with the revised SOW(s).

The purpose of the CoA, CLIN 0003, is to provide longer-term evaluation of the ReCell device after FDA approval, in order to track and confirm that any post-market commitments are addressed by Avita.

The purpose of the Pediatric Study, CLIN 0004, is to expand the approved range of patients for ReCell, specifically for pediatric patients, beyond those originally approved during the PMA process. The specific study design and objectives will be based on the PMA approval outcomes as well as consultation with BARDA, and will be intended to expand the range of patients able to be treated by ReCell.

Surge acquisition, CLIN 0005, will support additional acquisition of ReCell devices by BARDA, CDC, or other stakeholders.

**3 Clinical**

3.3 Post approval (Condition of Approval Study)

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.3.1.2 Submit protocol to BARDA for review | Protocol developed | Study Protocol |
| 3.3.6.1 Statistical analysis | Statistical analysis complete | Tables, Listings & Figures (i.e. Statistical analysis output) |
| 3.3.6.2 Clinical study report | CSR complete | CSR, review/submit to FDA |

3.3.6.4 Title: Final CoA CSR Review; Sufficiency for FDA submission

Objective/Description of Work: Post approval (COA study) will be carried out if an additional study is required by FDA as a condition of PMA approval. If a COA study is required, a new clinical study will need to be prepared and approved, including protocol with inclusion and exclusion criteria, endpoints, and IDE application written and submitted, FDA approval of the IDE, local IRB approval, clinical study site agreements, and local ethics approvals. The study protocol and all CSR reports, statistical analysis results, and final CSR reviews will be submitted to BARDA for review and comment prior to submitting to FDA.

Milestones:

3.3.1.1 Protocol developed

3.3.2.2 Last subject last visit

3.3.6.1 CRO completes statistical analysis

3.3.6.2 Final CSR review complete and data is determined to be sufficient for FDA submission

Deliverables:

3.3.1.2 Study Protocol submitted to BARDA

3.3.6.1 Tables, Listings & Figures (i.e. Statistical analysis output)

3.3.6.2 CSR, review/submit to FDA

CLIN 0004 – Option – Pediatric Study

Summary Table

| CLIN | WBS 1st Level Element | Title | WBS 2nd Level Element | Objectives |
|---|---|---|---|---|
| 0004 | 1 | Project Management | • 1.1 | • Provide Internal Project Management |
| | | | • 1.2 | • Provide Contract Management |
| | | | • 1.4 | • Establish Baseline and provide EV CPR Reports |

| CLIN | WBS 1st Level Element | Title | WBS 2nd Level Element | Objectives |
|---|---|---|---|---|
| | 2 | Non-Clinical Objectives | • 2.1 | • Quality Systems Upgrades |
| | | | • 2.2 | • Update the Economic Benefits of Medical Counter Measures Model |
| | | | • 2.3 | • Facilitate ReCell Sustainability through development of a robust commercialization plan |
| | 3 | Clinical Objectives | • 3.1 | • Pediatric Studies for Expanded Labelling |
| | | | • 3.2 | • Part 1 Donor site treatment in patients aged 1 – 16 years.<br>• Part 2 Treatment of patients aged 1 – 16 years with partial thickness injuries. |
| | 4 | Regulatory Objectives | • 4.1 | • PMA Supplements with expanded labelling for Donor Site Treatment and Pediatric partial thickness injury treatment<br>• Facilitate FDA Panel Preparation Activities |

**1. Program Management**

1.1. Internal Project Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.1.1 Integrated Master Project Plan | Upon delivery to and acceptance by BARDA | All required elements of this plan as listed in the contract. |

1.1.1. Title: Integrated Master Project Plan

Objective/Description of Work: Avita will compile all necessary materials and finalize all aspects of the project related to preparing the Integrated Master Project Plan. This will include finalizing critical path milestones, Work Breakdown Structure (WBS), and Risk Mitigation Plan. The final deliverable of the IMPP will represent the finalization and approval of all project elements between Avita and BARDA.

1.2 Contract Management

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.2.2 Reporting | Upon delivery to and acceptance by BARDA | All required reports as listed in the RFP and requested by BARDA |

1.2.3 Title: Reporting

Objective/Description of Work: Avita will comply with all reporting requirements as outlined and formatted in the RFP and as requested by BARDA. All Report information will be consolidated into the reports generated for CLIN 0001.

1.4 IMS and EVM

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 1.4.2 Performance Measurement Baseline | Performance Measurement Baseline Review (PMBR) | Performance Measurement Baseline Review Plan and Required Components – A plan detailing a schedule of deliverables, costs, milestones, and risks that will serve as the basis for measuring project progress. |
| 1.4.3 Integrated Master Schedule | IMS Approved by BARDA | The IMS shall be provided at the work package level in MS Project file format, for the PMBR and monthly thereafter, in order to monitor performance of the contract. |
| 1.4.4 Monthly Earned Value Performance Report | Delivery to and acceptance by BARDA | Monthly Earned Value Performance Report |
| 1.4.5 Supplemental monthly CAP report | Delivery to and acceptance by BARDA | Supplemental monthly CAP report |

1.4.3 Title: Performance Measurement Baseline

Objective/Description of Work: The Performance Measurement Baseline will provide a master schedule of deliverables, costs, and milestones in order to completely cover all items in the SOW. All required components will be submitted to BARDA within 90 days of contract award. BARDA and Avita will mutually agree on the budget, schedule and technical plan baselines as a result of the PMBR.

1.4.3 Title: Integrated Master Schedule (IMS)

Objective/Description of Work: The IMS will be used to monitor performance against the contract. Avita will develop an IMS in a format approved by BARDA in order to track key milestones, Go/No Go decision gates. The IMS will contain baseline start and finish, forecast start and finish, actual start and finish, predecessor and/or successor. Avita will provide a baseline IMS for the PMBR and monthly updates thereafter.

1.4.4 Title: Monthly Earned Value Performance Report

Objective/Description of Work: The Monthly Earned Value Performance Report will be generated from Avita's EVMS in order to track any project variances against the baseline. The report will contain technical, schedule, and cost status information in order to identify any issues that may impact project progress and/or cost.

1.4.5 Title: Supplemental Monthly CAP Report

Objective/Description of Work: The Supplemental Monthly CAP Report will be generated from Avita's EVMS and will contain cost information to report on the time phased budget, earned value, and actual costs of work performed. The report will be submitted monthly to BARDA for review.

## 2 Non-Clinical Objectives

2.1 Title Quality System Upgrades

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 2.1.1 Quality System Upgrade | Completion of Quality Systems Audit by independent 3rd Party | Audit Report(s) |

2.1.1 Title Quality System Upgrades

Objective/Description of Work: Perform additional independent 3rd party mock FDA audits and mitigation activities at Parker Hannifin and/or Avita Medical as required. Augment current Avita staff to oversee initial production builds to assure supplier compliance that all manufacturing records are accurate and complete (Quality Engineer). Additionally, we have recognized the need for a Quality Assurance/Regulatory Affairs Specialist to provide timely assessment of reports of device failure complaints and CAPA's, providing more accurate and relevant analysis, administration and reporting. This position will also facilitate quality and regulatory development and review of manufacturing and product changes, PMA supplements and Annual Reports.

2.2 Title Update the Burn Care Pathway Model

Objective/Description of Work: Goals of the research: To add to the underlying calculations, data, interface and documentation of the existing Burn Care Pathway Model.

2.2.1 Title Update the Burn Care Pathway Model with Pediatric Data

Objective/Description of Work: Although the existing Burn Care Model includes pediatric patients as well as indeterminate deep partial or superficial partial thickness burns, assumptions are currently in place regarding burn management and relevant inputs. In particular, accuracy of diagnosis impacts whether a partial thickness burn is treated like a full thickness burn, or whether the burn is assumed to heal without grafting. Additionally, although resource use for children reflects smaller body surface area, other costs are assumed equivalent between children and adults due to lack of pediatric-specific expert insight. As Avita is currently planning two clinical trials to support the use of ReCell in pediatric patients with partial thickness burns, additional detail can be added to the model following completion of these protocols. All optional tasks will require review and discussion between BARDA and Avita for need and scope, prior to submission of a COA request to proceed being initiated.

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 2.2.1.1 Trial-based resource use and costs | Data inputs incorporated into the Burn Care Pathway Model. | A summary file in MS Excel and data inputs incorporated into the Burn Care Pathway Model. |
| 2.2.1.2 Clinical Trial Evidence Review and Storyboard | Completion of Storyboard | Storyboard Presentation |
| 2.2.1.3 KOL Validation | KOL input compete | KOL proposed changes to validate model inputs. |

| | | |
|---|---|---|
| 2.2.1.4 Model Update/Expansion & Preliminary Results | Completion of Proposed changes to existing Burn Care Pathway Model | A brief set of slides (<10) documenting the pediatric partial thickness burn scenario methods and results. |
| 2.2.1.5 Model Finalization/Quality Control (QC) & Final Results | QC is complete and the model is locked down | Preliminary results slides will be updated to reflect final results |
| 2.2.1.6 Updated Technical Reporting | Completion of updated written technical report for the Burn Care Pathway Model | Updated written technical report for the Burn Care Pathway Model |
| 2.2.1.7 Title: Optional Additional Communications Presentations | Completion of Slide Presentation | Completed Slide Presentation |
| 2.2.1.8 Title: Optional Abstract/Poster | Completion of Abstract/Poster | Completed Abstract/Poster |
| 2.2.1.9 Title: Optional Manuscript | Completion of Manuscript | Completed Manuscript |

2.2.1.1 Title: Trial-based resource use and costs.

Objective/Description of Work: [**] (QI) will aid with the identification of trial-based resource use and costs through manual processing and review of hospital billing records. Avita will facilitate acquisition of the hospital billing records through the trial. These files would be provided in a HIPAA-compliant manner to QI project team members (for up to 200 patients based on power calculations from the partial thickness burn protocol). Data would be extracted according to a pre-approved process and template. A summary file in MS Excel would be provided for review upon completion, and data inputs incorporated into the Burn Care Pathway Model.

2.2.1.2 Title: Clinical Trial Evidence Review and Storyboard

Objective/Description of Work:

- Upon availability of the clinical trial evidence 01 will draft a brief set of slides detailing the specific fields that would be added to the model or updated using trial-based data;
- QI would present this information for comment;
- Upon receipt of consolidated feedback, QI will revise in a final storyboard prior to commencing with model changes.

2.2.1.3 Title: KOL validation

Objective/Description of Work: Targeted conversations with at least two pediatric burn surgeons regarding the proposed changes to validate model inputs.

2.2.1.4 Title: Model Update/Expansion & Preliminary Results

Objective/Description of Work:

- Following delivery of the final storyboard, QI will make proposed changes to the existing Burn Care Pathway Model, affecting both the underlying calculations and interface as relevant;

2.2.1.5 Title: Model Finalization/Quality Control (QC) & Final Results

Objective/Description of Work:

- Upon review of the preliminary model and results, minor clarifications or additional explorations will be addressed as QI moves forward to finalize the model and initiate the QC process;
- QC would include a full review, including ensuring that the following general areas have been examined (documentation available upon request):
- Clarity (screen orientation and design, assumptions, referencing, inputs, results)
- Accuracy (review input parameters/Visual Basic code/named ranges, formula auditing)
- Consistency (naming conventions, graphics, logos)
- Testing and model functionality (pressure testing with extreme values, scenario investigations)
- Once QC is complete and the model is locked down, the preliminary results slides will be updated to reflect final results, and these will be shared again with Avita.

2.2.1.6 Title: Updated Technical Reporting

Objective/Description of Work: QI will also update the written technical report for the Burn Care Pathway Model, in order to ensure that documentation remains aligned with the model itself, thus facilitating continued use as new individuals may need to use the model.

2.2.1.7 Title: Optional Additional Communications Presentations

Objective/Description of Work: QI help to develop content for presentation materials to facilitate targeted internal or external communication (a single presentation of no more than 30 slides).

2.2.1.8 Title: Optional Abstract/Poster

Objective/Description of Work: An abstract will be submitted to an appropriate industry conference meeting to be decided in consultation. This abstract will be written collaboratively. Once accepted, QI will develop the poster or presentation, in consultation, for presentation at the conference meeting.

2.2.1.9 Title: Optional Manuscript

Objective/Description of Work: Manuscript. 01 will prepare a manuscript for publication that summarizes the study's methods and findings for this model expansion. From a process standpoint, the draft manuscript will be submitted to Avita for review and comment, after which 01 will make one round of revisions. After approval, QI will submit the manuscript to a peer-reviewed journal mutually agreeable to [**] and BARDA/Avita. QI will conduct one round of narrative revisions requested by journal reviewers and will resubmit once, if necessary. Substantial revisions requested by journal reviewers, including revisions that require additional data analysis, or a mutual decision to resubmit the manuscript to a separate journal, may require a scope amendment for this task. 01 adheres to authorship guidelines as established by ICMJE (www.icmje.org/ethicalalauthor.html).

2.2.2 Title Optional Tasks to Update the Burn Care Pathway Model with Outpatient Data

Objective/Description of Work: Optional work is proposed to add to or amend the underlying calculations, interface and documentation of the existing Burn Care Model, to support discussions regarding outpatient use of ReCell. All optional tasks will require review and discussion between BARDA and Avita for need and scope, prior to submission of a COA request to proceed being initiated.

2.2.2.1 Title Option 1: Burn Care Model Expansion: Outpatients

Objective/Description of Work: One possible use for ReCell technology is in an outpatient setting, to alleviate the need for inpatient beds or time, which would be highly valuable to relieve the bottlenecks in the event of mass casualty. While the burn care model has been established to make use of trial data and inpatient resource use and costing assumptions, the outpatient setting differs significantly, with changes needed to accommodate:

- Defining the types of burns that could be managed in an outpatient setting (including primary outpatient intervention as well as post-discharge outpatient follow-up care);
- Resource use specific to these burn types and outpatient facilities;
- Unit costs specific to outpatient resource use.

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 2.2.2.1.1 Option 1 Task 1 Evidence Review and Storyboard | Completed Storyboard Shell | Completed Storyboard Shell |
| 2.2.2.1.2 Option 1 Task 2 KOL Interviews and Management | KOL Interviews Completed | Results of KOL Interviews |
| 2.2.2.1.3 Option 1 Task 3 Storyboard update | Presentation of Final Storyboard | Presentation of Final Storyboard |

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 2.2.2.1.4 Option 1 Task 4 Model Update/Expansion & Preliminary Results | Completion of Preliminary Results | Presentation of Preliminary Results |
| 2.2.2.1.5 Option 1Task 5 Model Finalization/Quality Control (QC) & Final Results | QC and Final Results complete | Presentation of Final Results |
| 2.2.1.1.6 Option 1 Task 6 Full Technical Reporting | Completion of Technical Report | Presentation of Final Technical Report |
| 2.2.2.1.7 Option 1 Task 7 Manuscript | Completion of Manuscript of publishable quality that summarize study methods and findings for this outpatient scenario. | Manuscript of publishable quality that summarize study methods and findings for this outpatient scenario. |
| 2.2.2.2 Option 2 Model Version 2.0 updates | Finalized Model | Updated Model |
| 2.2.2.3 Option 3 Bank of Hours for Scope Amendments | TBD | TBD |
| 2.2.2.4 Abstract/Poster | Completed Abstract/Poster | Completed Abstract/Poster |
| 2.2.2.5 Option 5 Additional Manuscripts | Completion of Manuscript | Completed Manuscript |

2.2.2.1.1 Title Option 1 Task 1 Evidence Review and Storyboard

Objective/Description of Work:

- Review the model and clinical literature to understand what burns may be managed as outpatient, and what that management would entail
- Develop a storyboard shell with all available data

2.2.2.1.2 Title Option 1 Task [**] KOL Interviews and Management

Objective/Description of Work:

- This task would include at least5-6 hours per KOL to ensure adequate feedback storyboard content and data gaps, and draft model content

2.2.2.1.3 Title Option 1 Task 3 Storyboard update

Objective/Description of Work:

- The KOL discussion responses will be folded into a storyboard revision. This storyboard will be presented for consolidated feedback a second time.
- Any comments will be addressed in a final version that will serve as the blueprint for amending the model.

2.2.2.1.4 Title. Option 1 Task 4 Model Update/Expansion & Preliminary Results

Objective/Description of Work:

- Make proposed changes to the existing Burn Care Model, affecting both the underlying calculations and interface.
- Generate preliminary results for review with Avita. Append additional slides (<10) to the storyboard to summarize the preliminary results for the outpatient setting.

2.2.2.1.5 Title. Option 1 Task 5 Model Finalization/Quality Control (QC) & Final Results

Objective/Description of Work:

- Update model based on Avita feedback on preliminary results.
- QC, including a full review, to ensure that the following areas have been examined (documentation available upon request):
    - Clarity (screen orientation and design, assumptions, referencing, inputs, results)
    - Accuracy (review input parameters/Visual Basic code/named ranges, formula auditing)
    - Consistency (naming conventions, graphics, logos)
    - Testing and model functionality (pressure testing with extreme values, scenario investigations)
- Lock down model and update storyboard slides to reflect final results

2.2.1.1.6 Title Option 1 Task 6 Full Technical Reporting

Objective/Description of Work:

- Create a technical report to detail the purpose, methods, and results for the outpatient setting.
- Refine report based on feedback

2.2.2.1.7 Title Option 1 Task 7 Manuscript

Objective/Description of Work:

- Prepare manuscript of publishable quality that summarize study methods and findings

2.2.2.2 Title Option 2 Model Version 2.0 updates

Objective/Description of Work:

Update the existing original model (version 1.0) in a second iteration (version 2.0). This task would entail summarizing the changes that will be made via slides; these would be shared with Avita for review and comment, after which a final summary of the agreed-upon updates will be circulated. This final summary will serve as the blueprint for model updates; after these are made and preliminary results are shared, the model will undergo targeted quality control and finalized

2.2.2.3 Title Option 3 Bank of Hours for Scope Amendments

Objective/Description of Work:

It has been observed that the details of data gaps and required effort to fill those may not be anticipated. Therefore, we propose that a bank of hours may permit us to pursue those data pieces or other adjustments to the scope on a time and materials basis.

2.2.2.4 Title Option 4 Abstract/Poster

Objective/Description of Work:

Up to four Abstract/Poster sets given the addition of a new scenario for dissemination, as well as possible additional topics, it may be valuable to plan for a flexible publication strategy. Potential topics for consideration include:

- Outpatient setting analysis
- Pediatric setting analysis
- Model Version 2.0 release with payer analyses
- Any additional data analyses

2.2.2.5 Title Option 5 Additional Manuscripts

Objective/Description of Work:

Up to three additional manuscripts Prepare additional manuscript(s) of publishable quality that summarize study methods and findings for a scenario or analysis of interest.

- Draft manuscript(s) will be submitted for review and comment
- Make one round of revisions.
- Submit the manuscript to a peer-reviewed journal mutually agreeable.
- Conduct one round of narrative revisions requested by journal reviewers and resubmit if necessary.

2.3 Title ReCell Commercialization and Sustainability Planning

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 2.3.1 Commercialization and Sustainability Planning | Commercialization and Sustainability Strategy Readiness | Quarterly and/or Bi-Annual Briefing and Written Reports to BARDA communicating product commercialization strategy and Sustainability. |

2.3.1 Title Commercialization Planning

Objective/Description of Work: BARDA will supplement resources to ensure sustainability through development of a robust commercialization plan including the following:

- Market Analysis and Planning
    - In-depth characterization of current (burn) market opportunity (SWOT, PEST), including competitive analysis, lessons learned from pioneers and launch risks and mitigation steps
    - Plan for increasing market adoption and penetration
        - US
        - OUS (EU, Asia Pac, ROW)
    - In-depth US pricing evaluation plan
    - Identify revenue maximizing price and volumes based on price elasticity of demand projections
- Promotional Plan Development (market strategy)/Strategic Product Plan
    - Value Proposition (features/benefits/claims)
    - Communication plan
        - Messaging plan
        - PR/Conference exhibit plan
    - Print assets plan
- Strategic and Communication Plan Validation
    - SWOT (Strengths, Weaknesses, Opportunities, Threats) Analysis
    - PEST (Political, Economic, Social, Technological) Analysis
- Payor/Access Planning (US reimbursement)/New Technology Add-On
- Sustainability Planning
    - Supply Chain management
    - Manufacturing Scale Up

**3 Clinical**

3.1 Pediatric Donor Site Study

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.1.1 Clinical Protocol | Protocol developed | Final Protocol |
| 3.1.2 Electronic Data Capture | Electronic Data Capture (EDC) on-line | Electronic Data Capture (EDC) on-line notification |
| 3.1.3 First Site Ready for Enrollment | First Site Ready for Enrollment | First Site Ready for Enrollment |

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.1.4 First Subject First Visit | First Subject First Visit (FSFV) Completed | First Subject First Visit |
| 3.1.5 50% Primary Effectiveness Endpoint Visit | 50% of Visits Complete | Sample Size Recommendation |
| 3.1.6 Last Subject Last Visit | Last Subject Last Visit (LSLV) Complete | Last Subject Last Visit |
| 3.1.7 Database Lock | Database Lock | Database Lock |
| 3.1.8 Data Analysis | Data Analysis Report | Data Analysis Report |
| 3.1.9 Draft CSR | Draft CSR Complete | Draft CSR Complete |
| 3.1.10 Final CSR | Final CSR Completed | Final CSR review complete and data is determined to be sufficient for FDA submission, Tables Listings & Figures. |

3.1 Title: Pediatric Donor Site Study

Objective/Description of Work: This is a prospective, within-subject paired, randomized (1:1), blinded evaluator, multicenter trial to investigate whether application of autologous skin cell suspension prepared with the ReCell device (i.e., RES) can be safely and effectively used to promote wound healing of donor-sites created for sourcing tissue during treatment of skin defects which require autografting. Additionally, the impact of the use of RES will be investigated with respect to donor site scar outcomes and physician/subject treatment preference as pre-specified secondary endpoints. Safety will be evaluated in terms of donor-site morbidity including but not limited to infection, allergic reaction, delayed healing, pain and scar. A minimum of 50 subjects will be enrolled in this study and a maximum of 100. Additional staff to support Field Clinical Support, Recruitment and Medical Science Liaison activities have been proposed to ensure the study is adequately staffed. These positions will be pre-coordinated with BARDA prior to hiring.

The clinical study will be prepared and approved, including:

- Protocol with inclusion and exclusion criteria and endpoints
- IDE application written and submitted
- FDA approval of the IDE
- Local IRB approvals
- Clinical study site agreements
- Clinical study site initiation visits
- Investigator Meetings

The study protocol and CSR reports will be submitted to BARDA for review and comment prior to submitting to FDA. Additionally, an independent medical monitor or a Clinical Events Committee (CEC) and Data Monitoring Committee (DMC) will be utilized.

3.2 Pediatric Partial Thickness Study

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 3.2.1 Clinical Protocol | Protocol developed | Final Protocol |
| 3.2.2 Electronic Data Capture | Electronic Data Capture (EDC) on-line | Electronic Data Capture (EDC) on-line notification |
| 3.2.3 First Site Ready for Enrollment | First Site Ready for Enrollment | First Site Ready for Enrollment |
| 3.2.4 First Subject First Visit | First Subject First Visit (FSFV) Completed | First Subject First Visit |
| 3.2.5 50% Primary Effectiveness Endpoint | 50% of Visits Complete | Interim Analysis Report, Tables Listings and Figures, and Sample Size Recommendation. |
| 3.2.6 Last Subject Last Visit | Last Patient Last Visit (LSLV) Complete | Last Subject Last Visit |
| 3.2.7 Database Lock | Database Lock | Database Lock |
| 3.2.8 Data Analysis | Data Analysis Report | Data Analysis Report |
| 3.2.9 Draft CSR | Draft CSR Complete | Draft CSR Complete |
| 3.2.10 Final CSR | Final CSR Completed | Final CSR review complete and data is determined to be sufficient for FDA submission, Tables Listings & Figures. |

3.2 Title: Pediatric Partial-thickness Study

Objective/Description of Work: This is a 2-arm, randomized (1:1), multicenter trial to compare the clinical performance of RES prepared from the ReCell® device versus dressings alone in males and females aged1-16 years with a partial-thickness burn injury involving 2 to 20% of their total body surface area (TBSA). It is hypothesized that application of RES will reduce the incidence of progression to surgical intervention with autografting. Additionally, this study will compare longer-term scar outcomes, and pain and distress experienced during dressing changes. It is anticipated that a minimum of 226 subjects and a maximum of 280 subjects will be enrolled in this study with approximately 113 subjects each randomized to receive application of RES or control dressings to the partial-thickness burn.

The clinical study will be prepared and approved, including:

- Protocol with inclusion and exclusion criteria and endpoints
- IDE application written and submitted
- FDA approval of the IDE
- Local IRB approvals
- Clinical study site agreements
- Clinical Study Site Initiation Visits
- Investigator Meetings

The study protocol and CSR reports will be submitted to BARDA for review and comment prior to submitting to FDA. Additionally, an independent monitor or a Clinical Events Committee (CEC) and Data Monitoring Committee (DMC) will be utilized.

**4 Regulatory**

4.1 Pediatric /Supplemental Regulatory activities

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 4.1.1 Pediatric IDE | FDA approval of pediatric IDE | Pediatric IDE Submission, IDE re-submission, IDE approval, Final Report |
| 4.1.2 Donor Site PMA supplement | FDA approval of expanded indication for Donor Sites | Submission for Donor Site label expansion |
| 4.1.3 Pediatric Partial – thickness Injury PMA supplement | FDA approval of expanded indication or Pediatric Partial- thickness injuries | Submission for Pediatric Partial-thickness injury label expansion |
| 4.1.4 Supplemental Regulatory actions | Activity requiring FDA supplemental materials, FDA PMA Panel if required. | Supplemental Regulatory actions as required i.e. FDA Meeting Minutes, Clinical Protocol Amendments, FDA pre-submission meeting, SAP, Follow-up Submissions. Avita will share both draft and final versions of any regulatory interactions. |
| 4.1.5 Annual IDE Reports | Annual IDE Reports Submitted | Annual IDE Report Delivered to BARDA (draft and final reports) |
| 4.1.5 Annual PMA Reports | Annual PMA Reports Submitted | Annual PMA Report Delivered to BARDA (draft and final reports) |

4.1 Title: Pediatric Indication and Supplemental Regulatory Support

Objective/Description of Work: Avita will make the regulatory filings with FDA for a pediatric IDE clinical trial and PMA supplements for expansion of labeling for Donor Sites and Pediatric Partial-thickness injury indications. Support FDA PMA Panel Prep if required. Submit Annual IDE and PMA reports.

CLIN 0005 – Procurement (Surge)

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.1.2.2 Product Manufacturing | Order Received | Additional product to meet surge capacity (Less than 2,000 Units) |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: BARDA would authorize the surge procurement order to acquire additional ReCell devices beyond the initial order. Upon receiving the order Avita would authorize the manufacturer to begin acquiring supplies for the manufacture of the additional devices.

Milestones:

7.1.2.1 Order Received

Deliverables:

7.1.2.2 Surge Capacity Product upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices according to the additional products required to meet surge capacity. Product will be deployed to designated VMI locations.

CLIN 0006 – Procurement (Surge)

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.1.2.2 Product Manufacturing | Order Received' | Additional product to meet surge capacity ([**] Units) |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: BARDA would authorize the surge procurement order to acquire additional ReCell devices beyond the initial order. Upon receiving the order Avita would authorize the manufacturer to begin acquiring supplies for the manufacture of the additional devices.

Milestones:

7.1.2.1 Order Received

Deliverables:

7.1.2.2 Surge Capacity Product – Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices according to the additional products required to meet surge capacity. Product will be deployed to designated VMI locations.

CLIN 0007 – Procurement (Surge)

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.1.2.2 Product Manufacturing | Order Received | Additional product to meet surge capacity ([**]) |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: BARDA would authorize the surge procurement order to acquire additional ReCell devices beyond the initial order. Upon receiving the order Avita would authorize the manufacturer to begin acquiring supplies for the manufacture of the additional devices.

Milestones:

7.1.2.1 Order Received

Deliverables:

7.1.2.2 Surge Capacity Product – Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices according to the additional products required to meet surge capacity. Product will be deployed to designated VMI locations.

CLIN 0008 – Procurement (Surge)

**7 Procurement**

7.1 Acquisition

| WBS# and Title | Milestone | Deliverable |
|---|---|---|
| 7.1.2.2 Product Manufacturing | Order Received | Additional product to meet surge capacity ([**] Units) |

7.1.1.2 Title: Product Manufacturing

Objective/Description of Work: BARDA would authorize the surge procurement order to acquire additional ReCell devices beyond the initial order. Upon receiving the order Avita would authorize the manufacturer to begin acquiring supplies for the manufacture of the additional devices.

Milestones:

7.1.2.1 Order Received

Deliverables:

7.1.2.2 Surge Capacity Product – Upon receiving the procurement order from BARDA, Avita will manufacture ReCell devices according to the additional products required to meet surge capacity. Product will be deployed to designated VMI locations.

**Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Double asterisks denote omissions.**

| AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | 1. CONTRACT ID CODE | PAGE OF PAGES 1 \| 3 |
|---|---|---|

| 2. AMENDMENT/MODIFICATION NO. | 3. EFFECTIVE DATE | 4. REQUISITION/PURCHASE REQ. NO. | 5. PROJECT NO. (*If applicable*) |
|---|---|---|---|
| 0004 | See Block 16C | OS222377 | |

| 6. ISSUED BY | CODE ASPR—BARDA | 7. ADMINISTERED BY (*if other then item 6*) | CODE ASPR—BARDA |
|---|---|---|---|
| ASPR-BARDA<br>200 Independence Ave., S.W.<br>Room 640-G<br>Washington DC 20201 | | ASPR-BARDA<br>200 Independence Ave., S.W.<br>Room 638-G<br>Washington DC 20201 | |

| 8. NAME AND ADDRESS OF CONTRACTOR (*No., street. county. State and ZIP Code*) | | 9A. AMENDMENT OF SOLICITATION NO. |
|---|---|---|
| AVITA MEDICAL AMERICAS,LLC 1476585<br>AVITA MEDICAL AMERICAS, LLC 92<br>28159 Avenue Stanford<br>Suite 220<br>Valencia CA 91355 | (x) | 9B. DATED (*SEE ITEM 11*) |
| | X | 10A. MODIFICATION OF CONTRACT/ORDER NO.<br>HHS0100201500028C |
| | | 10B. DATED (SEE ITEM 13)<br>09/29/2015 |
| CODE 1476585 | FACILITY CODE | |

**11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS**

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and dale specified for receipt of Offers ☐ is extended. ☐ is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified M the solicitation or as amended by one of the following methods: (a) By completing Items B and 15, and returning _____ copies of the amendment (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate teller or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER If try virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and Is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (*If required*) Net Increase [**]
2018.199TWNP.25103

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

| CHECK ONE | |
|---|---|
| | THIS CHANGE ORDER IS ISSUED PURSUANT TO: (*Specify authority*) THE CHANGES SET FORTH IN ITEM 14 ARE MADE iN THE CONTRACT ORDER NO. IN ITEM 10A. |
| | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (*such as changes in paying office, appropriation dale, etc.)* SET FORTH IN ITEM 14. PURSUANT TO THE AUTHORITY OF FAR43.103(b). |
| X | **C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:**<br>FAR 52.243-2 Changes — Cost Reimbursement |
| | **D. OTHER (Specify type of modification and authority)** |

**E. IMPORTANT**: Contractor ☐ is not. ☐ is required to sign this document and return 2 copies to the issuing office.

**14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)**

Tax ID Number: 20-2578762
DUNS Number: 026723570
To modify ARTICLE B.3 OPTION PRICES.

Funds Obligated Prior to this Modification: [**]
Funds Obligated with mod #04: [**]
Total Funds Obligated to Date: $50,414,137
PSC Code: 6505
Continued …

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged arid in lull farce and affect.

| 15A. NAME AND TITLE OF SIGNER (Type or print) | | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) | |
|---|---|---|---|
| Timothy Rooney CAO | | **Christopher Scott** | |
| **15B. CONTRACTOR/OFFEROR** | **15C. DATE SIGNED** | **16B. UNITED STATES OF AMERICA** | **16C. DATE SIGNED** |
| **/s/ Timothy Rooney**<br>***(Signature of person authorized to sign)*** | | /s/ Christopher Scott<br>***(Signature of Contracting Officer)*** | **7/2/18** |

**NAME OF OFFEROR OR CONTRACTOR**
AVITA MEDICAL AMERICAS, LLC 1476585

| ITEM NO. (A) | SUPPLIES/SERVICES (B) | QUANTITY (C) | UNIT (D) | UNIT PRICE (Li | AMOUNT (F) |
|---|---|---|---|---|---|
| | Expiration date: [**], 2022 (Unchanged) | | | | |
| | Delivery: 07/02/2018<br>Delivery Location Code: HHS/OS/ASPR<br>HHS/OS/ASPR<br>200 C St SW<br>WASHINGTON DC 20201 US | | | | |
| | Appr. Yr.: 2018 CAN: 199TWNP Object Class: 25103<br>FOB: Destination<br>Period of Performance: [**]/2015 to [**]/2022 | | | | |
| | Add Item 10 as follows: | | | | |
| 10 | ASPR-18-03004 — Avita's indirect cost rate true up for FY2016 and FY2017 ending [**]/17 – HHS0100201500028C<br>Obligated Amount: [**] | | | | [**] |

**ARTICLE B.3. OPTION PRICES are hereby modified as follows**

| CLIN | Period of Performance | Supplies! Services | Units (# of Product) | Unit Price ($) | Total ($) |
|---|---|---|---|---|---|
| | | **FIRM FIXED PRICE** | | | |
| 0003 (Option) | [**] Months | Phase IV post marketing commitments /Requirements (This is an option that may or may not be exercised during the base period as determined by the need and as established by the FDA) | N/A | N/A | [**] |
| **0009** | **[**]/15 — [**]/22** | **FY 2016/FY2017 Final Rate True Up** | **N/A** | **N/A** | **[**]** |
| | | **COST REIMBURSEMENT** | | | |
| **0004 (Option)** | **[**]/17 — [**]/22** | **Pediatric Study (This is an option that may or may not be exercised during the base** period for expansion of the **label indication with guidance from the FDA)** | [**] | [**] | [**] |
| | | **FIRM FIXED PRICE** | | | |
| 0005 (Option) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0006 (Option) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0007 (Option) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| 0008 (Option) | 36 Months | Additional Surge Capacity | [**] | [**] | [**] |
| **Total Unfunded Option CLINs 3, 5-8** | **60 Months** | **See Above Descriptions** | | | [**] |

*** CLIN 0009 is exercised with this modification**

**All other terms and conditions of this contract remain unchanged.**

**End of Modification #3**

**Exhibit 4.8**

**STANDARD INDUSTRIAL/COMMERCIAL MULTI-TENANT LEASE—GROSS**
**AMERICAN INDUSTRIAL REAL ESTATE ASSOCIATION**

**1. Basic Provisions ("Basic Provisions").**

1.1 **Parties:** This Lease ("Lease"), dated for reference purposes only, January 25, 2018 is made by and between **Hartco Ventura Inc.** **("Lessor")** and **Avita Medical Americas, LLC, A Delaware limited liability company** **("Lessee"),** (collectively the **"Parties,"** or individually a "**Party**").

1.2(a) Premises: That certain portion of the Building, including all improvements therein or to be provided by Lessor under the terms of this Lease, commonly known by the street address of 3007 Bunsen Avenue, Units I, J, K, L, M, N, located in the City of Ventura, County of Ventura, state of California with zip code 93003, as

outlined on Exhibit A attached hereto ("Premises"). The "Building" is that certain building containing the Premises and generally described as (describe briefly the nature of the

Building): An approximately 23,040 square feet (units, I, J, K, L, M, N), Part of a larger 88,080 square feet multi-tenant industrial complex located on approximately 192,500 square feet of MPD zoned land.

In addition to Lessee's rights to use and occupy the Premises as hereinafter specified, Lessee shall have non-exclusive rights to the Common Areas (as defined in Paragraph 2.7 below) as hereinafter specified, but shall not have any rights to the roof, exterior walls or utility raceways of the Building or to any other buildings in the Industrial Center. The Premises, the Building, the Common Areas, the land upon which they are located, along with all other buildings and improvements thereon, are herein collectively ref to as the "industrial Center." (Also see Paragraph 2.)

1.2(b) **Parking**: Twenty four (24) unreserved vehicle parking spaces ("**Unreserved Parking Spaces**"); and Twelve (12) reserved vehicle parking spaces ("**Reserved Parking Spaces**"). (Also see Paragraph 2.6.)

1.3 **Term:** 3 years and 0 months ("**Original Term**") commencing October 1, ,2018 ("**Commencement Date**") and ending September 30, 2021 (**Expiration Date**"). (Also see Paragraph 3.)

1.4 **Early Possession:** See Paragraph 49 ("**Early Possession Date**"). (Also see Paragraphs 3.2 and 3.3.)

1.5 **Base Rent:** $24,192.00 per month ("**Base Rent**') payable on the First day of each month commencing October 1, 2018. [ X ] If this box is checked, this Lease provides for the Base Rent to be adjusted per Addendum 51, attached hereto.

1.6(a) **Base Rent Paid Upon Execution:** as Base Rent for the period,

1.6(b) **Lessee's Share of Common Area Operating Expenses:** Zero percent ( %) ("**Lessee's Share**") as determined by

[ ] prorata square footage of the Premises as compared to the total square footage of the Building or [ ] other criteria as described in Addendum

1.7 **Security Deposit:** $24,192.00 ("**Security Deposit**"). (Also see Paragraph 5.)

1.8 **Permitted use** Manufacturing of medical products, which will entail the use of certain substances which may be subject to paragraph 6.2 below (including without limitation Isopropyl alcohol, solder, and alkaline batteries) ("**Permitted Use**") (Also see Paragraph 6.)

1.9 **Insuring Party.** Lessor is the "**Insuring Party**." (Also see Paragraph 8.)

1.10(a) **Real Estate Brokers.** The following real estate brokers) (collectively, the "**Brokers**") and brokerage relationships exist in this transaction and are

consented to by the Parties (check applicable boxes):

[ ] N/A represents Lessor exclusively ("**Lessor's Broker**");

[ ] N/A represents Lessee exclusively ("**Lessee's Broker**"); or

[ ] N/A represents both Lessor and Lessee ("Dual Agency"). (Also see Paragraph 15.)

1.10(b) Payment to Brokers. Upon the execution of this Lease by both Parties, Lessor shall pay to said Brokers) jointly, or in such separate shares as they may mutually designate in writing, a fee as set forth in a separate written agreement between Lessor and said Brokers) (or in the event there is no separate written agreement between Lessor and said Broker(s), the sum of $ N/A J for brokerage services rendered by said Brokers) in connection with this transaction.

1.11 Guarantor. The obligations of the Lessee under this Lease are to be guaranteed by ("Guarantor"). (Also see Paragraph 37.)

1.12 Addenda and Exhibits. Attached hereto is an Addendum or Addenda consisting of Paragraphs _____through _____, and Exhibits _____ through _____, all of which constitute a part of this Lease.

2. Premises, Parking and Common Areas.

2.1 Letting. Lessor hereby leases to Lessee, and Lessee hereby leases from Lessor, the Premises, for the term, at the rental, and upon all of the terms, covenants and conditions set forth in this Lease. Unless otherwise provided herein, any statement of square footage set forth in this Lease, or that may have been used in calculating rental and/or Common Area Operating Expenses, is an approximation which Lessor and Lessee agree is reasonable and the rental and Lessee's Share (as defined in Paragraph 1.6(b)) based thereon is not subject to revision whether or not the actual square footage is more or less.

2.2 Condition. Lessor shall deliver the Premises to Lessee clean and free of debris on the Commencement Date and warrants to Lessee that the existing plumbing, electrical systems fire sprinkler system, lighting, air conditioning and heating systems and loading doors, if any, in the Premises, other than those constructed by Lessee, shall be in good operating condition on the Commencement Date. If a non-compliance with said warranty exists as of the Commencement Date, Lessor shall, except as otherwise provided in this Lease, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non-compliance, rectify same at Lessor's expense. If Lessee does not give Lessor written notice of a non-compliance with this warranty within thirty (60) days after the Commencement Date, correction of thatnon-compliance shall be the obligation of Lessee at Lessee's sole cost and expense.

2.3 Compliance with Covenants, Restrictions and Building Code. Lessor warrants that any improvements (other than those constructed by Lessee or at Lessee's direction) on or in the Premises which have been constructed or installed by Lessor or with Lessor's consent or at Lessor's direction shall comply with all applicable covenants or restrictions of record and applicable building codes, regulations and ordinances in effect on the Commencement Date. Lessor further warrants to Lessee that Lessor has no knowledge of any claim having been made by any governmental agency that a violation or violations of applicable building codes, regulations, or ordinances exist with regard to the Premises as of the Commencement Date. Said warranties shall not apply to any Alterations or Utility Installations (defined in Paragraph 7.3(a)) made or to be made by Lessee. If the Premises do not comply with said warranties, Lessor shall, except as otherwise provided in this Lease, promptly after receipt of written notice from Lessee given within six (6) months following the Commencement Date and setting forth with specificity the nature and extent of such non-compliance, take such action, at Lessor's expense, as may be reasonable or appropriate to rectify the non-compliance.

2.4 Acceptance of Premises. Lessee's acceptance of the Premises is based upon Lessor's warranty and representations: (a) that the Premises (including but not limited to the electrical and fire sprinkler systems, security, environmental aspects, seismic and earthquake requirements, and compliance with the Americans with Disabilities Act and applicable zoning, municipal, county, state and federal laws, ordinances and regulations and any covenants or restrictions of record (collectively, "Applicable Laws")) are suitable for Lessee's intended use; and (b) that neither Lessor, nor any of Lessor's agents, has made any oral or written representations or warranties with respect to said matters other than as set forth in this Lease.

2.5 Lessee as Prior Owner/Occupant. The warranties made by Lessor in this Paragraph 2 shall be of no force or effect if immediately prior to the date set forth in Paragraph 1.1 Lessee was the owner or occupant of the Premises. In such event, Lessee shall, at Lessee's sole cost and expense, correct any non-compliance of the Premises with said warranties.

**2.6 Vehicle Parking.** Lessee shall be entitled to use the number of Unreserved Parking Spaces and Reserved Parking Spaces specified In Paragraph 1.2(b) on those portions of the Common Areas designated from time to time by Lessor for parking. Lessee shall not use more parking spaces than said number. Said parking spaces shall be used for parking by vehicles no larger than full-size passenger automobiles or pick-up trucks, herein called "Permitted Size Vehicles." Vehicles other than Permitted Size Vehicles shall be parked and loaded or unloaded as directed by Lessor In the Rules and Regulations (as defined in Paragraph 40) issued by Lessor. (Also see Paragraph 2.9.)

(a) Lessee shall not permit or allow any vehicles that belong to or are controlled by Lessee or Lessee's employees, suppliers, shippers, customers, contractors or invitees to be loaded, unloaded, or parked in areas other than those designated by Lessor for such activities. Lessee's employees, suppliers, shippers, customers contractors and invitees shall be permitted to access and use the loading facilities at the rear of the building, where the roll-up delivery doors are located, for pickup and delivery.

(b) If Lessee permits or allows any of the prohibited activities described In this Paragraph 2.6 then Lessor shall have the right, without notice, in addition to such other rights and remedies that it may have, to remove or tow away the vehicle Involved and charge the cost to Lessee, which cost shall be Immediately payable upon demand by Lessor.

(c) Lessor shall at the Commencement Date of this Lease, provide the parking facilities required by Applicable Law.

2.7 Common Areas-Definition. The term **"Common Areas"** Is defined as all areas and facilities outside the Premises and within the exterior boundary line of the Industrial Center and interior utility raceways within the Premises that are provided and designated by the Lessor from lime to time for the general nonexclusive use of Lessor, Lessee and other lessees of the Industrial Center and their respective employees, suppliers, shippers, customers, contractors and Invitees, Including parking areas, loading and unloading areas, trash areas, roadways, sidewalks, walkways, parkways, driveways and landscaped areas.

2.6 **Common Areas-Lessee's Rights.** Lessor hereby grants to Lessee, for the benefit of Lessee and Its employees, suppliers, shippers, contractors, customers and invitees, during the term of this I-ease, the non-exclusive right to use, in common with others entitled to such use, the Common Areas as they exist from time to time, subject to any rights, powers, and privileges reserved by Lessor under the terms hereof or under the terms of any rules and regulations or restrictions governing the use of the Industrial Center. Under no circumstances shall the right herein granted to use the Common Areas be deemed to include the right to store any property, temporarily or permanently, In the Common Areas. Any such storage shall be permitted only by the prior written consent of Lessor or Lessor's designated agent which consent may be revoked at any lime. In the event that any unauthorized storage shall occur then Lessor shall have the right, without notice, In addition to such other rights and remedies that it may have, to remove the property and charge the cost to Lessee, which cost shall be Immediately payable upon demand by Lessor.

2.9 Common Areas-Rules and Regulations. Lessor or such other person(s) as Lessor may appoint shall have the exclusive control and management of the Common Areas and shall have the right, from time to time, to establish, modify, amend and enforce reasonable Rules and Regulations with respect thereto In accordance with Paragraph 40. Lessee agrees to abide by and conform to ail such Rules and Regulations, and to cause its employees, suppliers, shippers, customers, contractors and Invitees to so abide and conform. Lessor shall not be responsible to Lessee for the non-compliance with said rules and regulations by other lessees of the Industrial Center.

2.10 Common Areas-Changes. Lessor shall have the right, In Lessor's sole discretion, from time to time:

(a) To make changes to the Common Areas, Including, without limitation, changes in the location, size, shape and number of driveways, entrances, parking spaces, parking areas, loading and unloading areas, Ingress, egress, direction of traffic, landscaped areas, walkways and utility raceways;

(b) To close temporarily any of the Common Areas for maintenance purposes so long as reasonable access to the Premises remains available;

(c) To designate other land outside the boundaries of the Industrial Center to be a part of the Common Areas;

(d) To add additional buildings and Improvements to the Common Areas;

(e) To use the Common Areas while engaged In making additional Improvements, repairs or alterations to the Industrial Center, or any portion thereof;

and

(f) To do and perform such other acts and make such other changes (n, to or with respect to the Common Areas and Industrial Center as Lessor may, In the exercise of sound business judgment, deem to be appropriate.

3. **Term.**

3.1 Term. The Commencement Date, Expiration Date and Original Term of this Lease are as specified in Paragraph 1.3.

3.2 Early Possession. If an Early Possession Date is specified in Paragraph 1.4 and If Lessee totally or partially occupies the Premises after the Early Possession Date but prior to the Commencement Date, the obligation to pay Base Rent shall be abated for the period of such early occupancy. All other terms of this Lease, however, (including but not limited to the obligations to pay Lessee's Share of Common Area Operating Expenses and to carry the Insurance required by Paragraph 8) shall be in effect during such period. Any such early possession shall not affect nor advance the Expiration Date of the Original Term.

**3.3 Delay in Possession.** II for any reason Lessor cannot deliver possession of the Premises to Lessee by the Early Possession Dale, II one is specified in Paragraph 1.4, or If no Early Possession Date is specified, by the Commencement Date, Lessor shall not be subject to any liability therefor, nor shall such failure affect the validity of this Lease, or the obligations of Lessee hereunder, or extend the term hereof, but in such case, Lessee shall not, except as otherwise provided herein, be obligated to pay rent or perform any other obligation of Lessee under the terms of this Lease until Lessor delivers possession of the Premises to Lessee. II possession of the Premises is not delivered to Lessee within sixty (60) days after the Commencement Dale, Lessee may, at its option, by notice in writing to Lessor within ten (10) days after the end of said sixty (60) day period, cancel this Lease, in which event the parties shall be discharged from all obligations hereunder; provided further, however That it such written notice of Lessee is not received by Lessor within said ten (10) day period, Lessee's right to cancel this Lease hereunder shall terminate and be of no further force or effect. Except as may be otherwise provided, and regardless of when the Original Term actually commences, if possession is not tendered to Lessee when required by this Lease and Lessee does not terminate this Lease, as aforesaid, the period free of the obligation to pay Base Rent, if any, that Lessee would otherwise have enjoyed shall run from the date of delivery of possession and continue for a period equal to the period during which the Lessee would have otherwise enjoyed under the terms hereof, but minus any days of delay caused by the acts, changes or omissions of Lessee.

4. **Rent.**

4.1 **Base Rent.** Lessee shall pay Base Rent and other tent or charges, as the same may be adjusted from time to time, to Lessor in lawful money of the United States, without offset or deduction, on or before the day on which it is due under the terms of this Lease. Base Rent and all other rent and charges for any period during he term hereof which is for less than one full month shall be prorated bused upon the actual number of days of the month involved: Payment of Base Rent and other charges shall be made to Lessor at its address stated herein or to such other persons or al such other addresses as Lessor may from time to lime designate (n writing to Lessee.

4.2 **Common Area Operating Expenses.** Lessee shall pay to Lessor during 'the term hereof, In addition to the Base Rent, Lessee's Share (as specified in Paragraph 1.6(b)) of all Common Area Operating Expenses, as hereinafter defined, during each calendar year of the term of this Lease, In accordance with the following provisions:

(a) "Common Area Operating Expenses" are defined, for purposes of this Lease, as all costs incurred by Lessor relating to the ownership and operation of the Industrial Center, Including, but not limited to, the following:

(i) The operation, repair and maintenance, In neat, clean, good order and condition, of the following:

(aa) The Common Areas, including parking areas, loading and unloading areas, trash areas, roadways, sidewalks, walkways, parkways, driveways, landscaped areas, striping, bumpers, irrigation systems, Common Area lighting facilities, fences and gates, elevators and roof.

(bb) Exterior signs and any tenant directories.

(cc) Fire detection and sprinkler systems.

(ii) The cost of water, gas, electricity and telephone to service the Common Areas.

(iii) Trash disposal, property management and security services and tile costs of any environmental Inspections.

(iv) Reserves set aside for maintenance and repair of Common Areas.

(v) Any Increase above the Base Real Property Taxes (as defined in Paragraph 10.2(b)) for the Building and the Common Areas.

(vi) Any "Insurance Cost Increase" (as defined In Paragraph 8.1).

(vii) The cost of insurance carried by Lessor with respect to the Common Areas.

(viii) Any deductible portion of an insured loss concerning the Building or the Common Areas.

(ix) Any other services to be provided by Lessor that are staled elsewhere in this Lease to be a Common Area Operating Expense.

(b) Any Common Area Operating Expenses and Real Property Taxes that are specifically attributable to the Building or to any other building in the industrial Center or to the operation. repair and maintenance thereof shall be allocated entirely in the Building or in such other building. However any Common Area Operating Expenses and Real Property Taxes that are not attributable to the Building or to any other building or to the operation, repair and maintenance thereof, shall be equitably allocated by Lessor to all buildings in the Industrial Center.

(c) The inclusion of the improvements, facilities and services set forth in Subparagraph 4.2(a) shall not be deemed to impose an obligation upon Lessor to either have said improvements or facilities or to provide those services unless the Industrial Center already has the same, Lessor already provides the services, or Lessor has agreed elsewhere in this Lease to provide the same or some of them.

(d) Lessee's Share of Common Area Operating Expenses shall be payable by Lessee within ten(10) days after a reasonably detailed statement of actual expenses is presented to Lessor, At Lessor's option, however, an amount may be estimated by Lessor from time to time of Lessee's Share of annual Common Area Operating Expenses and the same shall be payable monthly or quarterly, as Lessor shall designate, during each 12-month period of the Lease term, on the same day as the Base Rent is due hereunder. Lessor shall deliver to Lessee within sixty (60) days after the expiration of each calendar year a reasonably detailed statement showing Lessee's Share of the actual Common Area Operating Expenses incurred during the preceding year. If Lessee's payments under this Paragraph 4.2(d) during said preceding year exceed Lessee's Share as indicated on said statement, Lessor shall be credited the amount of such overpayment against Lessee's Share of Common Area Operating Expenses next becoming due. If Lessee's payments under this Paragraph 4.2(d) during said preceding year were less than Lessee's Share as Indicated on said statement, Lessee shat; pay to Lessor the amount of the deficiency within ten (10) days after delivery by Lessor to Lessee of said statement.

5. **Security Deposit.** Lessee shall deposit with Lessor upon Lessee's execution hereof the Security Deposit set forth In Paragraph 1.7 as security for Lessee's faithful performance of Lessee's obligations under this Lease. If Lessee fails to pay Base Rent or other rent or charges due hereunder, or otherwise Defaults under this Lease (as defined in Paragraph 13.1), Lessor may use, apply or retain all or any portion of said Security Deposit for the payment of any amount due Lessor or to reimburse or compensate Lessor for any liability, cost, expense, loss or damage (Including attorneys' fees) which Lessor may suffer or Incur by reason thereof. If Lessor uses or applies all or any portion of said Security Deposit, Lessee shall within ten (10) days after written request therefore deposit monies with Lessor sufficient to restore said Security Deposit to the full amount required by this Lease. Any time the Base Rent Increases during the term of this Lease, Lessee shall, upon written request from Lessor, deposit additional monies with Lessor as an addition to the Security Deposit so that the total amount of the Security Deposit shall at all times bear the same proportion to the then current Base Rent as the Initial Security Deposit bears to the initial Base Rent set forth in Paragraph 1.5. Lessor shall not be required to keep all or any part of the Security Deposit separate from Its general accounts. Lessor shall, at the expiration or earlier termination of the term hereof and after Lessee has vacated the Premises, return to Lessee (or, at Lessor's option, to the last assignee, if any, of Lessee's Interest herein), that portion of the Security Deposit not used or applied by Lessor. Unless otherwise expressly agreed In writing by Lessor, no part of the Security Deposit shall be considered to be held in trust, to bear Interest or other increment for its use, or to be prepayment for any monies to be paid by Lessee under this Lease.

6. **Use**.

6.1 **Permitted Use.**

(a) Lessee shall use and occupy the Premises only for the Permitted Use ;;et forth In Paragraph 1.8, or any other legal use which Is reasonably comparable thereto, and for no other purpose. Lessee shall not use or permit the use of the Premises In a manner that Is unlawful, creates waste or a nuisance, or that disturbs owners and/or occupants of, or causes damage to the Premises or neighboring premises or properties.

(b) Lessor hereby agrees to not unreasonably withhold or delay Its consent to any written request by Lessee, Lessee's assignees or subtenants and by prospective assignees-and subtenants of Lessee, Its assignees and subtenants, for a modification of said Permitted Use, so long as the same will not impair the structural integrity of the Improvements on the Premises or in the Building or the mechanical or electrical systems therein, does not conflict with uses by other lessees, Is not significantly more burdensome to the Premises or the Building and the improvements thereon, and Is otherwise permissible pursuant to this Paragraph 6. If Lessor elects to withhold such consent, Lessor shall within five (5) business days after such request give a written notification of same, which notice shall include an explanation of Lessor's reasonable objections to the change in use.

6.2 **Hazardous Substances.**

(a) **Reportable Uses Require Consent**. The term **"Hazardous Substance"** as used In this Lease shall mean any product, substance, chemical, material or waste whose presence, nature, quantity and/or Intensity of existence, use, manufacture, disposal, transportation, spill, release or effect, either by Itself or in combination with other materials expected to be on the Premises, Is either: (I) potentially Injurious to the public health, safety or welfare, the environment, or the Premises; (it) regulated or monitored by any governmental authority; or (iii) a basis for potential liability of Lessor to any governmental agency or third party under any applicable statute or common law theory. Hazardous Substance shall include, but not be limited to, hydrocarbons, petroleum, gasoline, crude oil or any products or by-products thereof. Lessee shall not engage in any activity in or about the Premises which constitutes a Reportable Use (as hereinafter defined) of Hazardous Substances without the express prior written consent of Lessor and compliance in a timely manner (at Lessee's sole cost and expense) with all Applicable Requirements (as defined in Paragraph 6.3). "Reportable Use" shall mean (i) the Installation or use of any above or below ground storage tank, (ii) the generation, possession, storage, use, transportation, or disposal of a Hazardous Substance that requires a permit from, or with respect to which a report, notice, registration or business plan is required to be filed with, any governmental authority, and (iii) the presence in, on or about the Premises of a Hazardous Substance with respect to which any Applicable Laws require that a notice be given to persons entering or occupying the Premises or neighboring properties. Notwithstanding the foregoing, Lessee may, without Lessor's prior consent, but upon notice to Lesser and In compliance with all Applicable Requirements, use any ordinary and customary materials reasonably required to be used by Lessee In the normal course of the Permitted Use, so long as such use is not a Reportable Use and does not expose the Premises or neighboring properties to any meaningful risk of contamination or damage or expose Lessor to any liability therefore. In addition, Lessor may (but without any obligation to do so) condition Its consent to any Reportable Use of any Hazardous Substance by Lessee upon Lessee's giving Lessor such additional assurances as Lessor, in its reasonable discretion, deems necessary to protect Itself, the public, the Premises and the environment against damage, contamination or Injury and/or liability therefore, including but not limited to the Installation (and, at Lessor's option, removal on or before Lease expiration or earlier termination) of reasonably necessary protective modifications to the Premises (such as concrete encasements) and/or the deposit of an additional Security Deposit under Paragraph 5 hereof.

(b) **Duty to Inform Lessor.** If Lessee knows, or has reasonable cause to believe, that a Hazardous Substance has come to be located in, on, under or about the Premises or the Building, other than as previously consented to by Lessor, Lessee shall Immediately give Lessor written notice thereof, together with a copy of any statement, report, notice, registration, application, permit, business plan, license, claim, action, or proceeding given to, or received from, any governmental authority or private party concerning the presence, spill, release, discharge of, or exposure to, such Hazardous Substance including but not limited to all such documents as may be involved in any Reportable Use involving the Premises, Lessee shall not cause or permit any Hazardous Substance to be spilled or released in, on, under or about the Premises (including, without limitation, through the plumbing or sanitary sewer system).

(c) Indemnification. Lessee shall indemnify, protect, defend and hold Lessor, its agents, employees, lenders and ground Lessor, if any, and the Premises; harmless from and against any and all damages, liabilities, judgments, costs, claims, Liens, expenses, penalties, loss of permits and attorneys' and consultants' lees arising out of or involving any Hazardous Substance brought onto the Premises by or for Lessee or by anyone-under Lessee's control. Lessee's obligations under this Paragraph 6.2(c) shall include, but not be limited to, the effects of any contamination or Injury to person, property or the environment created or suffered by Lessee, and the cost of investigation (including consultants' and attorneys' fees and testing), removal, remediation, restoration and/or abatement thereof, or of any contamination therein involved, and shall survive the expiration or earlier termination of this Lease. No termination, cancellation or release agreement entered Into by Lessor and Lessee shall release Lessee from its obligations under this Lease with respect to Hazardous Substances, unless specifically so agreed by Lessor In writing al the time of such agreement.

**6.3 Lessee's Compliance with Requirements**. Lessee shall, at Lessee's sole cost and expense, fully, diligently and in a timely manner, comply with all "Applicable Requirements," which term is used in this Lease to mean ail laws, rule;;, regulations, ordinances, directives, covenants, easements and restrictions of record, permits, the requirements of any applicable fire Insurance underwriter or rating bureau, and the recommendations of Lessor's engineers and/or consultants, relating in any manner to the Premises (including but not limited to matters pertaining to (f) Industrial hygiene, (if) environmental conditions on, in, under or about the Premises, Including soil and groundwater conditions, and (iii) the use, generation, manufacture, production, installation, maintenance, removal, transportation, storage, spill, or release of any Hazardous Substance), now In effect or which may hereafter come into effect. Lessee shall, within live (5) days after receipt of Lessor's written request, provide Lessor with copies of all documents and Information, Including but not limited to permits, registrations, manifests, applications, reports and certificates, evidencing Lessee's compliance with any Applicable Requirements specified by Lessor, and shall immediately upon receipt, notify Lessor in writing (with copies of any documents involved) of any threatened or actual claim, notice, citation, warning, complaint or report pertaining to or involving failure by Lessee or the Premises to comply with any Applicable Requirements.

**6.4 Inspection; Compliance with Law**. Lessor, Lessor's agents, employees, contractors and designated representatives, and the holders of any mortgages, deeds of trust or ground leases on the Premises **("Lenders")** shall have the right to enter the Premises at any time in the case of an emergency, and otherwise at reasonable times, for the purpose of inspecting the condition of the Premises and for verifying compliance by Lessee with this Lease and all Applicable Requirements (as defined in Paragraph 6.3), and Lessor shall be entitled to employ experts and/or consultants in connection therewith to advise Lessor with respect to Lessee's activities, including but not limited to Lessee's installation, operation, use, monitoring, maintenance, or removal of any Hazardous Substance on or from the Premises. The costs and expenses of any such inspections shall be paid by the party requesting same, unless a Default or Breach of this Lease by Lessee or a violation of Applicable Requirements or a contamination, caused or materially contributed to by Lessee, is found to exist or to be imminent, or unless the inspection is requested or ordered by a governmental authority as the result of any such existing or Imminent violation or contamination. In such case, Lessee shall upon request reimburse Lessor or Lessor's Lender, as the case may be, for the costs and expenses of such inspections.

**7. Maintenance, Repairs, Utility Installations, Trade Fixtures and Alterations.**

**7.1 Lessee's Obligations.**

(a) Subject to the provisions of Paragraphs 2.2 (Condition), 2.3 (Compliance with Covenants, Restrictions and Building Code), 7.2 (Lessor's Obligations), 9 (Damage or Destruction), and 14 (Condemnation), Lessee shall, at Lessee's sole cost and expense and at all times, keep the Premises and every part thereof in good order, condition and repair (whether or not such portion of the Premises requiring repair, or the means of repairing the same, are reasonably or readily accessible to Lessee, and whether or not the need for such repairs occurs as a result of Lessee's use, any prior use, the elements or the age of such portion of the Premises), including, without limiting the generality of the foregoing, all equipment or facilities specifically serving the Premises, such as, plumbing, heating, air conditioning, ventilating, electrical, lighting facilities, boilers, fired or unfired pressure vessels, fire hose connections if within the Premises, fixtures, Interior walls, interior surfaces of exterior walls, ceilings, floors, windows, doors, plate glass, and skylights, but excluding any items which are the responsibility of Lessor pursuant to Paragraph 7.2 below. Lessee, in keeping the Premises In good order, condition and repair, shall exercise and perform good maintenance practices. Lessee's obligations shall include restorations, replacements or renewals when necessary to keep the Premises and all improvements thereon or a part thereof in good order, condition and state of repair. The Lessee's Obligations shall include maintenance and repair of the Utility Installations and Alterations made by the prior Lessee to the interior of the Premises, as disclosed to the Lessee, specifically the heating, ventilation and air conditioning system serving the warehouse portion of the Premises, the clean room air handlers, and the interior restrooms.

(b) Lessee shall, at Lessee's sole cost and expense, procure and maintain a contract, with copies to Lessor, in customary form and substance for and with a contractor specializing and experienced In the Inspection, maintenance and service of the heating, air conditioning and ventilation system for the Premises. However, Lessor reserves the right, upon notice to Lessee, to procure and maintain the contract for the heating, air conditioning and ventilating systems, and if Lessor so elects, Lessee shall reimburse Lessor, upon demand, for the cost thereof.

(c) If Lessee fails to perform Lessee's obligations under Paragraph 7.1, Lessor may enter upon the Premises after ten (10) days' prior written notice to Lessee (except in the case of an emergency, in which case no notice shall be required), perform such obligations on Lessee's behalf, and put the Premises in good order, condition and repair, in accordance with Paragraph 13.2 below.

7.2 **Lessor's Obligations.** Subject to the provisions pf Paragraph 2.2 (Condition), 2.3 (Compliance with Covenants, Restrictions and Building Codes), 4.2 (Common Area Operating Expenses), 6 (Use), 7.1 (Lessee's Obligations), 9 (Damage or Destruction) and 14 (Condemnation), Lessor, subject to reimbursement pursuant to Paragraph 4.2, shall keep in good order, condition and repair the foundations, exterior walls, structural condition of interior bearing walls, exterior roof, fire sprinkler and/or standpipe and hose (if located in the Common Areas) or other automatic fire extinguishing system including fire alarm and/or smoke detection systems and equipment, fire hydrants, parking lots, walkways, parkways, driveways, landscaping fences, signs and utility systems serving the Common Areas and all parts thereof, as well as providing the services for which there Is a Common Area Operating Expense pursuant to Paragraph 4.2. Lessor shall not be obligated to paint the exterior or Interior surfaces of exterior walls nor shall Lessor be obligated to maintain, repair or replace windows, doors or plate glass of the Premises. Lessee expressly waives the benefit of any statute now or hereafter In effect which would otherwise afford Lessee the right to make repairs at Lessor's expense or to terminate this Lease because of Lessor's failure to keep the Building, Industrial Canter or Common Areas in good order, condition and repair.

(a) Lessor's Obligations shall include maintenance of all plumbing, heating, ventilation and air conditioning systems servicing the Premises.

7.3 **Utility Installations, Trade Fixtures, Alterations.**

(a) Definitions; Consent Required. The term **"Utility Installations"** Is used In this Lease to refer to all air lines, power panels, electrical distribution, security, fire protection systems, communications systems, lighting fixtures, heating, ventilating and air conditioning equipment, plumbing, and fencing In, on or about the Premises. The term "Trade Fixtures" shall mean Lessee's machinery and equipment which can be removed without doing material damage to the Premises. The term "Alterations" shall mean any modification of the improvements on the Premises which are provided by Lessor under the terms of this Lease, other than Utility Installations or Trade Fixtures. **"Lessee-Owned Alterations and/or Utility Installations"** are defined as Alterations and/or Utility Installations made by Lessee that are not yet owned by Lessor pursuant to Paragraph 7.4(a). Lessee shall not make nor cause to be made any Alterations or Utility Installations in, on, under or about the Premises without Lessor's prior written consent. Lessee May, however, make non-structural Utility Installations to the interior of the Premises (excluding the roof) without Lessor's consent but upon notice to Lessor, so long as they are not visible from the outside of the Premises, do not involve puncturing, relocating or removing the roof or any existing walls, or changing or interfering with the fire sprinkler or fire detection systems and the cumulative cost thereof during the term of this Lease as extended does not exceed $2,500.00.

(b) **Consent**. Any Alterations or Utility Installations that Lessee shall desire to make and which require the consent of the Lessor shall be presented to Lessor in written form with detailed plans. All consents given by Lessor, whether by virtue of Paragraph 7.3(a) or by subsequent specific consent, shall be deemed conditioned upon: (I) Lessee's acquiring all applicable permits required by governmental authorities; (Ii) the furnishing of copies of such permits together with a copy of the plans and specifications for the Alteration or Utility Installation to Lessor prior to commencement of the work thereon; and (Iii) the compliance by Lessee with all conditions of said permits In a prompt and expeditious manner. Any Alterations or Utility Installations by Lessee during the term of this Lease shall be done in a good and workmanlike manner, with good and sufficient materials, and be In compliance with all Applicable Requirements. Lessee shall promptly upon completion thereof furnish Lessor with as-built plans and specifications therefore. Lessor may, (but without obligation to do so) condition its consent to any requested Alteration or Utility Installation that costs $2,500.00 or more upon Lessee's providing Lessor with a lien and completion bond In an amount equal to one and one-half times the estimated cost of such Alteration or Utility Installation.

(c) **Lien Protection.** Lessee shall pay when due all claims for labor or materials furnished or alleged to have been furnished to or for Lessee at or for use on the Premises, which claims are or may be secured by any mechanic's or material man's lien against the Premises or any Interest therein. Lessee shall give Lessor not less than ten (10) days' notice prior to the commencement of any work In, on, or about the Premises, and Lessor shall have the right to post notices of non-responsibility In or on the Premises as provided by law. If Lessee shall, in good faith, contest the validity of any such lien, claim or demand, then Lessee shall, at its sole expense, defend and protect Itself, Lessor and the Premises against the same and shall pay and satisfy any such adverse judgment that may be rendered thereon before the enforcement thereof against the Lessor or the Premises. It Lessor shall require, Lessee shall furnish to Lessor a surely bond satisfactory to Lessor in an amount equal to one and one-half times the amount of such contested lien claim or demand, indemnifying Lessor against liability for the same, as required by law for the holding of the Premises free from the effect of such lien or claim. In addition, Lessor may require Lessee to pay Lessor's attorneys' fees and costs in participating in such action If Lessor shall decide it Is to Its best Interest to d:) so.

7.4 **Ownership, Removal, Surrender, and Restoration.**

(a) Ownership. Subject to Lessor's right to require their removal and, o cause Lessee to become the owner thereof as hereinafter provided in this Paragraph 7.4, all Alterations and Utility Installations made to the Premises by Lessee shall be the property of and owned by Lessee, but considered a part of the Premises. Lessor may, at any time and at its option, elect in writing to Lessee to be the owner of all or any specified part of the Lessee-Owned Alterations and Utility Installations. Unless otherwise instructed per Subparagraph 7.4(b) hereof, all Lessee-Owned Alterations and Utility Installations shall, at the expiration or earlier termination of this Lease, become the property of Lessor and remain upon the Premises and be surrendered with the Premises by Lessee. Notwithstanding the foregoing, Lessee shall be deemed the owner of any power generator installation on or about the Premises.

(b) Removal. Unless otherwise agreed in writing, Lessor may require that any or all Lessee-Owned Alterations or Utility Installations be removed by the expiration or earlier termination of this Lease, notwithstanding that their installation may have been consented to by Lessor. Lessor may require the removal at any time of all or any part of any Alterations or Utility Installations made without the required consent of Lessor.

(c) Surrender/Restoration. Lessee shall surrender the Premises by the end of the last day of the Lease term or any earlier termination date, clean and free of debris and in good operating order, condition and state of repair, ordinary wear and tear excepted. Ordinary wear and tear shall not include any damage or deterioration that would have been prevented by good maintenance practice or by Lessee performing all of Its obligations under this Lease. Except as otherwise agreed or specified herein, the Premises as surrendered, shall Include the Alterations and Utility Installations. The obligation of Lessee shall Include the repair of any damage occasioned by the installation, maintenance or removal of Lessee's Trade Fixtures, furnishings, equipment, and Lessee-Owned Alterations and Utility Installations, as well as the removal of any storage tank Installed by or for Lessee, and the removal, replacement, or remediation of any soil, material or ground water contaminated by Lessee, all as may then be required by Applicable Requirements and/or good practice. Lessee's Trade Fixtures shall remain the property of Lessee and shall be removed by Lessee subject to its obligation to repair and restore the Premises per this Lease.

8. Insurance; Indemnity.

8.1 **Payment of Premium Increases.**

(a) As used herein, the term **"Insurance Cost Increase"** is defined as. any increase In the actual cost of the insurance applicable to the Building and required to be carried by Lessor pursuant to Paragraphs 8.2(b), 8.3(a) and 8.3(b), ("Required Insurance"), over and above the Base Premium, as hereinafter defined, calculated on an annual basis. "Insurance Cost Increase" shall Include, but not be limited to, requirements of the holder of a mortgage or deed of trust covering the Premises, Increased valuation of the Promises, and/or a general premium rate Increase. he term 'Insurance Cost Increase" shall not, however, Include any premium increases resulting from **the nature of the occupancy of any other lessee of the**Building. If the parties Insert a dollar amount In Paragraph 1.9, such amount shall be considered the "Base Premium." If a dollar amount has not been Inserted In Paragraph 1.9 and If the Building has been previously occupied during the twelve (12) month period immediately preceding the Commencement Date, the 'Base Premium" shall be the annual premium applicable to such twelve (12) month period. If the Building was not fully occupied during such twelve (.12) month period, the "Base Premium" shall be the lowest annual premium reasonably obtainable for the Required Insurance as of the Commencement Date, assuming the most nominal use possible of the Building. In no event, however, shall Lessee be responsible for any portion of the premium cost attributable to liability Insurance coverage In excess of $1,000,000 procured under Paragraph 8.2(b).

(b) Lessee shall pay any Insurance Cost Increase to Lessor pursuant to Paragraph 4.2. Premiums for policy periods commencing prior to, or extending beyond, the term of this Lease shall be prorated to coincide with the corresponding Commencement Date or Expiration Date.

**8.2 Liability Insurance.**

(a) Carried by Lessee. Lessee shall obtain and keep In force during the, term of this Lease a Commercial General Liability policy of insurance protecting Lessee, Lessor and any Lender(s) whose names have been provided to Lessee in writing (as additional Insured) against claims for bodily Injury, personal Injury and property damage based upon, Involving or arising out of the ownership, use, occupancy or maintenance of the Premises and all areas appurtenant thereto. Such insurance shall be on an occurrence basis providing single limit coverage in an amount not less than $1,000,000 per occurrence with an "Additional Insured-Managers or Lessor of Premises" endorsement and contain the "Amendment of the Pollution Exclusion" endorsement for damage caused by heat, smoke or fumes from a hostile fire. The policy shall not contain any Infra-insured exclusions as between Insured persons or organizations, but shall Include coverage for liability assumed under this Lease as an "Insured contract" for the performance o'" Lessee's indemnity obligations under this Lease. The limits of said insurance required by this Lease or as carried by Lessee shall not, however, limit the liability. A Lessee nor relieve Lessee of any obligation hereunder. All insurance to be carried by Lessee shall be primary to and not contributory with any similar insurance carried by Lessor, whose Insurance shall be considered excess insurance only.

(b) Carried by Lessor. Lessor shall also maintain liability insurance described in Paragraph 8.2(a) above, in addition to and not in lieu of, the insurance required to be maintained by Lessee. Lessee shall not be named as an additional insured therein.

8.3 **Property Insurance-Building, Improvements end Rental Value.**

(a) Building and Improvements. Lessor shall obtain and keep In force during the term of this Lease a policy or policies in the name of Lessor, with loss payable to Lessor and to any Lender(s), Insuring against loss or damage to the Premises. Such insurance shall be for full replacement cost, as the same shall exist from time to time, or the amount required by any Lender(s), but in no event more than the commercially reasonable and available Insurable value thereof If, by reason of the unique nature or age of the Improvements involved, such latter amount Is less than full replacement cost. Lessee-Owned Alterations and Utility Installations, Trade Fixtures and Lessee's personal property shall be insured by Lessee pursuant to Paragraph 8.4. If the coverage Is available and commercially appropriate, Lessor's policy or policies shall insure against all risks of direct physical loss or damage (except the perils of flood and/or earthquake unless required by a Lender or included in the Base Premium), including coverage for any additional costs resulting from debris removal and reasonable amounts of coverage for the enforcement of any ordinance or law regulating the reconstruction or replacement of any undamaged sections of the Building required to be demolished or removed by reason of the enforcement of any building, zoning, safety or land use laws as the result of a covered loss, but not including plate glass insurance. Said policy or policies shall also contain an agreed valuation provision in lieu of any co-insurance clause, waiver of subrogation, and inflation guard protection causing an increase in the annual property insurance coverage amount by a factor of not less than the adjusted U.S. Department of Labor Consumer Price Index for All Urban Consumers for the city nearest to where the Premises are located.

(b) **Rental Value.** Lessor shall also obtain and keep In force during the term of this Lease a policy or policies In the name of Lessor, with loss payable to Lessor and any Lender(s), Insuring the loss of the full rental and other charges payable by all lessees of the Building to Lessor for one year (including all Real Property Taxes, insurance costs,. all Common Area Operating Expenses and any scheduled rental Increases). Said Insurance may Provide that In the event the Lease is terminated by reason of an insured loss, the period of indemnity for such coverage shall be extended beyond the date of the completion of repairs or replacement of the Premises, to provide for one full year's loss of rental revenues from the date of any such loss. Said insurance shall contain an agreed valuation provision in lieu of any co-insurance clause, and the amount of coverage shall be adjusted annually to reflect the projected rental income, Real Property Taxes, insurance premium costs and other expenses, if any, otherwise payable, for the next 12-month period. Common Area Operating Expenses shall include any deductible amount in the event of such loss.

(c) Adjacent Premises. Lessee shall pay for any increase in the premiums for the property insurance of the Building and for the Common Areas or other buildings in the Industrial Center if said increase is caused by Lessee's acts, omissions, use or occupancy of the premises.

(d) **Lessee's Improvements.** Since Lessor is the Insuring Party, Lessor shall not be required to insure Lessee-Owned Alterations and Utility Installations unless the item in question has become the property of Lessor under the terms of this Lease.

8.4 **Lessee's Property Insurance.** Subject to the requirements of Paragraph 8.5, Lessee at its cost shall either by separate policy or, at Lessor's option, by endorsement to a policy already carried, maintain insurance coverage on all of Lessee's personal property, Trade Fixtures and Lessee-Owned Alterations and Utility Installations in, on, or about the Premises similar in coverage to that carried by Lessor as the Insuring Party under Paragraph 8.3(a). Such insurance shall be full replacement cost coverage with a deductible not to exceed $1,000 per occurrence. The proceeds from any such insurance shall be used by Lessee for the replacement of personal property and the restoration of Trade Fixtures and Lessee-Owned Alterations and Utility Installations. Upon request from Lessor, Lessee shall provide Lessor with written evidence that such insurance is in force.

8.5 **Insurance Policies.** Insurance required hereunder shall be in companies duly licensed to transact business in the state where the Premises are located, and maintaining during the policy term a "General Policyholders Rating" of at least B+, V, or such other rating as may be required by a Lender, as set forth in the most current issue of "Best's Insurance Guide." Lessee shall not do or permit to be done anything which shall invalidate the insurance policies referred to in this Paragraph 8. Lessee shall cause to be delivered to Lessor, within seven (7) days after the earlier of the Early Possession Date or the Commencement Date, certified copies of, or certificates evidencing the existence and amounts of, the insurance required under Paragraph 8.2(a) and 8.4. No such policy shall be cancelable or subject to modification except after thirty (30) days' prior written notice to Lessor. Lessee shall at least thirty (30) days prior to the expiration of such policies, furnish Lessor with evidence of renewals or "insurance binders" evidencing renewal thereof, or Lessor may order such insurance and charge the cost thereof to Lessee, which amount shall be payable by Lessee to Lessor upon demand.

8.6 **Waiver of Subrogation.** Without affecting any other rights or remedies, Lessee and Lessor each hereby release and relieve the other, and waive their entire right to recover damages (whether in contract or in tort) against the other, for loss or damage to their property arising out of or incident to the perils required to be insured against under Paragraph 8. The effect of such releases and waivers of the right to recover damages shall not be limited by the amount of insurance carried or required, or by any deductibles applicable thereto. Lessor and Lessee agree to have their respective insurance companies issuing property damage insurance waive any right to subrogation that such companies may have against Lessor or Lessee, as the case may be, so long as the insurance is not invalidated thereby.

8.7 **Indemnity.** Except for Lessor's negligence and/or breach of express warranties, Lessee shall indemnify, protect, defend and hold harmless the Premises, Lessor and its agents, Lessor's master or ground Lessor, partners and Lenders, from and against any and all claims, loss of rents and/or damages, costs, liens, judgments, penalties, loss of permits, attorneys' and consultants' fees, expenses and/or liabilities arising out of, involving, or in connection with, the occupancy of the Premises by Lessee, the conduct of Lessee's business, any act, omission or neglect of Lessee, its agents, contractors, employees or invitees, and out of any Default or Breach by Lessee in the performance in a timely manner of any obligation on Lessee's part to be performed under this Lease. The foregoing shall include, but not be limited to the defense or pursuit of any claim or any action or proceeding involved therein, and whether or not (in the case of claims made against Lessor) litigated and/or reduced to judgment. In case any action or proceeding be brought against Lessor by reason of any of the foregoing matters, Lessee upon notice from Lessor shall defend the same at Lessee's expense by counsel reasonably satisfactory to Lessor and Lessor shall cooperate with Lessee in such defense. Lessor need not have first paid any such claim in order to be so indemnified.

8.8 **Exemption of Lessor from Liability.** Lessor shall not be liable for injury or damage to the person or goods, wares, merchandise or other property of Lessee, Lessee's employees, contractors, invitees, customers, or any other person in or about the Premises, whether such damage or injury is caused by or results from fire, steam, electricity, gas, water or rain, or from the breakage, leakage, obstruction or other defects of pipes, fire sprinklers, wires, appliances, plumbing, air conditioning or lighting fixtures, or from any other cause, whether said injury or damage results from conditions arising upon the Premises or upon other portions of the Building of which the Premises are a part, from other sources or places, and regardless of whether the cause of such damage or injury or the means of repairing the same is accessible or not. Lessor shall not be liable for any damages arising from any act or neglect of any other lessee of Lessor nor from the failure by Lessor to enforce the provisions of any other lease in the Industrial Center. Notwithstanding Lessor's negligence or breach of this Lease, Lessor shall under no circumstances be liable for injury to Lessee's business or for any loss of income or profit therefrom.

**9. Damage or Destruction.**

9.1 **Definitions.**

(a) **"Premises Partial Damage"** shall mean damage or destruction to the Premises, other than Lessee-Owned Alterations and Utility Installations, the repair cost of which damage or destruction is less than fifty percent (50%) of the then Replacement Cost (as defined in Paragraph 9.1(d)) of the Premises (excluding Lessee-Owned Alterations and Utility Installations and Trade Fixtures) immediately prior to such damage or destruction.

(b) **"Premises Total Destruction"** shall mean damage or destruction to the Premises, other than Lessee-Owned Alterations and Utility Installations, the repair cost of which damage or destruction is fifty percent (50%) or more of the then Replacement Cost of the Premises (excluding Lessee-Owned Alterations and Utility Installations and Trade Fixtures) immediately prior to such damage or destruction. In addition, damage or destruction to the Building, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures of any lessees of the Building, the cost of which damage or destruction is fifty percent (50%) or more of the then Replacement Cost (excluding Lessee-Owned Alterations and Utility Installations and Trade Fixtures of any lessees of the Building) of the Building shall, at the option of Lessor, be deemed to be Premises Total Destruction.

(c) **"Insured Loss"** shall mean damage or destruction to the Premises, other than Lessee-Owned Alterations and Utility Installations and Trade Fixtures, which was caused by an event required to be covered by the insurance described in Paragraph 8.3(a) irrespective of any deductible amounts or coverage limits involved.

(d) **"Replacement Cost"** shall mean the cost to repair or rebuild the improvements owned by Lessor at the time of the occurrence to their condition existing immediately prior thereto, including demolition, debris removal and upgrading required by the operation of applicable building codes, ordinances or laws, and without deduction for depreciation.

(e) **"Hazardous Substance Condition"** shall mean the occurrence or discovery of a condition involving the presence of, or a contamination by, a Hazardous Substance as defined in Paragraph 6,2(a), in, on, or under the Premises.

9.2 **Premises Partial Damage-Insured Loss.** If Premises Partial Damage that is an Insured Loss occurs, then Lessor shall, at Lessor's expense, repair such damage (but not Lessee's Trade Fixtures or Lessee-Owned Alterations and Utility Installations) as soon as reasonably possible and this Lease shall continue in full force and effect. In the event, however, that there is a shortage of insurance proceeds and such shortage is due to the fact that, by reason of the unique nature of the improvements in the Premises, full replacement cost insurance coverage was not commercially reasonable and available, Lessor shall have no obligation to pay for the shortage in insurance proceeds or to fully restore the unique aspects of the Premises unless Lessee provides Lessor with the funds to cover same, or adequate assurance thereof, within ten (10) days following receipt of written notice of such shortage and request therefore. If Lessor receives said funds or adequate assurance thereof within said ten (10) day period, Lessor shall complete them as soon as reasonably possible and this Lease shall remain in full force and effect. If Lessor does not receive such funds or assurance within said period, Lessor may nevertheless elect by written notice to Lessee within ten (10) days thereafter to make such restoration and repair as is commercially reasonable with Lessor paying any shortage in proceeds, in which case this Lease shall remain in full force and effect. If Lessor does not receive such funds or assurance within such ten (10) day period, and if Lessor does not so elect to restore and repair, then this Lease shall terminate sixty (60) days following the occurrence of the damage or destruction. Unless otherwise agreed, Lessee shall in no event have any right to reimbursement from Lessor for any funds contributed by Lessee to repair any such damage or destruction. Premises Partial Damage due to flood or earthquake shall be subject to Paragraph 9.3 rather than Paragraph 9.2 notwithstanding that there may be some insurance coverage, but the net proceeds of any such insurance shall be made available for the repairs if made by either Party.

9.3 **Partial Damage-Uninsured Loss.** If Premises Partial Damage that is not an Insured Loss occurs, unless caused by a negligent or willful act of Lessee (in which event Lessee shall make the repairs at Lessee's expense and this Lease shall continue in full force and effect), Lessor may at Lessor's option, either (i) repair such damage as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) give written notice to Lessee within thirty (30) days after receipt by Lessor of knowledge of the occurrence of such damage of Lessor's desire to terminate this Lease as of the date sixty (60) days following the date of such notice. In the event Lessor elects to give such notice of Lessor's intention to terminate this Lease, Lessee shall have the right within ten (10) days after the receipt of such notice to give written notice to Lessor of Lessee's commitment to pay for the repair of such damage totally at Lessee's expense and without reimbursement from Lessor. Lessee shall provide Lessor with the required funds or satisfactory assurance thereof within thirty (30) days following such commitment from Lessee. In such event this Lease shall continue in full force and effect, and Lessor shall proceed to make such repairs as soon as reasonably possible after the required funds are available. If Lessee does not give such notice and provide the funds or assurance thereof within the times specified above, this Lease shall terminate as of the date specified in Lessor's notice of termination.

9.4 **Total Destruction.** Notwithstanding any other provision hereof, if Premises Total Destruction occurs (including any destruction required by any authorized public authority), this Lease shall terminate sixty (60) days following the date of such Premises Total Destruction, whether or not the damage or destruction is an Insured Loss or was caused by a negligent or willful act of Lessee. In the event, however, that the damage or destruction was caused by Lessee, Lessor shall have the right to recover Lessor's damages from Lessee except as released and waived in Paragraph 9.7.

9.5 Damage Near End of Term. If at any time during the last six (6) months of the term of this Lease there is damage for which the cost to repair exceeds one month's Base Rent, whether or not an insured Loss, Lessor may, at Lessor's option, terminate this Lease effective sixty (60) days following the date of occurrence of such damage by giving written notice to Lessee of Lessor's election to do so within thirty (30) days after the date of occurrence of such damage. Provided, however, if Lessee at that time has an exercisable option to extend this Lease or to purchase the Premises, then Lessee may preserve this Lease by (a) exercising such option, and (b) providing Lessor with any shortage in insurance proceeds (or adequate assurance thereof) needed to make the repairs on or before the earlier of (i) the date which is ten (10) days after Lessee's receipt of Lessor's written notice purporting to terminate this Lease, or (ii) the day prior to the date upon which such option expires. If Lessee duly exercises such option during such period and provides Lessor with funds (or adequate assurance thereof) to cover any shortage in insurance proceeds, Lessor shall, at Lessor's expense repair such damage as soon as reasonably possible and this Lease shall continue in full force and effect. If Lessee fails to exercise such option and provide such funds or assurance during such period. then this Lease shall terminate as of the date set forth in the first sentence of this Paragraph 9.5.

9.6 Abatement of Rent; Lessee's Remedies

(a) In the event of (i) Premises Partial Damage or (ii) Hazardous Substance Condition for which Lessee is not legally responsible, the Base Rent, Common Area Operating Expenses and other charges, if any, payable by Lessee hereunder for the period during which such damage or condition, its repair, remediation or restoration continues, shall be abated in proportion to the degree to which Lessee's use of the Premises is impaired, but not in excess of proceeds from insurance required to be carried under Paragraph 8.3(b). Except for abatement of Base Rent, Common Area Operating Expenses and other charges, if any, as aforesaid, all other conditions of Lessee hereunder shall be performed by Lessee, and Lessee shall have no claim against Lessor for any damage suffered by reason of any such damage, destruction, repair, remediation or restoration.

(b) If Lessor shall be obligated to repair or restore the Premises under the provisions of this Paragraph 9 and shall not commence, in a substantial and meaningful way, the repair or restoration of the Premises within ninety (90) days after such obligation shall accrue, Lessee may, at any time prior to the commencement of such repair or restoration, give written notice to Lessor and to any Lenders of which Lessee has actual notice of Lessee's election to terminate this Lease on a date not less than sixty (60) days following the giving of such notice. If Lessee gives such notice to Lessor and such Lenders and such repair or restoration is not commenced within thirty (30) days after receipt of such notice, this Lease shall terminate as of the date specified in said notice. If Lessor or a Lender commences the repair or restoration of the Premises within thirty (30) days after the receipt of such notice. this Lease shall continue in full force and effect. "Commence" as used in this Paragraph 9.6 shall mean either the unconditional authorization of the preparation of the required plans, or the beginning of the actual work on the Premises, whichever occurs first.

9.7 **Hazardous Substance Conditions.** If a Hazardous Substance Condition occurs, unless Lessee is legally responsible therefore (in which case Lessee shall make the investigation and remediation thereof required by Applicable Requirements and this Lease shall continue in full force and effect, but subject to Lessor's rights under Paragraph 6.2(c) and Paragraph 13), Lessor may at Lessor's option either (i) investigate and remediate such Hazardous Substance Condition, if required, as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) if the estimated cost to investigate and remediate such condition exceeds twelve (12) times the then monthly Base Rent or $100,000 whichever is greater, give written notice to Lessee within thirty (30) days after receipt by Lessor of knowledge of the occurrence of such Hazardous Substance Condition of Lessor's desire to terminate this Lease as of the data sixty (60) days following the date of such notice. In the event Lessor elects to give such notice of Lessor's intention to terminate this Lease, Lessee shall have the right within ten (10) days after the receipt of such notice to give written notice to Lessor of Lessee's commitment to pay for the excess costs of (a) investigation and remediation of such Hazardous Substance Condition to the extent required by Applicable Requirements, over (b) an amount equal to twelve (12) times the then monthly Base Rent or $100,000, whichever is greater. Lessee shall provide Lessor with the funds required of Lessee or satisfactory assurance thereof within thirty (30) days following said commitment by Lessee. In such event this Lease shall continue in full force and effect, and Lessor shall proceed to make such investigation and remediation as soon as reasonably possible after the required funds are available. If Lessee does not give such notice and provide the required funds or assurance thereof within the time period specified above, this Lease shall terminate as of the date specified in Lessor's notice of termination.

**9.8 Termination-Advance Payments.** Upon termination of this Lease pursuant to this Paragraph 9, Lessor shall return to Lessee any advance payment made by Lessee to Lessor and so much of Lessee's Security Deposit as has not been, or is not then required to be, used by Lessor under the terms of this Lease.

**9.9 Waiver of Statutes.** Lessor and Lessee agree that the terms of this Lease shall govern the effect of any damage to or destruction of the Premises and the Building with respect to the termination of this Lease and hereby waive the provisions of any present or future statute to the extent it is inconsistent herewith.

10. Real Property Taxes.

10.1 Payment of Taxes. Lessor shall pay the Real Property Taxes, as defined in Paragraph 10.2(a), applicable to the Industrial Center, and except as otherwise provided in Paragraph 10.3, any increases in such amounts over the Base Real Property Taxes shall be included in the calculation of Common Area Operating Expenses in accordance with the provisions of Paragraph 4.2.

10.2 Real Property Tax Definitions.

(a) As used herein, the term "**Real Property Taxes**" shall include any form of real estate tax or assessment, general, special, ordinary or extraordinary, and any license fee, commercial rental tax, improvement bond or bonds, levy or tax (other than inheritance, personal income or estate taxes) imposed upon the Industrial Center by any authority having the direct or indirect power to tax, including any city, state or federal government, or any school, agricultural, sanitary, fire, street, drainage, or other improvement district thereof, levied against any legal or equitable interest of Lessor in the Industrial Center or any portion thereof, Lessor's right to rent or other income therefrom, and/or Lessor's business of leasing the Premises. The term "Real **Property Taxes**" shall also include any tax, fee, levy, assessment or charge, or any increase therein, imposed by reason. of events occurring, or changes in Applicable Law taking effect, during the term of this Lease, including but not limited to a change in the ownership of the Industrial Center or in the improvements thereon, the execution of this Lease, or any modification, amendment or transfer thereof, and whether or not contemplated by the Parties.

(b) As used herein, the term "**Base Real Property Taxes**" shall be the amount of Real Property Taxes, which are assessed against the Premises, Building or Common Areas in the calendar year during which the Lease is executed. In calculating Real Property Taxes for any calendar year, the Real Property Taxes for any real estate tax year shall be included in the calculation of Real Property Taxes for such calendar year based upon the number of days which such calendar year and tax year have in common.

10.3 **Additional Improvements.** Common Area Operating Expenses shall not include Real Property Taxes specified in the tax assessor's records and work sheets as being caused by additional improvements placed upon the Industrial Center by other lessees or by Lessor for the exclusive enjoyment of such other lessees. Notwithstanding Paragraph 10.1 hereof, Lessee shall, however, pay to Lessor at the time Common Area Operating Expenses are payable under Paragraph 4.2, the entirety of any increase in Real Property Taxes if assessed solely by reason of Alterations, Trade Fixtures or Utility Installations placed upon the Premises by Lessee or at Lessee's request.

10.4 Joint Assessment. If the Building is not separately assessed. Real Property Taxes allocated to the Building shall be an equitable proportion of the Real Properly Taxes for all of the land and improvements included within the tax parcel assessed, such proportion to be determined by Lessor from the respective valuations assigned in the assessor's work sheets or such other information as may be reasonably available. Lessor's reasonable determination thereof, in good faith, shall be conclusive.

10.5 **Lessee's Property Taxes.** Lessee shall pay prior to delinquency all taxes assessed against and levied upon Lessee-Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all personal property of Lessee contained in the Premises or stored within the Industrial Center. When possible, Lessee shall cause its Lessee-Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all other personal property to be assessed and billed separately from the real property of Lessor. If any of Lessee's said property shall be assessed with Lessor's real property, Lessee shall pay Lessor the taxes attributable to Lessee's property within ten (10) days after receipt of a written statement setting forth the taxes applicable to Lessee's property.

11. Utilities. Lessee shall pay directly for all utilities and services supplied to the Premises, including but not limited to electricity, telephone, security, gas and cleaning of the Premises, together with any taxes thereon. If any such utilities or services are not separately metered to the Premises or separately billed to the Premises, Lessee shall pay to Lessor a reasonable proportion to be determined by Lessor of alt such charges jointly metered or billed with other premises in the Building, in the manner and within the time periods set forth in Paragraph 4.2(d).

12. Assignment and Subletting.

12.1 Lessor's Consent Required.

(a) Lessee shall not voluntarily or by operation of law assign, transfer, mortgage or otherwise transfer or encumber (collectively, "assign") or sublet all or any part of Lessee's interest in this Lease or in the Premises without Lessor's prior written consent given under and subject to the terms of Paragraph 36.

(b) A change in the control of Lessee shall constitute an assignment requiring Lessor's consent. The transfer, on a cumulative basis, of twenty-five percent (25%) or more of the voting control of Lessee shall constitute a change in control for this purpose.

(c) The involvement of Lessee or its assets in any transaction, or series of transactions (by way of merger, sale acquisition financing, refinancing, transfer, leveraged buy-out or otherwise), whether or not a formal assignment or hypothecation of this Lease or Lessee's assets occurs, which results or will result in a reduction of the **Net Worth of** Lessee, as hereinafter defined, by an amount equal to or greater than twenty-five percent (25%) of such Net Worth of Lessee as it was represented to Lessor at the time of full execution and deliver] of this Lease or at the time of the most recent assignment to which Lessor has consented, or as it exists immediately prior to said transaction or transactions constituting such reduction, at whichever time said Net Worth of Lessee was or is greater, shall be considered an assignment of this Lease by Lessee to which Lessor may reasonably withhold its consent. "**Net Worth of Lessee**" for purposes of this Lease shall be the net worth of Lessee (excluding any Guarantors) established under generally accepted accounting principles consistently applied.

(d) An assignment or subletting of Lessee's interest in this Lease without Lessor's specific prior written consent shall, at Lessor's option, be a Default curable after notice per Paragraph 13.1, or a non-curable Breach without the necessity of any notice and grace, period. If Lessor elects to treat such unconsented to assignment or subletting as a non-curable Breach, Lessor shall have the right to either: (i) terminate this Lease, or (ii) upon thirty (30) days' written notice **("Lessor's Notice"),** increase the monthly Base Rent for the Premises to the greater of the then fair market rental value of the Premises, as reasonably determined by Lessor, or one hundred ten percent (110%) of the Base Rent then in effect. Pending determination of the new fair market rental value, if disputed by Lessee, Lessee shall pay the amount set forth in Lessor's Notice, with any overpayment credited against the next installment(s) of Base Rent coming due, and any underpayment for the period retroactively to the effective date of the adjustment being due and payable immediately upon the determination thereof. Further, in the event of such Breach and rental adjustment, (i) the purchase price of any option to purchase the Premises held by Lessee shall be subject to similar adjustment to the then fair market value as reasonably determined by Lessor (without the Lease being considered an encumbrance or any deduction for depreciation or obsolescence, and considering the Premises at its highest and best use and in good condition) or one hundred ten percent (110%) of the price previously in effect, (ii) any index-oriented rental or price adjustment formulas contained in this Lease shall be adjusted to require that the base index be determined with reference to the index applicable to the time of such adjustment, and (iii) any fixed rental adjustments scheduled during the remainder of the Lease term shall be increased in the same ratio as the new rental bears to the Base Rent in effect immediately prior to the adjustment specified in Lessor's Notice.

(e) Lessee's remedy for any breach of this Paragraph 12.1 by Lessor shall be limited to compensatory damages and/or injunctive relief.

(f) Lessor's consent shall not be required for any of the following: (i) change in domicile of the Lessee (e.g., a change from a foreign entity to a United States entity); (ii) any change in form of the Lessee which will not modify the ownership interests therein; (c) assignment or sublease to a subsidiary of the Lessee.

12.2 **Terms and Conditions Applicable to Assignment and Subletting.**

(a) Regardless of Lessor's consent, any assignment or subletting shall not (i) be effective without the express written assumption by such assignee or sublessee of the obligations of Lessee under this Lease, (ii) release Lessee of any obligations hereunder, nor (iii) alter the primary liability of Lessee for the payment of Base Rent and other sums due Lessor hereunder or for the performance of any other obligations to be performed by Lessee under this Lease.

(a) Lessor may accept any rent or performance of Lessee's obligations from any person other than Lessee pending approval or disapproval of an assignment. Neither a delay in the approval or disapproval of such assignment nor the acceptance of any rent for performance shall constitute a waiver or estoppel of Lessor's right to exercise itsd remedies for the Default or Breach by Lessee of any of the terms, covenants or conditions of this Lease.

(b) The consent of Lessor to any assignment or subletting shall not constitute a consent to any subsequent assignment or subletting by Lessee or to any subsequent or successive assignment or subletting by the assignee or sublessee. However, Lessor may consent to subsequent sublettings and assignments of the sublease or any amendments or modifications thereto without notifying Lessee or anyone else liable under this Lease or the sublease and without obtaining their consent, and such action shall not relieve such persons from liability under this Lease or the sublease.

(d) In the event of any Default or Breach of Lessee's obligation under this Lease Lessor may proceed directly against Lessee, any Guarantors or anyone else responsible for the performance of the Lessee's obligations under this Lease, including any sublessee, without first exhausting Lessor's remedies against any other person or entity responsible therefor to Lessor, or any security held by Lessor.

(e) Each request for consent to an assignment or subletting shall be in writing, accompanied by information relevant to Lessor's determination as to the financial and operational responsibility and appropriateness of the proposed assignee or sublessee, including but not limited to the intended use and/or required modification of the Premises, if any, together with a non-refundable deposit of $1,000 or ten percent (10%) of the monthly Base Rent applicable to the portion of the Premises which is the subject of the proposed assignment or sublease, whichever is greater, as reasonable consideration for Lessor's considering and processing the request for consent. Lessee agrees to provide Lessor with such other or additional information and/or documentation as may be reasonably requested by Lessor.

(f) Any assignee of, or sublessee under, this Lease shall by reason of accepting such assignment or entering into such sublease, be deemed for the benefit of Lessor, to have assumed and agreed to conform and comply with each and every term, covenant, condition and obligation herein to be observed or performed by Lessee during the term of said assignment or sublease, other than such obligations as are contrary to or inconsistent with provisions of an assignment or sublease to which Lessor has specifically consented in writing.

(g) The occurrence of a transaction described in Paragraph 12.2(c) shall give Lessor the right (but not the obligation) to require that the Security Deposit be increased by an amount equal to six (6) times the then monthly Base Rent, and Lessor may make the actual receipt by Lessor of the Security Deposit increase a condition to Lessor's consent to such transaction.

(h) Lessor, as a condition to giving its consent to any assignment or subletting, may require that the amount and adjustment schedule of the rent payable under this Lease be adjusted to what is then the market value and/or adjustment schedule for property similar to the Premises as then constituted, as determined by Lessor.

12.3 **Additional Terms and Conditions Applicable to Subletting.** The following terms and conditions shall apply to any subletting by Lessee of all or any part of the Premises and shall be deemed included in all subleases under this Lease whether or not expressly incorporated therein:

(a) Lessee hereby assigns and transfers to Lessor all of Lessee's interest in all rentals and income arising from any sublease of all or a portion of the Premises heretofore or hereafter made by Lessee, and Lessor may collect such rent and income and apply same toward Lessee's obligations under this Lease; provided, however, that until a Breach (as defined in Paragraph 13.1) shall occur in the performance of Lessee's obligations under this Lease, Lessee may, except as otherwise provided in this Lease, receive, collect and enjoy the rents accruing under such sublease. Lessor shall not, by reason of the foregoing provision or any other assignment of such sublease to Lessor, nor by reason of the collection of the rents from a sublessee, be deemed liable to the sublessee for any failure of Lessee to perform and comply with any of Lessee's obligations to such sublessee under such Sublease. Lessee hereby irrevocably authorizes and directs any such sublessee, upon receipt of a written notice from Lessor stating that a Breach exists in the performance of Lessee's obligations under this Lease, to pay to Lessor the rents and other charges due and to become due under the sublease. Sublessee shall rely upon any such statement and request from Lessor and shall pay such rents and other charges to Lessor without any obligation or right to inquire as to whether such Breach exists and notwithstanding any notice from or claim from Lessee to the contrary. Lessee shall have no right or claim against such sublessee, or, until the Breach has been cured, against Lessor, for any such rents and other charges so paid by said sublessee to Lessor.

(b) In the event of a Breach by Lessee in the performance of its obligations under this Lease, Lessor, at its option and without any obligation to do so, may require any sublessee to attorn to Lessor, in which event Lessor shall undertake the obligations of the sublessor under such sublease from the time of the exercise of said option to the expiration of such sublease; provided, however, Lessor shall not be liable for any prepaid rents or security deposit paid by such sublessee to such sublessor or for any other prior defaults or breaches of such sublessor under such sublease.

(c) Any matter or thing requiring the consent of the sublessor under a sublease shall also require the consent of Lessor herein.

(d) No sublessee under a sublease approved by Lessor shall further assign or sublet all or any part of the Premises without Lessor's prior written consent.

(e) Lessor shall deliver a copy of any notice of Default or Breach by Lessee to the sublessee, who shall have the right to cure the Default of Lessee within the grace period, if any, specified in such notice. The sublessee shall have a right of reimbursement and offset from and against Lessee for any such Defaults cured by the sublessee.

13. **Default; Breach; Remedies.**

13.1 **Default; Breach.** Lessor and Lessee agree that if an attorney is consulted by Lessor in connection with a Lessee Default or Breach (as hereinafter defined), $350.00 is a reasonable minimum sum per such occurrence for legal services and costs in the preparation and service of a notice of Default, and that Lessor may include the cost of such services and costs in said notice as rent due and payable to cure said default. A "**Default**" by Lessee is defined as a failure by Lessee to observe, comply with or perform any of the terms, covenants, conditions or rules applicable to Lessee under this Lease. **A** "**Breach**" by Lessee is defined as the occurrence of any one or more of the following Defaults, and, where a grace period for cure after notice is specified herein, the failure by Lessee to cure such Default prior to the expiration of the applicable grace period, and shall entitle Lessor to pursue the remedies set forth in Paragraphs 13.2 and/or 13.3:

(a) The vacating of the Premises without the intention to reoccupy same, or the abandonment of the Premises.

(b) Except as expressly otherwise provided in this Lease, the failure by Lessee to make any payment of Base Rent, Lessee's Share of Common Area Operating Expenses, or any other monetary payment required to be made by Lessee hereunder as and when due the failure by Lessee to provide Lessor with reasonable evidence of insurance or surety bond required under this Lease, or the failure of Lessee to fulfill any obligation under this Lease which endangers or threatens life or property, where such failure continues for a period of three (3) days following written notice thereof by or on behalf of Lessor to Lessee.

(c) Except as expressly otherwise provided in this Lease, the failure by Lessee to provide Lessor with reasonable written evidence (in duly executed original form, if applicable) of (i) compliance with Applicable Requirements per Paragraph 6.3, (ii) the inspection, maintenance and service contracts required under Paragraph 7.1(b), (iii) the rescission of an unauthorized assignment or subletting per Paragraph 12.1, (iv) a Tenancy Statement per Paragraphs 16 or 37, (v) the subordination or non-subordination of this Lease per Paragraph 30, (vi) the guaranty of the performance of Lessee's obligations under this Lease if required under Paragraphs 1.11 and 37, (vii) the execution of any document requested under Paragraph 42 (easements), or (viii) any other documentation or information which Lessor may reasonably require of Lessee under the terms of this lease, where any such failure continues for a period of ten (10) days following written notice by or on behalf of Lessor to Lessee.

(d) A Default by Lessee as to the terms, covenants, conditions or provisions of this Lease, or of the rules adopted under Paragraph 40 hereof that are to be observed, complied with or performed by Lessee, other than those described in Subparagraphs 13.1(a), (b) or (c), above, where such Default continues for a period of thirty (30) days after written notice thereof by or on behalf of Lessor to Lessee; provided, however, that if the nature of Lessee's Default is such that more than thirty (30) days are reasonably required for its cure, then it shall not be deemed to be a Breach of this Lease by Lessee if Lessee commences such cure within said thirty (30) day period and thereafter diligently prosecutes such cure to completion.

(e) The occurrence of any of the following events: (i) the making by Lessee of any general arrangement or assignment for the benefit of creditors; (ii) Lessee's becoming a "debtor" as defined in 11 U.S. Code Section 101 or any successor statute thereto (unless, in the case of a petition filed against Lessee, the same is dismissed within sixty (60) days); (iii) the appointment of a trustee or receiver to take possession of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where possession is not restored to Lessee within thirty (30) days; or (iv) the attachment, execution or other judicial seizure of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where such seizure is not discharged within thirty (30) days; provided, however, in the event that any provision of this Subparagraph 13.1 (e) is contrary to any applicable law, such provision shall be of no force or effect, and shall not affect the validity of the remaining provisions.

(f) The discovery by Lessor that any financial statement of Lessee or of any Guarantor, given to Lessor by Lessee or any Guarantor, was materially false.

(g) If the performance of Lessee's obligations under this Lease is guaranteed: (i) the death of a Guarantor, (ii) the termination of a Guarantor's liability with respect to this Lease other than in accordance with the terms of such guaranty, (iii) a Guarantor's becoming insolvent or the subject of a bankruptcy filing, (iv) a Guarantor's refusal to honor the guaranty, or (v) a Guarantor's breach of its guaranty obligation on an anticipatory breach basis, and Lessee's failure, within sixty (60) days following written notice by or on behalf of Lessor to Lessee of any such event, to provide Lessor with written alternative assurances of security, which, when coupled with the then existing resources of Lessee, equals or exceeds the combined financial resources of Lessee and the Guarantors that existed at the time of execution of this Lease.

13.2 **Remedies.** If Lessee fails to perform any affirmative duty or obligation of Lessee under this Lease, within ten (10) days after written notice to Lessee (or in case of an emergency, without notice), Lessor may at its option (but without obligation to do so), perform such duty or obligation on Lessee's behalf, including but not limited to the obtaining of reasonably required bonds, insurance policies, or governmental licenses, permits or approvals. The costs and expenses of any such performance by Lessor shall be due and payable by Lessee to Lessor upon invoice therefor. If any check given to Lessor by Lessee shall not be honored by the bank upon which it is drawn, Lessor, at its own option, may require all future payments to be made under this Lease by Lessee to be made only by cashier's check. In the event of a Breach of this Lease by Lessee (as defined in Paragraph 13.1), with or without further notice or demand, and without limiting Lessor in the exercise of any right or remedy which Lessor may have by reason of such Breach, Lessor may:

(a) Terminate Lessee's right to possession of the Premises by any lawful means, in which case this Lease and the term hereof shall terminate and Lessee shall immediately surrender possession of the Premises to Lessor. In such event Lessor shall be entitled to recover from Lessee: (i) the worth at the time of the award of the unpaid rent which had been earned at the time of termination; (ii) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that the Lessee proves could have been reasonably avoided; (iii) the worth at the time of award of the amount by which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss that the Lessee proves could be reasonably avoided; and (iv) any other amount necessary to compensate Lessor for all the detriment proximately caused by the Lessee's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, including but not limited to the cost of recovering possession of the Premises, expenses of reletting, including necessary renovation and alteration of the Premises, reasonable attorneys' fees, and that portion of any leasing commission paid by Lessor in connection with this Lease applicable to the unexpired term of this Lease. The worth at the time of award of the amount referred to in provision (iii) of the immediately preceding sentence shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco or the Federal Reserve Bank District in which the Premises are located at the time of award plus one percent (1%). Efforts by Lessor to mitigate damages caused by Lessee's Default or Breach of this Lease shall not waive Lessor's right to recover damages under this Paragraph 13.2. If termination of this Lease is obtained through the provisional remedy of unlawful detainer, Lessor shall have the right to recover in such proceeding the unpaid rent and damages as are recoverable therein, or Lessor may reserve the right to recover all or any part thereof in a separate suit for such rent and/or damages. If a notice and grace period required under Subparagraph 13.1(b), (c) or (d) was not previously given, a notice to pay rent or quit, or to perform or quit, as the case may be, given to Lessee under any statute authorizing the forfeiture of leases for unlawful detainer shall also constitute the applicable notice for grace period purposes required by Subparagraph 13.1(b),(c) or (d). In such case, the applicable grace period under the unlawful detainer statue shall run concurrently after the one such statutory notice, and the failure of Lessee to cure the Default within the greater of the two (2) such grace periods shall constitute both an unlawful detainer and a Breach of this Lease entitling Lessor to the remedies provided for in this Lease and/or by said statute.

(b) Continue the Lease and Lessee's right to possession in effect (in California under California Civil Code Section 1951.4) after Lessee's Breach and recover the rent as it becomes due, provided Lessee has the right to sublet or assign, subject only to reasonable limitations. Lessor and Lessee agree that the limitations on assignment and subletting in this Lease are reasonable. Acts of maintenance or preservation, efforts to relet the Premises, or the appointment of a receiver to protect the Lessor's interest under this Lease, shall not constitute a termination of the Lessee's right to possession.

(c) Pursue any other remedy now or hereafter available to Lessor under the laws or judicial decisions of the state wherein the Premises are located.

(d) The expiration or termination of this Lease and/or the termination of Lessee's right to possession shall not relieve Lessee from liability under any indemnity provisions of this Lease as to matters occurring or accruing during the term hereof or by reason of Lessee's occupancy of the Premises.

**13.3 Inducement Recapture In Event of Breach.** Any agreement by Lessor for free or abated rent or other charges applicable to the Premises, or for the giving or paying by Lessor to or for Lessee of any cash or other bonus, inducement or consideration for Lessee's entering into this Lease, all of which concessions are hereinafter referred to as **"Inducement Provisions"** shall be deemed conditioned upon Lessee's full and faithful performance of all of the terms, covenants and conditions of this Lease to be performed or observed by Lessee during the term hereof as the same may be extended. Upon the occurrence of a Breach (as defined in Paragraph 13.1) of this Lease by Lessee, any such Inducement Provision shall automatically be deemed deleted from this Lease and of no further force o; effect, and any rent, other charge, bonus, inducement or consideration theretofore abated, given or paid by Lessor under such an Inducement Provision shall be immediately due and payable by Lessee to Lessor, and recoverable by Lessor, as additional rent due under this Lease, notwithstanding any subsequent cure of said Breach by Lessee. The acceptance by Lessor of rent or the cure of the Breach which initiated the operation of this Paragraph 13.3 shall not be deemed a waiver by Lessor of the provisions of this Paragraph 13.3 unless specifically so stated in writing by Lessor at the time of such acceptance.

13.4 Late Charges. Lessee hereby acknowledges that late payment by Lessee to Lessor of rent and other sums due hereunder will cause Lessor to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult to ascertain. Such cots include, but are not limited to, processing and accounting charges, and late charges which may be imposed upon Lessor by the terms of any ground lease, mortgage or deed of trust covering the Premises. Accordingly, if any installment of rent or other sum due from Lessee shall not be received by Lessor or Lessor's designee within ten (10) days after such amount shall be due, then, without any requirement for notice to Lessee, Lessee shall pay to Lessor a late charge equal to six percent (6%) of such overdue amount. The parties hereby agree that such late charge represents a fair and reasonable estimate of the costs Lessor will incur by reason of late payment by Lessee. Acceptance of such late charge by Lessor shall in no event constitute a waiver of Lessee's Default or Breach with respect to such overdue amount, nor prevent Lessor from exercising any of the other rights and remedies granted hereunder. In the event that a late charge is payable hereunder, whether or no; collected, for three (3) consecutive installments of Base Rent, then notwithstanding Paragraph 4.1 or any other provision of this Lease to the contrary. Base Rant shall, at Lessor's option, become due and payable quarterly in advance.

13.5 Breach by Lessor. Lessor shall not be deemed in breach of this Lease unless Lessor fails within a reasonable time to perform an obligation required to be performed by Lessor. For purposes of this Paragraph 13.5, a reasonable time shall in no event be less than ten (10) days after receipt by Lessor, and by any Lender(s) whose name and address shall have been furnished to Lessee in writing for such purpose, of written notice specifying wherein such obligation of Lessor has not been performed; provided, however, that if the nature of Lessor's obligation is such that more than thirty (30) days after such notice are reasonably required for its performance, then Lessor shall not be in breach of this Lease if performance is commenced within such thirty (30) day period and thereafter diligently pursued to completion.

14. **Condemnation.** If the Premises or any portion thereof are taken under the power of eminent domain or sold under the threat of the exercise of said power (all of which are herein called "condemnation"), this Lease shall terminate as to the part so taken as of the date the condemning authority takes title or possession, whichever first occurs. If more than ten percent (10%) of the floor area of the Premise, or more than twenty-five percent (25%) of the portion of the Common Areas designated for Lessee's parking, is taken by condemnation, Lessee may, at Lessee's option, to be exercised in writing within ten (10) days after Lessor shall have given Lessee written notice of such taking (or in the absence of such notice, within ten (10) days after the condemning authority shall have taken possession) terminate this Lease as of the date the condemning authority takes such possession. If Lessee does not terminate this Lease in accordance with the foregoing, this Lease shall remain in full force and effect as to the portion of the Premises remaining, except that the Base Rent shall be reduced in the same proportion as the rentable floor area of the Premises taken bears to the total rentable floor area of the Premise. No reduction of Base Rent shall occur if the condemnation does not apply to any portion of the Premises. Any award for the taking of all or any part of the Premises under the power of eminent domain or any payment made under threat of the exercise of such power shall be the property of Lessor, whether such award shall be made as compensation for diminution of value of the leasehold or for the taking of the fee, or as severance damages; provided, however, that Lessee shall be entitled to any compensation, separately awarded to Lessee for Lessee's relocation expenses and/or loss of Lessee's Trade Fixtures. In ties event that this Lease is not terminated by reason of such condemnation, Lessor shall to the extent of its net severance damages received, over and above Lessee's Share of the legal anal other expenses incurred by Lessor in the condemnation natter, repair any damage to the Premises caused by such condemnation authority. Lessee shall be responsible for the payment of any amount in excess of such net severance damages required to complete such repair.

15. **Brokers'** Fees.

15.1 **Procuring Cause.** The Brokers) named in Paragraph 1.10 is/are the procuring cause of this Lease.

15.2 **Additional Terms.** Unless Lessor and Broker(s) have otherwise agreed in writing, Lessor agrees that: (a) if Lessee exercises any Option (as defined in Paragraph 39.1) granted under this Lease or any Option subsequently granted, or (b) if Lessee acquires any rights to the Premises or other premises in which Lessor has an interest, or (c) if Lessee remains in possession of tile Premises with tile consent of Lesser aft-3i the expiration of the term of this Lease after having failed to exercise an Option, or (d) if said Brokers are the procuring cause of any oilier lease or saie entered into between the Parties pertaining to the Premises and/or any adjacent property in which Lessor has an interest, or (e) if Base Rent is increased, whether by agreement or operation of an escalation c!-use herein, then as to any of said transactions, Lessor shall pay said Broker(s) a fee in accordance with the schedule of said Broker(s) in effect at the time of the execution of this Lease.

15.3 **Assumption of Obligations.** Any buyer or transferee of lessor's interest in this Lease whether such transfer is by agreement or by operation of law, shall be deemed to have assumed Lessor's obligation under this Paragraph 15. Each Broker shall be an intended third party beneficiary of the provisions of Paragraph 1.10 and of this Paragraph 15 to the. extent of its interest in any commission arising from this Lease and may enforce that right directly against Lessor and its successors.

**15.4 Representations and Warranties.** Lessee and Lessor each represent and warrant to the other that it has had no dealings with any person, firm, broker or finder other than as named in Paragraph 1.10(a) in connection with the negotiation of this Lease and/or the consummation of the transaction, contemplated hereby, and that no broker or other person, firm or entity ether than said named Broker(s) is entitled to any commission or finder's fee in connection with said transaction. Lessee and Lessor do each hereby agree to indemnify, protect, defend and hold the other harmless from and against liability for compensation or charges which may be claimed by any such unnamed broker, finder or other similar party by reason of any dealings or actions of the indemnifying Party, including any costs, expenses, and/or attorneys' fees reasonably incurred with respect thereto.

16. **Tenancy and Financial Statements.**

16.1 **Tenancy Statement.** Each Party (as "**Responding Party**") shall within ten (10) days after written notice from the other Party (the "**Requesting Party**") execute, acknowledge and deliver to the Requesting Party a statement in writing in a form similar to the then most current "Tenancy Statement" form published by the American Industrial Real Estate Association, plus such additional information, confirmation and/or statements as may be reasonably requested by the Requesting Party.

16.2 **Financial Statement.** If Lessor desires to finance, refinance, or sell the Premises or the Building, or any part thereof, Lessee and all Guarantors shall deliver to any potential lender or purchaser designated by Lessor such financial statements of Lessee and such Guarantors as may be reasonably required by such lender or purchaser, including but not limited to Lessee's financial statements for the past three (3) years. All such financial statements shall be received by Lessor and such lender or purchaser in confidence and shall be used only for the purposes herein set forth.

17. **Lessor's Liability.** The term "**Lessor**" as used herein shall mean the owner or owners at the time in question of the fee title to the Premises. In the event of a transfer of Lessor's tifle or interest in the Premises or in this Lease, Lessor shall deliver to the transferee or assignee (in cash or by credit) any unused Security Deposit held by Lessor at the time of such transfer or assignment. Except as provided in Paragraph 15.3, upon such transfer or assignment and delivery of the Security Deposit, as aforesaid, the prior Lessor shall be relieved of ail liability with respect to the obligations and/or covenants under this Lease thereafter to be performed by the Lessor. Subject to the foregoing, the obligations and/or covenants in this Lease to be performed by the Lessor shall be binding only upon the Lessor as hereinabove defined.

18. Severability. The invalidity of any provision of this Lease, as determined by a court of competent jurisdiction, shall in no way affect the validity of any other provision hereof.

19. **Interest on Past-Due Obligations.** Any monetary payment due Lessor hereunder, other than late charges, not received by Lessor within ten (10) days following the date on which it was due, shall bear interest from the date due at the prime rate charged by the largest state chartered bank in the state in which the Premises are located plus four percent (4%) per annum, but not exceeding the maximum rate allowed by law, in addition to the potential late charge provided for in Paragraph 13.4.

20. Time of Essence. Time is of the essence with respect to the performance of all obligations to be performed or observed by the Parties under this Lease.

21. Rent Defined. All monetary obligations of Lessee to Lessor under the terms of this Lease are deemed to be rent.

22. No Prior or other Agreenments; Broker Disclaimer. This Lease contains all agreements between the Parties with respect to any matter mentioned herein, and no other prior or contemporaneous agreement or understanding shall be effective. Lessor and Lessee each represents and warrants to the Brokers that it has made, and is relying solely upon, its own investigation as to the nature, quality, character and financial responsibility of the other Party to this Lease and as to the nature, quality and character of the Premises. Brokers have no responsibility with respect thereto or with respect to any default or breach hereof by either Party. Each Broker shall be an intended third party beneficiary of the provisions of this Paragraph 22.

**23. Notices**

**23.1 Notice Requirements.** All notices required or permitted by this Lease shall be in writing and may be delivered in person (by hand or by messenger or courier service) or may be sent by regular, certified or registered mail or U.S. Postal Service Express Mail, with postage prepaid, or by facsimile transmission or electronic mail during normal business hours, and shall be deemed sufficiently given if served in a manner specified in this Paragraph 23. The addresses noted adjacent to a Party's signature on this Lease shall be that Party's address for delivery or mailing of notice purposes. Either Party may by written notice to the other specify a different address for notice purposes, except that upon Lessee's taking possession of the Premises, the Premises shall constitute Lessee's address for the purpose of mailing or delivering notices to Lessee. A copy of all notices required or permitted to be given to Lessor hereunder shall be concurrently transmitted to such party or parties at such addresses as Lessor may from time to time hereafter designate by written notice to Lessee.

**23.2 Date of Notice.** Any notice sent by registered or certified mail, return receipt requested, shall be deemed given on the date of delivery shown on the receipt card, or if no delivery date is shown, the postmark thereon. If sent by regular mail, the notice shall be deemed given forty-eight (48) hours after the same is addressed as required herein and mailed with postage prepaid. Notices delivered by United States Express Mail or overnight courier that guarantees next day delivery shall be deemed given twenty-four (24) hours after delivery of the same to the United States Postal Service or courier. If any notice is transmitted by facsimile transmission or electronic mail, the same shall be deemed served or delivered on the first business day following confirmation of receipt of the transmission thereof. If notice is received after 5:00 p.m. or on a Saturday or a Sunday or a legal holiday, it shall be deemed received on the next business day.

**24. Waivers.** No waiver by Lessor of the Default or Breach of any term, covenant or condition hereof by Lessee, shall be deemed a waiver of any other term, covenant or condition hereof, or of any subsequent Default or Breach by Lessee of the same or any other term, covenant or condition hereof. Lessor's consent to, or approval of, any such act shall not be deemed to render unnecessary the obtaining of Lessor's consent to, or approval of, any subsequent or similar act by Lessee, or be construed as the basis of an estoppel to enforce the provision or provisions of this Lease requiring such consent. Regardless of Lessor's knowledge of a Default or Breach at the time of accepting rent, the acceptance of rent by Lessor shall not be a waiver of any Default or Breach by Lessee of any provision hereof. Any payment given Lessor by Lessee may be accepted by Lessor on account of moneys or damages due Lessor, notwithstanding any qualifying statements or conditions made by Lessee in connection therewith, which such statements and/or conditions shall be of no force or effect whatsoever unless specifically agreed to in writing by Lessor at or before the time of deposit of such payment.

**25. Recording.** Either Lessor or Lessee shall, upon request of the other, execute, acknowledge and deliver to the other a short form memorandum of this Lease for recording purposes. The Party requesting recordation shall be responsible for payment of any fees or taxes applicable thereto.

**27. Cumulative Remedies.** No remedy or election hereunder shall be deemed exclusive but shall, wherever possible, be cumulative with all other remedies at law or in equity.

**28. Covenants and Conditions.** All provisions of this Lease to be observed or performed by Lessee are both covenants and conditions.

29. **Binding Effect; Choice of Law.** This Lease shall be binding upon the Parties, their personal representatives, successors and assigns and be governed by the laws of the State in which the Premises are located. Any litigation between the Parties hereto concerning this Lease shall be initiated in the county in which the Premises are located.

**30. Subordination; Attornment; Non-Disturbance.**

**30.1 Subordination.** This Lease and any Option granted hereby shall be subject and subordinate to any ground lease, mortgage, deed of trust, or other hypothecation or security device (collectively, "Security Device"), now or hereafter placed by Lessor upon the real property of which the Premises are a part, to any and all advances made on the security thereof, and to all renewals, modifications, consolidations, replacements and extensions thereof. Lessee agrees that the Lenders holding any such Security Device shall have no duty, liability or obligation to perform any of the obligations of Lessor under this Lease, but that in the event of Lessor's default with respect to any such obligation, Lessee will give any Lender whose name and address have been furnished Lessee in writing for such purpose notice of Lessor's default pursuant to Paragraph 13.5. If any Lender shall elect to have this Lease and/or any Option granted hereby superior to the lien of its Security Device and shall give written notice thereof to Lessee, this Lease and such Options shall be deemed prior to such Security Device, notwithstanding the relative dates of the documentation or recordation thereof.

**30.2 Attornment.** Subject to the non-disturbance provisions of Paragraph 30.3, Lessee agrees to attorn to a Lender or any other party who acquires ownership of the Premises by reason of a foreclosure of a Security Device, and that in the event of such foreclosure, such new owner shall not: (i) be liable for any act or omission of any prior lessor or with respect to events occurring prior to acquisition of ownership, (ii) be subject to any offsets or defenses which Lessee might have against any prior lessor, or (iii) be bound by prepayment of more than one month's rent.

**30.3 Non-Disturbance.** With respect to Security Devices entered into by Lessor after the execution of this lease, Lessee's subordination of this Lease shall be subject to receiving assurance (a "non-disturbance agreement") from the Lender that Lessee's possession and this Lease, including any options to extend the term hereof, will not be disturbed so long as Lessee is not in Breach hereof and attorns to the record owner of the Premises.

**30.4 Self-Executing.** The agreements contained in this Paragraph 30 shall be effective without the execution of any further documents; provided, however, that upon written request from Lessor or a Lender in connection with a sale, financing or refinancing of Premises, Lessee and Lessor shall execute such further writings as may be reasonably required to separately document any such subordination or non-subordination, attornment and/or non-disturbance agreement as is provided for herein.

**31. Attorneys' Fees.** If any Party or Broker brings an action or proceeding to enforce the terms hereof or, declare rights hereunder, the Prevailing Party (as hereafter defined) in any such proceeding, action, or appeal thereon, shall be entitled to reasonable attorneys' fees. Such fees may be awarded in the same suit or recovered in a separate suit, whether or not such action or proceeding is pursued to decision or judgment. The term **"Prevailing Party"** shall include, without limitation, a Party or Broker who substantially obtains or defeats the relief sought, as the case may be, whether by compromise, settlement, judgment, or the abandonment by the other Party or Broker of its claim or defense. The attorneys' fee award shall not be computed in accordance with any court fee schedule, but shall be such as to fully reimburse all attorneys' fees reasonably incurred. Lessor shall be entitled to attorneys' fees, costs and expenses incurred in preparation and service of notices of Default and consultations in connection therewith, whether or not a legal action is subsequently commenced in connection with such Default or resulting Breach. Broker(s) shall be intended third party beneficiaries of this Paragraph 31.

**32. Lessor's Access; Showing Premises; Repairs.** Lessor and Lessor's agents shall have the right to enter the Premises at any time, in the case of an emergency, and otherwise at reasonable times for the purpose of showing the same to prospective purchasers, lenders, or lessees, and making such alterations, repairs, improvements or additions to the Premises or to the Building as Lessor may reasonably deem necessary. Lessor may at any time place on or about the Premises or Building any ordinary "For Sale" signs and Lessor may at any time during the last one hundred eighty (180) days of the term hereof place on or about the Premises any ordinary "For Lease" signs. All such activities of Lessor shall be without abatement of rent or liability to Lessee.

**33. Auctions.** Lessee shall not conduct, nor permit to be conducted, either voluntarily or involuntarily, any auction upon the Premises without first having obtained Lessor's prior written consent. Notwithstanding anything to the contrary in this Lease, Lessor shall not be obligated to exercise any standard of reasonableness in determining whether to grant such consent.

34. **Signs.** Lessee shall not place any sign upon the exterior of the Premises or the Building, except that Lessee may, with Lessor's prior written consent, install (but not on the roof) such signs as are reasonably required to advertise Lessee's own business so long as such signs are in a location designated by Lessor and comply with Applicable Requirements and the signage criteria established for the Industrial Center by Lessor. The installation of any sign on the Premises by or for Lessee shall be subject to the provisions of Paragraph 7 (Maintenance, Repairs, Utility Installations, Trade Fixtures and Alterations). Unless otherwise expressly agreed herein, Lessor reserves all rights to the use of the roof of the Building, and the right to install advertising signs on the Building, including the roof, which do not unreasonably interfere with the conduct of Lessee's business; Lessor shall be entitled to all revenues from such advertising signs. Notwithstanding the foregoing, Lessee shall be permitted at its sole expense to place a sign in the location as the signage occupied by the current lessee, and a monument sign near the street, subject to Lessor's approval, which shall not be unreasonably withheld.

**35. Termination; Merger.** Unless specifically stated otherwise in writing by Lessor, the voluntary or other surrender of this Lease by Lessee, the mutual termination or cancellation hereof, or a termination hereof by Lessor for Breach by Lessee, shall automatically terminate any sublease or lesser estate in the Premises; provided, however, Lessor shall, in the event of any such surrender, termination or cancellation, have the option to continue any one or all of any existing subtenancies. Lessor's failure within ten (10) days following any such event to make a written election to the contrary by written notice to the holder of any such lesser interest, shall constitute Lessor's election to have such event constitute the termination of such interest.

**36. Consents.**

(a) Except for Paragraph 33 hereof (Auctions) or as otherwise provided herein, wherever in this Lease the consent of a Party is required to an act by or for the other Party, such consent shall not be unreasonably withheld or delayed. Lessor's actual reasonable costs and expenses (including but not limited to architects', attorneys', engineers' and other consultants' fees) incurred in the consideration of, or response to, a request by Lessee for any Lessor consent pertaining to this Lease or the Premises, including but not limited to consents to an assignment a subletting or the presence or use of a Hazardous Substance, shall be paid by Lessee to Lessor upon receipt of an invoice and supporting documentation therefor. In addition to the deposit described in Paragraph 12.2(e), Lessor may, as a condition to considering any such request by Lessee, require that Lessee deposit with Lessor an amount of money (in addition to the Security Deposit held under Paragraph 5) reasonably calculated by Lessor to represent the cost Lessor will incur in considering and responding to Lessee's request. Any unused portion of said deposit shall be refunded to Lessee without interest. Lessor's consent to any act, assignment of this Lease or subletting of the Premises by Lessee shall not constitute an acknowledgment that no Default or Breach by Lessee of this Lease exists, nor shall such consent be deemed a waiver of any then existing Default or Breach, except as may be otherwise specifically stated in writing by Lessor at the time of such consent.

(b) All conditions to Lessor's consent authorized by this Lease are acknowledged by Lessee as being reasonable. The failure to specify herein any particular condition to Lessor's consent shall not preclude the impositions by Lessor at the time of consent of such further or other conditions as are then reasonable with reference to the particular matter for which consent is being given.

**37. Guarantor.**

37.1 Form of Guaranty. If there are to be any Guarantors of this Lease per Paragraph 1.11, the form of the guaranty to be executed by each such Guarantor shall be in the form most recently published by the American Industrial Real Estate Association, and each such Guarantor shall have the same obligations as Lessee under this lease, including but not limited to the obligation to provide the Tenancy Statement and information required in Paragraph 16.

37.2 **Additional Obligations of Guarantor.** It shall constitute a Default of the Lessee under this Lease if any such Guarantor fails or refuses, upon reasonable request by Lessor to give: (a) evidence of the due execution of the guaranty called for by this Lease, including the authority of the Guarantor (and of the party signing on Guarantor's behalf) to obligate such Guarantor on said guaranty, and resolution of its board of directors authorizing the making of such guaranty, together with a certificate of incumbency showing the signatures of the persons authorized to sign on its behalf, (b) current financial statements of Guarantor as may from time to time be requested by Lessor, (c) a Tenancy Statement, or (d) written confirmation that the guaranty is still in effect.

38. Quiet Possession. Upon payment by Lessee of the rent for the Premises and the performance of all of the covenants, conditions and provisions on Lessee's part to be observed and performed under this Lease, Lessee shall have quiet possession of the Premises for the entire term hereof subject to all of the provisions of this Lease.

39. Options.

39.1 Definition. As used in this Lease, the word "**Option**" has the following meaning: (a) the right to extend the term of this Lease or to renew this Lease or to extend or renew any lease that Lessee has on other property of Lessor; (b) the right of first refusal to lease the Premises or the right of first offer to lease the Premises or the right of first refusal to lease other property of Lessor or the right of first offer to lease other property of Lessor; (c) the right to purchase the Premises, or the right of first refusal to purchase the Premises, or the right of first offer to purchase the Premises, or the right to purchase other property of Lessor, or the right of first refusal to purchase other property of Lessor, or the right of first offer to purchase other property of Lessor.

39.2 Options Personal to Original Lessee. Each Option granted to Lessee in this Lease is personal to the original Lessee named in Paragraph 1.1 hereof, and cannot be voluntarily or involuntarily assigned or exercised by any person or entity other than said original Lessee while the original Lessee is in full and actual possession of the Premises and without the intention of thereafter assigning or subletting. The Options, if any, herein granted !o Lessee are not assignable, either as a part of an assignment of this Lease or separately or apart therefrom, and no Option may be separated from this Lease in any manner, by reservation or otherwise.

39.3 Multiple Options. In the event that Lessee has any multiple Options to extend or renew this Lease, a later option cannot be exercised unless the prior Options to extend or renew this Lease have been validly exercised.

39.4 Effect of Default on Options.

(a) Lessee shall have no right to exercise an Option, notwithstanding any provision in the grant of Option to the contrary: (i) during the period commencing with the giving of any notice of Default under Paragraph 13.1 and continuing until the noticed Default is cured, or (ii) during the period of time any monetary obligation due Lessor from Lessee is unpaid (without regard to whether notice thereof is given Lessee), or (iii) during the time Lessee is in Breach of this Lease, or (iv) in the event that Lessor has given to Lessee three (3) or more notices of separate Defaults under Paragraph 13.1 during the twelve (12) month period immediately preceding the exercise of the Option, whether or not the Defaults are cured.

(b) The period of time within which an Option may be exercised shall not be extended or enlarged by reason of Lessee's inability to exercise an Option because of the provisions of Paragraph 39.4(a)

(c) All rights of Lessee under the provisions of an Option shall terminate and be of no further force or effect, notwithstanding Lessee's due and timely exercise of the Option, if, after such exercise and during the term of this Lease, (i) Lessee fails to pay to Lessor a monetary obligation of Lessee for a period of thirty (30) days after such obligation becomes due (without any necessity of Lessor to give notice thereof to Lessee), or (ii) Lessor gives to Lessee three (3) or more notices of separate Defaults under Paragraph 13.1 during any twelve (12) month period, whether or not the Defaults are cured, or (iii) if Lessee commits a Breach of this Lease.

40. Rules and Regulations. Lessee agrees that it will abide by, and keep and observe all reasonable rules and regulations ("Rules and Regulations") which Lessor may make from time to time for the management, safety, care, and cleanliness of the grounds, the parking and unloading of vehicles and the preservation of good order, as well as for the convenience of other occupants or tenants of the Building and the Industrial Center and their invitees.

41. **Security Measures.** Lessee hereby acknowledges that the rental payable to Lessor hereunder does not include the cost of guard service or other security measures, and that Lessor shall have no obligation whatsoever to provide same. Lessee assumes ail responsibility for the protection of the Premises, Lessee, its agents and invitees and their property from the acts of third parties.

42. Reservations. Lessor reserves the right, from time to time, to grant, without the consent or joinder of Lessee, such easements, rights of way, utility raceways, and dedications that Lessor deems necessary, and to cause the recordation of parcel maps and restrictions, so long as such easements, rights of way, utility raceways, dedications, maps and restrictions do not reasonably interfere with the use of the Premises by Lessee. Lessee agrees to sign any documents reasonably requested by Lessor to effectuate any such easement rights, dedications, map or restrictions.

43. **Performance Under Protest.** If at any time a dispute shelf arise as to any amount or sum of money to be paid by one Party to the other under the provisions hereof, the Party against whom the obligation to pay the money is asserted shall have the right to make payment "under protest" and such payment shall not be regarded as a voluntary payment and there shall survive the right on the part of said Party to institute suit for recovery of such sum. If it shall be adjudged that there was no legal obligation on the part of said Party to pay such sum or any part thereof, said Party shall be entitled to recover such sum or so much thereof as it was not legally required to pay under the provisions of this Lease.

44. **Authority.** If either Party hereto is a corporation, trust, or general or limited partnership, each individual executing this Lease on behalf of such entity represents and warrants that he or she is duly authorized to execute and deliver this Lease on its behalf. If Lessee is a corporation, trust or partnership, Lessee shall, within thirty (30) days after request by Lessor, deliver to Lessor evidence satisfactory to Lessor of such authority.

45. Conflict. Any conflict between the printed provisions of this Lease and the typewritten or handwritten provisions shall be controlled by the typewritten or handwritten provisions.

46. **Offer.** Preparation of this Lease by either Lessor or Lessee or Lessor's agent or Lessee's agent and submission of same to Lessee or Lessor shall not be deemed an offer to lease. This Lease is not intended to be binding until executed and delivered by all Parties hereto.

47. Amendments. This Lease may be modified only in writing, signed by the parties in interest at the time of the modification. The Parties shall amend this Lease from time to time to reflect any adjustments that are made to the Base Rent or other rent payable under this Lease. As long as they do not materially change Lessee's obligations hereunder, Lessee agrees to make such reasonable non-monetary modifications to this Lease as may be reasonably required by an institutional insurance company or pension plan Lender in connection with the obtaining of normal financing or refinancing of the property of which the Premises are a part.

48. Multiple Parties. Except as otherwise expressly provided herein, if more than one person or entity is named herein as either Lessor or Lessee, the obligations of such multiple parties shall be the joint and several responsibility of all persons or entities named herein as such Lessor or Lessee.

49. In the case that Parker the current tenant vacates the property after March 1, 2018 but earlier than September 30, 2018 , then Avita to start paying the rent at a rate of $24,192.00 per month or portion thereof.

50. The building has major improvements and additional equipment on the roof by the current Tenant and Avita is taking the units as is and is responsible for their upkeep, subject to the provisions of Sections 7.1 and 7.2 above.

51. SEE RENT ADJUSTMENT(S), WHICH IS INCORPORATED HEREIN BY THIS REFERENCE AND MADE A PART HEREOF.

52. SEE OPTION(S) TO EXTEND, STANDARD LEASE ADDENDUM, WHICH IS INCORPORATED HEREIN BY THIS REFERENCE AND MADE A PART HEREOF.

53. Notwithstanding anything to the contrary herein, the Lessor will be responsible for its own trash collection and trash disposal. In this regard, the cost of trash disposal shall **not** be included in the Common Area Operating Expenses Lessee is required to pay pursuant to paragraph 4.2(a)(iii) above.

LESSOR AND LESSEE HAVE CAREFULLY READ AND REVIEWED THIS LEASE AND EACH TERM AND PROVISION CONTAINED HEREIN, AND BY THE EXECUTION OF THIS LEASE SHOW THEIR INFORMED AND VOLUNTARY CONSENT THERETO. THE PARTIES HEREBY AGREE THAT, AT THE TIME THIS LEASE IS EXECUTED, THE TERMS OF THIS LEASE ARE COMMERCIALLY REASONABLE AND EFFECTUATE THE INTENT AND PURPOSE OF LESSOR AND LESSEE WITH RESPECT TO THE PREMISES.

IF THIS LEASE HAS BEEN FILLED IN, IT HAS BEEN PREPARED FOR YOUR ATTORNEY'S REVIEW AND APPROVAL. FURTHER, EXPERTS SHOULD BE CONSULTED TO EVALUATE THE CONDITION OF THE PROPERTY FOR THE POSSIBLE PRESENCE OF ASBESTOS, UNDERGROUND STORAGE TANKS OR HAZARDOUS SUBSTANCES. NO REPRESENTATION OR RECOMMENDATION IS MADE BY THE AMERICAN INDUSTRIAL REAL ESTATE ASSOCIATION OR BY THE REAL ESTATE BROKERS OR THEIR CONTRACTORS, AGENTS OR EMPLOYEES AS TO THE LEGAL SUFFICIENCY, LEGAL EFFECT, OR TAX CONSEQUENCES OF THIS LEASE OR THE TRANSACTION TO WHICH IT RELATES; THE PARTIES SHALL RELY SOLELY UPON THE ADVICE OF THEIR OWN COUNSEL AS TO THE LEGAL AND TAX CONSEQUENCES OF THIS LEASE. IF THE SUBJECT PROPERTY IS IN A STATE OTHER THAN CALIFORNIA, AN ATTORNEY FROM THE STATE WHERE THE PROPERTY IS LOCATED SHOULD BE CONSULTED.

The parties hereto have executed this Lease at the place and on the dates specked above their respective signatures.

| | | | |
|---|---|---|---|
| Executed at:: | VENTURA, CA. | Executed at:: | Valencia, CA |
| On: | January 25, 2018 | On: | January 31, 2018 |
| By LESSOR: | | By LESSEE: | |
| | HARTCO-VENTURA INC. | | Avita Medical Americas, LLC |
| By: | /s/ JOHN SALEH | By: | /s/ TIMOTHY ROONEY |
| Name Printed: | JOHN SALEH | Name Printed: | TIMOTHY ROONEY |
| Title: | PRESIDENT | Title: | CAO |
| By: | | By: | |
| Name Printed: | | Name Printed: | |
| Title: | | Title: | |
| Address: | | Address: | |
| Telephone: ( ) | | Telephone: ( ) | |
| Facsimile: ( ) | | Facsimile: ( ) | |

**RENT ADJUSTMENT(S)**

ADDENDUM TO
STANDARD LEASE

Dated January 25, 2018

By and Between (Lessor) Hartco-Ventura Inc.

(Lessee) Avita Medical Americas

Property Address: 3007 Bunsen Ave., Units I,J,K,L,M,N

Paragraph 51

A. RENT ADJUSTMENTS:

The monthly rent for each month of the adjustment period(s) specified below shall be increased using the method(s) indicated below:

(Check Method(s) to be Used and Fill in Appropriately)

☐ I. **Cost of Living Adjustment(s) (COL)**

(a) On (Fill in COL Adjustment Date(s): _____

the monthly rent payable under paragraph 1.5 ("Base Rent") of the attached Lease shall be adjusted by the change, if any, from the Base Month specified below, in the Consumer Price Index of the Bureau of Labor Statistics of the U.S. Department of Labor for (select one): p CPI W (Urban Wage Earners and Clerical Workers) or p CPI U (All Urban Consumers), for (Fill in Urban Area):

_____, All Items (1982-1984 = 100), herein referred to as "C.P.I."

(b) The monthly rent payable in accordance with paragraph Alfa) of this Addendum shall be calculated as follows: the Base Rent set forth in paragraph 1.5 of the attached Lease, shall be multiplied by a fraction the numerator of which shall be the C.P I. of the calendar month 2 (two) months prior to the month(s) specified in paragraph AI(a) above during which the adjustment is to take effect, and the denominator of which shall be the C.P I. of the calendar month which is two (2) months prior to (select one): p the first month of the term of this Lease as set forth in paragraph 1.3 ("Base Month") or D (Fill in Other "Base Month"):

The sum so calculated shall constitute the new monthly rent hereunder, but in no event, shall any such new monthly rent be less than the rent payable for the month immediately preceding the date for rent adjustment.

(c) In the event the compilation and/or publication of the C.P.I. shall be transferred to any other governmental department or bureau or agency or shall be discontinued, then the index most nearly the same as the CP. I. shall be used to make such calculation. In the event that Lessor and Lessee cannot agree on such alternative index, then the matter shall be submitted for decision to the American Arbitration Association in accordance with the then rules of said association and the decision of the arbitrators shall be binding upon the parties. The cost of said Arbitrators shall be paid equally by Lessor and Lessee.

II. **Market Rental Value Adjustment(s) (MRV)**

(a) On (Fill in MRV Adjustment Date(s): _____

the monthly rent payable under paragraph 1.5 ("Base Rent") of the attached Lease shall be adjusted to the "Market Rental Value" of the property as follows:

1) Four months prior to the Market Rental Value (MRV) Adjustment Date(s) described above, Lessor and Lessee shall meet to establish an agreed upon new MRV for the specified term. If agreement cannot be reached, then:

i) Lessor and Lessee shall immediately appoint a mutually acceptable appraiser or broker to establish the new MRV within the next 30 days. Any associated costs will be split equally between the parties, or

ii) Both Lessor and Lessee shall each immediately select and pay the appraiser or broker of their choice to establish a MRV within the next 30 days. If, for any reason, either one of the appraisals is not completed within the next 30 days, as stipulated, then the appraisal that is completed at that time shall automatically become the new MRV If both appraisals are completed and the two appraisers/brokers cannot agree on a reasonable average MRV then they shall immediately select a third mutually acceptable appraiser/broker to establish a third MRV within the next 30 days. The average of the two appraisals closest in value shall then become the new MRV The costs of the third appraisal will be split equally between the parties.

2) In any event, the new MRV shall not be less than the rent payable for the month immediately preceding the date for rent adjustment.

(b) Upon the establishment of each New Market Rental Value as described in paragraph All:

1) the monthly rental sum so calculated for each term as specified in paragraph All(a) will become the new "Base Rent" for the purpose of calculating any further Cost of Living Adjustments as specified in paragraph Alfa) above and

2) the first month of each Market Rental Value term as specified in paragraph All(a) shall become the new "Base Month" for the purpose of calculating any further Cost of Living Adjustments as specified in paragraph AI(b).

☒☒ III. **Fixed Rental Adjustment(s) (FRA)**

The monthly rent payable under paragraph 1.5 ("Base Rent") of the attached Lease shall be increased to the following amounts on the dates set forth below:

| On (Fill in FRA Adjustment Date(s)): | The New Base Rental shall be: |
|---|---|
| October 1, 2019 | $ $24,883.20 |
| October 1, 2020 | $ $25,574.40 |
| | $ |
| | $ |

B. **NOTICE:** Unless specified otherwise herein, notice of any escalations other than Fixed Rental Adjustment(s) shall be made as specified in paragraph 23 of the attached Lease.

C. **BROKER'S FEE: N/A**

The Real Estate Brokers specified in paragraph 1.10 of the attached Lease shall be paid a Brokerage Fee for each adjustment specified above in accordance with paragraph 15 of the attached Lease.

**OPTION(S) TO EXTEND**
**STANDARD LEASE ADDENDUM**

**Dated** January 25, 2018

**By and Between (Lessor)** Hartco Ventura, Inc.

**By and Between (Lessee)** Avita Medical Americas, LLC, a Delaware limited liability company

**Address of Premises:** 3007 Bunsen Avenue, Units I, J, K, L, M, N Ventura, California 93003

Paragraph 52

**A. OPTION(S) TO EXTEND:**

Lessor hereby grants to Lessee the option to extend the term of this Lease for three additional three-year month period(s) commencing when the prior term expires upon each and all of the following terms and conditions:

(i) In order to exercise an option to extend, Lessee must give written notice of such election to Lessor and Lessor must receive the same at least 9 but not more than 12 months prior to the date that the option period would commence, time being of the essence. If proper notification of the exercise of an option is not given and/or received, such option shall automatically expire. Options (if there are more than one) may only be exercised consecutively.

(ii) The provisions of paragraph 39, including those relating to Lessee's Default set forth in paragraph 39.4 of this Lease, are conditions of this Option.

(iii) Except for the provisions of this Lease granting an option or options to extend the term, all of the terms and conditions of this Lease except where specifically modified by this option shall apply.

(iv) ~~This Option is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and without the intention of thereafter assigning or subletting~~. This option may be exercised by (A) the original Lessee, (B) any assignee or sublessee approved by the Lessor under the terms of Article 12, or (C) any assignee or sublessee exempted from the requirement of Lessor consent pursuant to paragraph 12.1(f).

(v) The monthly rent for each month of the option period shall be calculated as follows, using the method(s) indicated below:
(Check Method(s) to be Used and Fill in Appropriately)

☐ **I. Cost of Living Adjustment(s) (COLA)**

a. On (Fill in COLA Dates): _____

the Base Rent shall be adjusted by the change, if any, from the Base Month specified below, in the Consumer Price Index of the Bureau of Labor Statistics of the U.S. Department of Labor for (select one): ☐ CPI W (Urban Wage Earners and Clerical Workers) or ☐ CPI U (All Urban Consumers), for (Fill in Urban Area):

All Items (1982-1984 = 100), herein referred to as "CPI".

b. The monthly Base Rent payable in accordance with paragraph A.I.a. of this Addendum shall be calculated as follows: the Base Rent set forth in paragraph 1.5 of the attached Lease, shall be multiplied by a fraction the numerator of which shall be the CPI of the calendar month 2 months prior to the month(s) specified in paragraph A.I.a. above during which the adjustment is to take effect, and the denominator of which shall be the CPI of the calendar month which is 2 months prior to (select one): ☐ the first month of the term of this Lease as set forth in paragraph 1.3 ("Base Month") or ☐ (Fill in Other "Base Month"):

The sum so calculated shall constitute the new monthly Base Rent hereunder, but in no event, shall any such new monthly Base Rent be less than the Base Rent payable for the month immediately preceding the rent adjustment.

c. In the event the compilation and/or publication of the CPI shall be transferred to any other governmental department or bureau or agency or shall be discontinued, then the index most nearly the same as the CPI shall be used to make such calculation. In the event that the Parties cannot agree on such alternative index, then the matter shall be submitted for decision to the American Arbitration Association in accordance with the then rules of said Association and the decision of the arbitrators shall be binding upon the parties. The cost of said Arbitration shall be paid equally by the Parties.

☐ **II. Market Rental Value Adjustment(s) (MRV)**

a. On (Fill in MRV Adjustment Date (s)) _____

the Base Rent shall be adjusted to the "Market Rental Value" of the property as follows:

1) Four months prior to each Market Rental Value Adjustment Date described above, the Parties shall attempt to agree upon what the new MRV will be on the adjustment date. If agreement cannot be reached, within thirty days, then:

(a) Lessor and Lessee shall immediately appoint a mutually acceptable appraiser or broker to establish the new MRV within the next 30 days. Any associated costs will be split equally between the Parties, or

(b) Both Lessor and Lessee shall each immediately make a reasonable determination of the MRV and submit such determination, in writing, to arbitration in accordance with the following provisions:

(i) Within 15 days thereafter, Lessor and Lessee shall each select an independent third party ☐ appraiser or ☐ broker (**"Consultant"** - check one) of their choice to act as an arbitrator (Note: the parties may not select either of the Brokers that was involved in negotiating the Lease). The two arbitrators so appointed shall immediately select a third mutually acceptable Consultant to act as a third arbitrator.

(ii) The 3 arbitrators shall within 30 days of the appointment of the third arbitrator reach a decision as to what the actual MRV for the Premises is, and whether Lessor's or Lessee's submitted MRV is the closest thereto. The decision of a majority of the arbitrators shall be binding on the Parties. The submitted MRV which is determined to be the closest to the actual MRV shall thereafter be used by the Parties.

(iii) If either of the Parties fails to appoint an arbitrator within the specified 15 days, the arbitrator timely appointed by one of them shall reach a decision on his or her own, and said decision shall be binding on the Parties.

(iv) The entire cost of such arbitration shall be paid by the party whose submitted MRV is not selected, ie. the one that is NOT the closest to the actual MRV.

2) When determining MRV, the Lessor, Lessee and Consultants shall consider the terms of comparable market transactions which shall include, but not limited to, rent, rental adjustments, abated rent, lease term and financial condition of tenants.

3) Notwithstanding the foregoing, the new Base Rent shall not be less than the rent payable for the month immediately preceding the rent adjustment.

b. Upon the establishment of each New Market Rental Value:

1) the new MRV will become the new "Base Rent" for the purpose of calculating any further Adjustments, and

2) the first month of each Market Rental Value term shall become the new "Base Month" for the purpose of calculating any further Adjustments.

☒ **III. Fixed Rental Adjustment(s) (FRA)**

The Base Rent shall be increased to the following amounts on the dates set forth below:

| On (Fill in FRA Adjustment Date(s)): | The New Base Rent shall be: |
|---|---|
| October 1, 2021 | $26,496.00 |
| October 1, 2022 | $27,417.60 |
| October 1, 2023 | $28,839.20 |
| October 1, 2024 | $29,260.80 |
| October 1, 2025 | $30,182.40 |
| October 1, 2026 | $31,104.00 |
| October 1, 2027 | $32,025.60 |
| October 1, 2028 | $33,062.40 |
| October 1, 2029 | $34,099.20 |

☐ **IV. Initial Term Adjustments.**

The formula used to calculate adjustments to the Base Rate during the original Term of the Lease shall continue to be used during the extended term.

**B. NOTICE:**

Unless specified otherwise herein, notice of any rental adjustments, other than Fixed Rental Adjustments, shall be made as specified in paragraph 23 of the Lease.

~~**C. BROKER'S FEE:**~~

~~The Brokers shall be paid a Brokerage Fee for each adjustment specified above in accordance with paragraph 15 of the L**a**se or if applicable, paragraph 9 of the Sublease.~~

**NOTICE: These forms are often modified to meet changing requirements of law and industry needs. Always write or call to make sure you are utilizing the most current form: AIR Commercial Real Estate Association, 500 N Brand Blvd, Suite 900, Glendale, CA 91203. Telephone No. (213) 687-8777. Fax No.: (213) 687-8616.**

**STANDARD MULTI-TENANT OFFICE LEASE - GROSS**
AIR COMMERCIAL REAL ESTATE ASSOCIATION

1. **Basic Provisions ("Basic Provisions").**

1.1 **Parties**: This Lease ("**Lease**"), dated for reference purposes only October 3, 2016 is made by and between RIF III – Avenue Stanford, LLC, a California limited liability company ("**Lessor**") and Avita Medical Americas, LLC, a Delaware limited liability company ("**Lessee**"), (collectively the "**Parties**", or individually a "**Party**").

1.2(a) **Premises**: That certain portion of the Project (as defined below), known as Suite Numbers(s) 220, 2nd floo~~r(s)~~, consisting of approximately 11,825 rentable square feet (subject to remeasurement) ~~and approximately _ useable square foot~~ ("**Premises**"). The Premises are located at: 28159 Avenue Stanford, in the City of Valencia, County of Los Angeles, State of California, with zip code 91355. In addition to Lessee's rights to use and occupy the Premises as hereinafter specified, Lessee shall have non-exclusive rights to the Common Areas (as defined in Paragraph 2.7 below) as hereinafter specified, but shall not have any rights to the roof, the exterior walls, the area above the dropped ceilings, or the utility raceways of the building containing the Premises ("**Building**") or to any other buildings in the Project. The Premises, the Building, the Common Areas, the land upon which they are located, along with all other buildings and improvements thereon, are herein collectively referred to as the "**Project**." The Project consists of approximately 78,910 rentable square feet. (See also Paragraph 2)

1.2(b) **Parking**: Forty-Six (46) unreserved vehicle parking spaces at no additional expense for the term of the Leas~~and 0 reserved vehicle parking spaces at a monthly cost of $0.00 per unreserved space and $0.00 per reserved space~~. (See Paragraph 2.6)

1.3 **Term**: Four (4) years and One (1) month~~s~~ ("**Original Term**") commencing December 1, 2016 ("**Commencement Date**") and ending December 31, 2020 ("**Expiration Date**"). (See also Paragraph 3)

1.4 **Early Possession**: If the Premises are available Lessee may have non-exclusive possession of the Premises commencing Upon Lease execution; payment of total monies due; receipt of Certificate of Insurance and endorsement pursuant to Paragraph 8.2 herein, so long as Lessee does not interfere with the Lessor Improvements ("**Early Possession Date**"). (See also Paragraphs 3.2 and 3.3)

1.5 **Base Rent**: $19,511.25 per month ("**Base Rent**"), payable on the first (1st) day of each month commencing December 1, 2016. (See also Paragraph 4)

☑ If this box is checked, there are provisions in this Lease for the Base Rent to be adjusted. See Paragraph 50

1.6 **Lessee's Share of Operating Expense Increase**: Fourteen and Ninety-Nine Hundredths percent (14.99%) ("**Lessee's Share**"). In the event that that size of the Premises and/or the Project are modified during the term of this Lease, Lessor shall recalculate Lessee's Share to reflect such modification. Notwithstanding anything herein to the contrary, Lessee shall only be required to pay any increases in Operating Expenses, Insurance Premiums and Real Property Taxes over the Base Year.

1.7 **Base Rent and Other Monies Paid Upon Execution:**

(a) **Base Rent**: $19,511.25 for the period Dec. 1, 2016 – Dec. 31, 2016.

(b) **Security Deposit**: $63,961.41 ("**Security Deposit**"). (See also Paragraph 5)

(c) **Parking**: $0.00 for the period N/A.

(d) **Other**: $0.00 for N/A.

(e) **Total Due Upon Execution of this Lease**: $83,472.66.

1.8 **Agreed Use**: Administrative and professional office and storage of trade supplies and/or components in accordance with standard medical/pharmaceutical industry standards. (See also Paragraph 6)

1.9 **Base Year; Insuring Party**. The Base Year is 2016. Lessor is the "**Insuring Party**". (See also Paragraphs 4.2 and 8)

1.10 **Real Estate Brokers**: (See also Paragraph 15 and 25)

(a) **Representation**: The following real estate brokers (the "**Brokers**") and brokerage relationships exist in this transaction (check applicable boxes):

~~☐ _____ represents Lessor exclusively ("**Lessor's Broker**");~~

~~☐ _____ represents Lessee exclusively ("**Lessee's Broker**"); or~~

☑ CBRE, Inc. represents both Lessor and Lessee ("**Dual Agency**").

(b) **Payment to Brokers**: Upon execution and delivery of this Lease by both Parties, Lessor shall pay to the Brokers for the brokerage services rendered by the Brokers the fee agreed to in ~~the attached~~ a separate written agreement ~~or if no such agreement is attached, the sum of _____ or _____% of the total Base Rent payable for the Original Term, the sum of _____ or _____ of the total Base Rent payable during any period of time that the Lessee occupies the Premises subsequent to the Original Term, and/or the sum of _____ or _____% of the purchase price in the event that the Lessee or anyone affiliated with Lessee acquires from Lessor any rights to the Premises.~~

1.11 **Guarantor**. The obligations of the Lessee under this Lease shall be guaranteed by N/A ("**Guarantor**"). (See also Paragraph 37)

1.12 **Business Hours for the Building**: 8:00 a.m. to 6:00 p.m., Mondays through Fridays (except Building Holidays) and 9:00 a.m. to 1:00 p.m. on Saturdays and Sunday (except Building Holidays). "**Building Holidays**" shall mean the dates of observation of New Year's Day, President's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day, and any other recognized national or state. Lessor shall provide heating, ventilating and air conditioning systems ("HVAC") during Business Hours. Lessor acknowledges, during the initial term only, Lessee shall control the thermostat servicing the Premises.

1.13 **Lessor Supplied Services**. Notwithstanding the provisions of Paragraph 11.1, Lessor is NOT obligated to provide the following within the Premises:

☑ Janitorial services

☐ Electricity

☐ Other (specify): _____

1.14 **Attachments**. Attached hereto are the following, all of which constitute a part of this Lease:

☑ an Addendum consisting of Paragraphs 1.2, 2.2, 2.2 (a), 2.4, 2.6, 2.9, 6.1, 7.3 (d), 7.4 (b), 7.4 (c), 11, 12.2 (h), 23.1, 34 and 48 through 57;

☑ a plot plan depicting the Premises—Exhibit "A";

☐ a current set of the Rules and Regulations;

☐ a Work Letter;

☐ a janitorial schedule;

☑ other (specify): Tenant Move–In/Move–Out Checklist; Tenant Contact Information Sheet; Exhibit "B" – Lessor Improvements; Exhibit "C" – Acknowledgement of Premises.

2. **Premises**.

2.1 **Letting**. Lessor hereby leases to Lessee, and Lessee hereby leases from Lessor, the Premises, for the term, at the rental, and upon all of the terms, covenants and conditions set forth in this Lease. While the approximate square footage of the Premises may have been used in the marketing of the Premises for purposes of comparison, the Base Rent stated herein is NOT tied to square footage and is not subject to adjustment should the actual size be determined to be different. **Note: Lessee is advised to verify the actual size prior to executing this Lease.**

2.2 **Condition**. Lessor shall deliver the Premises to Lessee in a clean condition on the Commencement Date or the Early Possession Date, whichever first occurs ("**Start Date**"), and warrants that the existing electrical, plumbing, fire sprinkler, lighting, heating, ventilating and air conditioning systems ("**HVAC**"), and all other items which the Lessor is obligated to construct pursuant to the Work Letter attached hereto, if any, other than those constructed by Lessee, shall be in good operating condition on said date, that the structural elements of the roof, bearing walls and foundation of the Unit shall be free of material defects, and that the Premises do not contain hazardous levels of any mold or fungi defined as toxic under applicable state or federal law.

2.3 **Compliance**. Lessor does not warrant~~s to the best of its knowledge~~ that the improvements comprising the Premises and the Common Areas comply with the building codes that were in effect at the time that each such improvement, or portion thereof, was constructed, ~~and also~~ or that they will comply with all applicable laws, covenants or restrictions of record, regulations, and ordinances ("**Applicable Requirements**") in effect on the later date of either the Commencement Date or substantial completion of Lessor Improvements ~~Start Date~~. ~~Said warranty does not apply to the use to which Lessee will put the premises, modifications which may be required by the Americans with Disabilities Act or any similar laws as a result of Lessee's use (see Paragraph 49), or to any Alterations or Utility Installations (as defined in Paragraph 7.3(a)) made or to be made by Lessee~~. **NOTE: Lessee is responsible for determining whether or not the zoning and other Applicable Requirements are appropriate for Lessee's intended use, and acknowledges that past uses of the Premises may no longer be allowed**. ~~If~~ However, if improvements that are located on the Common Areas and the Premises do not comply with Applicable Requirements that are in effect and enforced against the Premises and Common Areas as of the date of this Lease ~~said warranty~~, Lessor shall, except as otherwise provided, promptly after receipt of written notice from Lessee setting forth with specificity the nature and extent of such non-compliance, rectify the same. If Lessee does not give Lessor written notice of the failure of the Premises and the Common Areas to comply with Applicable Requirements (that are in effect and enforced against the Premises and the Common Areas as of the date of htis Lease) within six (6) months following the later date of either the Commencement Date or substantial completion of Lessor Improvements (which notice must describe the non-compliance with specificity and be accompanied by any notices Lessee has received with respect thereto) then correction of that non-compliance shall be the obligtation of Lessee at Lessee's sole cost and expense. If the Applicable Requirements are hereafter changed so as to require during the term of this Lease the construction of an addition to or an alteration of the Premises, the remediation of any Hazardous Substance, or the reinforcement or other physical modification of the Premises ("**Capital Expenditure**"), Lessor and Lessee shall allocate the cost of such work as follows:

(a) Subject to Paragraph 2.3(c) below, if such Capital Expenditures are required as a result of the specific and unique use of the Premises by Lessee as compared with uses by tenants in general, Lessee shall be fully responsible for the cost thereof~~, provided, however that if such Capital Expenditure is required during the last 2 years of this Lease and the cost thereof exceeds 6 months' Base Rent, Lessee may instead terminate this Lease unless Lesser notifies Lessee, in writing, within 10 days after receipt of Lessee's termination notice that Lesser has elected to pay the difference between the actual cost there of and the amount equal to 6 months' Base Rent. If Lessee elects termination, Lessee shall immediately cease the use of the Premises which requires such Capital Expenditure and deliver to Lesser written notice specifying a termination date at least 90 days thereafter. Such termination date shall, however, in no event be earlier than the last day that Lessee could legally utilize the Premises without commencing such Capital Expenditure.~~

(b) If such Capital Expenditure is not the result of the specific and unique use of the Premises by Lessee (such as, governmentally mandated seismic modifications), then Lessor shall pay for such Capital Expenditure and Lessee shall only be obligated to pay, each month during the remainder of the term of this Lease or any extension thereof, on the date that on which the Base Rent is due, an amount equal to 1/144th of the portion of such costs reasonably attributable to the Premises. Lessee shall pay Interest on the balance but may prepay its obligation at any time. If, however, such Capital Expenditure is required during the last 2 years of this Lease or if Lessor reasonably determines that it is not economically feasible to pay its share thereof, Lessor shall have the option to terminate this Lease upon 90 days prior written notice to Lessee unless Lessee notifies Lessor, in writing, within 10 days after receipt of Lessor's termination notice that Lessee will pay for the entire cost of such Capital Expenditure in immediately available funds. If Lessor does not elect to terminate, and fails to tender its share of any such Capital Expenditure, Lessee may advance such funds and deduct same, with Interest, from Rent until Lessor's share of such costs have been fully paid. If Lessee is unable to finance Lessor's share, or if the balance of the Rent due and payable for the remainder of this Lease is not sufficient to fully reimburse Lessee on an offset basis, Lessee shall have the right to terminate this Lease upon 30 days written notice to Lessor.

(c) Notwithstanding the above, the provisions concerning Capital Expenditures are intended to apply only to nonvoluntary, unexpected, and new Applicable Requirements. If the Capital Expenditures are instead triggered by Lessee as a result of an actual or proposed change in use, change in intensity of use, or modification to the Premises then, and in that event, Lessee shall either: (i) immediately cease such changed use or intensity of use

and/or take such other steps as may be necessary to eliminate the requirement for such Capital Expenditure, or (ii) complete such Capital Expenditure at its own expense. Lessee shall not have any right to terminate this Lease.

2.4 **Acknowledgements**. Lessee acknowledges that: (a) it has been given an opportunity to inspect and measure the Premises, (b) Lessee has been advised by Lessor and/or Brokers to satisfy itself with respect to the size and condition of the Premises (including but not limited to the electrical, HVAC and fire sprinkler systems, security, environmental aspects, and compliance with Applicable Requirements), and their suitability for Lessee's intended use, (c) Lessee has made such investigation as it deems necessary with reference to such matters and assumes all responsibility therefor as the same relate to its occupancy of the Premises, (d) it is not relying on any representation as to the size of the Premises made by Brokers or Lessor, (e) the square footage of the Premises was not material to Lessee's decision to lease the Premises and pay the Rent stated herein, and (f)

neither Lessor, Lessor's agents, nor Brokers have made any oral or written representations or warranties with respect to said matters other than as set forth in this Lease. ~~In addition, Lesser acknowledges that: (i) Brokers have made no representations, premises or warranties concerning Lessee's ability to honor the Lease or suitability to occupy the Premises, and (ii) it is Lesser's solo responsibility to investigate the financial capability and/or suitability of all proposed tenants.~~

2.5 **Lessee as Prior Owner/Occupant.** The warranties made by Lessor in Paragraph 2 shall be of no force or effect if immediately prior to the Start Date, Lessee was the owner or occupant of the Premises. In such event, Lessee shall be responsible for any necessary corrective work.

2.6 **Vehicle Parking.** So long as Lessee is not in default, and subject to the Rules and Regulations attached hereto, and as established by Lessor from time to time, Lessee shall be entitled to rent and use the number of parking spaces specified in Paragraph 1.2(b) at the rental rate applicable from time to time for monthly parking as set by Lessor and/or its licensee.

(a) If Lessee commits, permits or allows any of the prohibited activities described in the Lease or the rules then in effect, then Lessor shall have the right, without notice, in addition to such other rights and remedies that it may have, to remove or tow away the vehicle involved and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor.

(b) The monthly rent per parking space specified in Paragraph 1.2(b) is subject to change upon 30 days prior written notice to Lessee. The rent for the parking is payable one month in advance prior to the first day of each calendar month.

2.7 **Common Areas—Definition.** The term **"Common Areas"** is defined as all areas and facilities outside the Premises and within the exterior boundary line of the Project and interior utility raceways and installations within the Premises that are provided and designated by the Lessor from time to time for the general nonexclusive use of Lessor, Lessee and other tenants of the Project and their respective employees, suppliers, shippers, customers, contractors and invitees, including, but not limited to, common entrances, lobbies, corridors, stairwells, public restrooms, elevators, parking areas, loading and unloading areas, trash areas, roadways, walkways, driveways and landscaped areas.

2.8 **Common Areas—Lessee's Rights.** Lessor grants to Lessee, for the benefit of Lessee and its employees, suppliers, shippers, contractors, customers and invitees, during the term of this Lease, the nonexclusive right to use, in common with others entitled to such use, the Common Areas as they exist from time to time, subject to any rights, powers, and privileges reserved by Lessor under the terms hereof or under the terms of any rules and regulations or restrictions governing the use of the Project. Under no circumstances shall the right herein granted to use the Common Areas be deemed to include the right to store any property (including without limitation, pallets), temporarily or permanently, in the Common Areas. Any such storage shall be permitted only by the prior written consent of Lessor or Lessor's designated agent, which consent may be revoked at any time. In the event that any unauthorized storage shall occur then Lessor shall have the right, without notice, in addition to such other rights and remedies that it may have, to remove the property and charge the cost to Lessee, which cost shall be immediately payable upon demand by Lessor.

2.9 **Common Areas—Rules and Regulations.** Lessor or such other person(s) as Lessor may appoint shall have the exclusive control and management of the Common Areas and shall have the right, from time to time, to adopt, modify, amend and enforce reasonable rules and regulations (**"Rules and Regulations"**) for the management, safety, care, and cleanliness of the grounds, the parking and unloading of vehicles and the preservation of good order, as well as for the convenience of other occupants or tenants of the Building and the Project and their invitees. The Lessee agrees to abide by and conform to all such Rules and Regulations, and shall use its best efforts to cause its employees, suppliers, shippers, customers, contractors and invitees to so abide and conform. Lessor shall not be responsible to Lessee for the noncompliance with said Rules and Regulations by other tenants of the Project.

2.10 **Common Areas—Changes.** Lessor shall have the right, in Lessor's sole discretion, from time to time:

(a) To make changes to the Common Areas, including, without limitation, changes in the location, size, shape and number of the lobbies, windows, stairways, air shafts, elevators, escalators, restrooms, driveways, entrances, parking spaces, parking areas, loading and unloading areas, ingress, egress, direction of traffic, landscaped areas, walkways and utility raceways;

(b) To close temporarily any of the Common Areas for maintenance purposes so long as reasonable access to the Premises remains available;

(c) To designate other land outside the boundaries of the Project to be a part of the Common Areas;

(d) To add additional buildings and improvements to the Common Areas;

(e) To use the Common Areas while engaged in making additional improvements, repairs or alterations to the Project, or any portion thereof; and

(f) To do and perform such other acts and make such other changes in, to or with respect to the Common Areas and Project as Lessor may, in the exercise of sound business judgment, deem to be appropriate.

3. **Term.**

3.1 **Term.** The Commencement Date, Expiration Date and Original Term of this Lease are as specified in Paragraph 1.3.

3.2 **Early Possession.** Any provision herein granting Lessee Early Possession of the Premises is subject to and conditioned upon the Premises being available for such possession prior to the Commencement Date. Any grant of Early Possession only conveys a non-exclusive right to occupy the Premises. If Lessee totally or partially occupies the Premises prior to the Commencement Date, the obligation to pay Base Rent shall be abated for the period of such Early Possession. All other terms of this Lease (including but not limited to the obligations to pay Lessee's Share of the Operating Expense Increase) shall be in effect during such period. Any such Early Possession shall not affect the Expiration Date.

3.3 **Delay In Possession.** Lessor agrees to use its best commercially reasonable efforts to deliver possession of the Premises to Lessee by the Commencement Date. If, despite said efforts, Lessor is unable to deliver possession by such date, Lessor shall not be subject to any liability therefor, nor shall such failure affect the validity of this Lease or change the Expiration Date. Lessee shall not, however, be obligated to pay Rent or perform its other obligations until Lessor delivers possession of the Premises and any period of rent abatement that Lessee would otherwise have enjoyed shall run from the date of delivery of possession and continue for a period equal to what Lessee would otherwise have enjoyed under the terms hereof, but minus any days of delay caused by the acts or omissions of Lessee. If possession is not delivered within ~~60~~ 90 days after the Commencement Date, as the same may be extended under the terms of any Work Letter executed be Parties, Lessee may, at its option, by notice in writing within 10 days after the end of such ~~60~~ 90 day period, cancel this Lease, in which event the Parties shall be discharged from all obligations hereunder. If such written notice is not received by Lessor within said 10 day period, Lessee's right to cancel shall terminate. If possession of the Premises is not delivered within 120 days after the Commencement Date, this Lease shall terminate unless other agreements are reached between Lessor and Lessee, in writing.

3.4 **Lessee Compliance.** Lessor shall not be required to deliver possession of the Premises to Lessee until Lessee complies with its obligation to provide evidence of insurance (Paragraph 8.5). Pending delivery of such evidence, Lessee shall be required to perform all of its obligations under this Lease from and after the Start Date, including the payment of Rent, notwithstanding Lessor's election to withhold possession pending receipt of such evidence of insurance. Further, if Lessee is required to perform any other conditions prior to or concurrent with the Start Date, the Start Date shall occur but Lessor may elect to withhold possession until such conditions are satisfied.

4. **Rent.**

4.1. **Rent Defined.** All monetary obligations of Lessee to Lessor under the terms of this Lease (except for the Security Deposit) are deemed to be rent (**"Rent"**).

4.2 **Operating Expense Increase.** Lessee shall pay to Lessor during the term hereof, in addition to the Base Rent, Lessee's Share (as specified in Paragraph 1.6) of the amount by which all Operating Expenses for each Comparison Year exceeds the amount of all Operating Expenses for the Base Year (i.e., 2016 as defined under the Base Year provided in Paragraph 1.9), such excess being hereinafter referred to as the **"Operating Expense Increase"**, in accordance with the following provisions:

(a) **"Base Year"** is as specified in Paragraph 1.9.

(b) **"Comparison Year"** is defined as each calendar year during the term of this Lease subsequent to the Base Year; provided, however, Lessee shall have no obligation to pay a share of the Operating Expense Increase applicable to the first 12 months of the Lease Term (other than such as are mandated by a governmental authority, as to which government mandated expenses Lessee shall pay Lessee's Share, notwithstanding they occur during the first twelve (12) months). Lessee's Share of the Operating Expense Increase for the first and last Comparison Years of the Lease Term shall be prorated according to that portion of such Comparison Year as to which Lessee is responsible for a share of such increase.

(c) The following costs relating to the ownership and operation of the Project, calculated as if the Project was at least 95% occupied, are defined as **"Operating Expenses"** :

(i) Costs relating to the operation, replacement, repair, and maintenance in neat, clean, safe, good order and condition,~~but not the replacemcnt~~ (see subparagraph (g)), of the following:

(aa) The Common Areas, including their surfaces, coverings, decorative items, carpets, drapes and window coverings, and including parking areas, loading and unloading areas, trash areas, roadways, sidewalks, walkways, stairways, parkways, driveways, landscaped areas, striping, bumpers, irrigation systems, Common Area lighting facilities, building exteriors and roofs, fences and gates

(bb) All heating, air conditioning, plumbing, electrical systems, life safety equipment, communication systems and other equipment used in common by, or for the benefit of, tenants or occupants of the Project, including elevators and escalators, tenant directories, fire detection systems including sprinkler system maintenance and repair.

(cc) All other areas and improvements that are within the exterior boundaries of the Project but outside of the Premises and/or any other space occupied by a tenant.

(ii) The cost of trash disposal, janitorial and security services, pest control services, and the costs of any environmental inspections;

(iii) The cost of any other service to be provided by Lessor that is elsewhere in this Lease stated to be an "Operating Expense";

(iv) The cost of the premiums for the insurance policies maintained by Lessor pursuant to paragraph 8 and any deductible portion of an insured loss concerning the Building or the Common Areas;

(v) The amount of the Real Property Taxes payable by Lessor pursuant to paragraph 10;

(vi) The cost of water, sewer, gas, electricity, and other publicly mandated services not separately metered;

(vii) Labor, salaries, and applicable fringe benefits and costs, materials, supplies and tools, used in maintaining and/or cleaning the Project and accounting and management fees attributable to the operation of the Project;

(viii) The cost of any capital improvement to the Building or the Project not covered under the provisions of Paragraph 2.3 provided; however, that Lessor shall allocate the cost of any such capital improvement over a 12 year period and Lessee shall not be required to pay more than Lessee's Share of 1/144th of the cost of such Capital Expenditure in any given month;

(ix) The cost to replace equipment or improvements that have a useful life for accounting purposes of 5 years or less.

(x) Reserves set aside for maintenance, repair and/or replacement of Common Area improvements and equipment.

(d) Any item of Operating Expense that is specifically attributable to the Premises, the Building or to any other building in the Project or to the operation, repair and maintenance thereof, shall be allocated entirely to such Premises, Building, or other building. However, any such item that is not specifically attributable to the Building or to any other building or to the operation, repair and maintenance thereof, shall be equitably allocated by Lessor to all buildings in the Project.

(e) The inclusion of the improvements, facilities and services set forth in Subparagraph 4.2(c) shall not be deemed to impose an obligation upon Lessor to either have said improvements or facilities or to provide those services unless the Project already has the same, Lessor already provides the services, or Lessor has agreed elsewhere in this Lease to provide the same or some of them.

(f) Lessee's Share of Operating Expense Increase is payable monthly on the same day as the Base Rent is due hereunder. The amount of such payments shall be based on Lessor's estimate of the Operating Expense Expenses. Within 60 days after written request (but not more than once each year) Lessor shall deliver to Lessee a reasonably detailed statement showing Lessee's Share of the actual Common Area Operating Expenses for the preceding year. If Lessee's payments during such Year exceed Lessee's Share, Lessee shall credit the amount of such over-payment against Lessee's future payments. If Lessee's payments during such Year were less than Lessee's Share, Lessee shall pay to Lessor the amount of the deficiency within 10 days after delivery by Lessor to Lessee of said statement. Lessor and Lessee shall forthwith adjust between them by cash payment any balance determined to exist with respect to that portion of the last Comparison Year for which Lessee is responsible as to Operating Expense Increases, notwithstanding that the Lease term may have terminated before the end of such Comparison Year.

~~(g) Operating Expenses shall not include the costs of replacement for equipment or capital components such as the roof, foundations. exterior walls or a Common Area capital improvement, such as the parking lot paving , elevators, fences that have a useful life for accounting purposes of 5 years or more.~~

(h) Operating Expenses shall not include any expenses paid by any tenant directly to third parties, or as to which Lessor is otherwise reimbursed by any third party, other tenant, or by insurance proceeds.

4.3 **Payment.** Lessee shall cause payment of Rent to be received by Lessor in lawful money of the United States on or before the day on which it is due, without offset or deduction (except as specifically permitted in this Lease). ~~All monetary amounts shall be rounded to the nearest whole dollar.~~ In the event that any invoice prepared by Lessor is inaccurate such inaccuracy shall not constitute a waiver and Lessee shall be obligated to pay the amount set forth in this Lease. Rent for any period during the term hereof which is for less than one full calendar month shall be prorated based upon the actual number of days of said month. Payment of Rent shall be made to Lessor at its address stated herein or to such other persons or place as Lessor may from time to time designate in writing. Acceptance of a payment which is less than the amount then due shall not be a waiver of Lessor's rights to the balance of such Rent, regardless of Lessor's endorsement of any check so stating. In the event that any check, draft, or other instrument of payment given by Lessee to Lessor is dishonored for any reason, Lessee agrees to pay to Lessor the sum of $25 in addition to any Late Charge and Lessor, at its option, may require all future Rent be paid by cashier's check. Payments will be applied first to accrued late charges and attorney's fees, second to accrued interest, then to Base Rent and Common Area Operating Expenses, and any remaining amount to any other outstanding charges or costs.

5. **Security Deposit.** Lessee shall deposit with Lessor upon execution hereof the Security Deposit as security for Lessee's faithful performance of its obligations under this Lease. If Lessee fails to pay Rent, or otherwise Defaults under this Lease, Lessor may use, apply or retain all or any portion of said Security Deposit for the payment of any amount already due Lessor, for Rents which will be due in the future, and/ or to reimburse or compensate Lessor for any liability, expense, loss or damage which Lessor may suffer or incur by reason thereof. Lessor may use, apply or retain all or any portion of the Security Deposit (i) first, for Lessee's repair obligations, including without limitation, the obligation to restore the Premises to the condition required under this Lease, (ii) second, to the payment of any rent or other sum in default or for the payment of any other sum to which Lessee may become obligated by reason of Lessee's default, and (iii) third, to compensate Lessor for any loss or damage which Lessor may suffer thereby. If Lessor uses or applies all or any portion of the Security Deposit, Lessee shall within 10 days after written request therefor deposit monies with Lessor sufficient to restore said Security Deposit to the full amount required by this Lease. If the Base Rent increases during the term of this Lease, Lessee shall, upon written request from Lessor, deposit additional monies with Lessor so that the total amount of the Security Deposit shall at all times bear the same proportion to the increased Base Rent as the initial Security Deposit bore to the initial Base Rent. Should the Agreed Use be amended to accommodate a material change in the business of Lessee or to accommodate a sublessee or assignee, Lessor shall have the right to increase the Security Deposit to the extent necessary, in Lessor's reasonable judgment, to account for any increased wear and tear that the Premises may suffer as a result thereof. If a change in control of Lessee occurs during this Lease and following such change the financial condition of Lessee is, in Lessor's reasonable judgment, significantly reduced, Lessee shall deposit such additional monies with Lessor as shall be sufficient to cause the Security Deposit to be at a commercially reasonable level based on such change in financial condition. Lessor shall not be required to keep the Security Deposit separate from its general accounts. Within 90 days after the expiration or termination of this Lease, Lessor shall return that portion of the Security Deposit not used or applied by Lessor. No part of the Security Deposit shall be considered to be held in trust, to bear interest or to be prepayment for any monies to be paid by Lessee under this Lease.

6. **Use.**

6.1 **Use.** Lessee shall use and occupy the Premises only for the Agreed Use,~~or any other legal use which is reasonably comparable thereto~~, and for no other purpose. Lessee shall not use or permit the use of the Premises in a manner that is unlawful, creates damage, waste or a nuisance, or that disturbs occupants of or causes damage to neighboring premises or properties. Other than guide, signal, ~~and~~ seeing eye dogs, and validated service animals, subject to Lessor's prior approval, Lessee shall not keep or allow in the Premises any pets, animals, birds fish, or reptiles. Lessor shall not unreasonably withhold or delay its consent to any written request for a modification of the Agreed Use, so long as the same will not impair the structural integrity of the improvements of the Building, will not adversely affect the mechanical, electrical, HVAC, and other systems of the Building, and/or will not affect the exterior appearance of the Building. If Lessor elects to withhold consent, Lessor shall within 7 days after such request give written notification of same, which notice shall include an explanation of Lessor's objections to the change in the Agreed Use.

6.2 **Hazardous Substances.**

(a) **Reportable Uses Require Consent.** The term "**Hazardous Substance**" as used in this Lease shall mean any product, substance, or waste whose presence, use, manufacture, disposal, transportation, or release, either by itself or in combination with other materials expected to be on the Premises, is either: (i) potentially injurious to the public health, safety or welfare, the environment or the Premises, (ii) regulated or monitored by any governmental authority, or (iii) a basis for potential liability of Lessor to any governmental agency or third party under any applicable statute or common law theory. Hazardous Substances shall include, but not be limited to, hydrocarbons, petroleum, gasoline, and/or crude oil or any products, byproducts or fractions thereof. Lessee shall not engage in any activity in or on the Premises which constitutes a Reportable Use of Hazardous Substances without the express prior written consent of Lessor and timely compliance (at Lessee's expense) with all Applicable Requirements. "**Reportable Use**" shall mean (i) the installation or use of any above or below ground storage tank, (ii) the generation, possession, storage , use, transportation, or disposal of a Hazardous Substance that requires a permit from, or with respect to which a report, notice, registration or

business plan is required to be filed with, any governmental authority, and/or (iii) the presence at the Premises of a Hazardous Substance with respect to which any Applicable Requirements requires that a notice be given to persons entering or occupying the Premises or neighboring properties. Notwithstanding the foregoing, Lessee may use any ordinary and customary materials reasonably required to be used in the normal course of the Agreed Use such as ordinary office supplies (copier toner, liquid paper, glue, etc.) and common household cleaning materials, so long as such use is in compliance with all Applicable Requirements, is not a Reportable Use, and does not expose the Premises or neighboring property to any meaningful risk of contamination or damage or expose Lessor to any liability therefor. In addition, Lessor may condition its consent to any Reportable Use upon receiving such additional assurances as Lessor reasonably deems necessary to protect itself, the public, the Premises and/or the environment against damage, contamination, injury and/or liability, including, but not limited to, the installation (and removal on or before Lease expiration or termination) of protective modifications (such as concrete encasements) and/or increasing the Security Deposit.

(b) **Duty to Inform Lessor**. If Lessee knows, or has reasonable cause to believe, that a Hazardous Substance has come to be located in, on, under or about the Premises, other than as previously consented to by Lessor, Lessee shall immediately give written notice of such fact to Lessor, and provide Lessor with a copy of any report, notice, claim or other documentation which it has concerning the presence of such Hazardous Substance.

(c) **Lessee Remediation**. Lessee shall not cause or permit any Hazardous Substance to be spilled or released in, on, under, or about the Premises (including through the plumbing or sanitary sewer system) and shall promptly, at Lessee's expense, comply with all Applicable Requirements and take all investigatory and/or remedial action reasonably recommended, whether or not formally ordered or required, for the cleanup of any contamination of, and for the maintenance, security and/or monitoring of the Premises or neighboring properties, that was caused or materially contributed to by Lessee, or pertaining to or involving any Hazardous Substance brought onto the Premises during the term of this Lease, by or for Lessee, or any third party.

(d) **Lessee Indemnification**. Lessee shall indemnify, defend and hold Lessor, its agents, employees, lenders and ground lessor, if any, harmless from and against any and all loss of rents and/or damages, liabilities, judgments, claims, expenses, penalties, and attorneys' and consultants' fees arising out of or involving any Hazardous Substance brought onto the Premises by or for Lessee, or any third party (provided, however, that Lessee shall have no liability under this Lease with respect to underground migration of any Hazardous Substance under the Premises from areas outside of the Project not caused or contributed to by Lessee). Lessee's obligations shall include, but not be limited to, the effects of any contamination or injury to person, property or the environment created or suffered by Lessee, and the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease. No termination, cancellation or release agreement entered into by Lessor and Lessee shall release Lessee from its obligations under this Lease with respect to Hazardous Substances, unless specifically so agreed by Lessor in writing at the time of such agreement.

(e) **Lessor Indemnification**. Lessor and its successors and assigns shall indemnify, defend, reimburse and hold Lessee, its employees and lenders, harmless from and against any and all environmental damages, including the cost of remediation, which result from Hazardous Substances which existed on the Premises prior to Lessee's occupancy or which are caused by the gross negligence or willful misconduct of Lessor, its agents or employees. Lessor's obligations, as and when required by the Applicable Requirements, shall include, but not be limited to, the cost of investigation, removal, remediation, restoration and/or abatement, and shall survive the expiration or termination of this Lease.

(f) **Investigations and Remediations**. Lessor shall retain the responsibility and pay for any investigations or remediation measures required by governmental entities having jurisdiction with respect to the existence of Hazardous Substances on the Premises prior to Lessee's occupancy, unless such remediation measure is required as a result of Lessee's use (including "Alterations", as defined in paragraph 7.3(a) below) of the Premises, in which event Lessee shall be responsible for such payment. Lessee shall cooperate fully in any such activities at the request of Lessor, including allowing Lessor and Lessor's agents to have reasonable access to the Premises at reasonable times in order to carry out Lessor's investigative and remedial responsibilities.

(g) **Lessor Termination Option**. If a Hazardous Substance Condition (see Paragraph 9.1(e)) occurs during the term of this Lease, unless Lessee is legally responsible therefor (in which case Lessee shall make the investigation and remediation thereof required by the Applicable Requirements and this Lease shall continue in full force and effect, but subject to Lessor's rights under Paragraph 6.2(d) and Paragraph 13), Lessor may, at Lessor's option, either (i) investigate and remediate such Hazardous Substance Condition, if required, as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) if the estimated cost to remediate such condition exceeds 12 times the then monthly Base Rent or $100,000, whichever is greater, give written notice to Lessee, within 30 days after receipt by Lessor of knowledge of the occurrence of such Hazardous Substance Condition, of Lessor's desire to terminate this Lease as of the date 60 days following the date of such notice. In the event Lessor elects to give a termination notice, Lessee may, within 10 days thereafter, give written notice to Lessor of Lessee's commitment to pay the amount by which the cost of the remediation of such Hazardous Substance Condition exceeds an amount equal to 12 times the then monthly Base Rent or $100,000, whichever is greater. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days following such commitment. In such event, this Lease shall continue in full force and effect, and Lessor shall proceed to make such remediation as soon as reasonably possible after the required funds are available. If Lessee does not give such notice and provide the required funds or assurance thereof within the time provided, this Lease shall terminate as of the date specified in Lessor's notice of termination.

6.3 **Lessee's Compliance with Applicable Requirements**. Except as otherwise provided in this Lease, Lessee shall, at Lessee's sole expense and regardless of the cost therefore or the time remaining on the term, fully, diligently and in a timely manner, materially comply with all Applicable Requirements, the requirements of any applicable fire insurance underwriter or rating bureau, and the recommendations of Lessor's engineers and/or consultants which relate in any manner to the Premises, without regard to whether said requirements are now in effect or become effective after the Start Date. Lessee shall, within 10 days after receipt of Lessor's written request, provide Lessor with copies of all permits and other documents, and other information evidencing Lessee's compliance with any Applicable Requirements specified by Lessor, and shall immediately upon receipt, notify Lessor in writing (with copies of any documents involved) of any threatened or actual claim, notice, citation, warning, complaint or report pertaining to or involving the failure of Lessee or the Premises to comply with any Applicable Requirements. Likewise, Lessee shall immediately give written notice to Lessor of: (i) any water damage to the Premises and any suspected seepage, pooling, dampness or other condition conducive to the production of mold; or (ii) any mustiness or other odors that might indicate the presence of mold in the Premises.

6.4 **Inspection; Compliance**. Lessor and Lessor's "**Lender**" (as defined in Paragraph 30) and consultants shall have the right to enter into Premises at any time, in the case of an emergency, and otherwise at reasonable times, after reasonable notice, for the purpose of inspecting the condition of the Premises and for verifying compliance by Lessee with this Lease. The cost of any such inspections shall be paid by Lessor, unless a violation of Applicable Requirements, or a Hazardous Substance Condition (see paragraph 9.1e) is found to exist or be imminent, or the inspection is requested or ordered by a governmental authority. In such case, Lessee shall upon request reimburse Lessor for the cost of such inspection, so long as such inspection is reasonably related to the violation or contamination. In addition, Lessee shall provide copies of all relevant material safety data sheets (**MSDS**) to Lessor within 10 days of the receipt of written request therefor.

7. **Maintenance; Repairs; Utility Installations; Trade Fixtures and Alterations**

7.1 **Lessee's Obligations**. Notwithstanding Lessor's obligation to keep the Premises in good condition and repair, Lessee shall be responsible for payment of the cost thereof to Lessor as additional rent for that portion of the cost of any maintenance and repair of the Premises, or any equipment (wherever located) that serves only Lessee or the Premises, to the extent such cost is attributable to abuse or misuse. In addition, Lessee rather than the Lessor shall be responsible for the cost of painting, repairing or replacing wall coverings, and to repair or replace any similar improvements within the Premises. Lessor may, at its option, upon reasonable notice, elect to have Lessee perform any particular such maintenance or repairs the cost of which is otherwise Lessee's responsibility hereunder."

7.2 **Lessor's Obligations**. Subject to the provisions of Paragraphs 2.2 (Condition), 2.3 (Compliance), 4.2 (Operating Expenses), 6 (Use), 7.1 (Lessee's Obligations), 9 (Damage or Destruction) and 14 (Condemnation), Lessor, subject to reimbursement pursuant to Paragraph 4.2, shall keep in good order,

condition and repair the foundations, exterior walls, structural condition of interior bearing walls, exterior roof, fire sprinkler system (excluding fire sprinkler systems, if any installed by or on behalf of Lessee, for which Lessee shall be responsible), common area fire alarm and/or smoke detection systems, fire hydrants, and parking lots (driveways) serving the Common Areas and all parts thereof. Lessee expressly waives the benefit of any statute now or hereafter in effect to the extent it is inconsistent with the terms of this Lease.

7.3 **Utility Installations; Trade Fixtures; Alterations.**

(a) **Definitions**. The term "**Utility Installations**" refers to all floor and window coverings, air lines, vacuum lines, power panels, electrical distribution, security and fire protection systems, communication cabling, lighting fixtures, HVAC equipment, and plumbing in or on the Premises. The term "**Trade Fixtures**" shall mean Lessee's machinery and equipment that can be removed without doing material damage to the Premises. The term" **Alterations**" shall mean any modification of the improvements, other than Utility Installations or Trade Fixtures, whether by addition or deletion."**Lessee Owned Alterations and/or Utility Installations**" are defined as Alterations and/or Utility Installations made by Lessee that are not yet owned by Lessor pursuant to Paragraph 7.4(a).

(b) **Consent**. Lessee shall not make any Alterations or Utility Installations to the Premises without Lessor's prior written consent. Lessee may, however, make non-structural Alterations or Utility Installations to the interior of the Premises (excluding the roof) without such consent but upon notice to Lessor, as long as they are not visible from the outside, do not involve puncturing, relocating or removing the roof, ceilings, floors or any existing walls, will not affect the electrical, plumbing, HVAC, and/or life safety systems, and the cumulative cost thereof during this Lease as extended

does not exceed $2000. Notwithstanding the foregoing, Lessee shall not make or permit any roof penetrations and/or install anything on the roof without the prior written approval of Lessor. Lessor may, as a precondition to granting such approval, require Lessee to utilize a contractor chosen and/or approved by Lessor. Any Alterations or Utility Installations that Lessee shall desire to make and which require the consent of the Lessor shall be presented to Lessor in written form with detailed plans. Consent shall be deemed conditioned upon Lessee's: (i) acquiring all applicable governmental permits, (ii) furnishing Lessor with copies of both the permits and the plans and specifications prior to commencement of the work, and (iii) compliance with all conditions of said permits and other Applicable Requirements in a prompt and expeditious manner. Any Alterations or Utility Installations shall be performed in a workmanlike manner with good and sufficient materials. Lessee shall promptly upon completion furnish Lessor with asbuilt plans and specifications. For work which costs an amount in excess of one month's Base Rent, Lessor may condition its consent upon Lessee providing a lien and completion bond in an amount equal to 150% of the estimated cost of such Alteration or Utility Installation and/or upon Lessee's posting an additional Security Deposit with Lessor.

(c) **Liens; Bonds**. Lessee shall pay, when due, all claims for labor or materials furnished or alleged to have been furnished to or for Lessee at or for use on the Premises, which claims are or may be secured by any mechanic's or materialmen's lien against the Premises or any interest therein. Lessee shall give Lessor not less than 10 days notice prior to the commencement of any work in, on or about the Premises, and Lessor shall have the right to post notices of non-responsibility. If Lessee shall contest the validity of any such lien, claim or demand, then Lessee shall, at its sole expense defend and protect itself, Lessor and the Premises against the same and shall pay and satisfy any such adverse judgment that may be rendered thereon before the enforcement thereof. If Lessor shall require, Lessee shall furnish a surety bond in an amount equal to 150% of the amount of such contested lien, claim or demand, indemnifying Lessor against liability for the same. If Lessor elects to participate in any such action, Lessee shall pay Lessor's attorneys' fees and costs.

7.4 **Ownership; Removal; Surrender; and Restoration**.

(a) **Ownership**. Subject to Lessor's right to require removal or elect ownership as hereinafter provided, all Alterations and Utility Installations made by Lessee shall be the property of Lessee, but considered a part of the Premises. Lessor may, at any time, elect in writing to be the owner of all or any specified part of the Lessee Owned Alterations and Utility Installations. Unless otherwise instructed per paragraph 7.4(b) hereof, all Lessee Owned Alterations and Utility Installations shall, at the expiration or termination of this Lease, become the property of Lessor and be surrendered by Lessee with the Premises.

(b) **Removal**. By delivery to Lessee of written notice from Lessor not earlier than 90 days before, and not later than 30 days after~~prior to~~ the end of the term of this Lease, Lessor may require that any or all Lessee Owned Alterations or Utility Installations be removed by the expiration or termination of this Lease (or within ten (10) days after delivery of Lessor's notice, if such notice is delivered after the expiration of the term). Lessor may require the removal at any time of all or any part of any Lessee Owned Alterations or Utility Installations made without the required consent. This paragraph 7.4(b) shall be subject to the provisions of Paragraph 7.4(b) in the Addendum of the Lease.

(c) **Surrender; Restoration**. Lessee shall surrender the Premises by the Expiration Date or any earlier termination date, with all of the improvements, parts and surfaces thereof clean and free of debris, and in good operating order, condition and state of repair, ordinary wear and tear excepted. "Ordinary wear and tear" shall not include any damage or deterioration that would have been prevented by good maintenance practice. Notwithstanding the foregoing, if this Lease is for 12 months or less, then Lessee shall surrender the Premises in the same condition as delivered to Lessee on the Start Date with NO allowance for ordinary wear and tear. Lessee shall repair any damage occasioned by the installation, maintenance or removal of Trade Fixtures, Lessee owned Alterations and/or Utility Installations, furnishings, and equipment as well as the removal of any storage tank installed by or for Lessee. Lessee shall also completely remove from the Premises any and all Hazardous Substances brought onto the Premises by or for Lessee, or any third party (except Hazardous Substances which were deposited via underground migration from areas outside of the Premises) even if such removal would require Lessee to perform or pay for work that exceeds statutory requirements. Trade Fixtures shall remain the property of Lessee and shall be removed by Lessee. Any personal property of Lessee not removed on or before the Expiration Date or any earlier termination date shall be deemed to have been abandoned by Lessee and may be disposed of or retained by Lessor as Lessor may desire. The failure by Lessee to timely vacate the Premises pursuant to this Paragraph 7.4(c) without the express written consent of Lessor shall constitute a holdover under the provisions of Paragraph 26 below.

8. **Insurance; Indemnity**.

8.1 **Insurance Premiums**. The cost of the premiums for the insurance policies maintained by Lessor pursuant to paragraph 8 are included as Operating Expenses (see paragraph 4.2 (c)(iv)). Said costs shall include increases in the premiums resulting from additional coverage related to requirements of the holder of a mortgage or deed of trust covering the Premises, Building and/or Project, increased valuation of the Premises, Building and/or Project, and/or a general premium rate increase. Said costs shall not, however, include any premium increases resulting from the nature of the occupancy of any other tenant of the Building. If the Project was not insured for the entirety of the Base Year, then the base premium shall be the lowest annual premium reasonably obtainable for the required insurance as of the Start Date, assuming the most nominal use possible of the Building and/or Project. ~~In no event, however, shall Lessee be responsible for any portion of the premium cost attributable to liability insurance coverage in excess of $2,000,000 procured under Paragraph 8.2(b).~~

8.2 **Liability Insurance**.

(a) **Carried by Lessee**. Lessee shall obtain and keep in force a Commercial General Liability policy of insurance protecting Lessee and Lessor as an additional insured against claims for bodily injury, personal injury and property damage based upon or arising out of the ownership, use, occupancy or maintenance of the Premises and all areas appurtenant thereto. Such insurance shall be on an occurrence basis providing single limit coverage in an amount not less than $1,000,000 per occurrence with an annual aggregate of not less than $2,000,000. Lessee shall add Lessor as an additional insured by means of an endorsement at least as broad as the Insurance Service Organization's "Additional Insured-Managers or Lessors of Premises" Endorsement and coverage shall also be extended to include damage caused by heat, smoke or fumes from a hostile fire. The policy shall not contain any intra-insured exclusions as between insured persons or organizations, but shall include coverage for liability assumed under this Lease as an "**insured contract**" for the performance of Lessee's indemnity obligations under this Lease. The limits of said insurance shall not, however, limit the liability of Lessee nor relieve Lessee of any obligation hereunder. Lessee shall provide an endorsement on its liability policy(ies) which provides that its insurance shall be primary to and not contributory with any similar insurance carried by Lessor, whose insurance shall be considered excess insurance only.

(b) **Carried by Lessor**. Lessor shall maintain liability insurance as described in Paragraph 8.2(a), in addition to, and not in lieu of, the insurance required to be maintained by Lessee. Lessee shall not be named as an additional insured therein.

8.3 **Property Insurance—Building, Improvements and Rental Value**.

(a) **Building and Improvements**. Lessor shall obtain and keep in force a policy or policies of insurance in the name of Lessor, with loss payable to Lessor, any ground-lessor, and to any Lender insuring loss or damage to the Building and/or Project. The amount of such insurance shall be equal to the full insurable replacement cost of the Building and/or Project, as the same shall exist from time to time, or the amount required by any Lender, but in no event more than the commercially reasonable and available insurable value thereof. Lessee Owned Alterations and Utility Installations, Trade Fixtures, and Lessee's personal property shall be insured by Lessee not by Lessor. If the coverage is available and commercially appropriate, such policy or policies shall insure against all risks of direct physical loss or damage (except the perils of flood and/or earthquake unless required by a Lender), including coverage for debris removal and the enforcement of any Applicable Requirements requiring the upgrading, demolition, reconstruction or replacement of any portion of the Premises as the result of a covered loss. Said policy or policies shall also contain an agreed valuation provision in lieu of any coinsurance clause, waiver of subrogation, and inflation guard protection causing an increase in the annual property insurance coverage amount by a factor of not less than the adjusted U.S. Department of Labor Consumer Price Index for All Urban Consumers for the city nearest to where the Premises are located. If such insurance

coverage has a deductible clause, Lessee shall be liable for such deductible amount in the event of an Insured Loss ~~the deductible amount shall not exceed $5,000 per occurrence~~.

(b) **Rental Value**. Lessor shall also obtain and keep in force a policy or policies in the name of Lessor with loss payable to Lessor and any Lender, insuring the loss of the full Rent for one year with an extended period of indemnity for an additional 180 days ("**Rental Value insurance**"). Said insurance shall contain an agreed valuation provision in lieu of any coinsurance clause, and the amount of coverage shall be adjusted annually to reflect the projected Rent otherwise payable by Lessee, for the next 12 month period.

(c) **Adjacent Premises**. Lessee shall pay for any increase in the premiums for the property insurance of the Building and for the Common Areas or other buildings in the Project if said increase is caused by Lessee's acts, omissions, use or occupancy of the Premises.

(d) **Lessee's Improvements**. Since Lessor is the Insuring Party, Lessor shall not be required to insure Lessee Owned Alterations and Utility Installations unless the item in question has become the property of Lessor under the terms of this Lease.

8.4 **Lessee's Property; Business Interruption Insurance; Worker's Compensation Insurance.**

(a) **Property Damage**. Lessee shall obtain and maintain insurance coverage on all of Lessee's personal property, Trade Fixtures, and Lessee Owned Alterations and Utility Installations. Such insurance shall be full replacement cost coverage with a deductible of not to exceed $ 1, 000 per occurrence. The proceeds from any such insurance shall be used by Lessee for the replacement of personal property, Trade Fixtures and Lessee Owned Alterations and Utility Installations. Lessee shall provide Lessor with written evidence that such insurance is in force.

(b) **Worker's Compensation Insurance.** Lessee shall obtain and maintain Worker's Compensation Insurance in such amount as may be required by Applicable Requirements.

(c) **Business Interruption.** Lessee shall obtain and maintain loss of income and extra expense insurance in amounts as will reimburse Lessee for direct or indirect loss of earnings attributable to all perils commonly insured against by prudent lessees in the business of Lessee or attributable to prevention of access to the Premises as a result of such perils.

(d) **No Representation of Adequate Coverage.** Lessor makes no representation that the limits or forms of coverage of insurance specified herein are adequate to cover Lessee's property, business operations or obligations under this Lease.

8.5 **Insurance Policies.** Insurance required herein shall be by companies maintaining during the policy term a "General Policyholders Rating" of at least A-, VII, as set forth in the most current issue of "Best's Insurance Guide", or such other rating as may be required by a Lender. Lessee shall not do or permit to be done anything which invalidates the required insurance policies. Lessee shall, prior to the Start Date, deliver to Lessor certified copies of policies of such insurance or certificates with copies of the required endorsements evidencing the existence and amounts of the required insurance. No such policy shall be cancelable or subject to modification except after 10 days prior written notice to Lessor. Lessee shall, at least 30 days prior to the expiration of such policies, furnish Lessor with evidence of renewals or "insurance binders" evidencing renewal thereof, or Lessor may order such insurance and charge the cost thereof to Lessee, which amount shall be payable by Lessee to Lessor upon demand. Such policies shall be for a term of at least one year, or the length of the remaining term of this Lease, whichever is less. If either Party shall fail to procure and maintain the insurance required to be carried by it, the other Party may, but shall not be required to, procure and maintain the same.

8.6 **Waiver of Subrogation.** Without affecting any other rights or remedies. Lessee and Lessor each hereby release and relieve the other, and waive their entire right to recover damages against the other, for loss of or damage to its property arising out of or incident to the perils required to be insured against herein. The effect of such releases and waivers is not limited by the amount of insurance carried or required, or by any deductibles applicable hereto. The Parties agree to have their respective property damage insurance carriers waive any right to subrogation that such companies may have against Lessor or Lessee, as the case may be, so long as the insurance is not invalidated thereby.

8.7 **Indemnity.** Except for Lessor's gross negligence or willful misconduct, Lessee shall indemnify, protect, defend and hold harmless the Premises, Lessor and its agents. Lessor's master or ground lessor, partners and Lenders, from and against any and all claims, loss of rents and/or damages, liens, judgments, penalties, attorneys' and consultants' fees, expenses and/or liabilities arising out of, involving, or in connection with, the use and/or occupancy of the Premises by Lessee. If any action or proceeding is brought against Lessor by reason of any of the foregoing matters. Lessee shall upon notice defend the same at Lessee's expense by counsel reasonably satisfactory to Lessor and Lessor shall cooperate with Lessee in such defense. Lessor need not have first paid any such claim in order to be defended or indemnified.

8.8 **Exemption of Lessor and its Agents from Liability.** Notwithstanding the negligence or breach of this Lease by Lessor or its agents, neither Lessor nor its agents shall be liable under any circumstances for: (i) injury or damage to the person or goods, wares, merchandise or other property of Lessee, Lessee's employees, contractors, invitees, customers, or any other person in or about the Premises, whether such damage or injury is caused by or results from fire, steam, electricity, gas, water or rain, indoor air quality, the presence of mold or from the breakage, leakage, obstruction or other defects of pipes, fire sprinklers, wires, appliances, plumbing, HVAC or lighting fixtures, or from any other cause, whether the said injury or damage results from conditions arising upon the Premises or upon other portions of the Building, or from other sources or places, (ii) any damages arising from any act or neglect of any other tenant of Lessor or from the failure of Lessor or its agents to enforce the provisions of any other lease in the Project, or (iii) injury to Lessee's business or for any loss of income or profit therefrom or shall Lessor be liable for consequential or punitive damages. Instead, it is intended that Lessee's sole recourse in the event of such damages or injury be to file a claim on the insurance policy(ies) that Lessee is required to maintain pursuant to the provisions of paragraph 8.

8.9 **Failure to Provide Insurance.** Lessee acknowledges that any failure on its part to obtain or maintain the insurance required herein will expose Lessor to risks and potentially cause Lessor to incur costs not contemplated by this Lease, the extent of which will be extremely difficult to ascertain. Accordingly, for any month or portion thereof that Lessee does not maintain the required insurance and/or does not provide Lessor with the required binders or certificates evidencing the existence of the required insurance, the Base Rent shall be automatically increased, without any requirement for notice to Lessee, by an amount equal to 10% of the then existing Base Rent or $100, whichever is greater. The parties agree that such increase in Base Rent represents fair and reasonable compensation for the additional risk/costs that Lessor will incur by reason of Lessee's failure to maintain the required insurance. Such increase in Base Rent shall in no event constitute a waiver of Lessee's Default or Breach with respect to the failure to maintain such insurance, prevent the exercise of any of the other rights and remedies granted hereunder, nor relieve Lessee of its obligation to maintain the insurance specified in this Lease.

9. **Damage or Destruction.**

9.1 **Definitions.**

(a) "**Premises Partial Damage**" shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations, which can reasonably be repaired in ~~3~~ 6 months or less from the date of the damage or destruction, and the cost thereof does not exceed a sum equal to 6 month's Base Rent. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

(b) "**Premises Total Destruction**" shall mean damage or destruction to the improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which cannot reasonably be repaired in ~~3~~ 6 months or less from the date of the damage or destruction and/or the cost thereof exceeds a sum equal to 6 month's Base Rent. Lessor shall notify Lessee in writing within 30 days from the date of the damage or destruction as to whether or not the damage is Partial or Total.

(c) "**Insured Loss**" shall mean damage or destruction to improvements on the Premises, other than Lessee Owned Alterations and Utility Installations and Trade Fixtures, which was caused by an event required to be covered by the insurance described in Paragraph 8.3(a), irrespective of any deductible amounts or coverage limits involved.

(d) "**Replacement Cost**" shall mean the cost to repair or rebuild the improvements owned by Lessor at the time of the occurrence to their condition existing immediately prior thereto, including demolition, debris removal and upgrading required by the operation of Applicable Requirements, and without deduction for depreciation.

(e) "**Hazardous Substance Condition**" shall mean the occurrence or discovery of a condition involving the presence of, or a contamination by, a Hazardous Substance, in, on, or under the Premises which requires restoration.

9.2 **Partial Damage—Insured Loss.** If a Premises Partial Damage that is an Insured Loss occurs, then Lessor shall, at Lessor's expense, repair such damage (but not Lessee's Trade Fixtures or Lessee Owned Alterations and Utility Installations) as soon as reasonably possible and this Lease shall continue in full force and effect; provided, however, that Lessee shall, at Lessor's election, make the repair of any damage or destruction the total cost to repair of which is $5,000 or less, and, in such event, Lessor shall make any applicable insurance proceeds available to Lessee on a reasonable basis for that purpose. Notwithstanding the foregoing, if the required insurance was not in force or the insurance proceeds are not sufficient to effect such repair, the Insuring Party shall promptly contribute the shortage in proceeds as and when required to complete said repairs. In the event, however, such shortage was due to the fact that, by reason of the unique nature of the improvements, full replacement cost insurance coverage was not commercially reasonable and available, Lessor

shall have no obligation to pay for the shortage in insurance proceeds or to fully restore the unique aspects of the Premises unless Lessee provides Lessor with the funds to cover same, or adequate assurance thereof, within 10 days following receipt of written notice of such shortage and request therefor. If Lessor receives said funds or adequate assurance thereof within said 10 day period, the party responsible for making the repairs shall complete them as soon as reasonably possible and this Lease shall remain in full force and effect. If such funds or assurance are not received, Lessor may nevertheless elect by written notice to Lessee within 10 days thereafter to: (i) make such restoration and repair as is commercially reasonable with Lessor paying any shortage in proceeds, in which case this Lease shall remain in full force and effect, or (ii) have this Lease terminate 30 days thereafter. Lessee shall not be entitled to reimbursement of any funds contributed by Lessee to repair any such damage or destruction. Premises Partial Damage due to flood or earthquake shall be subject to Paragraph 9.3, notwithstanding that there may be some insurance coverage, but the net proceeds of any such insurance shall be made available for the repairs if made by either Party.

9.3 **Partial Damage—Uninsured Loss.** If a Premises Partial Damage that is not an Insured Loss occurs, unless caused by a negligent or willful act of Lessee (in which event Lessee shall make the repairs at Lessee's expense), Lessor may either: (i) repair such damage as soon as reasonably possible at Lessor's expense, in which event this Lease shall continue in full force and effect, or (ii) terminate this Lease by giving written notice to Lessee within 30 days after receipt by Lessor of knowledge of the occurrence of such damage. Such termination shall be effective 60 days following the date of such notice. In the event Lessor elects to terminate this Lease, Lessee shall have the right within 10 days after receipt of the termination notice to give written notice to Lessor of Lessee's commitment to pay for the repair of such damage without reimbursement from Lessor. Lessee shall provide Lessor with said funds or satisfactory assurance thereof within 30 days after making such commitment. In such event this Lease shall continue in full force and effect, and Lessor shall proceed to make such repairs as soon as reasonably possible after the required funds are available. If Lessee does not make the required commitment, this Lease shall terminate as of the date specified in the termination notice.

9.4 **Total Destruction.** Notwithstanding any other provision hereof, if a Premises Total Destruction occurs, this Lease shall terminate 60 days following such Destruction. If the damage or destruction was caused by the gross negligence or willful misconduct of Lessee, Lessor shall have the right to recover Lessor's damages from Lessee, except as provided in Paragraph 8.6.

9.5 **Damage Near End of Term.** If at any time during the last 6 months of this Lease there is damage for which the cost to repair exceeds one month's Base Rent, whether or not an Insured Loss, Lessor may terminate this Lease effective 60 days following the date of occurrence of such damage by giving a written termination notice to Lessee within 30 days after the date of occurrence of such damage. Notwithstanding the foregoing, if Lessee at that time has an exercisable option to extend this Lease or to purchase the Premises, then Lessee may preserve this Lease by, (a) exercising such option and (b) providing Lessor with any shortage in insurance proceeds (or adequate assurance thereof) needed to make the repairs on or before the earlier of (i) the date which is 10 days after Lessee's receipt of Lessor's written notice purporting to terminate this Lease, or (ii) the day prior to the date upon which such option expires. If Lessee duly exercises such option during such period and provides Lessor with funds (or adequate assurance thereof) to cover any shortage in insurance proceeds, Lessor shall, at Lessor's commercially reasonable expense, repair such damage as soon as reasonably possible and this Lease shall continue in full force and effect. If Lessee fails to exercise such option and provide such funds or assurance during such period, then this Lease shall terminate on the date specified in the termination notice and Lessee's option shall be extinguished.

9.6 **Abatement of Rent; Lessee's Remedies.**

(a) **Abatement.** In the event of Premises Partial Damage or Premises Total Destruction or a Hazardous Substance Condition for which Lessee is not responsible under this Lease, the Rent payable by Lessee for the period required for the repair, remediation or restoration of such damage shall be abated in proportion to the degree to which Lessee's use of the Premises is impaired, but not to exceed the proceeds received from the Rental Value insurance. All other obligations of Lessee hereunder shall be performed by Lessee, and Lessor shall have no liability for any such damage, destruction, remediation, repair or restoration except as provided herein.

(b) **Remedies.** If Lessor is obligated to repair or restore the Premises and does not commence, in a substantial and meaningful way, such repair or restoration within 90 days after such obligation shall accrue, Lessee may, at any time prior to the commencement of such repair or restoration, give written notice to Lessor and to any Lenders of which Lessee has actual notice, of Lessee's election to terminate this Lease on a date not less than 60 days following the giving of such notice. If Lessee gives such notice and such repair or restoration is not commenced within 30 days thereafter, this Lease shall terminate as of the date specified in said notice. If the repair or restoration is commenced within such 30 days, this Lease shall continue in full force and effect. "Commence" shall mean either the unconditional authorization of the preparation of the required plans, or the beginning of the actual work on the Premises, whichever first occurs.

9.7 **Termination; Advance Payments**. Upon termination of this Lease pursuant to Paragraph 6.2(g) or Paragraph 9, an equitable adjustment shall be made concerning advance Base Rent and any other advance payments made by Lessee to Lessor. Lessor shall, in addition, return to Lessee so much of Lessee's Security Deposit as has not been, or is not then required to be, used by Lessor.

10. **Real Property Taxes.**

10.1 **Definitions.** As used herein, the term "**Real Property Taxes**" shall include any form of assessment; real estate, general, special, ordinary or extraordinary, or rental levy or tax (other than inheritance, personal income or estate taxes); improvement bond; and/or license fee imposed upon or levied against any legal or equitable interest of Lessor in the Project, Lessor's right to other income therefrom, and/or Lessor's business of leasing, by any authority having the direct or indirect power to tax and where the funds are generated with reference to the Project address ~~and where the proceeds so generated are to be applied by the city, county or other local taxing authority of a jurisdiction within which the Project is located~~. **"Real Property Taxes"** shall also include any tax, fee, levy, assessment or charge, or any increase therein: (i) imposed by reason of events occurring during the term of this Lease, including but not limited to, a change in the ownership of the Project, (ii) a change in the improvements thereon, and/or (iii) levied or assessed on machinery or equipment provided by Lessor to Lessee pursuant to this Lease.

10.2 **Payment of Taxes.** Except as otherwise provided in Paragraph 10.3, Lessor shall pay the Real Property Taxes applicable to the Project, and said payments shall be included in the calculation of Operating Expenses in accordance with the provisions of Paragraph 4.2.

10.3 **Additional Improvements.** Operating Expenses shall not include Real Property Taxes specified in the tax assessor's records and work sheets as being caused by additional improvements placed upon the Project by other lessees or by Lessor for the exclusive enjoyment of such other lessees. Notwithstanding Paragraph 10.2 hereof, Lessee shall, however, pay to Lessor at the time Operating Expenses are payable under Paragraph 4.2, the entirety of any increase in Real Property Taxes if assessed solely by reason of Alterations, Trade Fixtures or Utility Installations placed upon the Premises by Lessee or at Lessee's request or by reason of any alterations or improvements to the Premises made by Lessor subsequent to the execution of this Lease by the Parties.

10.4 **Joint Assessment**. If the Building is not separately assessed. Real Property Taxes allocated to the Building shall be an equitable proportion of the Real Property Taxes for all of the land and improvements included within the tax parcel assessed, such proportion to be determined by Lessor from the respective valuations assigned in the assessor's work sheets or such other information as may be reasonably available. Lessor's reasonable determination thereof, in good faith, shall be conclusive.

10.5 **Personal Property Taxes.** Lessee shall pay prior to delinquency all taxes assessed against and levied upon Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all personal property of Lessee contained in the Premises. When possible, Lessee shall cause its Lessee Owned Alterations and Utility Installations, Trade Fixtures, furnishings, equipment and all other personal property to be assessed and billed separately from the real property of Lessor. If any of Lessee's said property shall be assessed with Lessor's real property, Lessee shall pay Lessor the taxes attributable to Lessee's property within 10 days after receipt of a written statement setting forth the taxes applicable to Lessee's property.

11. **Utilities and Services.**

11.1 **Services Provided by Lessor.** Lessor shall provide (i) heating, ventilation, air conditioning, (ii) reasonable amounts of electricity for normal lighting and office machines, and (iii) water for reasonable and normal drinking and lavatory use in connection with an office in each case, during only those hours set forth in Section 1.12 of this Lease, and replacement light bulbs and/or fluorescent tubes and ballasts for standard overhead fixtures. Lessor shall also provide janitorial services to the ~~Premises and~~ Common Areas ~~5 times per week, excluding Building Holidays, or pursuant to the attached janitorial schedule, if any.~~ Lessor shall not, however, be required to provide janitorial services to ~~kitchens or storage areas included within~~ any portion of the Premises.

11.2 **Services Exclusive to Lessee.** Lessee shall pay for all water, gas, light, power, telephone and other utilities and services specially or exclusively supplied and/or metered exclusively to the Premises or to Lessee, together with any taxes thereon. If a service is deleted by Paragraph 1.13 and such service is not separately metered to the Premises, Lessee shall pay at Lessor's option, either Lessee's Share or a reasonable proportion to be determined by Lessor of all charges for such jointly metered service.

11.3 ~~**Hours of Service**. Said services and utilities shall be provided during times set forth in Paragraph 1.12. Utilities and services required at other times shall be subject to advance request and reimbursement by Lessee to Lessor of the cost thereof.~~

11.4 **Excess Usage by Lessee.** Lessee shall not make connection to the utilities except by or through existing outlets and shall not install or use machinery or equipment in or about the Premises that uses excess water, lighting or power, or suffer or permit any act that causes extra burden upon the utilities or services, including but not limited to security and trash services, over standard office usage for the Project. Lessor shall require Lessee to reimburse Lessor for any excess expenses or costs that may arise out of a breach of this subparagraph by Lessee. Lessor may, in its sole discretion, install at Lessee's expense supplemental equipment and/or separate metering applicable to Lessee's excess usage or loading.

11.5 **Interruptions.** There shall be no abatement of rent and Lessor shall not be liable in any respect whatsoever for the inadequacy, stoppage, interruption or discontinuance of any utility or service due to riot, strike, labor dispute, breakdown, accident, repair or other cause beyond Lessor's reasonable control or in cooperation with governmental request or directions.

12. **Assignment and Subletting.**

12.1 **Lessor's Consent Required.**

(a) Lessee shall not voluntarily or by operation of law assign, transfer, mortgage or encumber (collectively,"**assign or assignment**") or sublet all or any part of Lessee's interest in this Lease or in the Premises without Lessor's prior written consent.

(b) Unless Lessee is a corporation and its stock is publicly traded on a national stock exchange, a change in the control of Lessee shall constitute an assignment requiring consent. The transfer, on a cumulative basis, of 25% or more of the voting control of Lessee shall constitute a change in control for this purpose.

(c) The involvement of Lessee or its assets in any transaction, or series of transactions (by way of merger, sale, acquisition, financing, transfer, leveraged buyout or otherwise), whether or not a formal assignment or hypothecation of this Lease or Lessee's assets occurs, which results or will result in a reduction of the Net Worth of Lessee by an amount greater than 25% of such Net Worth as it was represented at the time of the execution of this Lease or at the time of the most recent assignment to which Lessor has consented, or as it exists immediately prior to said transaction or transactions constituting such reduction, whichever was or is greater, shall be considered an assignment of this Lease to which Lessor may withhold its consent. "**Net Worth of Lessee**" shall mean the net worth of Lessee (excluding any guarantors) established under generally accepted accounting principles.

(d) An assignment or subletting without consent shall, at Lessor's option, be a Default curable after notice per Paragraph 13.1(c), or a noncurable Breach without the necessity of any notice and grace period. If Lessor elects to treat such unapproved assignment or subletting as a noncurable Breach, Lessor may either: (i) terminate this Lease, or (ii) upon 30 days written notice, increase the monthly Base Rent to 110% of the Base Rent then in effect. Further, in the event of such Breach and rental adjustment, (i) the purchase price of any option to purchase the Premises held by Lessee shall be subject to similar adjustment to 110% of the price previously in effect, and (ii) all fixed and non-fixed rental adjustments scheduled during the remainder of the Lease term shall be increased to 110% of the scheduled adjusted rent.

(e) Lessee's remedy for any breach of Paragraph 12.1 by Lessor shall be limited to compensatory damages and/or injunctive relief.

(f) Lessor may reasonably withhold consent to a proposed assignment or subletting if Lessee is in Default at the time consent is requested.

(g) Notwithstanding the foregoing, allowing a de minimis portion of the Premises, i e. 20 square feet or less, to be used by a third party vendor in connection with the installation of a vending machine or payphone shall not constitute a subletting.

12.2 **Terms and Conditions Applicable to Assignment and Subletting**.

(a) Regardless of Lessor's consent, no assignment or subletting shall: (i) be effective without the express written assumption by such assignee or sublessee of the obligations of Lessee under this Lease, (ii) release Lessee of any obligations hereunder, or (iii) alter the primary liability of Lessee for the payment of Rent or for the performance of any other obligations to be performed by Lessee.

(b) Lessor may accept Rent or performance of Lessee's obligations from any person other than Lessee pending approval or disapproval of an assignment. Neither a delay in the approval or disapproval of such assignment nor the acceptance of Rent or performance shall constitute a waiver or estoppel of Lessor's right to exercise its remedies for Lessee's Default or Breach.

(c) Lessor's consent to any assignment or subletting shall not constitute a consent to any subsequent assignment or subletting.

(d) In the event of any Default or Breach by Lessee, Lessor may proceed directly against Lessee, any Guarantors or anyone else responsible for the performance of Lessee's obligations under this Lease, including any assignee or sublessee, without first exhausting Lessor's remedies against any other person or entity responsible therefore to Lessor, or any security held by Lessor.

(e) Each request for consent to an assignment or subletting shall be in writing, accompanied by information relevant to Lessor's determination as to the financial and operational responsibility and appropriateness of the proposed assignee or sublessee, including but not limited to the intended use and/or required modification of the Premises, if any, together with a fee of $500 as consideration for Lessor's considering and processing said request. Lessee agrees to provide Lessor with such other or additional information and/or documentation as may be reasonably requested. (See also Paragraph 36)

(f) Any assignee of, or sublessee under, this Lease shall, by reason of accepting such assignment, entering into such sublease, or entering into possession of the Premises or any portion thereof, be deemed to have assumed and agreed to conform and comply with each and every term, covenant, condition and obligation herein to be observed or performed by Lessee during the term of said assignment or sublease, other than such obligations as are contrary to or inconsistent with provisions of an assignment or sublease to which Lessor has specifically consented to in writing.

(g) Lessor's consent to any assignment or subletting shall not transfer to the assignee or sublessee any Option granted to the original Lessee by this Lease unless such transfer is specifically consented to by Lessor in writing. (See Paragraph 39.2)

12.3 **Additional Terms and Conditions Applicable to Subletting**. The following terms and conditions shall apply to any subletting by Lessee of all or any part of the Premises and shall be deemed included in all subleases under this Lease whether or not expressly incorporated therein:

(a) Lessee hereby assigns and transfers to Lessor all of Lessee's interest in all Rent payable on any sublease, and Lessor may collect such Rent and apply same toward Lessee's obligations under this Lease; provided, however, that until a Breach shall occur in the performance of Lessee's obligations, Lessee may collect said Rent. In the event that the amount collected by Lessor exceeds Lessee's then outstanding obligations any such excess shall be refunded to Lessee. Lessor shall not, by reason of the foregoing or any assignment of such sublease, nor by reason of the collection of Rent, be deemed liable to the sublessee for any failure of Lessee to perform and comply with any of Lessee's obligations to such sublessee. Lessee hereby irrevocably authorizes and directs any such sublessee, upon receipt of a written notice from Lessor stating that a Breach exists in the performance of Lessee's obligations under this Lease, to pay to Lessor all Rent due and to become due under the sublease. Sublessee shall rely upon any such notice from Lessor and shall pay all Rents to Lessor without any obligation or right to inquire as to whether such Breach exists, notwithstanding any claim from Lessee to the contrary.

(b) In the event of a Breach by Lessee, Lessor may, at its option, require sublessee to attorn to Lessor, in which event Lessor shall undertake the obligations of the sublessor under such sublease from the time of the exercise of said option to the expiration of such sublease; provided, however, Lessor shall not be liable for any prepaid rents or security deposit paid by such sublessee to such sublessor or for any prior Defaults or Breaches of such sublessor.

(c) Any matter requiring the consent of the sublessor under a sublease shall also require the consent of Lessor.

(d) No sublessee shall further assign or sublet all or any part of the Premises without Lessor's prior written consent.

(e) Lessor shall shall not be required to deliver a copy of any notice of Default or Breach by Lessee to the sublessee, who shall not have the right to cure ~~the~~ any Default of Lessee ~~within the grace period, if any, specified in such notice. The sublessee shall have a right of reimbursement and offset from and against Lessee for any such Defaults cured by the sublessee~~.

13. **Default; Breach; Remedies**.

13.1 **Default; Breach.** A "**Default**" is defined as a failure by the Lessee to comply with or perform any of the terms, covenants, conditions or Rules and Regulations under this Lease. A "**Breach**" is defined as the occurrence of one or more of the following Defaults, and the failure of Lessee to cure such Default within any applicable grace period:

(a) The abandonment of the Premises; or the vacating of the Premises without providing a commercially reasonable level of security, or where the coverage of the property insurance described in Paragraph 8.3 is jeopardized as a result thereof, or without providing reasonable assurances to minimize potential vandalism, or where Lessor reasonably determines that such abandonment materially and adversely impacts Lessor's ability to sell or obtain financing for the Premises or any portion thereof.

(b) The failure of Lessee to make any payment of Rent or any Security Deposit required to be made by Lessee hereunder , whether to Lessor or to a third party, when due, to provide reasonable evidence of insurance or surety bond, or to fulfill any obligation under this Lease which endangers or threatens life or property, where such failure continues for a period of 3 business days following written notice to Lessee. THE ACCEPTANCE BY LESSOR OF A PARTIAL PAYMENT OF RENT OR SECURITY DEPOSIT SHALL NOT CONSTITUTE A WAIVER OF ANY OF LESSOR'S RIGHTS, INCLUDING LESSOR'S RIGHT TO RECOVER POSSESSION OF THE PREMISES.

(c) The failure of Lessee to allow Lessor and/or its agents access to the Premises or the commission of waste, act or acts constituting public or private nuisance, and/or an illegal activity on the Premises by Lessee, where such actions continue for a period of 3 business days following written notice to Lessee.

(d) The failure by Lessee to provide (i) reasonable written evidence of compliance with Applicable Requirements, (ii) the service contracts, (iii) the rescission of an unauthorized assignment or subletting, (iv) an Estoppel Certificate or financial statements, (v) a requested subordination, (vi) evidence concerning any guaranty and/or Guarantor, (vii) any document requested under Paragraph 41, (viii) material data safety sheets (MSDS), or

(ix) any other documentation or information which Lessor may reasonably require of Lessee under the terms of this Lease, where any such failure continues for a period of 10 days following written notice to Lessee.

(e) A Default by Lessee as to the terms, covenants, conditions or provisions of this Lease, or of the rules adopted under Paragraph 2.9 hereof, other than those described in subparagraphs 13.1(a), (b) or (c), above, where such Default continues for a period of 30 days after written notice; provided, however, that if the nature of Lessee's Default is such that more than 30 days are reasonably required for its cure, then it shall not be deemed to be a Breach if Lessee commences such cure within said 30 day period and thereafter diligently prosecutes such cure to completion.

(f) The occurrence of any of the following events: (i) the making of any general arrangement or assignment for the benefit of creditors; (ii) becoming a "**debtor**" as defined in 11 U.S.C. § 101 or any successor statute thereto (unless, in the case of a petition filed against Lessee, the same is dismissed within 60 days); (iii) the appointment of a trustee or receiver to take possession of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where possession is not restored to Lessee within 30 days; or (iv) the attachment, execution or other judicial seizure of substantially all of Lessee's assets located at the Premises or of Lessee's interest in this Lease, where such seizure is not discharged within 30 days; provided, however, in the event that any provision of this subparagraph is contrary to any applicable law, such provision shall be of no force or effect, and not affect the validity of the remaining provisions.

(g) The discovery that any financial statement of Lessee or of any Guarantor given to Lessor was materially false.

(h) If the performance of Lessee's obligations under this Lease is guaranteed: (i) the death of a Guarantor, (ii) the termination of a Guarantor's liability with respect to this Lease other than in accordance with the terms of such guaranty, (iii) a Guarantors becoming insolvent or the subject of a bankruptcy filing, (iv) a Guarantor's refusal to honor the guaranty, or (v) a Guarantors breach of its guaranty obligation on an anticipatory basis, and Lessee's failure, within 60 days following written notice of any such event, to provide written alternative assurance or security, which, when coupled with the then existing resources of Lessee, equals or exceeds the combined financial resources of Lessee and the Guarantors that existed at the time of execution of this Lease.

13.2 **Remedies**., If Lessee fails to perform any of its affirmative duties or obligations, within 10 days after written notice (or in case of an emergency, without notice), Lessor may, at its option, perform such duty or obligation on Lessee's behalf, including but not limited to the obtaining of reasonably required bonds, insurance policies, or governmental licenses, permits or approvals. Lessee shall pay to Lessor an amount equal to 115% of the costs and expenses incurred by Lessor in such performance upon receipt of an invoice therefor. In the event of a Breach, Lessor may, with or without further notice or demand, and without limiting Lessor in the exercise of any right or remedy which Lessor may have by reason of such Breach:

(a) Terminate Lessee's right to possession of the Premises by any lawful means, in which case this Lease shall terminate and Lessee shall immediately surrender possession to Lessor. In such event Lessor shall be entitled to recover from Lessee: (i) the unpaid Rent which had been earned at the time of termination; (ii) the worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that the Lessee proves could have been reasonably avoided; (iii) the worth at the time of award of the amount by which the unpaid rent for the balance of the term after the time of award exceeds the amount of such rental loss that the Lessee proves could be reasonably avoided; and (iv) any other amount necessary to compensate Lessor for all the detriment proximately caused by the Lessee's failure to perform its obligations under this Lease or which in the ordinary course of things would be likely to result therefrom, including but not limited to the cost of recovering possession of the Premises, expenses of reletting, including necessary renovation and alteration of the Premises, reasonable attorneys' fees, and that portion of any leasing commission paid by Lessor in connection with this Lease applicable to the unexpired term of this Lease. The worth at the time of award of the amount referred to in provision (iii) of the immediately preceding sentence shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of the District within which the Premises are located at the time of award plus one percent. Efforts by Lessor to mitigate damages caused by Lessee's Breach of this Lease shall not waive Lessor's right to recover damages under Paragraph 12. If termination of this Lease is obtained through the provisional remedy of unlawful detainer, Lessor shall have the right to recover in such proceeding any unpaid Rent and damages as are recoverable therein, or Lessor may reserve the right to recover all or any part thereof in a separate suit. If a notice and grace period required under Paragraph 13.1 was not previously given, a notice to pay rent or quit, or to perform or quit given to Lessee under the unlawful detainer statute shall also constitute the notice required by Paragraph 13.1. In such case , the applicable grace period required by Paragraph 13.1 and the unlawful detainer statute shall run concurrently, and the failure of Lessee to cure the Default within the greater of the two such grace periods shall constitute both an unlawful detainer and a Breach of this Lease entitling Lessor to the remedies provided for in this Lease and/or by said statute.

(b) Continue the Lease and Lessee's right to possession and recover the Rent as it becomes due, in which event Lessee may sublet or assign, subject only to reasonable limitations. Acts of maintenance, efforts to relet, and/or the appointment of a receiver to protect the Lessor's interests, shall not constitute a termination of the Lessee's right to possession.

(c) Pursue any other remedy now or hereafter available under the laws or judicial decisions of the state wherein the Premises are located. The expiration or termination of this Lease and/or the termination of Lessee's right to possession shall not relieve Lessee from liability under any indemnity provisions of this Lease as to matters occurring or accruing during the term hereof or by reason of Lessee's occupancy of the Premises.

13.3 **Inducement Recapture**. Any agreement for free or abated rent or other charges, or for the giving or paying by Lessor to or for Lessee of any cash or other bonus, inducement or consideration for Lessee's entering into this Lease, all of which concessions are hereinafter referred to as "**Inducement Provisions**", shall be deemed conditioned upon Lessee's full and faithful performance of all of the terms, covenants and conditions of this Lease. Upon Breach of this Lease by Lessee, any such Inducement Provision shall automatically be deemed deleted from this Lease and of no further force or effect, and any rent, other charge, bonus, inducement or consideration theretofore abated, given or paid by Lessor under such an Inducement Provision shall be immediately due and payable by Lessee to Lessor, notwithstanding any subsequent cure of said Breach by Lessee. The acceptance by Lessor of rent or the cure of the Breach which initiated the operation of this paragraph shall not be deemed a waiver by Lessor of the provisions of this paragraph unless specifically so stated in writing by Lessor at the time of such acceptance.

13.4 **Late Charges**. Lessee hereby acknowledges that late payment by Lessee of Rent will cause Lessor to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult to ascertain. Such costs include, but are not limited to, processing and accounting charges, and late charges which may be imposed upon Lessor by any Lender. Accordingly, if any Rent shall not be received by Lessor within 5 days after such amount shall be due, then, without any requirement for notice to Lessee, Lessee shall immediately pay to Lessor a one-time late charge equal to 10% of each such overdue amount or $100, whichever is greater. The parties hereby agree that such late charge represents a fair and reasonable estimate of the costs Lessor will incur by reason of such late payment. Acceptance of such late charge by Lessor shall in no event constitute a waiver of Lessee's Default or Breach with respect to such overdue amount, nor prevent the exercise of any of the other rights and remedies granted hereunder. In the event that a late charge is payable hereunder, whether or not collected, for 3 consecutive installments of Base Rent, then notwithstanding any provision of this Lease to the contrary, Base Rent shall, at Lessor's option, become due and payable quarterly in advance.

13.5 **Interest**. Any monetary payment due Lessor hereunder, other than late charges, not received by Lessor, when due as to scheduled payments (such as Base Rent) or within 30 days following the date on which it was due for nonscheduled payment, shall bear interest from the date when due, as to scheduled payments, or the 31st day after it was due as to nonscheduled payments. The interest ("Interest") charged shall be computed at the rate of 10% per annum but shall not exceed the maximum rate allowed by law. Interest is payable in addition to the potential late charge provided for in Paragraph 13.4.

13.6 **Breach by Lessor**.

(a) **Notice of Breach**. Lessor shall not be deemed in breach of this Lease unless Lessor fails within a reasonable time to perform an obligation required to be performed by Lessor. For purposes of this Paragraph, a reasonable time shall in no event be less than 30 days after receipt by Lessor, and any Lender whose name and address shall have been furnished Lessee in writing for such purpose, of written notice specifying wherein such obligation of Lessor has not been performed; provided, however, that if the nature of Lessor's obligation is such that more than 30 days are reasonably required for its performance, then Lessor shall not be in breach if performance is commenced within such 30 day period and thereafter diligently pursued to completion.

(b) **Performance by Lessee on Behalf of Lessor**. In the event that neither Lessor nor Lender cures said breach within 30 days after receipt of said notice, or if having commenced said cure they do not diligently pursue it to completion, then Lessee may deliver an additional written notice to Lessor and Lender that Lessee intends to cure said breach at Lessor's expense if Lessor or Lender fail to commence to cure such breach within five (5) business days following their respective receipt of such additional notice. If Lessee delivers said additional notice and neither Lessor nor Lender cures said breach, or if having commenced to cure they do not diligently pursue it to completion, within such additional five (5) day period, then Lessee may elect to cure said breach at Lessee's expense and offset from Rent the actual and reasonable cost to perform such cure, provided however , that such offset shall not exceed an amount equal to the greater of one month's Base Rent or the Security Deposit, reserving Lessee's right to seek reimbursement from Lessor for any such expense in excess of such offset. Lessee shall document the cost of said cure and supply said documentation to Lessor. Lessee's sole remedy for a breach by Lessor shall be to cure the breach as provided in this Paragraph 13.6(b) and Lessee shall have no right to terminate the Lease by reason thereof.

14. **Condemnation**. If the Premises or any portion thereof are taken under the power of eminent domain or sold under the threat of the exercise of said power (collectively "**Condemnation**"), this Lease shall terminate as to the part taken as of the date the condemning authority takes title or possession, whichever first occurs. If more than 10% of the rentable floor area of the Premises, or more than 25% of Lessee's Reserved Parking Spaces, if any, are taken by Condemnation, Lessee may, at Lessee's option, to be exercised in writing within 10 days after Lessor shall have given Lessee written notice of such taking (or in the absence of such notice, within 10 days after the condemning authority shall have taken possession) terminate this Lease as of the date the condemning authority takes such possession. If Lessee does not terminate this Lease in accordance with the foregoing, this Lease shall remain in full force and effect as to the portion of the Premises remaining, except that the Base Rent shall be reduced in proportion to the reduction in utility of the Premises caused by such Condemnation. Condemnation awards and/or payments shall be the property of Lessor, whether such award shall be made as compensation for diminution in value of the leasehold, the value of the part taken, or for severance damages; provided, however, that Lessee shall be entitled to any compensation paid by the condemnor for Lessee's relocation expenses, loss of business goodwill and/or Trade Fixtures, without regard to whether or not this Lease is terminated pursuant to the provisions of this Paragraph. All Alterations and Utility Installations made to the Premises by Lessee, for purposes of

Condemnation only, shall be considered the property of the Lessee and Lessee shall be entitled to any and all compensation which is payable therefor. In the event that this Lease is not terminated by reason of the Condemnation, Lessor shall repair any damage to the Premises caused by such Condemnation.

15. **Brokerage Fees**.

15.1 ~~**Additional Commission**. If a separate brokerage fee agreement is attached then in addition to the payments owed pursuant to Paragraph 1.10 above, and unless Lesser and the Brokers otherwise agree in writing, Lessor agrees that: (a) if Lessee exercises any Option, (b) if Lessee or anyone affiliated with Lessee acquires from Lesser any rights to the Promises or other promises owned by Lessor and located within the Project, (c) if Lessee remains in possession of the Premises, with the consent of Lesser, after the expiration of this Lease, or (d) if Base Rent is increased, whether by agreement or operation of an escalation clause herein, then, Lesser shall pay Brokers a fee in accordance with the schedule attached to such brokerage fee agreement~~.

15.2 ~~**Assumption of Obligations**. Any buyer or transferee of Lesser's interest in this Lease shall be deemed to have assumed Lesser's obligation hereunder. Brokers shall be third party beneficiaries of the provisions of Paragraphs 1.10, 15, 22 and 31. If Lessor fails to pay to Brokers any amounts due as and for brokerage fees pertaining to this Lease when due, then such amounts shall accrue Interest. In addition, if Lesser fails to pay any amounts to Lessee's Broker when due, Lessee's Broker may send written notice to Lessor and Lessee of such failure and if Lessor fails to pay such amounts within 10 days after said notice, Lessee, shall pay said monies to its Broker and offset such amounts against Rent. In addition, Lessee's Broker shall be deemed to be a third party beneficiary of any commission agreement entered into by and/or between Lesser and Lessor's Broker for the limited purpose of collecting any brokerage fee owed~~.

15.3 **Representations and Indemnities of Broker Relationships**. Lessee and Lessor each represent and warrant to the other that it has had no dealings with any person, firm, broker or finder (other than the Brokers, if any) in connection with this Lease, and that no one other than said named Brokers is entitled to any commission or finder's fee in connection herewith. Lessee and Lessor do each hereby agree to indemnify, protect, defend and hold the other harmless from and against liability for compensation or charges which may be claimed by any such unnamed broker, finder or other similar party by reason of any dealings or actions of the indemnifying Party, including any costs, expenses, attorneys' fees reasonably incurred with respect thereto.

16. **Estoppel Certificates.**

(a) Each Party (as "**Responding Party**") shall within 10 days after written notice from the other Party (the "**Requesting Party**") execute, acknowledge and deliver to the Requesting Party a statement in writing in form similar to the then most current "**Estoppel Certificate**" form published by the AIRCommercial Real Estate Association, plus such additional information, confirmation and/or statements as may be reasonably requested by the Requesting Party.

(b) If the Responding Party shall fail to execute or deliver the Estoppel Certificate within such 10 day period, the Requesting Party may execute an Estoppel Certificate stating that: (i) the Lease is in full force and effect without modification except as may be represented by the Requesting Party, (ii) there are no uncured defaults in the Requesting Party's performance, and (iii) if Lessor is the Requesting Party, not more than one month's rent has been paid in advance. Prospective purchasers and encumbrancers may rely upon the Requesting Party's Estoppel Certificate, and the Responding Party shall be estopped from denying the truth of the facts contained in said Certificate.

(c) If Lessor desires to finance, refinance, or sell the Premises, or any part thereof, Lessee and all Guarantors shall within 10 days after written notice from Lessor deliver to any potential lender or purchaser designated by Lessor such financial statements as may be reasonably required by such lender or purchaser, including but not limited to Lessee's financial statements for the past 3 years. All such financial statements shall be received by Lessor and such lender or purchaser in confidence and shall be used only for the purposes herein set forth.

17. **Definition of Lessor**. The term "**Lessor**" as used herein shall mean the owner or owners at the time in question of the fee title to the Premises, or, if this is a sublease, of the Lessee's interest in the prior lease. In the event of a transfer of Lessor's title or interest in the Premises or this Lease, Lessor shall deliver to the transferee or assignee (in cash or by credit) any unused Security Deposit held by Lessor. Upon such transfer or assignment and delivery of the Security Deposit, as aforesaid, the prior Lessor shall be relieved of all liability with respect to the obligations and/or covenants under this Lease thereafter to be performed by the Lessor. Subject to the foregoing, the obligations and/or covenants in this Lease to be performed by the Lessor shall be binding only upon the Lessor as hereinabove defined.

18. **Severability**. The invalidity of any provision of this Lease, as determined by a court of competent jurisdiction, shall in no way affect the validity of any other provision hereof.

19. **Days**. Unless otherwise specifically indicated to the contrary, the word "**days**" as used in this Lease shall mean and refer to calendar days.

20. **Limitation on Liability**. The obligations of Lessor under this Lease shall not constitute personal obligations of Lessor or its partners, members, directors, officers or shareholders, and Lessee shall look to the Project, and to no other assets of Lessor, for the satisfaction of any liability of Lessor with respect to this Lease, and shall not seek recourse against Lessor's partners, members, directors, officers or shareholders, or any of their personal assets for such satisfaction. For purposes of determining the value of lessor's interest in the Premises, the Project shall be deemed to be encumbered by a loan amount equal to seventy percent (70%) of the fair market value of the Project, as determined as of the date lessee's claim arises.

21. **Time of Essence**. Time is of the essence with respect to the performance of all obligations to be performed or observed by the Parties under this Lease.

22. **No Prior or Other Agreements; Broker Disclaimer**. This Lease contains all agreements between the Parties with respect to any matter mentioned herein, and no other prior or contemporaneous agreement or understanding shall be effective. ~~Lesser and Lessee each represents and warrants to the Brokers that it has made, and is relying solely upon, its own investigation as to the nature, quality, character and financial responsibility of the other Party to this Lease and as to the use, nature, quality and character of the Promises. Brokers have no responsibility with respect thereto or with respect to any default or broach hereof by either Party.~~

23. **Notices**.

23.1 **Notice Requirements**. All notices required or permitted by this Lease or applicable law shall be in writing and may be delivered in person (by hand or by courier) or may be sent by regular, certified or registered mail or U.S. Postal Service Express Mail, with postage prepaid, or by facsimile transmission, and shall be deemed sufficiently given if served in a manner specified in this Paragraph 23. The addresses noted adjacent to a Party's signature on this Lease shall be that Party's address for delivery or mailing of notices. Either Party may by written notice to the other specify a different address for notice, except that upon Lessee's taking possession of the Premises, the Premises shall constitute Lessee's address for notice. A copy of all notices to Lessor shall be concurrently transmitted to such party or parties at such addresses as Lessor may from time to time hereafter designate in writing.

23.2 **Date of Notice**. Any notice sent by registered or certified mail, return receipt requested, shall be deemed given on the date of delivery shown on the receipt card, or if no delivery date is shown, the postmark thereon. If sent by regular mail the notice shall be deemed given 72 hours after the same is addressed as required herein and mailed with postage prepaid. Notices delivered by United States Express Mail or overnight courier that guarantees next day delivery shall be deemed given 24 hours after delivery of the same to the Postal Service or courier. Notices transmitted by facsimile transmission or similar means shall be deemed delivered upon telephone confirmation of receipt (confirmation report from fax machine is sufficient), provided a copy is also delivered via delivery or mail. If notice is received on a Saturday, Sunday or legal holiday, it shall be deemed received on the next business day.

24. **Waivers**.

(a) No waiver by Lessor of the Default or Breach of any term, covenant or condition hereof by Lessee, shall be deemed a waiver of any other term, covenant or condition hereof, or of any subsequent Default or Breach by Lessee of the same or of any other term, covenant or condition hereof. Lessor's consent to, or approval of, any act shall not be deemed to render unnecessary the obtaining of Lessor's consent to, or approval of, any subsequent or similar act by Lessee, or be construed as the basis of an estoppel to enforce the provision or provisions of this Lease requiring such consent.

(b) The acceptance of Rent by Lessor shall not be a waiver of any Default or Breach by Lessee. Any payment by Lessee may be accepted by Lessor on account of moneys or damages due Lessor, notwithstanding any qualifying statements or conditions made by Lessee in connection therewith, which such statements and/or conditions shall be of no force or effect whatsoever unless specifically agreed to in writing by Lessor at or before the time of deposit of such payment.

(c) THE PARTIES AGREE THAT THE TERMS OF THIS LEASE SHALL GOVERN WITH REGARD TO ALL MATTERS RELATED THERETO AND HEREBY WAIVE THE PROVISIONS OF ANY PRESENT OR FUTURE STATUTE TO THE EXTENT THAT SUCH STATUTE IS INCONSISTENT WITH THIS LEASE.

25. **Disclosures Regarding The Nature of a Real Estate Agency Relationship**.

(a) When entering into a discussion with a real estate agent regarding a real estate transaction, a Lessor or Lessee should from the outset

understand what type of agency relationship or representation it has with the agent or agents in the transaction. Lessor and Lessee acknowledge being advised by the Brokers in this transaction, as follows:

(i) Lessor's Agent. A Lessor's agent under a listing agreement with the Lessor acts as the agent for the Lessor only. A Lessor's agent or subagent has the following affirmative obligations: To the Lessor: A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Lessor. To the Lessee and the Lessor: a. Diligent exercise of reasonable skills and care in performance of the agent's duties. b. A duty of honest and fair dealing and good faith, c. A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential information obtained from the other Party which does not involve the affirmative duties set forth above.

(ii) Lessee's Agent. An agent can agree to act as agent for the Lessee only. In these situations, the agent is not the Lessor's agent, even if by agreement the agent may receive compensation for services rendered, either in full or in part from the Lessor. An agent acting only for a Lessee has the following affirmative obligations. To the Lessee: A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Lessee.To the Lessee and the Lessor: a. Diligent exercise of reasonable skills and care in performance of the agent's duties. b. A duty of honest and fair dealing and good faith.,c. A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the Parties. An agent is not obligated to reveal to either Party any confidential information obtained from the other Party which does not involve the affirmative duties set forth above.

(iii) Agent Representing Both Lessor and Lessee. A real estate agent, either acting directly or through one or more associate licenses, can legally be the agent of both the Lessor and the Lessee in a transaction, but only with the knowledge and consent of both the Lessor and the Lessee. In a dual agency situation, the agent has the following affirmative obligations to both the Lessor and the Lessee: a. A fiduciary duty of utmost care, integrity, honesty and loyalty in the dealings with either Lesser or the Lessee. b. Other duties to the Lessor and the Lessee as stated above in subparagraphs (i) or (ii). In representing both Lessor and Lessee, the agent may not without the express permission of the respective Party, disclose to the other Party that the Lessor will accept rent in an amount less than that indicated in the listing or that the Lessee is willing to pay a

higher rent than that offered. The above duties of the agent in a real estate transaction do not relieve a Lessor or Lessee from the responsibility to protect their own interests. Lessor and Lessee should carefully read all agreements to assure that they adequately express their understanding of the transaction. A real estate agent is a person qualified to advise about real estate. If legal or tax advise is desired, consult a competent professional.

~~(b) Brokers have no responsibility with respect to any default or breach hereof by either Party. The Parties agree that no lawsuit or other legal proceeding involving any breach of duty, error or omission relating to this Lease may be brought against Broker more than one year after the Start Date and that the liability (including court costs and attorneys' fees), of any Broker with respect to any such lawsuit and/or legal proceeding shall not exceed the fee received by ouch Broker pursuant to this Lease; provided, however, that the foregoing limitation on each Broker's liability shall not be applicable to any gross negligence or willful misconduct of such Broker.~~

~~(c) Lessor and Lessee agree to identify to Brokers as "Confidential" any communication or information given Brokers that is considered by such Party to be confidential.~~

26. **No Right To Holdover**. Lessee has no right to retain possession of the Premises or any part thereof beyond the expiration or termination of this Lease. In the event that Lessee holds over, then the Base Rent shall be increased to 150% of the Base Rent applicable immediately preceding the expiration or termination. Nothing contained herein shall be construed as consent by Lessor to any holding over by Lessee.

27. **Cumulative Remedies**. No remedy or election hereunder shall be deemed exclusive but shall, wherever possible, be cumulative with all other remedies at law or in equity.

28. **Covenants and Conditions; Construction of Agreement**. All provisions of this Lease to be observed or performed by Lessee are both covenants and conditions. In construing this Lease, all headings and titles are for the convenience of the Parties only and shall not be considered a part of this Lease. Whenever required by the context, the singular shall include the plural and vice versa. This Lease shall not be construed as if prepared by one of the Parties, but rather according to its fair meaning as a whole, as if both Parties had prepared it.

29. **Binding Effect; Choice of Law**. This Lease shall be binding upon the Parties, their personal representatives, successors and assigns and be governed by the laws of the State in which the Premises are located. Any litigation between the Parties hereto concerning this Lease shall be initiated in the county in which the Premises are located.

30. **Subordination; Attornment; Non-Disturbance**.

30.1 **Subordination**. This Lease and any Option granted hereby shall be subject and subordinate to any ground lease, mortgage, deed of trust, or other hypothecation or security device (collectively, "**Security Device**"), now or hereafter placed upon the Premises, to any and all advances made on the security thereof, and to all renewals, modifications, and extensions thereof. Lessee agrees that the holders of any such Security Devices (in this Lease together referred to as "**Lender**") shall have no liability or obligation to perform any of the obligations of Lessor under this Lease. Any Lender may elect to have this Lease and/or any Option granted hereby superior to the lien of its Security Device by giving written notice thereof to Lessee, whereupon this Lease and such Options shall be deemed prior to such Security Device, notwithstanding the relative dates of the documentation or recordation thereof.

30.2 **Attornment**. In the event that Lessor transfers title to the Premises, or the Premises are acquired by another upon the foreclosure or termination of a Security Devise to which this Lease is subordinated (i) Lessee shall, subject to the non-disturbance provisions of Paragraph 30.3, attorn to such new owner, and upon request, enter into a new lease, containing all of the terms and provisions of this Lease, with such new owner for the remainder of the term hereof, or, at the election of the new owner, this Lease will automatically become a new lease between Lessee and such new owner, and (ii) Lessor shall thereafter be relieved of any further obligations hereunder and such new owner shall assume all of Lessor's obligations, except that such new owner shall not: (a) be liable for any act or omission of any prior lessor or with respect to events occurring prior to acquisition of ownership; (b) be subject to any offsets or defenses which Lessee might have against any prior lessor, (c) be bound by prepayment of more than one month's rent, or (d) be liable for the return of any security deposit paid to any prior lessor which was not paid or credited to such new owner.

30.3 **Non-Disturbance**. With respect to Security Devices entered into by Lessor after the execution of this Lease, Lessee's subordination of this Lease shall be subject to receiving a commercially reasonable non-disturbance agreement (a "**Non-Disturbance Agreement**") from the Lender which Non-Disturbance Agreement provides that Lessee's possession of the Premises, and this Lease, including any options to extend the term hereof, will not be disturbed so long as Lessee is not in Breach hereof and attorns to the record owner of the Premises. Further, within 60 days after the execution of this Lease, Lessor shall, if requested by Lessee, use its commercially reasonable efforts to obtain a Non-Disturbance Agreement from the holder of any pre-existing Security Device which is secured by the Premises. In the event that Lessor is unable to provide the Non-Disturbance Agreement within said 60 days, then Lessee may, at Lessee's option, directly contact Lender and attempt to negotiate for the execution and delivery of a Non-Disturbance Agreement.

30.4 **Self-Executing**. The agreements contained in this Paragraph 30 shall be effective without the execution of any further documents; provided, however, that, upon written request from Lessor or a Lender in connection with a sale, financing or refinancing of the Premises, Lessee and Lessor shall execute such further writings as may be reasonably required to separately document any subordination, attornment and/or Non-Disturbance Agreement provided for herein.

31. **Attorneys' Fees**. If any Party or Broker brings an action or proceeding involving the Premises whether founded in tort, contract or equity, or to declare rights hereunder, the Prevailing Party (as hereafter defined) in any such proceeding, action, or appeal thereon, shall be entitled to reasonable attorneys' fees. Such fees may be awarded in the same suit or recovered in a separate suit, whether or not such action or proceeding is pursued to decision or judgment. The term, "**Prevailing Party**" shall include, without limitation, a Party or Broker who substantially obtains or defeats the relief sought, as the case may be, whether by compromise, settlement, judgment, or the abandonment by the other Party or Broker of its claim or defense. The attorneys' fees award shall not be computed in accordance with any court fee schedule, but shall be such as to fully reimburse all attorneys' fees reasonably incurred. In addition, Lessor shall be entitled to attorneys' fees, costs and expenses incurred in the preparation and service of notices of Default and consultations in connection therewith, whether or not a legal action is subsequently commenced in connection with such Default or resulting Breach ($200 is a reasonable minimum per occurrence for such services and consultation).

32. **Lessor's Access; Showing Premises; Repairs**. Lessor and Lessor's agents shall have the right to enter the Premises at any time, in the case of an emergency, and otherwise at reasonable times after reasonable prior notice for the purpose of showing the same to prospective purchasers, lenders, or tenants, and making such alterations, repairs, improvements or additions to the Premises as Lessor may deem necessary or desirable and the erecting, using and maintaining of utilities, services, pipes and conduits through the Premises and/or other premises as long as there is no material adverse effect on Lessee's use of the Premises. All such activities shall be without abatement of rent or liability to Lessee.

33. **Auctions**. Lessee shall not conduct, nor permit to be conducted, any auction upon the Premises without Lessor's prior written consent. Lessor shall not be obligated to exercise any standard of reasonableness in determining whether to permit an auction.

34. **Signs**: Publicity. Lessor may place on the Premises ordinary "For Sale" signs at any time and ordinary "For Lease" signs during the last 6 months of the term hereof. Lessor may not place any sign on the exterior of the Building that covers any of the windows of the Premises. Except for ordinary "For Sublease" signs which may be placed only on the Premises. Lessee shall not place any sign upon the Project without Lessor's prior written consent. All signs must comply with all Applicable Requirements. Lessor shall have the right to publicize Lessor and Lessee's relationship regarding this Lease.

35. **Termination; Merge**r. Unless specifically stated otherwise in writing by Lessor, the voluntary or other surrender of this Lease by Lessee, the mutual

termination or cancellation hereof, or a termination hereof by Lessor for Breach by Lessee, shall automatically terminate any sublease or lesser estate in the Premises; provided, however, that Lessor may elect to continue any one or all existing subtenancies. Lessor's failure within 10 days following any such event to elect to the contrary by written notice to the holder of any such lesser interest, shall constitute Lessor's election to have such event constitute the termination of such interest.

36. **Consents**. Except as otherwise provided herein, wherever in this Lease the consent of a Party is required to an act by or for the other Party, such consent shall not be unreasonably withheld or delayed. Lessor's actual reasonable costs and expenses (including but not limited to architects', attorneys', engineers' and other consultants' fees) incurred in the consideration of, or response to, a request by Lessee for any Lessor consent, including but not limited to consents to an assignment, a subletting or the presence or use of a Hazardous Substance, shall be paid by Lessee upon receipt of an invoice and supporting documentation therefor. Lessor's consent to any act, assignment or subletting shall not constitute an acknowledgment that no Default or Breach by Lessee of this Lease exists, nor shall such consent be deemed a waiver of any then existing Default or Breach, except as may be otherwise specifically stated in writing by Lessor at the time of such consent. The failure to specify herein any particular condition to Lessor's consent shall not preclude the imposition by Lessor at the time of consent of such further or other conditions as are then reasonable with reference to the particular matter for which consent is being given. In the event that either Party disagrees with any determination made by the other hereunder and reasonably requests the reasons for such determination, the determining party shall furnish its reasons in writing and in reasonable detail within 10 business days following such request.

37. **Guarantor**.

37.1 **Execution**. The Guarantors, if any, shall each execute a guaranty in the form most recently published by the AIR Commercial Real Estate Association.

37.2 **Default**. It shall constitute a Default of the Lessee if any Guarantor fails or refuses, upon request to provide: (a) evidence of the execution of the guaranty, including the authority of the party signing on Guarantor's behalf to obligate Guarantor, and in the case of a corporate Guarantor, a certified copy of a resolution of its board of directors authorizing the making of such guaranty, (b) current financial statements, (c) an Estoppel Certificate or (d) written confirmation that the guaranty is still in effect.

38. **Quiet Possession**. Subject to payment by Lessee of the Rent and performance of all of the covenants, conditions and provisions on Lessee's part to be observed and performed under this Lease, Lessee shall have quiet possession and quiet enjoyment of the Premises during the term hereof.

39. **Options**. If Lessee is granted an Option as defined below, then the following provisions shall apply.

39.1 **Definition**. "**Option**" shall mean: (a) the right to extend or reduce the term of or renew this Lease or to extend or reduce the term of or renew any lease that Lessee has on other property of Lessor; (b) the right of first refusal or first offer to lease either the Premises or other property of Lessor; (c) the right to purchase, the right of first offer to purchase or the right of first refusal to purchase the Premises or other property of Lessor.

39.2 **Options Personal To Original Lessee**. Any Option granted to Lessee in this Lease is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and, if requested by Lessor, with Lessee certifying that Lessee has no intention of thereafter assigning or subletting.

39.3 **Multiple Options**. In the event that Lessee has any multiple Options to extend or renew this Lease, a later Option cannot be exercised unless the prior Options have been validly exercised.

39.4 **Effect of Default on Options**.

(a) Lessee shall have no right to exercise an Option: (i) during the period commencing with the giving of any notice of Default and continuing until said Default is cured, (ii) during the period of time any Rent is unpaid (without regard to whether notice thereof is given Lessee), (iii) during the time Lessee is in Breach of this Lease, or (iv) in the event that Lessee has been given 3 or more notices of separate Default, whether or not the Defaults are cured, during the 12 month period immediately preceding the exercise of the Option.

(b) The period of time within which an Option may be exercised shall not be extended or enlarged by reason of Lessee's inability to exercise an Option because of the provisions of Paragraph 39.4(a).

(c) An Option shall terminate and be of no further force or effect, notwithstanding Lessee's due and timely exercise of the Option, if, after such exercise and prior to the commencement of the extended term or completion of the purchase, (i) Lessee fails to pay Rent for a period of 30 days after such Rent becomes due (without any necessity of Lessor to give notice thereof), or (ii) if Lessee commits a Breach of this Lease.

40. **Security Measures**. Lessee hereby acknowledges that the Rent payable to Lessor hereunder does not include the cost of guard service or other security measures, and that Lessor shall have no obligation whatsoever to provide same. Lessee assumes all responsibility for the protection of the Premises, Lessee, its agents and invitees and their property from the acts of third parties. In the event, however, that Lessor should elect to provide security services, then the cost thereof shall be an Operating Expense.

41. **Reservations**.

(a) Lessor reserves the right: (i) to grant, without the consent or joinder of Lessee, such easements, rights and dedications that Lessor deems necessary, (ii) to cause the recordation of parcel maps and restrictions, (iii) to create and/or install new utility raceways, so long as such easements, rights, dedications, maps, restrictions, and utility raceways do not unreasonably interfere with the use of the Premises by Lessee. Lessor may also: change the name, address or title of the Building or Project upon at least 90 days prior written notice; provide and install, at Lessee's expense. Building standard graphics on the door of the Premises and such portions of the Common Areas as Lessor shall reasonably deem appropriate; grant to any lessee the exclusive right to conduct any business as long as such exclusive right does not conflict with any rights expressly given herein; and to place such signs, notices or displays as Lessor reasonably deems necessary or advisable upon the roof, exterior of the Building or the Project or on signs in the Common Areas. Lessee agrees to sign any documents reasonably requested by Lessor to effectuate such rights. The obstruction of Lessee's view, air, or light by any structure erected in the vicinity of the Building, whether by Lessor or third parties, shall in no way affect this Lease or impose any liability upon Lessor.

(b) Lessor also reserves the right to move Lessee to other space of comparable size in the Building or Project. Lessor must provide at least 45 days prior written notice of such move, and the new space must contain improvements of comparable quality to those contained within the Premises. Lessor shall pay the reasonable out of pocket costs that Lessee incurs with regard to such relocation, including the expenses of moving and necessary stationary revision costs. In no event, however, shall Lessor be required to pay an amount in excess of two months Base Rent. Lessee may not be relocated more than once during the term of this Lease.

(c) Lessee shall not: (i) use a representation (photographic or otherwise) of the Building or Project or their name(s) in connection with Lessee's business; or (ii) suffer or permit anyone, except in emergency, to go upon the roof of the Building.

42. **Performance Under Protest**. If at any time a dispute shall arise as to any amount or sum of money to be paid by one Party to the other under the provisions hereof, the Party against whom the obligation to pay the money is asserted shall have the right to make payment "under protest" and such payment shall not be regarded as a voluntary payment and there shall survive the right on the part of said Party to institute suit for recovery of such sum. If it shall be adjudged that there was no legal obligation on the part of said Party to pay such sum or any part thereof, said Party shall be entitled to recover such sum or so much thereof as it was not legally required to pay. A Party who does not initiate suit for the recovery of sums paid "under protest" within 6 months shall be deemed to have waived its right to protest such payment.

43. **Authority; Multiple Parties; Execution**

(a) If either Party hereto is a corporation, trust, limited liability company, partnership, or similar entity, each individual executing this Lease on behalf of such entity represents and warrants that he or she is duly authorized to execute and deliver this Lease on its behalf. Each Party shall, within 30 days after request, deliver to the other Party satisfactory evidence of such authority.

(b) If this Lease is executed by more than one person or entity as "Lessee", each such person or entity shall be jointly and severally liable hereunder. It is agreed that any one of the named Lessees shall be empowered to execute any amendment to this Lease, or other document ancillary thereto and bind all of the named Lessees, and Lessor may rely on the same as if all of the named Lessees had executed such document.

(c) This Lease may be executed by the Parties in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument.

44. **Conflict**. Any conflict between the printed provisions of this Lease and the typewritten or handwritten provisions shall be controlled by the typewritten or handwritten provisions.

45. **Offer**. Preparation of this Lease by either party or their agent and submission of same to the other Party shall not be deemed an offer to lease to the other Party. This Lease is not intended to be binding until executed and delivered by all Parties hereto.

46. **Amendments**. This Lease may be modified only in writing, signed by the Parties in interest at the time of the modification. As long as they do not materially change Lessee's obligations hereunder, Lessee agrees to make such reasonable non monetary modifications to this Lease as may be reasonably required by a Lender in connection with the obtaining of normal financing or refinancing of the Premises.

47. **Waiver of Jury Trial. THE PARTIES HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING INVOLVING THE PROPERTY OR ARISING OUT OF THIS AGREEMENT.**

48. **Arbitration of Disputes**. An Addendum requiring the Arbitration of all disputes between the Parties and/or Brokers arising out of this Lease ☑ is ☐ is not attached to this Lease.

49. **Americans with Disabilities Act**. Since compliance with the Americans with Disabilities Act (ADA) is dependent upon Lessee's specific use of the Premises, Lessor makes no warranty or representation as to whether or not the Premises comply with ADA or any similar legislation. In the event that Lessee's use of the Premises requires modifications or additions to the Premises in order to be in ADA compliance. Lessee agrees to make any such necessary modifications and/or additions at Lessee's expense.

LESSOR AND LESSEE HAVE CAREFULLY READ AND REVIEWED THIS LEASE AND EACH TERM AND PROVISION CONTAINED HEREIN, AND BY THE EXECUTION OF THIS LEASE SHOW THEIR INFORMED AND VOLUNTARY CONSENT THERETO. THE PARTIES HEREBY AGREE THAT, AT THE TIME THIS LEASE IS EXECUTED, THE TERMS OF THIS LEASE ARE COMMERCIALLY REASONABLE AND EFFECTUATE THE INTENT AND PURPOSE OF LESSOR AND LESSEE WITH RESPECT TO THE PREMISES.

**ATTENTION: NO REPRESENTATION OR RECOMMENDATION IS MADE BY THE AIR COMMERCIAL REAL ESTATE ASSOCIATION OR BY ANY BROKER AS TO THE LEGAL SUFFICIENCY, LEGAL EFFECT, OR TAX CONSEQUENCES OF THIS LEASE OR THE TRANSACTION TO WHICH IT RELATES. THE PARTIES ARE URGED TO:**

**1. SEEK ADVICE OF COUNSEL AS TO THE LEGAL AND TAX CONSEQUENCES OF THIS LEASE.**

 

**2. RETAIN APPROPRIATE CONSULTANTS TO REVIEW AND INVESTIGATE THE CONDITION OF THE PREMISES. SAID INVESTIGATION SHOULD INCLUDE BUT NOT BE LIMITED TO: THE POSSIBLE PRESENCE OF HAZARDOUS SUBSTANCES, THE ZONING AND SIZE OF THE PREMISES, THE STRUCTURAL INTEGRITY, THE CONDITION OF THE ROOF AND OPERATING SYSTEMS, COMPLIANCE WITH THE AMERICANS WITH DISABILITIES ACT AND THE SUITABILITY OF THE PREMISES FOR LESSEE'S INTENDED USE.**
**WARNING: IF THE PREMISES ARE LOCATED IN A STATE OTHER THAN CALIFORNIA, CERTAIN PROVISIONS OF THE LEASE MAY NEED TO BE REVISED TO COMPLY WITH THE LAWS OF THE STATE IN WHICH THE PREMISES ARE LOCATED.**

The parties hereto have executed this Lease at the place and on the dates specified above their respective signatures.

Executed at: LA, CA
On: 10-25-16

**By LESSOR**:
RIF III – Avenue Stanford, LLC, a California limited liability company

By: Rexford Industrial Realty, L.P., a Maryland limited partnership, its Managing Member

By: Rexford Industrial Realty, Inc., a Maryland corporation, its General Partner

By: /s/ Howard Schwimmer
Name Printed: Howard Schwimmer
Title: Co-Chief Executive Officer

By: _____
Name Printed: _____
Title: _____
Address: 11620 Wilshire Blvd, Suite 1000
Los Angeles, CA 90025
Telephone:(310) 966-1680
Facsimile:(310) 966-1690
Email: _____
Email: _____
Federal ID No. _____

Executed at: _____
On: _____

**By LESSEE**:
Avita Medical Americas, LLC, a Delaware limited liability company

By: /s/ Troy Barring
Name Printed: Troy Barring
Title: Chief Operating Officer

By: _____
Name Printed: _____
Title: _____
Address: _____
_____
Telephone: (___) _____
Facsimile: (___) _____
Email: _____
Email: _____
Federal ID No. _____

**LESSOR'S BROKER:**
CBRE, Inc.
Attn: Craig Peters
Address: 234 S. Brand Blvd., Suite 800 Glendale, CA 91204
Telephone: (818) 907-4639
Facsimile: (818) 907-4702
Email: richard.ramirez@cbre.com
Broker/Agent DRE License #: 00409987/00906542

**LESSEE'S BROKER:**
CBRE, Inc.
Attn: Richard Ramirez
Address: 234 S. Brand Blvd., Suite 800 Glendale, CA 91204
Telephone: (818)907-4639
Facsimile: (818) 907-4702
Email: richard.ramirez@cbre.com
Broker/Agent DRE License #: 00409987/01792270

**NOTICE: These forms are often modified to meet changing requirements of law and industry needs. Always write or call to make sure you are utilizing the most current form: AIR Commercial Real Estate Association, 800 W 6th Street, Suite 800, Los Angeles, CA 90017. Telephone No. (213) 687-8777. Fax No.: (213) 687-8616.**

ADDENDUM TO STANDARD INDUSTRIAL/COMMERCIAL
MULTI-TENANT LEASE—GROSS
**AVITA MEDICAL AMERICAS, LLC**
**28159 AVENUE STANFORD, UNIT 220, VALENCIA, CA 91355**

This Addendum to the Standard Multi-Tenant Office Lease—Gross (this "Addendum") is entered into by and between **RIF III – Avenue Stanford, LLC, a California Limited Liability Company** ("Lessor"), and **Avita Medical Americas, LLC, a Delaware limited liability company** ("Lessee"), as of the date set forth in the first page of the form Lease to which this Addendum is attached (the "Form Lease"). The promises, covenants, agreements and declarations made and set forth herein are intended to and shall have the same force and effect as if set forth in the body of the Form Lease. To the extent that the provisions of this Addendum are inconsistent with the terms and conditions of the Form Lease, the provisions of this Addendum shall control. Except for purposes of determining whether a conflict exists between the Form Lease and this Addendum, the term "Lease" (as used herein and in the Form Lease) shall include the provisions of this Addendum.

1.2 Premises (continued). The parties acknowledge that Paragraph 1.2(a) of the Form Lease contains Lessor's best estimate of what the rentable square footage of the Premises will be upon delivery of possession after the completion of the Lessor Improvements (as defined in Paragraph 52 below). Lessor shall notify Lessee of the actual rentable area of the Premises calculated in conformity with the BOMA Standard, and the rentable footage of the Premises contained in this Lease shall be modified accordingly unless Lessee contests Lessor's measurement or application of the BOMA Standard (in which case Lessor and Lessee shall promptly appoint a mutually acceptable party to re-measure the Premises in accordance with the BOMA Standard, and such party's determination shall be binding on Lessor and Lessee). In the event that the rentable square footage of the Premises, measured in conformity with the BOMA Standard, differs from the square footage set forth in Paragraph 1.2(a) of the Form Lease, then the Base Rent (Paragraph 1.5), Lessee's Share of Common Area Operating Expenses (Paragraph 1.6), and the Security Deposit (Paragraph 1.7) shall be recalculated to reflect any changes from the rentable square footage of the Premises set forth in Paragraph 1.2(a) of the Form Lease, based on the BOMA Standard. Any such recalculations along with the re-measured rentable square footage of the Premises shall be confirmed by the Acknowledgment of Premises, in the form attached hereto as Exhibit "C", executed by Lessor and Lessee. As used herein, the "BOMA Standard" shall mean the Standards of Measurement for Industrial Buildings (ANSI/BOMA Z65.2-2012) published by the Building Owners and Managers Association International.

2.2. Condition (continued). Lessee acknowledges that upon delivery of the Premises to Lessee, the Premises shall be in its then conditionAS-IS AND WITH ALL ITS FAULTS, including without limitation, any faults and conditions specifically referenced in the Lease. No person acting on behalf of Lessor is authorized to make, and Lessee acknowledges and agrees that Lessor has not made and specifically negates and disclaims, any representations, warranties, promises, covenants, agreements or guaranties of any kind or character whatsoever, whether express or implied, oral or written, past, present or future, of, as to, concerning or with respect to the Premises.

Lessor and Lessee shall jointly inspect the Premises prior to the date Lessee takes possession of the same and memorialize the condition of the Premises in the attached move-in premises condition form. Any portion of the Premises that is not depicted in saidmove-in premises condition form (or the entire Premises, if Lessor and Lessee neglect to prepare such move-in premises condition form) shall be deemed to be in good condition and repair.

2.2(a) Lessor's Disclosure Regarding Hazardous Substances. LESSOR HEREBY DISCLOSES TO LESSEE THAT, BASED ON THE AGE OF THE BUILDING, LESSOR HAS REASONABLE CAUSE TO BELIEVE THAT ASBESTOS-CONTAINING MATERIALS MAY BE PRESENT IN THE BUILDING AND THE PREMISES. LESSEE ACKNOWLEDGES THAT LESSOR HAS SATISFIED ITS OBLIGATION TO NOTIFY LESSEE OF THE PRESENCE OF ASBESTOS-CONTAINING MATERIALS IN THE BUILDING PURSUANT TO CALIFORNIA HEALTH & SAFETY CODE SECTION 25359.7, AND LESSEE SHALL NOT DISTURB ANY MATERIALS THAT MAY CONTAIN ASBESTOS.

Lessee Initials: 

2.4. Acknowledgements (continued). Without limiting the generality of Paragraph 2.4 of the Form Lease, Lessee represents and warrants that it has obtained (or will obtain) all required occupancy permits from the City of Santa Clarita and other agencies having jurisdiction over the Premises.

2.6. Parking (continued). The parking areas of the property shall be used for parking of Permitted Size Vehicles and, subject to Lessor's rules and regulations, the loading and unloading of trucks only. The use by Lessee of those areas for storage material (including pallets) is expressly prohibited. All material shall be stored within the building.

2.9 Common Areas – Rules & Regulations (continued). Lessee will make use of all of the Common Areas (including, without limitation, all loading and unloading areas) in a cooperative, harmonious fashion, and shall not block or unreasonably interfere with access by others in the Project to their premises or loading areas.

6.1. Use (continued). Other than guide, signal, seeing-eye dogs, and validated service animals, subject to Lessor's prior approval, Lessee shall not keep or allow in the Premises any pets, animals, birds, fish or reptiles.

7.3(d) Utility Installations (continued). Without limiting Lessor's other rights under this Lease, Lessor reserves the right to install new or additional utility facilities in and/or through the Premises for the benefit of Lessor or Lessee or any other portion of the Project, without limitation, drains, plumbing, water, sewers, gas, electrical systems, security systems, communication systems, fire sprinklers, fire protection and detection systems.

7.4(b) Removal (continued). Notwithstanding Paragraph 7.4(b) of the Form Lease, Lessee may include the following notice (in bold, all capitalized twelve point type) in its request for consent to any Utility Installation or Alterations which Lessee desires to make to the Premises: **"LESSOR'S RESPONSE TO THIS REQUEST FOR CONSENT MUST INCLUDE LESSOR'S ELECTION TO REQUIRE LESSEE TO REMOVE THE SUBJECT UTILITY INSTALLATION OR ALTERATION AT THE EXPIRATION OF THE LEASE TERM OR LESSOR WILL BE DEEMED TO HAVE WAIVED ITS RIGHT TO REQUIRE LESSEE TO REMOVE SAID UTILITY INSTALLATION OR ALTERATION".** Lessee shall not be required to remove the particular Utility Installation or Alteration at the expiration of the Term if the foregoing bold all capitalized language was included in Lessee's request for consent and Lessor failed to make such election in its response thereto; provided, however, that Lessor's waiver, if any, shall automatically (and retroactively) be void if this Lease terminates as a result of Lessee's default.

7.4(c) Surrender/Restoration (continued). Without limiting Lessee's obligations under the Lease, Lessee acknowledges that it shall have the affirmative obligation to remove all racking and floor striping from the Premises by or before the expiration or earlier termination of the Original Term or the Option Term, if any. As guidance to the Parties, removal of the aforementioned racking shall include, without limitation, removal of the concrete anchor bolts associated therewith, all of which cut flush at the surface and pushed into the concrete one inch or more below the slab. Lessee shall clean all resulting holes and shall fill the same with epoxy flush to the floor's surface. Lessee understands that the holes created for any anchor bolts placed by or on behalf of Lessee must be drilled one inch deeper than the length of the anchor bolts themselves to permit removal in the manner provided above. Furthermore, if Lessee places (or causes to be placed) any floor striping in the Premises, then following removal of any such floor striping (i) there shall be no residual staining or other indication that such stripping existed and (ii) Lessee must re-seal the floor with a sealant reasonably acceptable to Lessor. If Lessee elects to stripe the floor of the Premises, then Lessee shall utilize a floor striping material which can be removed and which will not permeate into the flooring. The foregoing does not constitute Lessor's consent to Lessee's placement of any racking and/or floor striping in the Premises, which placement shall be governed by the provision of the Lease.

11. Utilities & Services (continued). Lessee shall not use the trash bins of the Project other than for disposal of ordinary office refuse. In no event shall Lessee use the bins for the disposal of large items, such as (but not limited to) packing crates, furniture, storage pallets.

Lessee shall be responsible and pay for all separately metered utilities servicing the Premises.

12.2(h) Terms and Conditions Applicable to Both Assignment and Subletting (continued) If Lessor consents to any assignment or subletting of Lessee's interest in this Lease, as a condition thereto which the parties hereby agree is reasonable, Lessee shall pay to Lessor fifty percent (50%) of any "Transfer Premium," as that term is defined in this Paragraph 12.2(h), actually received by Lessee from the assignee or Sublessee in connection with the Transfer. "Transfer Premium" shall mean all rent, additional rent or other consideration payable by such assignee or Sublessee in connection with a assignment or subletting in excess of the Base Rent and Common Area Operating Expenses payable by Lessee under this Lease during the term of the applicable assignment or subletting on a per rentable area square foot basis if less than all of the Premises is transferred (unless all or a portion of the subject space is subject to different Base Rent and Common Area Operating Expenses terms, in which case, to the extent applicable, such different terms shall be applicable), after deducting the expenses incurred or to be incurred by Lessee for the following, to the extent commercially reasonable under the circumstances, (collectively, "Transfer Costs"): (i) any changes, alterations and improvements to the Premises in connection with the subject assignment or subletting, (ii) any space planning, architectural or design fees or expenses incurred in marketing such space or in connection with such Transfer, (iii) any customary and market reasonable improvement allowance or other customary and market reasonable monetary concessions provided to the assignee or Sublessee, (iv) any brokerage commissions incurred by Lessee in connection with the assignment or subletting, (v) reasonable good faith attorneys' fees incurred by Lessee in connection with the assignment or subletting (excluding, in all cases, the fees of any "in-house" attorneys), and (vi) any lease takeover costs incurred by Lessee in connection with the assignment or subletting. "Transfer Premium" shall also include, but not be limited to, key money, bonus money or other cash consideration actually paid by assignee or Sublessee to Lessee in connection with such assignment or subletting, and any payment in excess of fair market value for services rendered by Lessee to the assignee or Sublessee or for assets, fixtures, inventory, equipment, or furniture transferred by Lessee to assignee or Sublessee in connection with such assignment or subletting. The determination of the amount of Lessor's applicable share of the Transfer Premium shall be made on a monthly basis as rent or other consideration is received by Lessee under the assignment or subletting. For purposes of calculating the Transfer Premium on a monthly basis, (x) Lessee's Transfer Costs shall be deemed to be expended by Lessee in equal monthly amounts over the entire term of the subject assignment or subletting (provided, however, at the election of Lessee, in its sole discretion, Lessee may amortize all or any portion of such Transfer Costs over a shorter period or may elect to allocate such Transfer Costs to the earliest portion of the term of such Transfer until such Transfer Costs are exhausted) and (y) the Rent paid for the subject space by Lessee shall be computed after adjusting such rent to the actual effective rent to be paid, taking into consideration any and all cash concessions actually paid in cash to Lessee by Lessor in connection therewith. For purposes of calculating any such effective rent all such concessions shall be amortized on a straight-line basis without interest over the relevant term.

23.1 Notices (Continued). Copies of any notices delivered to Lessor shall be sent concurrently to Rexford Industrial Realty, L.P., 11620 Wilshire Boulevard, Suite 1000, Los Angeles, CA 90025, Tel. 310.966.1680, Fax 310.966-1690; Attn.: General Counsel, DLanzer@rexfordindustrial.com and to Kenneth S. Fields, Esq., Greenberg Glusker Fields Claman & Machtinger LLP, 1900 Avenue of the Stars, 21 st Floor, Los Angeles, CA 90067; Tel. 310.201.7462; Fax 310.201.2376; KFields@greenbergglusker.com.

34. Signs (continued). Lessee, at its sole expense, shall have the option to install suite identity signage on the unit entry. Should Lessee execute the option to install signage, Lessee must obtain Lessor's approval of design and configuration prior to the installation. Lessor may also provide the option of common signage. Subject to the then current Building/Project standard signage program, Lessee shall have the ability to install exterior building signage outside the lobby entrance and suite adjacent identity signage at Lessee's sole cost and expense.

48. Arbitration of Disputes. Attached hereto and made a part hereof.

49. Americans with Disabilities Act (Continued). Pursuant to California Civil Code Section 1938, Lessor hereby discloses that the Premises have not undergone an inspection by a Certified Access Specialist to determine whether the Premises meet all applicable construction-related accessibility standards.

50. Rent Adjustment. Attached hereto and made a part hereof.

51. Option to Extend. Attached hereto and made a part hereof.

52. Lessor Improvements. Lessor shall, at Lessor's sole cost and expense, complete the following improvements to the Premises, as depicted on the attached Exhibit "B", using building standard materials:

i. Demise Premises from balance of mezzanine;

ii. Cap existing staircase area;

iii. Modify existing staircase area & adjacent existing office with sidelights similar to existing offices and matching carpet, if available in two (2) new offices;

iv. Install one (1) lunchroom with sink, ventilation, dishwasher and building standard plastic laminate cabinetry (both upper & lower). Lessee shall be responsible for purchasing the dishwasher and refrigerator. Lessor shall provide plumbing and power for the dishwasher and power for the refrigerator.

v. Install storage room which shall be divided internally into two (2) separate storage areas;

vi. Expand existing storage closet area at suite entrance and install closet lighting;

vii. Provide Voice/Date hub to Premises IT closet (expanded storage closet);

viii. Install power pulls for twelve (12) cubicles in locations agreeable to Lessee;

ix. Install three (3) interior offices with sidelights similar to existing offices and matching carpet, if available with approximate 10' x l2' dimensions; and

x. Install building standard VCT in breakroom.

Lessee acknowledges and agrees that the Lessor Improvement work will be continuing during Lessee's occupancy and, although Lessor will use commercially reasonable efforts to minimize any disturbance to Lessee, some disturbance is unavoidable and the Lessor shall, and shall cause its contractors to, use commercially reasonable efforts to minimize the dust, noise and other interference with Lessee's business operations and to protect Lessee's employees and invitees from injury and Lessee's personal property and Trade Fixtures at the Premises from damage; however, Lessee understands that some interference is unavoidable and the provisions of Paragraph 8.8 of the Form Lease shall apply in connection therewith.

Lessee shall be solely responsible for moving any furniture, fixtures, or any of Lessee's personal property within the Premises, if necessary, at Lessee's sole cost and expense, so that Lessor can perform the Lessor Improvements.

53. Solar Energy. Lessee agrees and understands that Lessor shall have the right (provided that the exercise of Lessor's rights does not materially and adversely affect Lessee's use and occupancy of the Premises or subject Lessee to additional costs, without Lessee's consent, to place a solar electric generating system on the roof of the Building or enter into a lease for the roof of the Building whereby such roof lessee shall have the right to install a solar electric generating system on the roof of the Building, and Lessor and its agents shall have access to the roof to accomplish the foregoing.

54. Provisions Regarding Bankruptcy.

a. Assumption of Lease.

In addition to any rights or remedies of Lessor under the terms of this Lease, in the event Lessee engages in any one or more of the acts contemplated by the provisions of Section 13.1(f) above and in the event of an assumption of this Lease by a debtor or by a trustee, such debtor or trustee shall within fifteen (15) days after such assumption (i) cure any default or provide adequate assurance that any default will be promptly cured; and (ii) compensate Lessor for actual pecuniary loss or provide adequate assurance that compensation will be made for actual pecuniary loss including, but not limited to, all attorneys' fees and costs incurred by Lessor resulting from any such proceedings; and (iii) provide adequate assurance of future performance. Lessor and Lessee agree that such fifteen (15) day period is reasonable in view of the fact that the Premises is one of a part of an integrated retail center where the performance by each tenant of its obligations has an effect on the well being of all other tenants and Lessor. Any proposed assignee, including shareholders of a corporate assignee of this Lease, must assume and agree to personally guarantee the performance by assignee of the terms, provisions and covenants of this Lease.

b. Relief From Automatic Stay.

If any of the events described in Section 13.1(f) shall occur with regard to Lessee, Lessee hereby irrevocably consents to immediate relief from the automatic stay under 11 U.S.C. Section 362(d).

55. Confidentiality. It is understood that Lessee shall hold the terms and conditions of this Lease in the strictest of confidence. Lessee shall not disclose the terms of this Lease to any other existing or prospective tenants in the building

56. Interpretation. The Form Lease and this Addendum shall be deemed to have been drafted by both parties and shall not be interpreted against any person as drafter. In addition, prior drafts of the Lease or this Addendum or any letters of intent regarding the same shall not be used in any way to interpret the provisions hereof.

57. REIT Provisions. Lessee understands that, in order for an indirect owner of Lessor to qualify as a REIT, the following requirements (the "REIT Requirements") must be satisfied:

57.1 Subleasing. Anything contained in this Lease to the contrary notwithstanding, Lessee shall not sublet the Premises on any basis such that the rent or other amounts to be paid by the sublessee thereunder would be based, in whole or in part, on either (i) the net income or profits derived by the business activities of the proposed sublessee, or (b) any other formula such that any portion of the Rent would fail to qualify as "rents from real property" within the meaning of Section 856(d) of the Internal Revenue Code, or any similar or successor provision hereto.

57.2 Personal Property Limitation. Anything contained in the Lease to the contrary notwithstanding, the average of the fair market values of the items of personal property that are leased to Lessee under the Lease at the beginning and at the end of any year shall not exceed fifteen percent (15%) of the average of the aggregate fair market values of the leased property at the beginning and at the end of such year (the "Personal Property Limitation"). If Lessor reasonably anticipates that the Personal Property Limitation will be exceeded with respect to the leased property for any year, Lessor shall notify Lessee, and Lessee either (i) shall purchase at fair market value any personal property anticipated to be in excess of the Personal Property Limitation ("Excess Personal Property") either from Lessor or a third party or (ii) shall lease the Excess Personal Property from a third party. In either case, Lessee's Base Rent obligation shall be equitably adjusted. Notwithstanding anything to the contrary set forth above, Lessee shall not be responsible in any way for determining whether Lessee has exceeded or will exceed the Personal Property Limitation and shall not be liable to Lessor or any of its shareholders in the event that the Personal Property Limitation is exceeded, as long as Lessee meets its obligation to acquire or lease any Excess Personal Property as provided above. This section is intended to ensure that the Rent qualifies as "rents from real property," within the meaning of Section 856(d) of the Internal Revenue Code, or any similar or successor provisions thereto, and shall be interpreted in a manner consistent with such intent.

57.3 REIT Requirements. Lessee agrees, and agrees to use its reasonable efforts to cause its affiliates, to cooperate in good faith with Lessor to ensure that the terms of this Paragraph are satisfied. Lessee agrees, and agrees to use reasonable efforts to cause its affiliates, upon request by Lessor to take reasonable action necessary to ensure compliance with all REIT Requirements. If Lessee becomes aware that the REIT Requirements are not, or will not be, satisfied, Lessee shall notify, or use reasonable efforts to cause its affiliates to notify Lessor of such noncompliance. Notwithstanding anything herein to the contrary, in the event that Lessee defaults in its obligations under this Paragraph 57 with respect to the REIT Requirements and fails to cure the same within thirty (30) days after written notice from Lessor, then Lessor's sole remedy for Lessee's Breach of its obligations under this Paragraph 57 shall be to terminate the Lease (provided, however, that the preceding shall not limit Lessor's right to pursue all other available remedies in connection with a Default or Breach by Lessee of any other obligations or provisions under the Lease other than those set forth in this Paragraph 57).

**[SIGNATURE PAGE FOLLOWS]**

NOW, THEREFORE, the parties have executed this Addendum and the Lease as of the date set forth above.

**LESSOR**

RIF III – AVENUE STANFORD, LLC, A CALIFORNIA LIMITED LIABILITY COMPANY

By: Rexford Industrial Realty, L.P., a Maryland limited partnership, Its Managing Member

By: Rexford Industrial Realty, Inc., a Maryland corporation, Its General Partner

By: /s/ Howard Schwimmer

Name Printed: Howard Schwimmer

Title: Co-Chief Executive Officer

**LESSEE**

AVITA MEDICAL AMERICAS, LLC, A DELAWARE LIMITED LIABILITY COMPANY

By: /s/ Troy Barring

Name Printed: Troy Barring

Title: Chief Operating Officer

By: _____

Name Printed: _____

Title: _____

**ARBITRATION AGREEMENT**
**Standard Lease Addendum**

| | |
|---|---|
| **Dated** | October 3, 2016 |
| **By and Between (Lessor)** | RIF III - Avenue Stanford, LLC, a California limited liability company |
| **(Lessee)** | Avita Medical Americas, LLC, a Delaware limited liability company |
| **Address of Premises:** | 28159 Avenue Stanford, Unit 220 Valencia, California, 91355 |

Paragraph 48

A. **ARBITRATION OF DISPUTES:**

Except as provided in Paragraph B below, the Parties agree to resolve any and all claims, disputes or disagreements arising under this Lease, including, but not limited to any matter relating to Lessor's failure to approve an assignment, sublease or other transfer of Lessee's interest in the Lease under Paragraph 12 of this Lease, any other defaults by Lessor, or any defaults by Lessee by and through arbitration as provided below and irrevocably waive any and all rights to the contrary. The Parties agree to at all times conduct themselves in strict, full, complete and timely accordance with the terms hereof and that any attempt to circumvent the terms of this Arbitration Agreement shall be absolutely null and void and of no force or effect whatsoever.

B. **DISPUTES EXCLUDED FROM ARBITRATION:**

The following claims, disputes or disagreements under this Lease are expressly excluded from the arbitration procedures set forth herein: 1. Disputes for which a different resolution determination is specifically set forth in this Lease, 2. All claims by either party which (a) seek anything other than enforcement or determination of rights under this Lease, or (b) are primarily founded upon matters of fraud, willful misconduct, bad faith or any other allegations of tortious action, and seek the award of punitive or exemplary damages, 3. Claims relating to (a) Lessor's exercise of any unlawful detainer rights pursuant to applicable law or (b) rights or remedies used by Lessor to gain possession of the Premises or terminate Lessee's right of possession to the Premises, all of which disputes shall be resolved by suit filed in the applicable court of jurisdiction, the decision of which court shall be subject to appeal pursuant to applicable law 4. Any claim or dispute that is within the jurisdiction of the Small Claims Court and 5. All claims arising under Paragraph 39 of this Lease.

C. **APPOINTMENT OF AN ARBITRATOR:**

All disputes subject to this Arbitration Agreement, shall be determined by binding arbitration before: ☑ a retired judge of the applicable court of jurisdiction (e.g., the Superior Court of the State of California) affiliated with Judicial Arbitration & Mediation Services, Inc. ("JAMS"), ☐ the American Arbitration Association ("AAA") under its commercial arbitration rules, ☐ _____ _____ _____ , or as may be otherwise mutually agreed by Lessor and Lessee (the "Arbitrator"). Such arbitration shall be initiated by the Parties, or either of them, within ten (10) days after either party sends written notice (the "Arbitration Notice") of a demand to arbitrate by registered or certified mail to the other party and to the Arbitrator. The Arbitration Notice shall contain a description of the subject matter of the arbitration, the dispute with respect thereto, the amount involved, if any, and the remedy or determination sought. If the Parties have agreed to use JAMS they may agree on a retired judge from the JAMS panel. If they are unable to agree within ten days, JAMS will provide a list of three available judges and each party may strike one. The remaining judge (or if there are two, the one selected by JAMS) will serve as the Arbitrator. If the Parties have elected to utilize AAA or some other organization, the Arbitrator shall be selected in accordance with said organization's rules. In the event the Arbitrator is not selected as provided for above for any reason, the party initiating arbitration shall apply to the appropriate Court for the appointment of a qualified retired judge to act as the Arbitrator.

D. **ARBITRATION PROCEDURE:**

1. **PRE-HEARING ACTIONS.** The Arbitrator shall schedule a pre-hearing conference to resolve procedural matters, arrange for the exchange of information, obtain stipulations, and narrow the issues. The Parties will submit proposed discovery schedules to the Arbitrator at the pre-hearing conference. The scope and duration of discovery will be within the sole discretion of the Arbitrator. The Arbitrator shall have the discretion to order a pre-hearing exchange of information by the Parties, including, without limitation, production of requested documents, exchange of summaries of testimony of proposed witnesses, and examination by deposition of parties and third-party witnesses. This discretion shall be exercised in favor of discovery reasonable under the circumstances. The Arbitrator shall issue subpoenas and subpoenas duces tecum as provided for in the applicable statutory or case law (e.g., in California Code of Civil Procedure Section 1282.6).

2. **THE DECISION.** The arbitration shall be conducted in the city or county within which the Premises are located at a reasonably convenient site. Any Party may be represented by counsel or other authorized representative. In rendering a decision(s), the Arbitrator shall determine the rights and obligations of the Parties according to the substantive laws and the terms and provisions of this Lease. The Arbitrator's decision shall be based on the evidence introduced at the hearing, including all logical and reasonable inferences therefrom. The Arbitrator may make any determination and/or grant any remedy or relief that is just and equitable. The decision must be based on, and accompanied by, a written statement of decision explaining the factual and legal basis for the decision as to each of the principal controverted issues. The decision shall be conclusive and binding, and it may thereafter be confirmed as a judgment by the court of applicable jurisdiction, subject only to challenge on the grounds set forth in the applicable statutory or case law (e.g., in California Code of Civil Procedure Section 1286.2). The validity and enforceability of the Arbitrator's decision is to be determined exclusively by the court of appropriate jurisdiction pursuant to the provisions of this Lease. The Arbitrator may award costs, including without limitation. Arbitrator's fees and costs, attorneys' fees, and expert and witness costs, to the prevailing party, if any, as determined by the Arbitrator in his discretion.

Whenever a matter which has been submitted to arbitration involves a dispute as to whether or not a particular act or omission (other than a failure to pay money) constitutes a Default, the time to commence or cease such action shall be tolled from the date that the Notice of Arbitration is served through and until the date the Arbitrator renders his or her decision. Provided, however, that this provision shall NOT apply in the event that the Arbitrator determines that the Arbitration Notice was prepared in bad faith.

 

Whenever a dispute arises between the Parties concerning whether or not the failure to make a payment of money constitutes a default, the service of an Arbitration Notice shall NOT toll the time period in which to pay the money. The Party allegedly obligated to pay the money may, however, elect to pay the money "under protest" by accompanying said payment with a written statement setting forth the reasons for such protest. If thereafter, the Arbitrator determines that the Party who received said money was not entitled to such payment, said money shall be promptly returned to the Party who paid such money under protest together with Interest thereon as defined in Paragraph 13.5. If a Party makes a payment "under protest" but no Notice of Arbitration is filed within thirty days, then such protest shall be deemed waived. (See also Paragraph 42 or 43)

**RENT ADJUSTMENT(S)**
**STANDARD LEASE ADDENDUM**

| | |
|---|---|
| **Dated** | October 3, 2016 |
| **By and Between (Lessor)** | RIF III – Avenue Stanford, LLC, a California limited liability company |
| **(Lessee)** | Avita Medical Americas, LLC, a Delaware limited liability company |
| **Address of Premises:** | 28159 Avenue Stanford, Unit 220<br>Valencia, California, 91355 |

Paragraph 50

A. **RENT ADJUSTMENTS:**

The monthly rent for each month of the adjustment period(s) specified below shall be increased using the method(s) indicated below: (Check Method(s) to be Used and Fill in Appropriately)

☐ ~~**i. Cost of Living Adjustment(s) (COLA)**~~

~~a. On (fill in COLA Dates: _____~~

~~the Base Rent shall be adjusted by the change, if any, from the Base Month specified below, in the Consumer Price Index of the Bureau of Labor Statistics of the U.S. Department of Labor for (select one):☐ CPI W (Urban Wage Earners and Clerical Workers) or ☐ CPI U (All Urban Consumers), for (Fill in Urban Area):~~

~~_____, All Items~~

~~(1982-19884 = 100), herein referred to as "CPI".~~

~~b. The monthly Base Rent payable in accordance with paragraph A.I.a. of this Addendum shall be calculated as follows: the Base Rent set forth in paragraph 1.5 of the attached Lease, shall be multiplied by a fraction the numerator of which shall be the CPI of the calendar month 2 months prior to the month(s) specified in paragraph A.I.a. above during which the adjustment is to take effect, and the denominator of which shall be the CPI of the calendar month which is 2 months prior to (select one): the ☐ first month of the term of this Lease as set forth in paragraph 1.3 ("Base Month") or ☐ (Fill in Other "Base Month"):_____. The sum so calculated shall constitute the new monthly Base Rent hereunder, but in no event, shall any such new monthly Base Rent be less than the Base Rent payable for the month immediately preceding the Base Rent adjustment.~~

~~c. In the event the compilation and/or publication of the CPI shall be transferred to any other governmental department or bureau or agency or shall be discontinued, then the index most nearly the same as the CPI shall be used to make such calculation, In the event that the Parties cannot agree on such alternative index, then the matter shall be submitted for decision to the American Arbitration Association in accordance with the then rules of said Association and the decision of the arbitrators shall be binding upon the parties. The cost of said Arbitration shall be paid equally by the Parties.~~

☐ ~~**II. Market Rental Value Adjustment(s) (MRV)**~~

~~a. On (fill in MRV Adjustment Date(s):_____~~

~~the Base Rent shall be adjusted to the "Market Rental Value" of the property as follows:~~

~~1) Four months prior to each Market Rental Value Adjustment Date described above, the Parties shall attempt to agree upon what the now MRV will bo on the adjustment date. If agreement cannot bo reached within thirty days, then:~~

~~(a) Lesser and Lessee shall immediately appoint a mutually acceptable appraiser or broker to establish the now MRV within the next 30 days. Any associated costs will be split equally between the Parties, or~~

~~(b) Both Lessor and Lessee shall each immediately make a reasonable determination of the MRV and submit such determination, in writing, to arbitration in accordance with the following provisions:~~

~~(i) Within 15 days thereafter, Lessor and Lessee shall each select an ☐ appraiser or [] broker **("Consultant"** chock one) of their choice to act as an arbitrator. The two arbitrators so appointed shall immediately select a third mutually acceptable Consultant to act as a third arbitrator.~~

~~(ii) The 3 arbitrators shall within 30 days of the appointment of the third arbitrator reach a decision as to what the actual MRV for the Promises is, and whether Lesser's or Lessee's submitted MRV is the closest thereto. The decision of a majority of the arbitrators shall be binding on the Parties. The submitted MRV which is determined to bo the closest to the actual MRV shall thereafter bo used by the Parties.~~

 

~~(iii) If either of the Parties fails to appoint an arbitrator within the specified 16 days, the arbitrator timely appointed by one of them shall reach a decision on his or her own, and said decision shall be binding on the Parties.~~

~~(iv) The entire cost of such arbitration shall be paid by the party whose submitted MRV is not selected, i.e., the one that is NOT the closest to the actual MRV.~~

~~2) When determining MRV, the Lessor, Lessee and Consultants shall consider the terms of comparable market transactions which shall include, but no limited to, rent, rental adjustments, abated rent, lease term and financial condition of tenants.~~

~~3) Notwithstanding the foregoing, the now Base Rent shall not be less than the rent payable for the month immediately preceding the rent adjustment.~~

~~b. Upon the establishment of each New Market Rental Value:~~

~~1) the now MRV will become the new "Base Rent" for the purpose of calculating any further Adjustments, and~~

~~2) the first month of each Market Rental Value term shall become the now 'Base Month' for the purpose of calcu~~**~~at~~**~~ting any further Adjustments.~~

☑ **III. Fixed Rental Adjustment(s) (FRA)**

The Base Rent shall be increased to the following amounts on the dates set forth below:

| On (Fill in FRA Adjustment Date(s)): | The New Base Rent shall be: |
|---|---|
| December 1, 2017 | $20,096.59 |
| December 1, 2018 | $20,699.49 |
| December 1, 2019 | $521,320.47 |
| | |
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| | |

In addition to the Base Kent, Lessee shall only be required to pay any increases in Operating Expenses, Insurance Premiums and Real Property Taxes over the Base Year.

☐ ~~**IV. Initial Term Adjustments.**~~

~~The formula used to calculate adjustments to the Base Rate during the original Term of the Lease shall continue to be used during the extended term~~.

B. **NOTICE:**

Unless specified otherwise herein, notice of any such adjustments, other than Fixed Rental Adjustments, shall be made as specified in paragraph 23 of the Lease.

~~C. **BROKER'S FEE:**~~

~~The Brokers shall be paid a Brokerage Fee for each adjustment specified above in accordance with paragraph 15 of the Lease or if applicable, paragraph 9 of the Sublease.~~

**OPTION(S) TO EXTEND**

**STANDARD LEASE ADDENDUM**

| | |
|---|---|
| **Dated** | October 3, 2016 |
| **By and Between (Lessor)** | RIF III – Avenue Stanford, LLC, a California limited liability company |
| **By and Between (Lessee)** | Avita Medical Americas, LLC, a Delaware limited liability company |
| **Address of Premises:** | 28159 Avenue Stanford, Unit 220<br>Valencia, California, 91355 |

Paragraph 51

A. **OPTION(S) TO EXTEND:**

Lessor hereby grants to Lessee the option to extend the term of this Lease for one(1) additional thirty-six (36) month period(s) commencing when the prior term expires upon each and all of the following terms and conditions:

(i) In order to exercise an option to extend, Lessee must give written notice of such election to Lessor and Lessor must receive the same at least 6 but not more than 9 months prior to the date that the option period would commence, time being of the essence. If proper notification of the exercise of an option is not given and/or received, such option shall automatically expire. Options (if there are more than one) may only be exercised consecutively.

(ii) The provisions of paragraph 39, including those relating to Lessee's Default set forth in paragraph 39.4 of this Lease, are conditions of this Option.

(iii) Except for the provisions of this Lease granting an option or options to extend the term, all of the terms and conditions of this Lease except where specifically modified by this option shall apply.

(iv) This Option is personal to the original Lessee, and cannot be assigned or exercised by anyone other than said original Lessee and only while the original Lessee is in full possession of the Premises and without the intention of thereafter assigning or subletting.

(v) The monthly rent for each month of the option period shall be calculated as follows, using the method(s) indicated below: (Check Method(s) to be Used and Fill in Appropriately)

☐ ~~**I. Cost of Living Adjustment(s) (COLA)**~~

~~a. On (Fill in COLA Dates):~~

~~the Base Rent shall be adjusted by the Change, if any, from the Base Month specified below, in the Consumer Price Index of the Bureau of Labor Statistics of the U.S. Department of Labor for (select one): ☐ CPI W (Urban Wage Earners and Clerical Workers) or ☐ CPI U (All Urban Consumers), for (Fill in Urban Area):~~

~~All items (1982-1984 = 100), herein referred to as "CPI".~~

~~b. The monthly Base Rent payable in accordance with paragraph A.I.a. of this Addendum shall be calculated as follows: the Base Rent set forth in paragraph 1.5 of the attached Lease, shall be multiplied by a fraction the numerator of which shall be the CPI of the calendar month 2 months prior to the month(s) specified in paragraph A.I.a. above during which the adjustment is to take effect, and the denominator of which shall be the CPI of the calendar month which is 2 months prior to (select one): ☐ the first month of the term of this Lease as set forth in paragraph 1.3 ("Base Month") or ☐ (Fill in Other "Base Month"):~~

~~The sum so calculated shall constitute the new monthly Base Rent hereunder, but in no event, shall any such new monthly Base Rent be less than the Base Rent payable for the month immediately preceding the rent adjustment.~~

~~c. In the event the compilation and/or publication of the CPI shall be transferred to any other governmental department or bureau or agency or shall be discontinued, then the index most nearly the same as the CPI shall be used to make such calculation. In the event that the Parties cannot agree on such alternative index, then the matter shall be submitted for decision to the American Arbitration Association in accordance with the then rules of said Association and the decision of the arbitrators shall be binding upon the parties. The cost of said Arbitration shall be paid equally by the Parties.~~

☑ **II. Market Rental Value Adjustment(s) (MRV)**

a. On (Fill in MRV Adjustment Date(s)) January 1, 2021

the Base Rent shall be adjusted to the "Market Rental Value" of the property as follows, but in no event less than a three percent (3%) increase over the Base Rent then in effect:

1) Four months prior to each Market Rental Value Adjustment Date described above, the Parties shall attempt to agree upon what the new MRV will be on the adjustment date. If agreement cannot be reached, within thirty days, then:

(a) Lessor and Lessee shall immediately appoint a mutually acceptable appraiser or broker to establish the new MRV within the next 30

days. Any associated costs will be split equally between the Parties, or

(b) Both Lessor and Lessee shall each immediately make a reasonable determination of the MRV and submit such determination, in writing, to arbitration in accordance with the following provisions:

(i) Within 15 days thereafter, Lessor and Lessee shall each select an ☐ appraiser or ☑ broker (“**Consultant**” - check one) of their choice to act as an arbitrator. The two arbitrators so appointed shall immediately select a third mutually acceptable Consultant to act as a third arbitrator.

(ii) The 3 arbitrators shall within 30 days of the appointment of the third arbitrator reach a decision as to what the actual MRV for the Premises is, and whether Lessor’s or Lessee’s submitted MRV is the closest thereto. The decision of a majority of the arbitrators shall be binding on the Parties. The submitted MRV which is determined to be the closest to the actual MRV shall thereafter be used by the Parties.

(iii) If either of the Parties fails to appoint an arbitrator within the specified 15 days, the arbitrator timely appointed by one of them shall reach a decision on his or her own, and said decision shall be binding on the Parties.

(iv) The entire cost of such arbitration shall be paid by the party whose submitted MRV is not selected, ie. the one that is NOT the closest to the actual MRV.

2) When determining MRV, the Lessor, Lessee and Consultants shall consider the terms of comparable market transactions which shall include, but no limited to, rent, rental adjustments, abated rent, lease term and financial condition of tenants.

3) Notwithstanding the foregoing, the new Base Rent shall not be less than the rent payable for the month immediately preceding the rent adjustment.

b. Upon the establishment of each New Market Rental Value:

1) the new MRV will become the new “Base Rent” for the purpose of calculating any further Adjustments, and

2) the first month of each Market Rental Value term shall become the new “Base Month” for the purpose of calculating any further Adjustments.

c. In addition to the Base Rent, Lessee shall only be required to pay any increases in Operating Expenses, insurance Premiums and Real Property Taxes over the Base Year.

☑ **III. Fixed Rental Adjustment(s) (FRA)**

The Base Rent then in effect immediately preceding the FRA Adjustment Date shall be increased to the following amounts per the formula and on the dates set forth below:

| On (Fill in FRA Adjustment Date(s)): | The ~~Now~~ Base Rent shall be: |
|---|---|
| January 1, 2022 | increased by three percent (3%) |
| January 1, 2023 | increased by three percent (3%) |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |

☐ ~~**IV Initial Term Adjustments.**~~

~~The formula used to calculate adjustments to the Base Rote during the original Term of the Lease shall continue to be used during the extended term~~

**B. NOTICE:**

Unless specified otherwise herein, notice of any rental adjustments, other than Fixed Rental Adjustments, shall be made as specified in paragraph 23 of the Lease.

~~**C. BROKER’S FEE:**~~

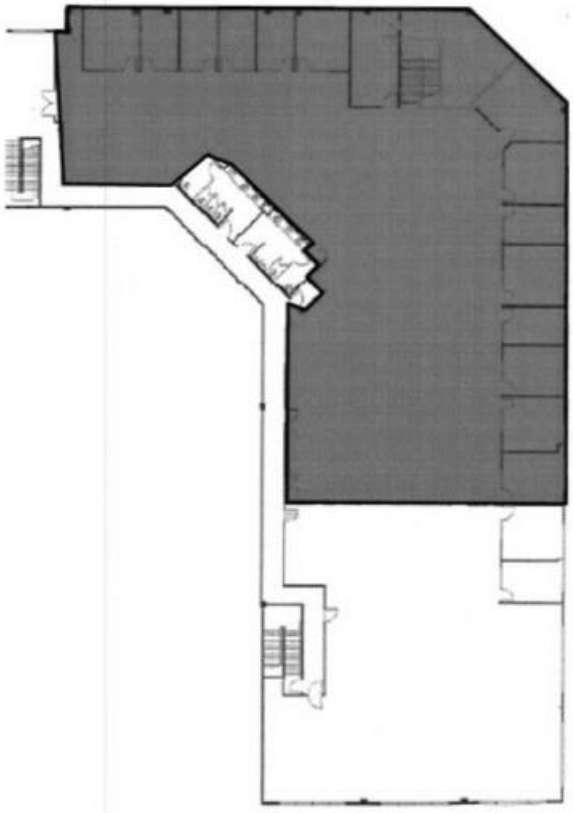
~~The Brokers shall be paid a Brokerage Fee for each adjustment specified above in accordance with paragraph 15 of the Lease or if applicable), paragraph 0 of the Sublease.~~

**NOTICE: These forms are often modified to meet changing requirements of law and industry needs. Always write or call to make sure you are utilizing the most current form: AIR Commercial Real Estate Association, 500 N Brand Blvd, Suite 900, Glendale, CA 91203. Telephone No. (213) 687-8777. Fax No.: (213) 687-8616.**

 **FORM OE-4-04/14E**

**EXHIBIT "A"**

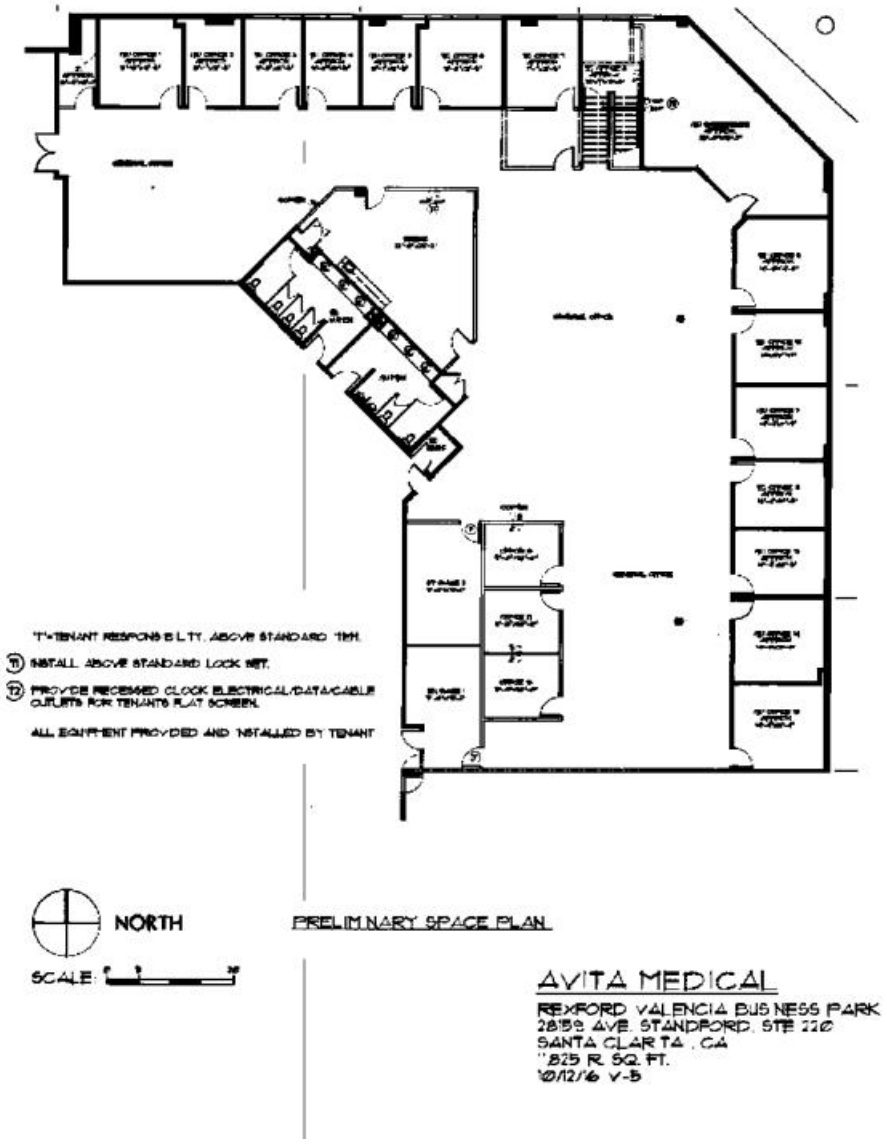
**SITE PLAN**



Not to scale. Does not constitute a representation or warranty regarding the Project or any portion thereof, and Lessor reserves the right to modify any portion of the Project in its sole discretion as provided in the Lease.

**EXHIBIT "B"**

**LESSOR IMPROVEMENTS**




PRELIMINARY SPACE PLAN

AVITA MEDICAL

REXFORD VALENCIA BUSINESS PARK
28159 AVE. STANDFORD, STE 220
SANTA CLARITA, CA
±825 R. SQ. FT.
10/12/16 V-5

# GENERAL NOTES

1. DEMISE PREMISES FROM BALANCE OF MEZZANINE
2. CAP EXISTING STAIRCASE AREA.
3. MODIFY EXISTING STAIRCASE AREA AND ADJACENT EXISTING OFFICE WITH SIDELIGHTS SIMILAR TO EXISTING OFFICES AND MATCHING CARPET, IF AVAILABLE, IN 2 NEW OFFICES.
4. INSTALL LUNCHROOM WITH SINK, VENTILATION, DISHWASHER AND BUILDING STANDARD PLASTIC LAMINATE CABINETRY (BOTH UPPER AND LOWER) LESSEE WILL BE RESPONSIBLE FOR PURCHASING THE DISHWASHER AND REFRIGERATOR. LESSOR SHALL PROVIDE PLUMBING AND POWER FOR THE DISHWASHER AND POWER FOR THE REFRIGERATOR.
5. INSTALL STORAGE ROOM WHICH SHALL BE DIVIDED INTERNALLY INTO TWO (2) SEPARATE STORAGE AREAS.
6. EXPAND EXISTING STORAGE CLOSET AREA AT SUITE ENTRANCE AND INSTALL CLOSET LIGHTING.
7. PROVIDE VOICE / DATA HUB TO PREMISES IT CLOSET (EXPANDED STORAGE CLOSET).
8. INSTALL POWER PULLS FOR TWELVE (12) CUBICLES IN LOCATIONS AGREEABLE TO LESSEE.
9. INSTALL THREE (3) INTERIOR OFFICES WITH SIDELIGHTS SIMILAR TO EXISTING OFFICES AND MATCHING CARPET, IF AVAILABLE WITH APPROXIMATE 10' X 12' DIMENSIONS.
10. INSTALL BUILDING STANDARD VCT AT BREAK ROOM.
11. EXISTING CARPET TO REMAIN, U.O.N.

# PARTITION TYPES/ELECTRICAL SYMBOLS

- DEMOLISHED PARTITION
- EXISTING TO REMAIN
- NEW ONE HOUR PARTITION
- NEW DEMISING/INSULATED PARTITION
- NEW INTERIOR NON STRUCTURAL PARTITION

- DUPLEX
- 20 AMP CIRCUIT
- DATA WALL OUTLET
- DATA/TELEPHONE WALL OUTLET

**EXHIBIT "C"**

**ACKNOWLEDGEMENT OF PREMISES**

Lessor: RIF III – Avenue Stanford, LLC, a California limited liability company

Lessee: Avita Medical Americas, LLC, a Delaware limited liability company

This Acknowledgment of Premises (this "Acknowledgment") is made by Lessor and Lessee pursuant to that certain Standard Multi-Tenant Office Lease – Gross, dated as of October 3, 2016 (the "Lease") for certain premises located at 28159 Avenue Stanford, Unit 220, Valencia, California, 91355, and as further described in the Lease (the "Premises"). This Acknowledgment is made pursuant to Paragraphs 1.2(a) of the Lease. Capitalized terms used herein but not defined herein shall have the meaning given them in the Lease.

1. Re-measurement of Premises. The rentable square footage of the Premises has been re-measured in accordance with Paragraph 1.2 of the Addendum to the Lease. Based on such re-measurement, the rentable square footage of the Premises is determined to be _____ rentable square feet. Accordingly, the Base Rent, Lessee's Share of Common Area Operating Expenses and the Security Deposit are hereby recalculated (and the Lease is hereby amended to reflect the same) as follows:

a. Base Rent. Paragraph 1.5 of the Lease is hereby amended to provide that the Base Rent payable by Lessee during the Original Term shall be as follows:

| Period of Original Term | Monthly Base Rent |
|---|---|
| From the Commencement Date to the last day of the twelfth (12th) full calendar month of the Term | $ _____ |
| From the first day of the thirteenth (13th) full calendar month of the Term | $ _____ |
| From the first day of the twenty-fifth (25th) full calendar month of the Term | $ _____ |
| From the first day of the thirty-seventh (37th) full calendar month of the Term | $ _____ |

b. Lessee's Share of Common Area Operating Expenses. Paragraph 1.6 of the Lease is hereby amended to provided that Lessee's Share of Common Area Operating Expenses shall be _____ percent (_____%) ("Lessee's Share").

c. Security Deposit. Paragraph 1.7(c) of the Lease is hereby amended to provide that the Security Deposit shall be $_____ ("Security Deposit").

d. Base Rent and Other Monies Paid Upon Execution. Lessor and Lessee shall reconcile any discrepancy in the amounts that Lessee paid upon execution pursuant to Paragraph 1.7 of the Lease for Base Rent and the Security Deposit in order to reflect the modifications set forth in this Acknowledgment. With respect to any overpayment of such amounts by Lessee, Lessor shall have the right to apply such overpayment to future Base Rent due under the Lease or to refund such overpayment to Lessee. With respect to any underpayment of such amounts by Lessee, Lessee shall pay the difference to Lessor within fifteen (15) days after the execution of this Acknowledgment.

2. Miscellaneous. This Acknowledgment is incorporated into the Lease, and forms an integral part thereof. This Acknowledgment shall be construed and interpreted in accordance with the terms of the Lease for all purposes. Except as modified by this Acknowledgment, the Lease remains unchanged, and, as modified by this Acknowledgment, the Lease is in full force and effect. In the event of any conflict between the terms of this Acknowledgment and the Lease, this

Acknowledgment shall control. This Acknowledgment may be executed in several counterparts, each of which may be deemed an original, but all of which together shall constitute one and the same Acknowledgment. In addition, properly executed, authorized signatures may be transmitted via facsimile and upon receipt shall constitute an original signature.

**LESSOR**
RIF III – Avenue Stanford, LLC,
a California limited liability company

By: Rexford Industrial Realty, L.P.,
a Maryland limited Partnership
Its Managing Member

By: Rexford Industrial Realty, Inc.,
a Maryland corporation,
Its General Partner

By: /s/ Howard Schwimmer
Name Printed: Howard Schwimmer
Title: Co-Chief Executive Officer

**LESSEE**
Avita Medical Americas, LLC,
a Delaware limited liability company

By: _____
Name Printed: _____
Title: _____

By: _____
Name Printed: _____
Title: _____

Rexford INDUSTRIAL

## TENANT MOVE-IN/MOVE-OUT CHECKLIST

ENTITY NAME: _____
TENANT NAME: _____
PREMISES ADDRESS: _____
MOVE-IN DATE: _____
MOVE-OUT DATE: _____

*Unless otherwise noted, the premises are clean, in good working order and undamaged. Occupant accepts the Premises as-is with the exceptions listed below. This inspection form is made a part of and is subject to the terms and conditions of the Commercial Lease for the above referenced Premises.*

| **OFFICE AREAS** | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| CARPET | | |
| FLOORING | | |
| CEILING | | |
| DOORS | | |
| HVAC | | |
| LIGHTS | | |
| WALLS | | |
| WINDOW COVERINGS | | |
| KITCHEN AREA | | |

| **RESTROOMS** | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| FLOORING | | |
| CEILING | | |
| DOORS | | |
| LIGHTS | | |
| WALLS | | |
| FIXTURES | | |
| MIRRORS | | |
| PLUMBING | | |
| FANS | | |

| **WAREHOUSE** | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| FLOORING | | |
| CEILING | | |
| MAN DOORS | | |
| LOADING DOORS | | |
| LIGHTS | | |
| WALLS | | |
| SKYLIGHTS | | |
| COLUMNS | | |
| DOCK EQUIPMENT | | |
| FIRE SPRINKLERS | | |
| ELEC PANEL/DISTRIBUTION | | |

| **SINGLE TENANT BUILDING** | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| LANDSCAPE | | |
| PAVING / YARD AREA | | |
| EXTERIOR MISC | | |

| **ADDITIONAL COMMENTS** | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| | | |
| | | |

DATE LOCKSMITH REKEYED: _____
NUMBER OF KEYS GIVEN TO TENANT: _____

*The "Move-In Condition" portion of this form is to be completed at the time of initial possession of the Premises. Receipt of a copy of this inspection form is hereby acknowledged.*

TENANT SIGNATURE: _____
DATE: _____
LANDLORD SIGNATURE: _____
DATE: _____

*The "Move-Out Condition" portion of this form is to be completed at the time of Tenant move-out of the Premises. Receipt of a copy of this inspection form is hereby acknowledged.*

TENANT SIGNATURE: _____
DATE: _____
LANDLORD SIGNATURE: _____
DATE: _____

**Tenant Contact Information**

**Please complete and return this form immediately to:**

Rexford Industrial, LLC
11620 Wilshire Boulevard, Suite 1000
Los Angeles, California 90025

Tel. (310) 966-1680
Fax. (310) 966-1690

**Tenant Contact Information**

1. Lessee Full Legal Name: _____

   Office Main: (_____) _____ Mobile: (_____) _____
   Email Address: _____

2. Leased Premises Address: _____

3. On-Site Contact Name/Title: _____

   Office Main: (_____) _____ Mobile: (_____) _____
   Email Address: _____

4. Accounts Payable Contact Name: _____

   Office Main: (_____) _____ Mobile: (_____) _____
   Email Address: _____
   Mailing Address (if different): _____

**Tenant Business Information**

5. Nature of Business: _____ NAICS (6-digit) Code for Business: _____
6. Total Number of Employees at this location: _____
7. Product or Service is Used by **Consumers** or by **Other Businesses** (circle one)
8. Does your business engage in Ecommerce? (circle one) YES NO

   **If answer is "No" then continue to question 12**

9. Percent of Product or Service sold direct to **consumers** via the Internet _____
10. Percent of Product or Service sold direct to **businesses** via the Internet _____
11. Where does the Product/Service Originate From? _____
12. Percent of Product or Service that is Sourced in CA _____
13. Percent of Product or Service that is Sourced in USA but outside CA _____
14. Percent of Product or Service that is Imported from outside USA _____
15. Where is the Product/Service distributed to? _____
16. Percent of Product or Service that is distributed to or consumed in CA _____
17. Percent of Product or Service that is distributed to or consumed in USA, but outside of CA _____
18. Percent of Product or Service that is exported to outside of USA _____
19. Signature: _____ Date: _____

**ACKNOWLEDGEMENT OF PREMISES**

Lessor: RIF III – Avenue Stanford, LLC, a California limited liability company

Lessee: Avita Medical Americas, LLC, a Delaware limited liability company

This Acknowledgment of Premises (this "Acknowledgment") is made by Lessor and Lessee pursuant to that certain Standard Multi-Tenant Office Lease – Gross, dated as of October 3, 2016 (the "Lease") for certain premises located at 28159 Avenue Stanford, Unit 220, Valencia, California, 91355, and as further described in the Lease (the "Premises"). This Acknowledgment is made pursuant to Paragraphs 1.2(a) of the Lease. Capitalized terms used herein but not defined herein shall have the meaning given them in the Lease.

1. Re-measurement of Premises. The rentable square footage of the Premises has been re-measured in accordance with Paragraph 1.2 of the Addendum to the Lease. Based on such re-measurement, the rentable square footage of the Premises is determined to be 11,809 rentable square feet. Accordingly, the Base Rent, Lessee's Share of Common Area Operating Expenses and the Security Deposit are hereby recalculated (and the Lease is hereby amended to reflect the same) as follows:

a. Base Rent. Paragraph 1.5 of the Lease is hereby amended to provide that the Base Rent payable by Lessee during the Original Term shall be as follows:

| Period of Original Term | Monthly Base Rent |
|---|---|
| From the Commencement Date to the last day of the twelfth (12th) full calendar month of the Term | $ 19,484.85 |
| From the first day of the thirteenth (13th) full calendar month of the Term | $ 20,069.40 |
| From the first day of the twenty-fifth (25th) full calendar month of the Term | $ 20,671.48 |
| From the first day of the thirty-seventh (37th) full calendar month of the Term | $ 21,291.62 |

b. Lessee's Share of Common Area Operating Expenses. Paragraph 1.6 of the Lease is hereby amended to provided that Lessee's Share of Common Area Operating Expenses shall be Fourteen and Ninety-Four Hundredths percent (14.94%) ("Lessee's Share").

c. Security Deposit. Paragraph 1.7(c) of the Lease is hereby amended to provide that the Security Deposit shall be $63,874.86 ("Security Deposit").

d. Base Rent and Other Monies Paid Upon Execution. Lessor and Lessee shall reconcile any discrepancy in the amounts that Lessee paid upon execution pursuant to Paragraph 1.7 of the Lease for Base Rent and the Security Deposit in order to reflect the modifications set forth in this Acknowledgment. With respect to any overpayment of such amounts by Lessee, Lessor shall have the right to apply such overpayment to future Base Rent due under the Lease or to refund such overpayment to Lessee. With respect to any underpayment of such amounts by Lessee, Lessee shall pay the difference to Lessor within fifteen (15) days after the execution of this Acknowledgment.

2. Miscellaneous. This Acknowledgment is incorporated into the Lease, and forms an integral part thereof. This Acknowledgment shall be construed and interpreted in accordance with the terms of the Lease for all purposes. Except as modified by this Acknowledgment, the Lease remains unchanged, and, as modified by this Acknowledgment, the Lease is in full force and effect. In the event of any conflict between the terms of this Acknowledgment and the Lease, this Acknowledgment shall control. This Acknowledgment may be executed in several counterparts, each of which may be deemed an original, but all of which together shall constitute one and the same Acknowledgment. In addition, properly executed, authorized signatures may be transmitted via facsimile and upon receipt shall constitute an original signature.

**LESSOR**
RIF III – Avenue Stanford, LLC,
a California limited liability company

By: Rexford Industrial Realty, L.P.,
a Maryland limited Partnership
Its Managing Member

By: Rexford Industrial Realty, Inc.,
a Maryland corporation,
Its General Partner

By: /s/ Howard Schwimmer
Name Printed: Howard Schwimmer
Title: Co-Chief Executive Officer

**LESSEE**
Avita Medical Americas, LLC,
a Delaware limited liability company

By: /s/ Troy Barring
Name Printed: Troy Barring
Title: Chief operating officer

By: _____
Name Printed: _____
Title: _____

**FIRST AMENDMENT TO LEASE**

**THIS FIRST AMENDMENT TO LEASE AGREEMENT** (the "**Amendment**") is entered into as of the 14th day of December, 2016, by and between RIF III – AVENUE STANFORD, LLC, a California limited liability company ("**Landlord**") and AVITA MEDICAL AMERICAS, LLC, a Delaware limited liability company ("**Tenant**").

W I T N E S S E T H:

WHEREAS, Landlord and Tenant have entered into that certain Standard Multi-Tenant Office Lease—Gross dated October 3, 2016 (the "**Original Lease**"), pursuant to which Landlord leased to Tenant certain premises consisting of approximately 11,825 square feet located at 28159 Avenue Stanford, Suite 220, Valencia, California 91355 (the "**Premises**"), such Original Lease, as heretofore modified, being herein referred to as the "**Lease**".

WHEREAS, Landlord and Tenant desire to modify the Lease to, among other things, extend the Commencement Date and the Expiration Date of the Lease, on the terms and conditions set forth below.

A G R E E M E N T:

NOW THEREFORE, in consideration of the Premises and the mutual covenants hereinafter contained, the parties hereto agree as follows:

1. Except as otherwise expressly provided herein, all defined terms used in this Amendment shall have the same respective meanings as are provided for such defined terms in the Lease.

2. The Commencement Date as set forth in Section 1.3 of the Original Lease is hereby extended to December 30, 2016.

3. The Expiration Date as set forth in Section 1.3 of the Original Lease is hereby extended to January 31, 2021.

4. The Base Rent Paid Upon Execution of the Lease as set forth in Section 1.7 (a) of the Original Lease shall be applied to the first full month of the Lease, which is January 2017. Accordingly, concurrently upon execution of this Amendment, Tenant shall deliver to Landlord payment of prorated Base Rent for the month of December in the total amount of $1,258.79.

5. Notwithstanding anything in the Original Lease to the contrary, the Base Year of the Lease shall be 2017.

6. Tenant warrants, represents and certifies to Landlord that as of the date of this Amendment, (i) Landlord is not in default under the Lease, (ii) Tenant does not have any defenses or offsets to payment of rent and performance of its obligations under the Lease as and when the same become due; and (iii) Tenant has no remaining renewal, extension or termination options or rights of first offer or first refusal.

7. Insofar as the specific terms and provisions of this Amendment purport to amend or modify or are in conflict with the specific terms, provisions and exhibits of the Lease, the terms and provisions of this Amendment shall govern and control; in all other respects, the terms, provisions and exhibits of the Lease shall remain unmodified and in full force and effect.

8. Landlord and Tenant hereby agree that (i) this Amendment is incorporated into and made a part of the Lease, (ii) any and all references to the Lease hereinafter shall include this Amendment, and (iii) the Lease and all terms, conditions and provisions of the Lease are in full force and effect as of the date hereof, except as expressly modified and amended hereinabove.

9. Each party hereto, and their respective successors and assigns shall be authorized to rely upon the signatures of all of the parties hereto on this Amendment which are delivered by facsimile or PDF as constituting a duly authorized, irrevocable, actual, current delivery of this Amendment with original ink signatures of each person and entity. This Amendment may be executed in counterparts, each of which shall be deemed an original part and all of which together shall constitute a single agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have signed this Amendment as of the day and year first above written.

**TENANT:**

AVITA MEDICAL AMERICAS, LLC,
a Delaware limited liability company

By: /s/ Troy Barring
Name: Troy Barring
Title: COO

By: _____
Name: _____
Title: _____

**LANDLORD:**

RIF III – AVENUE STANFORD, LLC,
a California limited liability company

By: Rexford Industrial Realty, L.P.,
a Maryland limited partnership,
its Managing Member

By: Rexford Industrial Realty, Inc.,
a Maryland corporation,
its General Partner

By: /s/ Howard Schwimmer
Name: Howard Schwimmer
Title: Co-Chief Executive Officer

**SECOND AMENDMENT TO LEASE**

**THIS SECOND AMENDMENT TO LEASE AGREEMENT** (the "**Amendment**") is entered into as of the 4th day of December, 2017, by and between RIF III – Avenue Stanford. LLC. a California limited liability company **("Landlord")** and Avita Medical Americas, LLC, a Delaware limited liability company **("Tenant").**

W I T N E S S E T H:

WHEREAS, Landlord and Tenant have entered into a Lease dated October 3, 2016, as amended by the First Amendment to Lease, dated as of December 14, 2016, pursuant to which Landlord leased to Tenant certain premises consisting of approximately 11,809 square feet located at 28159 Avenue Stanford, Suite 220. Valencia, California. 91355 (the **"Original Premises"),** such lease, as heretofore modified, being herein referred to as the**"Lease"**.

NOW, THEREFORE, Landlord and Tenant desire to modify the Lease to, among other things, to expand the Premises upon the terms and conditions set forth herein.

A G R E E M E N T:

NOW THEREFORE, in consideration of the Premises and the mutual covenants hereinafter contained, the parties hereto agree as follows:

1. Effective February 1, 2018 (the **"Expansion Date"),** the "Premises" (as defined in the Lease) shall be expanded to include that certain premises commonly known as 28159 Avenue Stanford, Suite 200, Valencia, California, 91355, comprised of an approximately 5,656 rentable square foot unit (the **"Expansion Premises")**. on the terms and conditions set forth in the Lease, as hereby amended. Effective upon the Expansion Date, all references in the Lease to the "Premises" shall also include the Expansion Premises, except as expressly provided in this Amendment.

2. Subject to Section 7 below, Tenant shall accept the Expansion Premises in its "as is" condition, without any representations or warranties. The taking of possession of the Expansion Premises shall be conclusive evidence that Tenant accepts the Expansion Premises and that the Expansion Premises were in good condition at the time possession was taken except for any punchlist items agreed to in writing by Landlord and Tenant pursuant to the attached Move-In/Move-Out checklist. Prior to the Expansion Date, Tenant shall deliver to Landlord a Certificate of Insurance and Endorsement for the Expansion Premises in compliance with Section 8 of the Lease. Notwithstanding the foregoing, Tenant shall be granted early possession of the Expansion Premises upon Substantial Completion of the Landlord Work (defined below), so long as (i) Tenant is not in Default under the Lease, (ii) upon full execution of this Amendment, (iii) upon Lessor's receipt of a Certificate of Insurance and Endorsement for the Expansion Premises pursuant to Paragraph 8.2 of the Lease, and (iv) payment of total monies due as described under Paragraph 8 of this Amendment. During such early possession

of the Expansion Premises, Tenant shall be bound by its obligations under the Lease but shall not be obligated to pay the monthly Base Rent or Common Area Operating Expenses payable by Tenant to Landlord for the Expansion Premises as set forth in the Lease, as amended by this Amendment.

3. Base Rent.

   a. Tenant shall continue to pay Base Rent for the Original Premises pursuant to the Lease.

   b. The term for the Expansion Premises shall commence on the Expansion Date and shall expire January 31, 2021 (the"**Expansion Premises Term**") The monthly Base Rent for the Expansion Premises shall be as follows:

| Period | Monthly Base Rent |
|---|---|
| February 1, 2018 — January 31, 2019 | $ 10,180.80 |
| February 1, 2019 — January 31, 2020 | $ 10,463.60 |
| February 1, 2020 — January 31, 2021 | $ 10,746.40 |

4. Tenant shall continue to pay Common Area Operating Expenses as provided in the Lease applicable to the Original Premises pursuant to the Lease. During the Expansion Premises Term, Tenant shall pay all increases in Common Area Operating Expenses over the Base Year, during the Expansion Premises Term. Lessee's Share (as defined in Paragraph 1.6 of the Lease) of the Common Area Operating Expenses for the Expansion Premises is seven and fourteen hundredths percent (7.14%).

5. The "Base Year" for the Expansion Premises shall be calendar year 2018.

6. Landlord currently holds a Security Deposit for the Original Premises in the amount of $63,874.86. The Security Deposit for the Expansion Premises shall be $32,239.20 and shall be held by Landlord in accordance with the terms of Section 5 of the Lease. Upon the Expansion Date, the Security Deposit to be held by Landlord for the Premises shall be a total of $96,114.06.

7. Landlord shall, at Tenant's sole cost and expense, on a one-time basis only, (i) construct four (4) additional offices in the Expansion Premises, as shown on Exhibit "A", (ii) install one (1) dishwasher in a mutually agreeable location; and (iii) install two (2) 6'x8' cased openings to connect the Original Premises with the Expansion Premises, as shown on Exhibit "A" (collectively, the "**Landlord Work**"), using Project standard materials, specification. guidelines and procedures (except to the extent otherwise designated by Landlord). The exact scope and specifications for each element of the Landlord Work shall be determined by Landlord. Landlord shall be permitted to perform the Landlord Work during Tenant's occupancy of the Premises, during normal business hours (or any hours), without any obligation to pay overtime or other premiums. Tenant shall not (and Tenant shall ensure that its agents do not) interfere with the performance of the Landlord Work and shall cooperate with Landlord in connection with the performance of the Landlord Work, including, without limitation, by moving any equipment and other properly which Landlord or its contractor may request be moved at Tenant's sole cost and expense. Landlord shall have no responsibility for, or for any reason be liable to Tenant for, any direct or indirect injury to or interference with

Tenant's business arising from the performance of the Landlord Work, nor shall Tenant be entitled to any compensation or damages for loss of the use of the whole or any part of the Premises or of Tenant's personal properly or improvements resulting from the performance of the Landlord Work or Landlord's or Landlord's contractor's or agent's actions in connection with the performance of the Landlord Work, or for any inconvenience or annoyance occasioned by the performance of the Landlord Work or Landlord's or Landlord's contractor's or agent's actions in connection with the performance of the Landlord Work. Tenant shall be responsible for any increase in the cost of performing the Landlord Work resulting from any act or omission of Tenant or its agents, employees, contractors. In addition, should Tenant request any change in the scope of the Landlord Work, then Tenant shall be responsible for all costs and expenses incurred by Landlord in connection therewith (payable upon demand); provided, however. Landlord shall have no obligation to change the scope of the Landlord Work (and any election to do so shall be in Landlord's sole and absolute discretion).

For purposes of this Amendment, **"substantial Completion"** of the Expansion Premises shall occur when, in the opinion of the construction manager (whether an employee or agent of Landlord or a third-party construction manager), the Landlord Work is substantially completed except for punch list items which do not prevent in any material way the use of the Premises for the purposes for which it was intended.

The cost of The Landlord Work shall be amortized on a straight line basis over the Expansion Premises Term, which such amortization Tenant shall be required to pay to Landlord. $1,670.28 per month (the "**Improvement Amortization**"). The Improvement Amortization shall be subject to the same terms and conditions as Rent under the Lease.

8. Landlord shall. at Landlord's sole cost and expense, on a one-time basis only, install vertical blinds at the Expansion Premises, similar to the blinds at the Original Premises (collectively, (the **"Blind Work")**. using Project standard materials. specifications, guidelines and procedures (except to the extent otherwise designated by Landlord). Landlord shall be permitted to perform the Blind Work during Tenant's occupancy of the Premises, during normal business hours (or any hours), without any obligation to pay overtime or other premiums. Tenant shall not (and Tenant shall ensure that its agents do not) interfere with the performance of the Blind Work and shall cooperate with Landlord in connection with the performance of the Blind Work. including, without limitation, by moving any equipment and other property which Landlord or its contractor may request be moved at Tenant's sole cost and expense Landlord shall have no responsibility for, or for any reason be liable to Tenant for, any direct or indirect injury to or interference with Tenant's business arising from the performance of the Blind Work, nor shall Tenant be entitled to any compensation or damages for loss of the use of the whole or any part of the Premises or of Tenant's personal property or improvements resulting from the performance of the Blind Work or Landlord's or Landlord's contractor's or agent's actions in connection with the performance of the Landlord Work, or for any inconvenience or annoyance occasioned by the performance of the Blind Work or Landlord's or Landlord's contractor's or agent's actions in connection with the performance of the Blind Work. Tenant shall be responsible for any increase in the cost of performing the Blind Work resulting from any act or omission of Tenant or its agents, employees, contractors. In addition, should Tenant request any change in the scope of the Blind Work, then Tenant shall be responsible for all costs and expenses incurred by Landlord in connection therewith (payable upon demand); provided, however. Landlord shall have no obligation to change the scope of the Blind Work (and any election to do so shall be in Landlord's sole and absolute discretion).

9. Upon execution of this Amendment, a total of $44,090.28 shall be due. which is the sum of the Security Deposit for the Expansion Premises ($32,239.20), the Improvement Amortization for the calendar month of February 2018 ($1,670.28) and the Base Rent for the Expansion Premises for the calendar month of February 2018 ($10,180.80).

10. Notwithstanding anything herein to the contrary but subject to Tenant not being in default and all prior rental payments having been received by Landlord not later than the fifth (5th) of each month, the Base Rent (and only the Base Rent) applicable to the Expansion Premises only, for the calendar month of March 2018 shall be discounted by one hundred percent (100%) (the **"Expansion Premises Base Rent Credit"**). Tenant understands and agrees that the foregoing Expansion Premises Base Rent Credit is conditioned upon Tenant's not being in default under this Lease. Accordingly, upon the occurrence of any default under this Lease, the foregoing Expansion Premises Base Rent Credit shall immediately become null and void, and any Base Rent previously credited to Tenant shall immediately become due and payable, and Tenant shall no longer receive any credit on account of such Expansion Premises Base Rent Credit.

11. Upon the Expansion Date, Tenant shall be entitled to the use of an additional sixteen (16) unreserved vehicle parking spaces, the use of which shall be subject to the terms and conditions of Section 2.6 of the Lease.

12. Tenant warrants, represents and certifies to Landlord that as of the date of this Amendment, (i) Landlord is not in default under the Lease, (ii) Tenant does not have any defenses or offsets to payment of rent and performance of its obligations under the Lease as and when the same become due; (iii) Tenant has not heretofore assigned or sublet all or any portion of its interest in the Lease or in the Original Premises; (iv) no other person, firm or entity has any right, title or interest in the Lease or in the Original Premises through Tenant; and (v) Tenant has the full right, legal power and actual authority to enter into this Amendment without the consent of any person, firm or entity.

13. Tenant represents and warrants that it has dealt with no broker, agent or other person in connection with this transaction and that no broker, agent or other person brought about this transaction, other than CBRE, Inc. and Tenant agrees to indemnify and hold Landlord harmless from and against any claims by any other broker, agent or other person claiming a commission or other form of compensation by virtue of having dealt with Tenant with regard to this leasing transaction.

14. Except as otherwise expressly provided herein, all defined terms used in this Amendment shall have the same respective meanings as are provided for such defined terms in the Lease. Insofar as the specific terms and provisions of this Amendment purport to amend or modify or are in conflict with the specific terms, provisions and exhibits of the Lease, the terms and provisions of this Amendment shall govern and control; in all other respects, the terms, provisions and exhibits of the Lease shall remain unmodified and in full force and effect.

15. Landlord and Tenant hereby agree that (i) this Amendment is incorporated into and made a part of the Lease, (ii) any and all references to the Lease hereinafter shall include this Amendment, and (iii) the Lease and all terms, conditions and provisions of the Lease are in full force and effect as of the date hereof, except as expressly modified and amended hereinabove.

16. A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or Landlord may not prohibit the Tenant or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the Tenant or tenant, if requested by the Tenant or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Premises.

    Landlord makes the following statement based on Landlord's actual knowledge in order to comply with California Civil Code Section 1938: The Building and the Premises have not undergone an inspection by a Certified Access Specialist (CASp). Landlord and Tenant hereby mutually agree that in the event a CASp inspection is requested by Tenant, the fee for the CASp inspection and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within and outside the Premises noted in the CASp inspection shall be paid by Tenant

17. LANDLORD HEREBY DISCLOSES TO TENANT THAT, BASED ON THE AGE OF THE BUILDING, LANDLORD HAS REASONABLE CAUSE TO BELIEVE THAT ASBESTOS-CONTAINING MATERIALS MAY BE PRESENT IN THE BUILDING AND THE PREMISES. TENANT ACKNOWLEDGES THAT LANDLORD HAS SATISFIED ITS OBLIGATION TO NOTIFY TENANT OF THE PRESENCE OF ASBESTOS-CONTAINING MATERIALS IN THE BUILDING PURSUANT TO CALIFORNIA HEALTH & SAFETY CODE SECTION 25359.7, AND TENANT SHALL NOT DISTURB ANY MATERIALS THAT MAY CONTAIN ASBESTOS.

18. Tenant agrees and understands that Landlord shall have the right (provided that the exercise of Landlord's rights does not materially and adversely affect Tenant's use and occupancy of the Premises or subject Tenant to additional costs, without Tenant's consent, to place a solar electric generating system on the roof of the Building or enter into a lease for the roof of the Building whereby such roof lessee shall have the right to install a solar electric generating system on the roof of the Building, and Landlord and its agents shall have access to the roof to accomplish the foregoing.

19. Each party hereto, and their respective successors and assigns shall be authorized to rely upon the signatures of all of the parties hereto on this Amendment which are delivered by facsimile or PDF as constituting a duly authorized, irrevocable, actual, current delivery of this Amendment with original ink signatures of each person and entity. This Amendment may be executed in counterparts, each of which shall be deemed an original part and all of which together shall constitute a single agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have signed this Amendment as of the day and year first above written.

**TENANT:**

AVITA MEDICAL AMERICAS, LLC,
a Delaware limited liability company

By: /s/ Timothy J. Rooney
Name: Timothy J. Rooney
Title: Chief Administrative Officer
Date: Dec 4, 2017

**LANDLORD:**

RIF III – AVENUE STANFORD, LLC,
a California limited liability company

By: Rexford Industrial Realty, L.P.,
a Maryland limited partnership,
Its Managing Member

By: Rexford Industrial Realty, Inc.,
a Maryland corporation,
Its General Partner

By: /s/ Howard Schwimmer
Name Printed: Howard Schwimmer
Title: Co-Chief Executive Officer
Date: Dec 5, 2017 | 2:22 PM PST

EXHIBIT “A”

The Landlord Work Plan

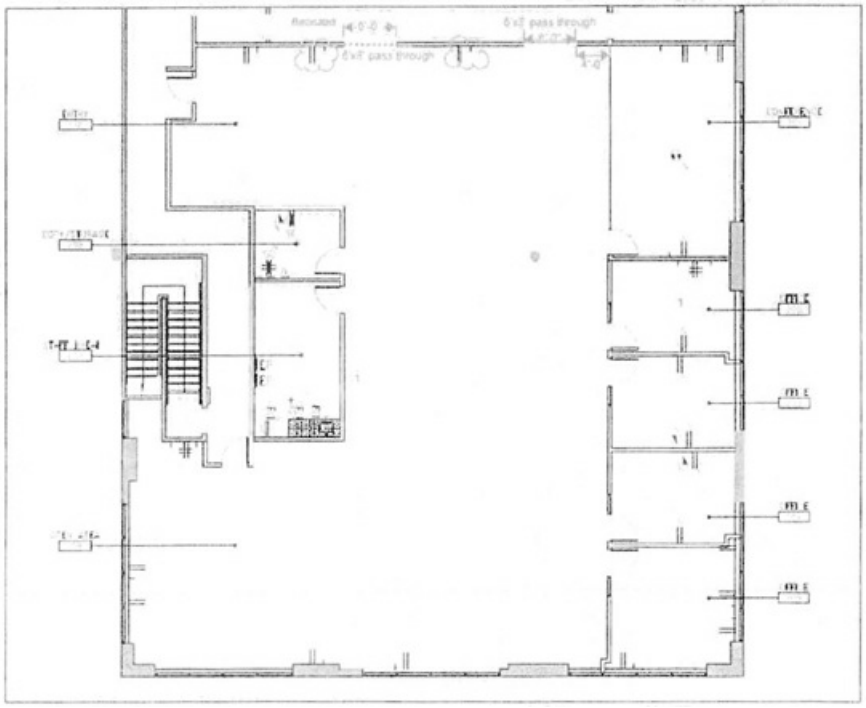
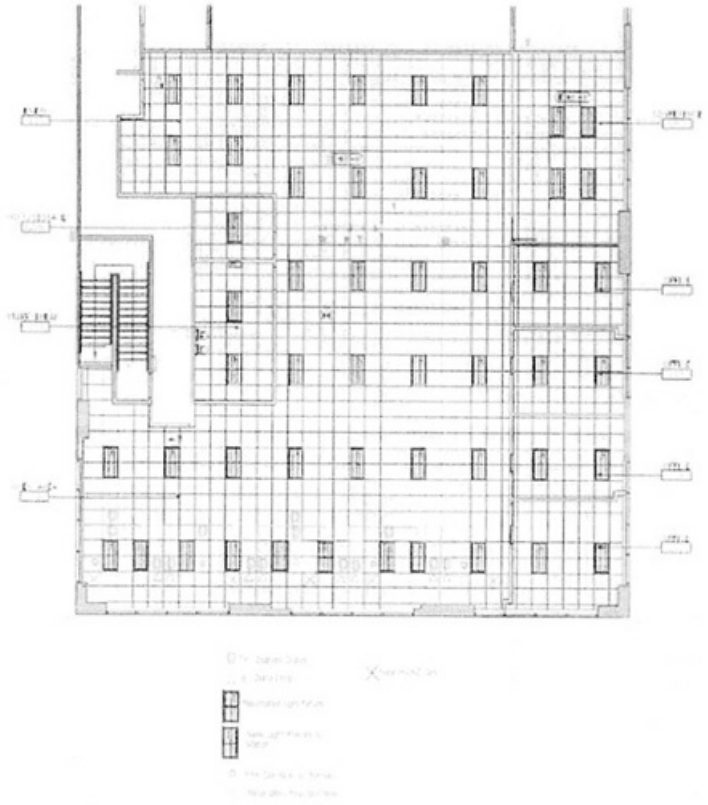


EXHIBIT “A” CONTINUED



Rexford Industrial

# TENANT MOVE-IN/MOVE-OUT CHECKLIST

| | |
|---|---|
| ENTITY NAME: | |
| TENANT NAME: | |
| PREMISES ADDRESS: | |
| POSSESSION DATE: | |
| MOVE-OUT DATE: | |

*Unless otherwise noted, the premises are clean, in good working order and undamaged. Occupant accepts the Premises as is with the exceptions listed below. This inspection form is made a part of and is subject to the terms and conditions of the Commercial Lease for the above referenced Premises.*

| OFFICE AREAS | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| CARPET | | |
| FLOORING | | |
| CEILING | | |
| DOORS | | |
| HVAC | | |
| LIGHTS | | |
| WALLS | | |
| WINDOW COVERINGS | | |
| KITCHEN AREA | | |

| RESTROOMS | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| FLOORING | | |
| CEILING | | |
| DOORS | | |
| LIGHTS | | |
| WALLS | | |
| FIXTURES | | |
| MIRRORS | | |
| PLUMBING | | |
| FANS | | |

| WAREHOUSE | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| FLOORING | | |
| CEILING | | |
| MAN DOORS | | |
| LOADING DOORS | | |
| LIGHTS | | |
| WALLS | | |
| SKYLIGHTS | | |
| COLUMNS | | |
| DOCK EQUIPMENT | | |
| FIRE SPRINKLERS | | |
| ELEC PANEL/DISTRIBUTION | | |

| SINGLE TENANT BUILDING | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| LANDSCAPE | | |
| PAVING / YARD AREA | | |
| EXTERIOR MISC | | |

| ADDITIONAL COMMENTS | MOVE-IN CONDITION | MOVE-OUT CONDITION |
|---|---|---|
| | | |
| | | |

*The "Move-In Condition" portion of this form is to be completed at the time of initial possession of the Premises. Receipt of a copy of this inspection form is hereby acknowledged.*

| | |
|---|---|
| TENANT SIGNATURE: | |
| DATE: | |
| LANDLORD SIGNATURE: | |
| DATE: | |

*The "Move Out Condition" portion of this form is to be completed at the time of Tenant move-out of the Premises. Receipt of a copy of this inspection form is hereby acknowledged.*

| | |
|---|---|
| TENANT SIGNATURE: | |
| DATE: | |
| LANDLORD SIGNATURE: | |
| DATE: | |