# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 20-F/A (Amendment No. 1)

$\times$	ark One)		
	REGISTRATION STATEMENT PURSUANT TO	· · · · · · · · · · · · · · · · · · ·	URITIES EXCHANGE ACT OF 1934
	ANNUAL DEPONE DIDCHANG TO CECTION (	OR	ZOHANCE ACT OF 1034
Ц	ANNUAL REPORT PURSUANT TO SECTION 1	I3 OR 15(d) OF THE SECURITIES EX  For the fiscal year ended  OR	CHANGE ACT OF 1934
	TRANSITION REPORT PURSUANT TO SECTI		S EXCHANGE ACT OF 1934
_		ne transition period from to	S EXCERNINGE FIGURE 100.
		OR	
	SHELL COMPANY REPORT PURSUANT TO S	ECTION 13 OR 15(d) OF THE SECU	RITIES EXCHANGE ACT OF 1934
	Date	e of event requiring this shell company report	
		Commission file number 001-39059	
		avital medical medical transforming lives	•
	Avit	ta Medical Limited	$\mathbf{d}$
		ct name of Registrant as specified in its charter translation of Registrant's name into English)	
		Australia	
	(Ju	risdiction 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	
	0 14 4.	(Address of principal executive offices)	
	Securiues register	red or to be registered pursuant to Section 12(b) o Trading	Name of each exchange on which registered
	Title of each class	Symbol(s) CELS	or to be registered
	American Depositary Shares (each		
	representing 20 Ordinary Shares)	GEES	The NASDAQ Stock Market LLC
	Securities registered	or to be registered pursuant to Section 12(g) of the	ne Act. None
	Securities registered		ne Act. None
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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 Form 20-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 Form 20-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 Form 20-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 Form 20-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)	<u>A\$ (7,305,987)</u>	
Earnings per share			<del></del>		<del></del>	
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	<del>+</del> () ===10	7 (-11 -) 22310	+ (====) ====	+ (=.55) 55-M	.4 (5.5 -) 551165	
operations			A\$(0.05) cents			

	As of June 30,			As of December 31,	
(In Australian dollars)	2018	2017	2016		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

Exhibit 15.1 included with this registration statement on Form 20-F contains the preliminary, unaudited consolidated statements of profits or loss and other comprehensive income, consolidated statements of financial position, consolidated statements of cash flows and consolidated statements of changes in equity for the fiscal year ended June 30, 2019 as submitted as Appendix 4E in connection with the ongoing listing of our ordinary shares on the Australian Securities Exchange.

### **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

<u>Month</u>	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	<u>A</u> \$	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 global third-party manufacturers, Baxter International Inc., Hospira (a division of Pfizer), Thermo Fisher Scientific, Lyophilization Services of New England 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.

We rely on third parties to conduct, supervise and monitor our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug product candidates and our business could be substantially harmed.

We rely on clinical research organizations, or CROs, and clinical trial sites to ensure our clinical trials are conducted properly and on time. While we will have agreements governing their activities, we will have limited influence over their actual performance. CROs manage and monitor the clinical trials, duties and functions, and we will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's Good Clinical Practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA, and comparable foreign regulatory authorities, enforce these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our future clinical trials may be deemed unreliable and the FDA or other foreign regulatory authorities may require us to perform additional clinical trials before approving any marketing applications.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates. If any such event were to occur, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Further, switching or adding additional CROs involves additional costs and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

#### 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 <a href="https://avitamedical.com">https://avitamedical.com</a>. 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 and non-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 prepare Spray-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 cm², 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<sup>2</sup> 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.

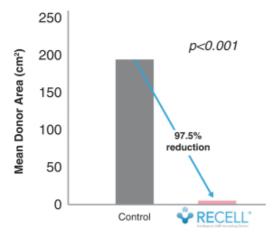
#### The RECELL System Clinical Results in Thermal Burns

RECELL Pivotal Clinical Trial in Second-Degree Acute Thermal Burns

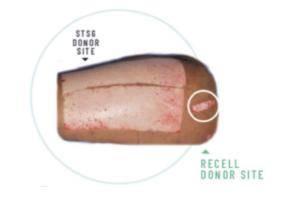
One of the two randomized, controlled clinical trials of the RECELL System supporting the September 2018 FDA approval was a study of patients with partial-thickness (second-degree burns) conducted at 12 U.S. burn centers. The pivotal trial evaluated 101 adult patients with thermal, partial-thickness 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</li>

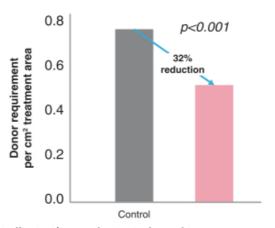
In the clinical trial, use of the RECELL System in the trial was safe and well tolerated with adverse experiences typical for the type of burn injury sustained. The results of this trial were published in a peer-reviewed scientific publication, the *Journal of Burn Care & Research*, in September 2018.

## 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 and non-inferiority in complete wound closure.

The pivotal clinical trial achieved its co-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 a 12-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.

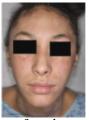
#### **Facial Burn Case Study**













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 a 16-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 of Spray-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<sub>2</sub> laser ablation followed by the application of Spray-On Skin Cells, CO<sub>2</sub> 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 injuries) 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 announced on September 17, 2019 that the FDA approved an IDE application to conduct a trauma injuries (soft-tissue injuries) pivotal clinical trial. We plan to commence a U.S. clinical trial within the next six months in the use of the RECELL System for the treatment of trauma injuries 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 the Spray-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 lists. 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

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 Form 20-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.

#### **Internal Controls**

A material weakness was identified in our internal control over financial reporting relating to the application of tax legislation across jurisdictions, specifically our controls over tracking and monitoring the disclosures related to accumulated tax losses by jurisdiction.

We are taking steps to remediate this deficiency. We intend to implement a more rigorous process to track and monitor our accumulated tax losses and we have hired an external income tax specialist to review our application of tax legislation across jurisdictions. We believe that the above actions will be effective in remediating the material weakness described above. However, the material weakness cannot be considered remediated until the controls operate for a sufficient period of time and management has concluded, through testing, that our internal controls are operating effectively.

Any future failure to maintain such internal controls could adversely impact our ability to report our financial results on a timely and accurate basis, which could result in our inability to satisfy our reporting obligations or result in material misstatements in our financial statements. If our financial statements are not accurate, investors may not have a complete understanding of our operations or may lose confidence in our reported financial information, which could result in a material adverse effect on our business or have a negative effect on the trading price of our ordinary shares and ADRs.

# 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". In addition, Exhibit 15.1 included with this registration

statement on Form 20-F contains the preliminary, unaudited consolidated statements of profits or loss and other comprehensive income, consolidated statements of financial position, consolidated statements of cash flows and consolidated statements of changes in equity for the fiscal year ended June 30, 2019 as submitted as Appendix 4E in connection with the ongoing listing of our ordinary shares on the Australian Securities Exchange.

### 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. Pricing is not expected to be a significant factor in connection with our revenue growth. 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. We do not consider pricing to be a critical component of revenue growth, instead, as indicated above, market acceptance, adoption and penetration of the RECELL System 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 Dece	mber 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						
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
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 of Non-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 its Non-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	Dr. Michael Perry	Open ended	12-month notice period	12 months
Director		contract		
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
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, 2019

	Short-term Benefits				Post- employment Benefits	Share	y-settled e-based ments	Total	Proportion Elemen Remuner Related Perform (Other to Option Issued)	t of ation I to ance han ns	Proportion of Elements of Remuneration Not Related to Performance(2)
	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	_	_	_	-,,.01		_	61,040	0%	0%	100%
Louis Drapeau	60,811	_	_	_	_	_	_	60,811	0%	0%	100%
Damien McDonald	_	_	_	_	_	61,128	_	61,128	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(3)	663,926	515,159	27,608	_	43,148	536,679	401,752	2,188,272	24%	25%	34%
Timothy Rooney	444 600	4.45.000	46.550		22.400		400.045	ECE 050	400/	00/	600/
CAO and Interim CFO Dale Sander	441,683	147,893	16,550	_	23,106		136,647	765,879	19%	0%	63%
CFO(4)	379,908	246,299	31,660	270,450	23,193		80,727	1,032,237	24%	0%	68%
Erin Liberto	3/3,300	240,299	31,000	2/0,430	23,133	_	00,727	1,032,237	24/0	0 /0	0070
CCO	398,353	147,893	41,897	_	22,530	_	207,097	817,770	18%	0%	57%
Andrew Quick	000,000	,	12,001		,		,	,···			
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			

<sup>(1)</sup> Non-salary cash-based incentives % is equal to profit share and bonuses divided by total compensation. Shares or units % is equal to shares or units divided by total compensation.

<sup>(2)</sup> 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%. Proportion of elements of remuneration not related to performance is equal to the sum of salary, fees and leave, non-monetary benefits, pension and superannuation and other compensation, divided by total compensation. As an example, for Dr. Michael Perry, this calculation would be as follows: (A\$663,926+A\$27,608+A\$43,148) / A\$2,188,272 = 34%

- (3) 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
- (4) 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	G	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	— November 1,	_	_	1,750,000	131,950	6,050,000	4,330,000	_	4,330,000	1,720,000	
		2018 November 30,	500,000	32,839	_	_	500,000	_	_	_	500,000	
		2018 November, 30	3,420,000	196,822	_	_	3,420,000	_	_	_	3,420,000	
		2018	360,000	84,816	_	_	360,000	_	_	_	360,000	6,000,000
Andrew Quick	4,518,750	— November 1,	_	_	_	_	4,518,750	3,211,250	_	3,211,250	1,307,500	
		2018 November 30,	500,000	32,839	_	_	500,000	_	_	_	500,000	
		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	— November 1,	_	_	_	_	4,000,000	2,300,000	_	2,300,000	1,700,000	
		2018 November 30,	2,110,000	138,574	_	_	2,110,000	_	_	_	2,110,000	
		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	— November 1,	_	_	_	_	3,000,000	1,520,000	_	1,520,000	1,480,000	
		2018 November 30,	2,610,000	171,412	_	_	2,610,000	_	_	_	2,610,000	
		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 independent non-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:

	2018	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\$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 Ordina (A\$		
	High	Low	
	A\$	A\$	
<u>Fiscal Year Ended June 30,</u>	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	
May 2019	.490	.335	
June 2019	.440	.340	
July 2019	.445	.375	
August 2019	.485	.370	

# 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\$
<u>Fiscal Year Ended June 30,</u>		
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
May 2019	7.17	4.99
June 2019	6.23	4.69
July 2019	6.51	5.25
August 2019	6.50	4.51

# **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	100,982,978	A\$4,544,234
	proceeds of A\$4,544,234 and incurring A\$248,720 in expenses.		
July 11, 2016	We sold 100,164,831 Ordinary Shares at a price of A\$0.09 per share raising gross	100,164,831	A\$9,048,102
	proceeds of A\$9,048,102 and incurring A A\$506,452 in expenses.		

#### **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 vendormanaged 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 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. The audited financial statements included in reliance upon the report of Grant Thornton Audit Pty Ltd, independent registered public accountants, upon the authority of said firm 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: \$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

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\$.05 (or less) per ADS

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

\$.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depositary

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

Any charges incurred by the depositary or its agents for servicing the

deposited securities

For:

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

Any cash distribution to ADS holders

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders

Depositary services

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

Cable and facsimile transmissions (when expressly provided in the deposit agreement)

Converting foreign currency to U.S. dollars

As necessary

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 <u>pro rata</u> 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.
- In addition, Exhibit 15.1 included with this registration statement on Form 20-F contains the preliminary, unaudited consolidated statements of profits or loss and other comprehensive income, consolidated statements of financial position, consolidated statements of cash flows and consolidated statements of changes in equity for the fiscal year ended June 30, 2019 as submitted as Appendix 4E in connection with the ongoing listing of our ordinary shares on the Australian Securities Exchange.

# ITEM 18. FINANCIAL STATEMENTS

We have elected to provide financial statements pursuant to Item 17. See the Index to the Financial Statements on page F-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

Exhibit	Description
8.1*	<u>List of subsidiaries of the registrant</u>
15.1*	Preliminary unaudited final report of June 30, 2019; results announced to the Australian market on August 30, 2019

- \* Previously filed.

  + Certain identified confidential information has been redacted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

# **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/ Michael Perry

By: Michael Perry

Title: Chief Executive Officer

Date: September 25, 2019

# INDEX TO THE FINANCIAL STATEMENTS

Avita Medical Limited	
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#### 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 September 19, 2019

# **Consent of Independent Registered Public Accounting Firm**

We have issued our report dated September 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 September 19, 2019

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

	Notes	2018	Year Ended June 30, 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

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

	Notes	June 2018	30, 2017
ASSETS	11000		
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

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

	Notes	2018	Year Ended June 30, 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

# 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

# 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

# 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	_	_	_	_	_	_
<ul> <li>Foreign currency translation</li> </ul>					(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

#### 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,

### 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,

### 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.

### 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

### 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.

#### (i) 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

### 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

### 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.

### 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.

### 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.

#### (g) 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.

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

#### (g) 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.

### 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.

### 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.

### 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

### 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

### 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	
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	
	Sale of goods	Revenue         A\$1,198,861	Revenue         A\$1,198,861         A\$901,376	

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	

## 4. REVENUES AND EXPENSES (CONTINUED)

		2	Year Ended June 30, 2018 2017	
(c)	Finance costs			
	Other loans	A\$2	26,586 A\$12,75	54 <u>A\$21</u>
		A\$2	26,586 A\$12,75	54 A\$21
			<del></del>	
		2018	Year Ended June 30, 2017	
(d)	Depreciation, impairment and amortization included	2018		2016
(u)	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\$84,164
		=======================================	: =====================================	1401,101
			Year Ended June 30,	
		2018	2017	2016
(e)	Cost of sales	<u>A\$511,646</u>	A\$463,285	A\$401,568
			Year Ended June 30,	
<b>(f)</b>	Lease payments and other expenses included in profit or less	2018 A\$463,095	2017 A \$ 419 102	2016 A \$ 202, 412
(1)	Lease payments and other expenses included in profit or loss	A\$403,095	<u>A\$418,193</u>	A\$283,412
		_		
		2018	Year Ended June 30, 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:

	2018	Year Ended June 30, 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

## 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

	2018	Year Ended June 30 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)

At June 30, 2018

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

## 6. INCOME TAX (CONTINUED)

			2018	As of June 30, 2017	2016
(c) Non-current assets – Deferred tax assets					
The balance comprises temporary differences attributable t	:0:				
Provisions		A\$	122,243	A\$ 48,513	A\$ 82,074
Property, plant and equipment			10,155	12,945	13,905
Intangible assets		1	1,025,616	735,400	611,343
Other			2,378	(766)	
Total deferred tax assets		1	1,160,392	796,092	707,322
Set off deferred tax liabilities pursuant to set-off provisions	S		_		
		1	1,160,392	796,092	707,322
Deferred tax assets not brought to account as realization is	not considered				
probable		(1	1,160,392)	(796,092)	(707,322)
Deferred tax assets recognized		<b>A</b> \$	_	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	<u> </u>	509,260

A\$10,155

A\$1,025,616

A\$ 2,378

A\$1,160,302

A\$122,153

## 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:

		Relevant Tax	
Jurisdiction	Total Losses	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 o	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		

### 8. CURRENT ASSETS - TRADE AND OTHER RECEIVABLES

As of June 30,		
2018	2017	
A\$ 263,421	A\$ 259,012	
(23,452)	(88,859)	
239,969	170,153	
2,434,430	1,048,634	
2,762,958	851,747	
A\$5,437,357	A\$2,070,534	
	2018 A\$ 263,421 (23,452) 239,969 2,434,430 2,762,958	

#### (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	<del>_</del>	_
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*	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

<sup>\*</sup> Past due not impaired ("PDNI")

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.

<sup>\*\*</sup> Considered impaired ("CI")

## 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).

## 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
11 July 1, 2010, net of accumulated depreciation	A\$ 94,491
Additions	432,592
-	
Additions	432,592
Additions Depreciation charge for the year	432,592 (139,703)
Additions Depreciation charge for the year As of June 30, 2017, net of accumulated depreciation	432,592 (139,703)
Additions Depreciation charge for the year As of June 30, 2017, net of accumulated depreciation As of June 30, 2017	432,592 (139,703) <b>A\$ 387,380</b>

## 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	
carrying amount of trade and other payables	1 1 4 5 3 4 5 7 3 5 6 2	1 1 φ 2,00	

### (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.

### 12. CURRENT LIABILITIES – PROVISIONS

	Α	s 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.
- A provision is recognized for long service leave due to employees at the end of the year.

## 13. CONTRIBUTED EQUITY

	As of Jun	ie 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	<u> </u>	(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	<u> </u>	(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.

## 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.

## 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	100%	100%	100%	_	_
	Kingdom					
Avita Medical Americas LLC	United	100%	100%	100%	_	_
	States					
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.

## 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

### 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)	80.0	(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.

## 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

## 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:

	2	2018		017
Grant date	05/18/2017		05/	18/2017
Share price at date of grant	A\$	80.0	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	2	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	06/2	7/2017	0	6/27/2017	
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	

## 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:

	2	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:

	2	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	

## 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%	

	Tran	iche 5	Tr	Tranche 6		Tranche 6 Tranche 7		Tranche 6 Tranche 7		Tranche 8
Grant date	11/3	30/2017	11	1/30/2017	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	11/3	30/2027	11	1/30/2027	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.

## 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	<b>EMEA</b>	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%.

## 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	<b>EMEA</b>	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		· <del></del>		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		<u> </u>	<u> </u>	A\$ 4,017,455

	Asia P	Pacific	1	EMEA	Ame	ricas		Total
Year ended June 30, 2017		•						
Revenue								
Sale of goods	A\$ 4	52,662	A\$	448,714	A\$	_	A\$	901,376
Other revenues from external customers	1	97,488		23,537	6,8	86,236		7,107,261
Interest received	1	16,559		1,218		5,932		123,709
Total revenue and other income per consolidated statement								
of profit or loss and other comprehensive income	A\$ 7	66,709	<b>A</b> \$	473,469	A\$ 6,8	92,168	<b>A</b> \$	8,132,346
Segment net operating loss before tax	A\$(1,5	59,592)	A\$(2	2,836,165)	A\$(2,3	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)

## 18. SEGMENT INFORMATION (CONTINUED)

	Asia Pacific	<b>EMEA</b>	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	<del></del>	· · · · · · · · · · · · · · · · · · ·		<u>A\$2,546,089</u>
	Asia Pacific	<b>EMEA</b>	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				<u>A\$(11,243,843)</u>
		Continuin	g Operations	
W	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	A\$254,072	A\$1,049,931	A\$2,740,913	3,951,391
				3,331,331
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

#### 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 Ju	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.

### 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 Ju	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.

#### 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:	2018	Post Tax Loss (Higher)/Lower 2017	2016	2018	Equity Higher/(Lower) 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.

#### 19. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (CONTINUED)

The remaining contractual maturities of the Company's financial liabilities are:

	As of Jun	e 30,
	2018	2017
6 months or less	A\$3,487,582	A\$2,363,734
6-12 months	<del>_</del>	_
1-3 years	<del>-</del>	_
	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

#### 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

	Min	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:

	Minii	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.

	2018	Year ended June 30, 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

#### 22. PARENT ENTITY INFORMATION

Information relating to Avita Medical Limited:	As of June 30,			
		2018		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'.

#### 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	2018	Year ended June 30, 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)

#### 23. DEED OF CROSS GUARANTEE (CONTINUED)

		2018	As of June 30,		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	(2	163,194,156	)	(	134,977,180)
Reserves		4,503,523			3,234,341
TOTAL EQUITY	<b>A</b> \$	4,110,395		<b>A</b> \$	3,063,183

#### 24. INVESTMENTS

		As of 30 June		
	2018	2017	2016	
Investment in MVP shares	<del>\$</del> —	\$	\$453,892	
Fair value gain on investment	<u> </u>		265,261	
Carrying amount of investment	<b>\$</b> —	<b>\$</b> —	\$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		<b>A</b> \$(1.59) cents	<b>A</b> \$(0.91) cents	

## 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		<u> </u>	
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

## AVITA MEDICAL LIMITED CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS (IN AUSTRALIAN DOLLARS) (UNAUDITED)

	Half-year ended	
Cook flows from anaroting activities	2018	2017
Cash flows from operating activities	A # (DO DOE G 4D)	A # (44 0 4D 400)
Payments to suppliers and employees	A\$(20,305,643)	A\$(11,943,480)
Interest paid	<del>-</del>	(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 I	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

## 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				payment	currency translation	Total A\$ 5,121,832
Loss for the period		equity	losses	payment reserve	currency translation reserve A\$(277,017)	<b>A\$ 5,121,832</b> (7,250,597)
Loss for the period Other comprehensive income		equity	losses \$A(132,218,352) (7,250,597) —	payment reserve	currency translation reserve <b>A\$(277,017)</b> — (55,390)	<b>A\$ 5,121,832</b> (7,250,597) (55,390)
Loss for the period		equity	losses \$A(132,218,352)	payment reserve	currency translation reserve A\$(277,017)	<b>A\$ 5,121,832</b> (7,250,597)
Loss for the period Other comprehensive income		equity	losses \$A(132,218,352) (7,250,597) —	payment reserve	currency translation reserve <b>A\$(277,017)</b> — (55,390)	<b>A\$ 5,121,832</b> (7,250,597) (55,390)
Loss for the period Other comprehensive income Total comprehensive loss for the period Transactions with owners in their capacity as owners: Share-based payments		equity A\$134,806,022 ———————————————————————————————————	losses \$A(132,218,352) (7,250,597) —	payment reserve	currency translation reserve <b>A\$(277,017)</b> — (55,390)	<b>A\$ 5,121,832</b> (7,250,597) (55,390) ( <b>7,305,987</b> )
Loss for the period Other comprehensive income Total comprehensive loss for the period Transactions with owners in their capacity as owners: Share-based payments New shares		equity A\$134,806,022	losses \$A(132,218,352) (7,250,597) —	payment reserve  A\$ 2,811,179  ———————————————————————————————————	currency translation reserve <b>A\$(277,017)</b> — (55,390)	<b>A\$ 5,121,832</b> (7,250,597) (55,390) (7,305,987)  726,855 17,028,964
Loss for the period Other comprehensive income Total comprehensive loss for the period Transactions with owners in their capacity as owners: Share-based payments New shares Cost of share placement		equity A\$134,806,022 ———————————————————————————————————	losses	payment reserve  A\$ 2,811,179	currency translation reserve <b>A\$(277,017)</b> — (55,390)	<b>A\$ 5,121,832</b> (7,250,597) (55,390) ( <b>7,305,987</b> )
Loss for the period Other comprehensive income Total comprehensive loss for the period Transactions with owners in their capacity as owners: Share-based payments New shares		equity A\$134,806,022	losses \$A(132,218,352) (7,250,597) —	payment reserve  A\$ 2,811,179  ———————————————————————————————————	currency translation reserve <b>A\$(277,017)</b> — (55,390)	<b>A\$ 5,121,832</b> (7,250,597) (55,390) (7,305,987)  726,855 17,028,964

### 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) (UNAUDITED)

#### 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 (IN AUSTRALIAN DOLLARS) (UNAUDITED)

#### 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,

#### 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,		
Revenue	2018	2017		
revenue				
Sale of goods	A\$1,813,195	A\$ 607,761		
	A\$ 1,813,195	A\$ 607,761		
Other Income	<del></del>			
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

#### 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:

	4 ' D 'C	Continuing Operations		m . 1
Half-year ended December 31, 2018	Asia Pacific	Europe	Americas	Total
·				
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	· <del></del>	<u> </u>		
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	· <del></del>	<u> </u>		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

#### 4. OPERATING SEGMENTS (CONTINUED)

	Asia Pacific	Continuing Operations Europe	Americas	Total
Half-year ended December 31, 2017	risia i acipie	Бигорс	1 mereus	Total
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	<del></del>			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	<u>A\$188,210,306</u>	<u>A\$162,801,028</u>
	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

#### 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	d 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

#### 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	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.

#### 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.

	Tra	Tranche 1		nche 2	Tra	anche 3	Th	Tranche 4		
Grant date	11	11/1/2018		1/1/2018	1:	1/1/2018	1	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.

	Tra	Tranche 1		anche 2	Tr	anche 3	Tr	Tranche 4		
Grant date	11	11/1/2018		11/1/2018		11/1/2018		1/1/2018		
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 the two-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

#### 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		Tra	ınche 2	Tra	anche 3	Tra	Tranche 4	
Grant date	11/	11/30/2018		/30/2018	11	/30/2018	11	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/	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 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.