AVITA THERAPEUTICS, INC.

ANNUAL REPORT

FISCAL YEAR ENDED JUNE 30, 2020

AVITA THERAPEUTICS, INC.
LETTER FROM THE CHAIRMAN AND CEO

Dear Shareholders:

The global pandemic has caused a very challenging year for the world and for AVITA Therapeutics, Inc. and our healthcare peers. Our foremost focus has been on the safety, health and well-being of our employees, physician partners and patients.

From an operational viewpoint, for our employees located in our main headquarters in Valencia, CA, we have implemented comprehensive work from home and social distancing policies. With that said, our manufacturing facility in Ventura, CA continues to operate without any interruptions, and, importantly, we have no anticipated disruptions to our supply chain or distribution network and have sufficient raw materials to meet expected demand. As we look ahead, there is a lot we are unable to predict with respect to viral peaks and vaccine development, but we will continue to monitor the situation and weigh data and guidance to adjust policies and practices so as to maintain safety while continuing our various company growth objectives.

Despite the challenging backdrop of COVID-19, we are focused on driving forth our burns franchise, while also continuing the development of our multiple pipeline candidates. Turning first to burns, our RECELL® Autologous Cell Harvesting Device (RECELL System) for the treatment of acute thermal burns in adults has been well-received by burn surgeons and we are now in 85 of 134 major burn centers across the US. As you may recall, the RECELL System, which was granted FDA premarket approval (PMA) in September 2018 allows for point of care preparation of Spray-On Skin™ Cells, an autologous cellular suspension comprised of the patient's own skin cells necessary to regenerate healthy epidermis.

Although sporadic COVID-19 hospital restrictions remain throughout the country, which continue to limit account access, travel and sales activity as well as in-person operating room support is generally allowed in the majority of our centers. Thus, our sales force has remained active during the pandemic. We are very pleased with our success in modifying our training protocols and we now perform the majority of trainings remotely. Our commercial organization consisting of 21 field sales personnel (consisting of Regenerative Tissue Specialists, Clinical Training Specialists and regional directors) has implemented comprehensive digital and audio outreach programs and medical education events, virtual case support and site training. These events reliably drive positive RECELL acceptance and should fuel further adoption. Additionally, we have over 20 virtual training and education events either confirmed or in the process of being scheduled in September and October.

Looking beyond adult burns, our R&D efforts continue with further clinical development of the RECELL System in additional indications in pediatric burns, soft tissue or trauma wounds, vitiligo and potentially chronic wounds. We are working towards submitting new analyses to FDA with the goal of expanding our label to increase total body surface area indicated for treatment with RECELL and in treating patients younger than 18 years of age

FDA has approved an Investigational Device Exemption (IDE) for our Vitiligo Pivotal Clinical Study in addition to IDE approvals of our U.S. Soft Tissue Repair Clinical Study and Pediatric Scald Clinical Study. Our efforts with enrollment and recruitment in these studies are ongoing. However, with COVID-19, investigational studies in some areas have been de-prioritized at institutions and we have thus seen a slowdown in enrollment of some of our trials. In response to the latter, we have put in place several enrollment initiatives utilizing third parties to help with direct site outreach, enrollment assistants, study branding materials, digital marketing and social networking to help jumpstart recruitment activities for our clinical studies.

We continue with our cell and gene sponsored research programs aimed to provide preclinical proof-of-concept of our Spray-On Skin™ Cell suspension as a delivery vehicle for our modified cells, for rejuvenation and for the treatment of genetic skin disorders. The Sponsored Research program with University of Colorado, Gates Center in Epidermolysis Bullosa is underway and we are currently in the contracting phase to finalize an academic partnership in skin rejuvenation.

We are working on determining additional scientific components of our Spray-On Skin™ Cells suspension, characterization of the RECELL System, and the design of the device to support further development of the platform in other injuries and defects of the skin, and to expand upon our existing intellectual property estate. Across our development efforts, we have approximately 9 pending publications projected to be published in Q4 2020 and early 2021.

Turning to a corporate update, in June of this year, a statutory scheme of arrangement was implemented under Australian law to change the domicile of AVITA from Australia to the U.S. The AVITA group of companies is comprised of AVITA Therapeutics, Inc. ("AVITA Therapeutics" or the "Company") and its subsidiaries, including AVITA Medical Limited (collectively, "AVITA Group"). Under the scheme of arrangement, AVITA Therapeutics, being a company incorporated in the State of Delaware in the U.S. became the new parent company of the AVITA Group, and all of the issued and outstanding ordinary shares of AVITA Medical Limited, the former parent of the AVITA Group were exchanged for newly issued shares of common stock of the Company, on the basis of one share of the Company's common stock for every 100 ordinary shares of AVITA Medical. Holders of Avita Medical's American Depository Shares ("ADSs") (each of which represented 20 ordinary shares of AVITA Medical) received one share of the Company's common stock for every five ADSs held. We believe these changes will allow us to better access the US financial and healthcare markets.

As we navigate through this unprecedented pandemic, the safety and welfare of our employees, patients, physician partners, and stakeholders are paramount. Despite these unusual times, we remain extremely excited about our RECELL System and the potential for new indications to improve patients' lives. Our Board of Directors is committed to working alongside management to achieve these goals and continue to deliver value for our shareholders. We are grateful for the ongoing support of all our shareholders, employees, the Biomedical Advanced Research and Development Authority (BARDA), medical professionals and patients. Together we will continue our work towards addressing unmet medical needs in therapeutic skin restoration.

Lou Panaccio
Non-Executive Chairman
AVITA Therapeutics, Inc.

Dr. Michael Perry
Chief Executive Officer
AVITA Therapeutics, Inc.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended June 30, 2020
or
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____
Commission File Number: 001-39059

AVITA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**85-1021707**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

28159 Avenue Stanford
Suite 220
Valencia, CA 91355
(Address of principal executive offices and Zip Code)

Registrant's telephone number, including area code: (661) 367-9170

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**RCEL**	**The NASDAQ Stock Market LLC**

Securities registered pursuant to section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☐
Emerging growth company ☒	

If an emerging growth company, indicate by check mark if the registrant has selected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒
The aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was approximately $963,450,796 on December 31, 2019, using the closing price on that day of $45.5
The number of shares of the registrant's $0.0001 par value common stock outstanding as of August 20, 2020 was 21,468,494.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") and our other public filings contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements give expectations or forecasts of future events. Forward-looking statements can sometimes, but not always, be identified by words such as "believe," "expect," "anticipate," "estimate," "project," "plan," "should," "intend," "may," "will," "would," "potential" and similar expressions to future periods. Forward-looking statements are not based on historical facts but rather represent current expectations and assumptions. Forward-looking statements include statements we make about matters such as: future revenues; solvency; future industry market conditions; future changes in our capacity and operations; future operating and overhead costs; intellectual property; regulatory and related approvals; the conduct or outcome of pre-clinical or clinical (human) studies; operational and management restructuring activities (including implementation of methodologies and changes in the board of directors); future employment and contributions of personnel; effects on the global economy of the COVID-19 virus; tax and interest rates; productivity, business process, rationalization, investment, acquisition and acquisition integrations, consulting, operational, tax, financial and capital projects and initiatives; changes in the legal or regulatory environment; and future working capital, costs, revenues, business opportunities, cash flows, margins, earnings and growth.

Forward-looking statements relate to the future and are subject to many risks, assumptions and uncertainties, including those risks set forth in this Annual Report in Part I, Item IA Risk Factors and elsewhere. Although we believe the expectations reflected in the forward-looking statements are reasonable, actual results, developments and business decisions could differ materially from those contemplated by such forward-looking statements. The environment in which we operate is highly competitive, highly regulated and rapidly changing and it is not possible for our management to predict all risks, as new risks emerge from time to time.

All subsequent written and oral forward-looking statements by or attributable to us or persons acting on our behalf are expressly qualified in their entirety by these factors. We undertake no obligation to publicly update or revise any forward-looking statements whether as a result of new information, future developments or otherwise, except as may be required by law.

Currency

In this Annual Report, all references to "dollars" or "$" are to the currency of the United States, and all references to "Australian dollars", "A$" or "AUD$" are to the currency of Australia.

Redomicile Share Exchange

On June 29, 2020, we completed a redomicile transaction ("**Redomicle Transaction**"), as a result of which the location of incorporation of the parent of the AVITA Group (as defined herein) was moved from Australia to the State of Delaware. On the effective date of the Redomicile Transaction, all of the issued and outstanding ordinary shares of AVITA Medical Limited (AVITA Medical), the former parent of the AVITA Group and the predecessor entity of AVITA Therapeutics, Inc. ("**AVITA Therapeutics**" or the "**Company**"), were exchanged for newly issued shares of common stock of the Company, on the basis of one share of the Company's common stock for every 100 ordinary shares of AVITA Medical. Holders of Avita Medical's American Depository Shares ("**ADSs**") (each of which represented 20 ordinary shares of AVITA Medical) received one share of the Company's common stock for every five ADSs held. Pursuant to the Redomicile Transaction, we are the successor issuer to AVITA Medical as provided by Rule 12g-3(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

All share and per share information in this Annual Report have been retroactively adjusted to reflect the effect of the Redomicile Transaction for all periods presented, unless otherwise indicated.

PART I

Item 1. BUSINESS

General

The AVITA group of companies (comprising AVITA Therapeutics, Inc. ("**AVITA Therapeutics**" or the "**Company**") and its subsidiaries, including AVITA Medical Limited ("**AVITA Medical**")) (collectively, "**AVITA Group**" or "we", "us", or "our") is a regenerative medicine group with a technology platform positioned to address unmet medical needs in burn injuries, trauma injuries, chronic wounds, and dermatological and aesthetics indications, including vitiligo. Our patented and proprietary platform technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. Our medical device works by preparing Spray-On Skin™ Cells, an autologous cellular suspension comprised of the patient's skin cells, which is then sprayed on the patient in order to regenerate natural healthy epidermis.

Our first United States ("**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, and simultaneously significantly reducing the amount of donor skin required. The RECELL System is designed to be used at the point of care as a standalone product, or in combination with "skin transplants", known as split-thickness skin autografts, depending on the depth of the burn injury. The pivotal studies leading to the RECELL System's FDA premarket approval ("**PMA**") for the treatment of acute thermal burns, demonstrated that the RECELL System treated burns using 97.5 percent less donor skin when used alone in second-degree burns, and 32 percent less donor skin when used with autograft for third-degree burns compared to standard of care autografting. In these studies a statistically significant reduction in donor skin required to treat burn patients with the RECELL System was realized without any associated compromise to healing or safety outcomes. Donor site outcomes from the clinical trial for second-degree burns also revealed a statistically significant reduction in patient-reported pain, increased patient satisfaction and improved scar outcomes.

Our compelling data from prospective, randomized, controlled clinical trials conducted at major United States burn centers, health economics modeling, 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.

Following receipt of our PMA, we commenced commercializing the RECELL System in January 2019 in the U.S., and we expect the dominant focus of our commercial efforts to be directed towards the U.S. market going forward.

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

Our website address is www.avitamedical.com. Information contained on our website is not part of or incorporated into this report. We make our periodic reports, together with any amendments, available on our website, free of charge, as soon as reasonably practicable after we electronically file or furnish the reports with the Securities and Exchange Commission, or SEC or with the Australian Securities Exchange, or ASX. The SEC maintains an internet site, www.sec.gov, which contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Copies of announcements made by the Company to the ASX are available on ASX's website (www.asx.com.au).

Corporate History

AVITA Therapeutics, a Delaware corporation, was originally formed in April 2020. The former parent company of the AVITA Group, AVITA Medical , was formed under the laws of the Commonwealth of Australia in

December of 1992, and has operated as AVITA Medical since 2008. AVITA Medical's ordinary shares originally began trading in Australia on the Australian Securities Exchange ("**ASX**") on August 9, 1993. AVITA Medical's ordinary shares, in the form of American Depositary Shares ("**ADSs**"), began trading on the NASDAQ Stock Market LLC ("**NASDAQ**") on October 1, 2019 under the ticker symbol "RCEL".

With effect from June 29, 2020, a statutory scheme of arrangement was implemented under Australian law to change the domicile of the AVITA Group from Australia to the U.S.. Under the scheme of arrangement, AVITA Therapeutics, being a company incorporated in the State of Delaware in the U.S., became the new parent company of the AVITA Group, and all ordinary shares in AVITA Medical (including ordinary shares represented by ADSs) held by securityholders were exchanged for shares of common stock or CHESS Depositary Interests ("**CDIs**"). As a result, the existing listing of AVITA Medical on the ASX (as its primary listing) and on NASDAQ (as its secondary listing) was inverted and replaced with a new listing of AVITA Therapeutics on NASDAQ (as its primary listing) under the existing ticker symbol, "RCEL", and on the ASX (as its secondary listing) under the existing ticker symbol, "AVH". AVITA Therapeutics' shares of common stock trade on NASDAQ and its CDIs trade on ASX (with five CDIs trading on ASX representing one share of common stock on NASDAQ).

Markets and Limitations of Standard of Care

Acute Thermal Burns

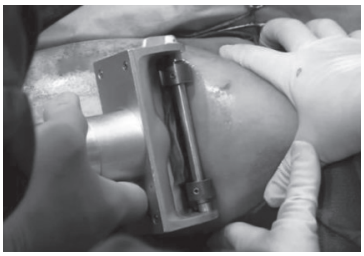
Acute thermal burns are life-threatening and debilitating injuries that are among the most challenging and expensive traumatic injuries to manage. These injuries require complex surgical procedures, long and costly hospitalization, potential for clinical complications, rehabilitation and scar treatment. 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 hospital admission, 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, disaggregated, markets for the treatment of burns and thus we do not devote significant commercial resources to those countries.

The severity of the burn injury is generally assessed based on the area burned, and the depth of the injury. The area 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 (circumferential) would be roughly 9% TBSA, while a burn covering an entire leg (circumferential) would be roughly 18% TBSA. The depth of the burn, referred to in terms of "degree" is generally classified into four categories:

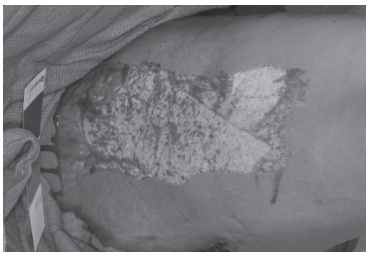
- First-degree or superficial burns: Burns that do not penetrate through the outer layer of the skin, known as the epidermis, and typically heal naturally (e.g. severe sunburn).
- Second-degree or partial-thickness burns: Characterized by extending through the epidermis and including varying amounts of damage to the underlying dermis. This type of burn can further be subdivided into superficial dermal, mid-dermal and deep partial-thickness burns.
- Third-degree or full-thickness burns: Characterized by injury to the entire dermal tissue down to the subcutaneous fat.
- Fourth-degree burns: Such burns extend beyond the subcutaneous fat tissue into the underlying structures, such as muscle or bone.

Burn treatment is determined in large by the area and depth of the injury. Deeper (e.g., deep partial-thickness) burns are commonly treated with autologous split-thickness skin grafts ("**STSGs**") to achieve definitive closure of the burn wound. In a STSG, or autograft, donor skin is harvested from a healthy area of the patient using a device called a dermatome as detailed in the pictures below. The donor skin is then typically perforated into a mesh-like structure that can be expanded and transferred to the burn injury that has been prepared to remove all pre-existing necrotic or infected tissue.

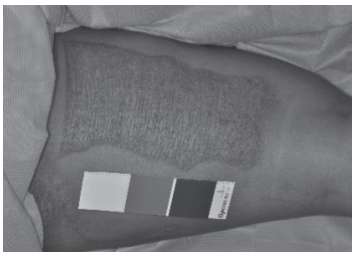
Harvesting of Donor Skin for Use in Autografting



Harvesting skin from donor site for autograft



Donor site wound created while harvesting skin for autograft



Donor site scar 52 weeks post-donor site harvest

Treatment with STSG generates additional trauma for the patient due to the creation of a new wound via the harvesting of healthy donor skin. Although the use of STSG has been a standard treatment for more than 50 years, autografting is associated with significant pain, itching, 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 injury 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 allogeneic skin graft, for example allograft (cadaver skin) or xenograft (typically pig skin). The overall cost of treatment with STSG is expensive, for example it would cost approximately $579,000 and require 59.4 days in hospital for a patient with a 40% TBSA mixed or full-thickness burn.
To address the limitations associated with high TBSA injuries, notably lack of donor skin available for harvest, researchers have developed alternatives such as cultured epidermal autografts ("**CEA**") in which a full-thickness 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, includes the time it takes to grow the sheets of skin (approximately three weeks), the lack of melanocytes that provide pigmentation, and the high cost. As a result, CEAs have been lifesaving in patients hospitalized with very severe large surface area burns where there is often no other alternative for treatment.

Trauma Wounds (Soft Tissue Injuries)

Trauma wounds or soft tissue injuries include abrasions, lacerations, punctures, gunshot wounds, crush wounds, and degloving. These injuries may be caused by trauma, infectious disease, or even surgery itself. Similar to burns, soft tissue repair is associated with areas of skin loss. While minor skin defects may be primarily closed with standard wound care, larger open defects often require more complicated approaches including use of skin grafts, tissue flaps or dermal matrices. Open wounds associated with traumatic injuries caused 4.5 million hospital visits in the United States in 2017 and are therefore the largest opportunity for the RECELL System.

We believe that the RECELL System will have clinical applications beyond skin graft patients, particularly for the treatment of open wounds greater than 5% TBSA. Relevantly, patients treated for open 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 United States also treat trauma patients requiring autografting. Soft tissue injuries also utilize the same treatment protocol as burns and the RECELL System has already demonstrated positive outcomes in soft tissue repair both in the United States, and internationally. We believe the soft tissue injury market is highly complementary to our existing commercialization efforts related to the United States burn market.

On October 30, 2019, the FDA approved the Company's Investigational Device Exemption ("**IDE**") application to conduct a pivotal trial evaluating the safety and effectiveness of the RECELL System in combination with meshed autografting for the treatment of acute full-thickness skin defects, such as degloving (a type of injury where the skin is ripped from the underlying tissue), crush wounds (a break in the external surface of the body), abrasions, lacerations, and surgical wounds.

On March 2, 2020 and, pursuant to the abovementioned IDE, we initiated a prospective, multi-center, randomized controlled study to compare the clinical performance of conventional skin grafting with and without the use of the RECELL System on acute non-burn full-thickness skin defects. Each patient will have a control wound treated with conventional skin grafting and a wound treated with expanded skin grafting in combination with the RECELL System. The study's two primary effectiveness endpoints are:

- Incidence of healing by eight weeks post treatment.
- Donor skin sparing, evaluated by comparing the ratios of donor skin required to treat the wounds.

Healing will be evaluated by a qualified clinician blinded to the treatment allocation. Additional long-term safety and effectiveness data collected over the course of the study will include blinded evaluation of scar outcomes and patient treatment preference.

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, such 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 underlying autoimmune disease. One challenge in terms of achieving the desired patient outcome is that stopping the spread of vitiligo may not restore pigmentation to the areas already damaged.
- Treatments to restore pigmentation including makeup and coverups, dermabrasion, laser, phototherapy combinations, and autografts.

Survey results reveal a low level of patient satisfaction with current treatment options. The majority of vitiligo patients in the United States are treated by dermatologists. It is estimated that worldwide vitiligo prevalence is

between 0.5-2% of the population. China accounts for the highest population of vitiligo patients with an estimated 12.5 million cases, followed by the United States with 6.5 million cases, the European Union ("**EU**") with 5.3 million, and Japan with 2 million.

On December 23, 2019, the FDA approved our IDE application to conduct a feasibility study evaluating the safety and effectiveness of the RECELL System for repigmentation of depigmented lesions associated with stable vitiligo. The randomized controlled study's primary effectiveness measure is the percent area of repigmented skin 24 weeks after treatment, as evaluated by a clinician blinded to the treatment assignment. Additional effectiveness data cofllected over the course of the 24-week study will include blinded evaluator categorization of treatment success and patient rating of repigmentation. The Company expects to commence enrollment in the vitiligo feasibility study in the second half of the 2020 calendar year.

In addition, on July 1, 2020, the FDA separately approved our IDE application for a pivotal study in vitiligo which is titled "A Prospective Multi-Arm Blinded-Evaluator Within-Subject Randomized Controlled Clinical Study to Investigate the Safety and Effectiveness of RECELL for Repigmentation of Stable Vitiligo." The Company expects to commence enrollment in the vitiligo pivotal study in the second half of the 2020 calendar year.

The Company continues to have a high degree of confidence that the RECELL System can be an effective therapeutic offering for patients with stable vitiligo. More than 1,000 patients have been treated with the RECELL System for vitiligo outside of the United States, and to date there are eight (8) publications demonstrating the benefits of the RECELL System in vitiligo.

Sponsored Research

The RECELL System has been studied in a wide variety of indications and has been shown to enable patients to regenerate natural healthy skin in instances where the patient's outer skin covering, or epidermis, has been lost or damaged due to injury, defects or other flaws. In addition to these existing applications of the RECELL System, we are interested in pursuing related opportunities where the RECELL System's ability to harness the natural healing capabilities of the body could be supplemented with genetically modified cells in patients suffering from certain genetic skin disorders. In this way, the RECELL System could potentially be used as a "delivery vehicle" for other therapeutic offerings.

In November 2019, we entered into a research collaboration with the Gates Center for Regenerative Medicine at the University of Colorado School of Medicine ("**Gates Center**") for the purposes of seeking to establish proof-of-concept and explore further development of a spray-on treatment of genetically modified cells for patients with epidermolysis bullosa ("**EB**"). Pursuant to this collaboration, we will pair the RECELL System Spray-On Skin™ Cells technology and expertise with the Gates Center's innovative, patent pending combined reprogramming and gene editing technology to allow cells to function properly. Under the arrangement with the Gates Center, we retain the option to exclusively license technologies emerging from the partnership for further development and commercialization. EB is a group of rare and incurable skin disorders caused by mutations in genes encoding structural proteins resulting in skin fragility and blistering, leading to chronic wounds and, in some sub-types, an increased risk of squamous cell carcinoma or death. There are no approved curative therapies, and current treatment is palliative—focused primarily on pain and nutritional management, itching relief, wound care, and bandaging.

Beyond EB, we are pursing an additional research collaboration for application of the RECELL System within the aesthetics markets, estimated to be a $10 billion market in the United States alone in 2018.

Chronic Wounds

The chronic and other hard-to-heal wound market consists of a broad population of more than 6 million patients in the United States suffering from conditions such as venous leg ulcers, diabetic foot ulcers, pressure ulcers and

non-healing surgical wounds. Chronic and other hard-to-heal wounds represent a $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 (physciological) 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.

The RECELL System has been used to treat venous leg ulcers and diabetic foot ulcers outside of the United States, and there are numerous peer-reviewed journals illustrating associated benefits to patients with those health challenges. The Company is considering, though has not sought FDA approval, commencing a pivotal study in one or both of the indications mentioned above. The Company expects to make a determination to proceed with a pivotal study towards the end of the 2020 calendar year, or early in the 2021 calendar year.

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, advanced wound dressings, pentoxifylline, and aspirin therapy. Surgical management, inclusive of skin grafting, is 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 United States.

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 United States. In the United States, it is estimated that approximately 1.3 million people have a DFU, and over $15 billion was spent on the care of this condition. Current standard of care for DFUs includes offloading therapy to help redistribute foot pressure away from the ulcer, and moist wound therapy. For DFUs non-responsive to standard of care, surgical closureutilizing autografts, skin substitutes, or biologics is often required.

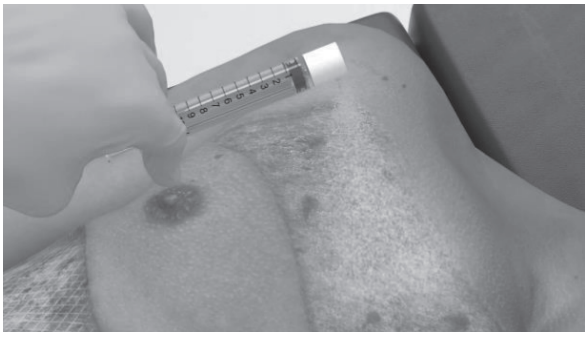
The RECELL System

The RECELL® Autologous Cell Harvesting System ("**RECELL System**") allows for the preparation of Spray-On Skin™ Cells, an autologous cellular suspension comprised of the patient's own skin cells necessary to regenerate natural healthy epidermis. These Spray-On Skin Cells are prepared at the point of care in as little as 30 minutes, providing a new way to treat thermal burns and other wounds, skin injuries or defects of the skin. The regenerative skin cell suspension includes keratinocytes, fibroblasts, and melanocytes, all of which play critical roles in wound healing. The ability of the RECELL System to retain melanocytes in the cell suspension is notable as these cells 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 United States, the RECELL System is approved by the FDA for use in the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL System is approved for use by appropriately-licensed healthcare professionals at the patient's 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 United States, the RECELL System is produced in a configuration that allows 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. The RECELL System is produced in a configuration that allows for treatment of up to 320 cm² for the markets in Australia. In the European Union, the RECELL System received CE-mark approval for the treatment of burns, chronic wounds, scars and vitiligo. Together with our local Japanese partner, Cosmotec Co. Ltd. (COSMOTEC), we are also pursuing Pharmaceuticals and Medical Devices Act ("**JPMDA**") application for approval to market the RECELL System in Japan for use in the treatment of burns and potentially other applications.

The RECELL System Clinical Results

The September 2018 FDA approval of the RECELL System for use in the treatment of acute thermal burns in patients 18 years 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 journals and have been presented at burn focused meetings and other major medical conferences. Presentations by key opinion leaders on the clinical use of RECELL have been made at over 20 medical conferences in 2018 and 2019, many of which include highlighting the pivotal clinical trial results as well as 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 IDE Compassionate Use and Continued Access research programs made available prior to receipt of PMA from the FDA.

In addition to an 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.

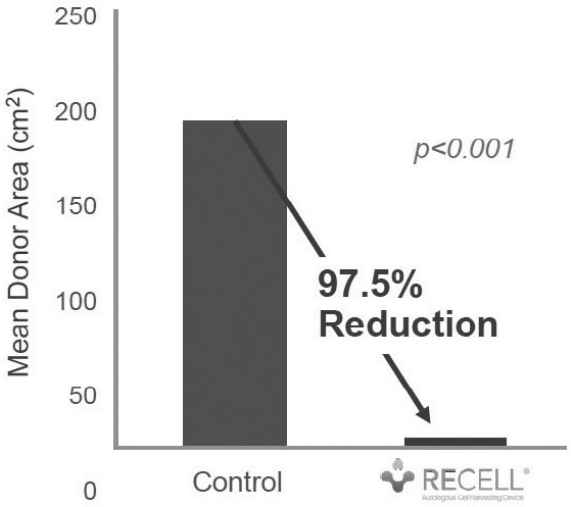
The RECELL System Clinical Results in Thermal Burns

RECELL Pivotal Clinical Trial in Second-Degree Acute Thermal Burns

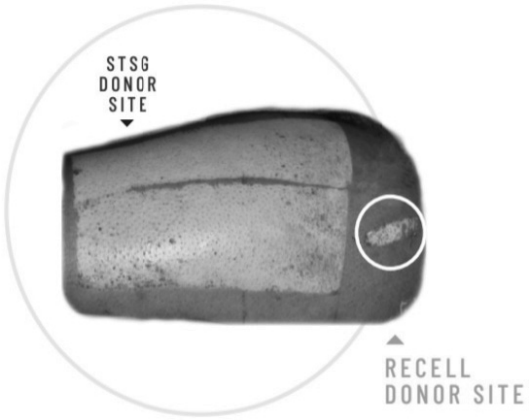
One of the two randomized, controlled clinical trials of the RECELL System supporting the September 2018 FDA approval was a study of patients with partial thickness (second-degree burns) conducted at 12 U.S. burn centers. The pivotal trial evaluated 101 adult patients with thermal, partial-thickness 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 up to Week 8 ($p\leq0.0025$)
- Significantly higher patient satisfaction with donor-site appearance at long term study endpoints ($p\leq0.0025$)
- Significantly better donor-site scarring results ($p\leq0.0025$)

- Significantly greater incidence of donor-site healing at one and two weeks ($p<0.001$), with an odds ratio of 4:3 at two weeks

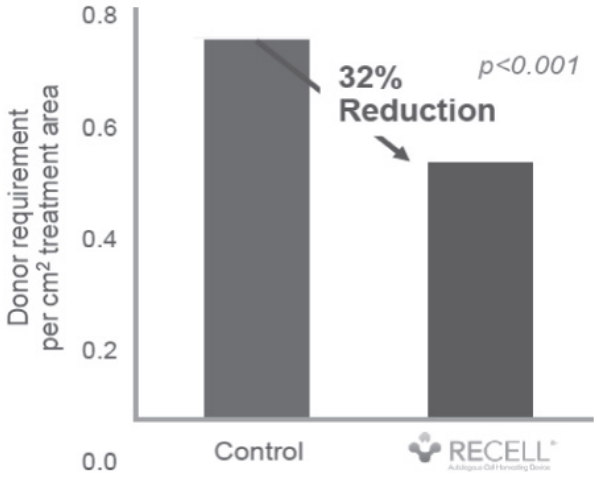
In the clinical trial, use of the RECELL System in the trial was safe and well tolerated with adverse experiences typical for the type of burn injury sustained. The results of this trial were published in a peer-reviewed scientific publication, the *Journal of Burn Care & Research*, in September 2018.

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 burn wounds (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 for complete, definitive 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 mean 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 autograft 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 the peer-reviewed scientific publication, *Burns*, in December 2018, and appeared in print in June 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*, published in May 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 $37,000, for patients with 10% TBSA and approximately $150,000, for patients with 40% TBSA. For full-thickness burns, treatment using the RECELL System reduced total treatment cost by 3%, or approximately $6,000 for patients with 10% TBSA, and by 42% or approximately $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 $39.4 million to $32.6 million, saving 17% or approximately $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 following:

- The Arizona Burn Center would save approximately $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 $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).

Additional RECELL Clinical Results Outside of Pivotal Data

A series of clinical outcomes have been presented at medical conferences and evaluated multiple patient categories and burn types in more than 150 burn patients that were treated under FDA-approved IDE Compassionate Use and Continued Access programs made available to patients prior to receipt of PMA from the FDA.

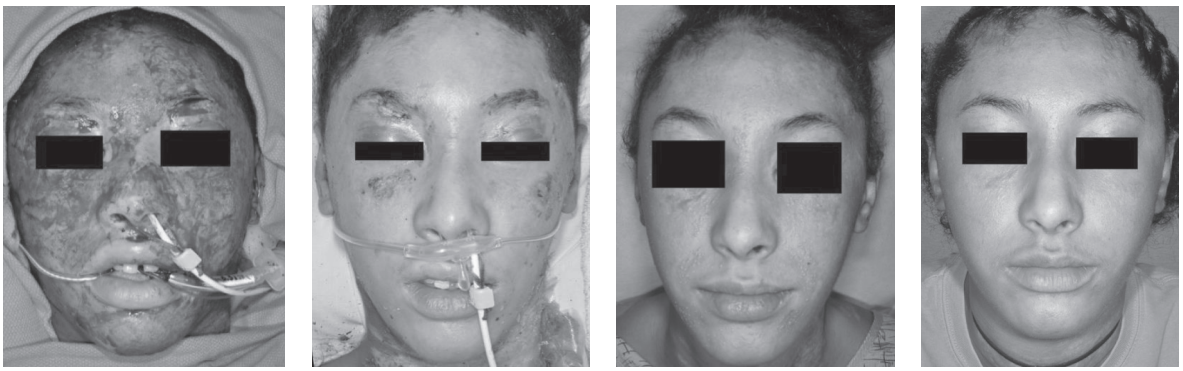
RECELL in Treatment of Facial Burns (interim review of Compassionate Use)

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 scarring at the seams of the grafts, resulting in substantial patient dissatisfaction with the outcome.

As described in a peer-reviewed scientific publication in *Journal of Burn Care and Research,* published in March 2020, 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 2.1 to 40.7 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 study 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

Facial Burn Case Study



Treatment Day | 1 Week Post-treatment | 1 Month Post-treatment | 1 Year Post-treatment

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 (interim review of Continued Access and Compassionate Use)

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 United States, 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. Under the FDA IDE Compassionate Use and Continued Access Program, 33 pediatric patients with mixed-depth and full-thickness (third-degree) were treated with Spray-On Skin Cells. The age range of patients was from 0.8 to 14.2 years and mean TBSA was 46% (range 20-90%). The presentation was selected as a "Best of the Best Abstract" out of more than 500 abstract submissions to the ABA meeting.

In this review 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. Healing data at 4 weeks post-treatment showed that 88.1% of the wounds were healed and at 8 weeks 92.4% of the wounds were healed. Researchers discussed the use of RECELL as a promising treatment option for pediatric burn patients.

A randomized, controlled clinical trial using the RECELL System in the treatment of pediatric patients with 2nd-degree (partial-thickness) burn wounds is currently underway.

RECELL Treatment of Donor Sites (interim review of Compassionate Use)

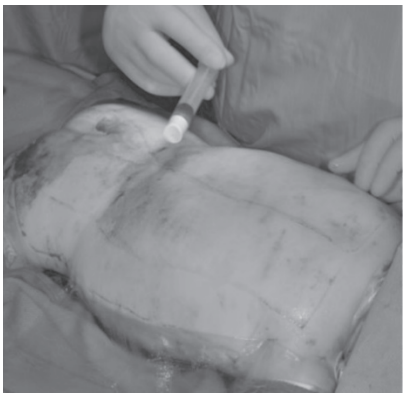
In large TBSA injuries a patient may not have enough donor skin available to allow for immediate treatment of the entire area of burn injuries with traditional autografting techniques. In severely burned patients with extensive injuries, surgeons often must wait until the donor sites have healed so that 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, 430 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 54.1% with 32% of subjects having a Baux score greater than 100. Two weeks after treatment, 91% of the donor sites had healed in this vulnerable patient population. 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 treated using the RECELL System is extremely beneficial in this population of patients with extensive life-threatening injuries and limited available donor skin.

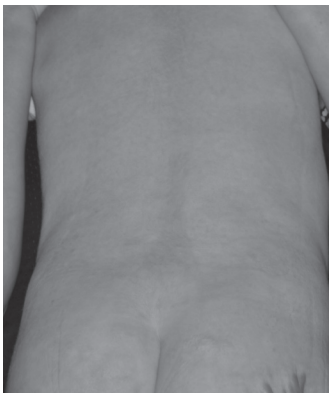
A representative patient in the study was a 16-month-old female with a 30% TBSA mixed depth thermal burn with donor sites taken from her back. Spray-On Skin Cells were applied to her donor site wound. The donor sites were 100% re-epithelialized by within two weeks of treatment. At one-year follow-up 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.

Donor Site Case Study



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

RECELL in Treatment of Patients with Extensive Burns (Large TBSA Patients, interim review of Compassionate Use)

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 review of 22 patients with life-threatening thermal burn injuries, Spray-On Skin Cells was 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 96% of the wounds achieving complete wound closure two months after treatment. Data was compared to pivotal RCT data in which patients with equal to or less than 50% TBSA burns, were treated with the same combination (n=53 burn wounds) and the rate of healing was similar to the large TBSA patients, with 87.2% of wounds achieving full healing two months after treatment. Researchers reported that there were no device-related adverse events.

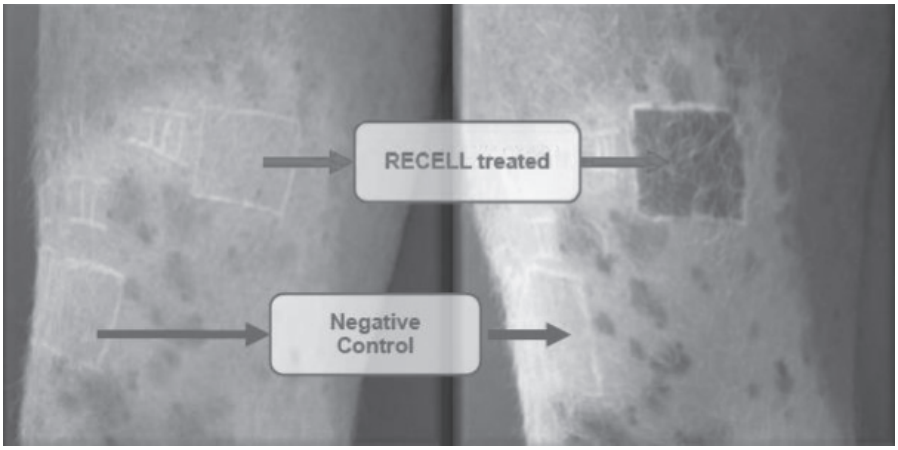
The RECELL System Clinical Results in Vitiligo

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

The median repigmentation six months after treatment was 78% in the sites treated with the combination of CO_2 laser ablation followed by the application of Spray-On Skin Cells, compared to zero median repigmentation in the control groups consisting of treatment with CO_2 laser ablation alone or no treatment. The repigmentation for the sites treated with the combination of CO_2 laser ablation followed by the application of Spray-On Skin Cells was assessed as good or excellent by 70% of the patients. No adverse effects or long-term side effects were seen in the recipient sites. Researchers concluded that treatment with the combination of CO_2 laser ablation followed

by the application of Spray-On Skin Cells resulted in a high percentage of repigmentation and was well tolerated in both stable segmental vitiligo and piebaldism patients. Photographs before and after treatment for a patient participating in the study are included below.

Vitiligo Patient Pre- and Six-Months Post Treatment



Baseline (pre-treatment) Six months post-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. 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.

U.S. Stable Vitiligo Pivotal Study:

On June 2, 2020 the Company announced that it had submitted an IDE supplement to the FDA to support the initiation of a pivotal clinical trial to investigate the RECELL System for the treatment of stable vitiligo. On July 1, 2020, the FDA approved the IDE application for the pivotal study which is titled "A Prospective Multi-Arm Blinded-Evaluator Within-Subject Randomized Controlled Clinical Study to Investigate the Safety and Effectiveness of RECELL for Repigmentation of Stable Vitiligo." The Company expects to initiate this study in the second half of the 2020 calendar year, and has already commenced interactions with potential study sites and associated investigational review boards.

U.S. Stable Vitiligo Feasibility Study:

Separate to the abovementioned pivotal study, we confirmed on December 30, 2019 that the FDA approved the Company's IDE application to conduct a feasibility study evaluating the safety and effectiveness of the RECELL System for repigmentation of depigmented lesions associated with stable vitiligo.

This study is a single site study being conducted at the University of Massachusetts Medical School in ten (10) patients that have had stable vitiligo for at least one year. Areas of the vitiligo lesion will be randomly treated with slightly varying cell suspensions prepared using RECELL to confirm response rates and optimal suspension parameters. The randomized controlled study's primary effectiveness measure is the percent area of repigmented skin 24 weeks after treatment, as evaluated by a clinician blinded to the treatment assignment.

Additional effectiveness data collected over the course of the 24-week study will include blinded evaluator categorization of treatment success and patient rating of repigmentation. This study is expected to deliver additional clinical and investigative data, in addition to that derived in relation to the pivotal study.

The RECELL System Clinical Results 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 the control group (14 versus 20 days, respectively)
- Significantly fewer complications (p=0.047) were seen in the RECELL System group versus the control group (4 versus 11, respectively)
- The RECELL System group had good elasticity and texture, similar color, and less scar tissue growth at borders between normal and grafted skin versus control group
- Scarring was significantly less (p=0.005) in the RECELL System group versus the control group
- 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* (Hayes PD, Harding KG, Johnson SM, McCollum C, Téot L, Mercer K, Russell D. A pilot multi-centre prospective randomised controlled trial of RECELL for the treatment of venous leg ulcers. International Wound Journal. 2020 Jun;17(3):742-52.), 52 patients with venous leg ulcers were evaluated as part of a prospective, randomized, controlled trial. Patients enrolled in the study had a venous leg ulcer for longer than 4 weeks and were randomized to a Treatment group that received RECELL and compression therapy or a Control group that received compression therapy alone. At Week 14, patients treated with RECELL had a statistically greater decrease in their ulcer area compared to the Control ($p<0.05$). When ulcers were broken out into groups by size, ulcers >10-80 cm^2 achieved a significantly higher mean percentage of re-epithelialization over Control ($p<0.05$), whereas ulcers 2-10 cm^2 showed no significant

difference (both at Week 14). Overall, patients reported significant improvements in pain and consistent improvements in quality of life for the RECELL group compared to the Control. There were no differences in the safety-related events between the RECELL and Control groups aligning with the already-established favorable safety profile associated with the device.

In a study presented to the *European Wound Management Association*, (P Hayes, K Harding, S Johnson, C McCollum, K Mercer, D Russell, L Teot. The effectiveness of autologous cell suspensions to elicit positive changes in quality of life in patients with venous leg ulcers. European Wound Management Association; 2016 May 11-13; Bremen, Germany), 52 patients with venous leg ulcers were evaluated as part of a prospective, randomized, controlled trial. Patients enrolled in the study had a venous leg ulcer for longer than 4 weeks and were randomized to a Treatment group that received RECELL and compression therapy or a Control group that received compression therapy alone. At Week 14, patients treated with RECELL had a statistically greater decrease in their ulcer area compared to the Control group. When ulcers were broken out into groups by size, ulcers >10-80 cm^2 achieved a significantly higher incidence of healing, whereas ulcers 2-10 cm^2 showed no significant difference from the Control group. Overall, patients reported significant improvements in pain and consistent improvements in quality of life for the RECELL group compared to the Control group. There were no differences in the safety-related events between the RECELL and Control groups aligning with the already-established favorable safety profile associated with the device.

In a feasibility study accepted for publication in *Wound Repair and Regeneration* (Rashid ST, Cavale N, Bowling FL. A pilot feasibility study of non-cultured autologous skin cell suspension for healing diabetic foot ulcers. Wound Repair and Regeneration. 2020 Jul), 16 patients with diabetic foot ulcers greater than 3 weeks duration were enrolled in the prospective case series. Their ulcers, ranging in severity, were treated with Spray-On Skin Cells prepared using the RECELL System. The ulcers ranged in size from 3.0 cm^2 to 29.5 cm^2, included a range of depths, including those with exposed tendon, and had a mean duration of 60.4 weeks. Comparable healing outcomes were obtained independent of ulcer duration, depth, or presence of infection. All ulcers reduced in size after RECELL System treatment and 46% of ulcers with complete healing data (n=13) were fully healed in 26 weeks. Adverse events observed were typical for the diabetic foot ulcer patient population.

We are not presently pursuing an IDE application to commence additional clinical investigations in the United States, but may elect to do so in the near future subject to resources, capital and broader economic factors, including the impact of the COVID-19 pandemic.

U.S. Pediatric Early Intervention Pediatric Study:

In March 2020, we initiated 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. Enrollment of this study is ongoing, with the first patient being treated in March 2020.

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

- Incidence of healing on or before Day 21
- Percent area requiring autografting
- Incidence of conventional autografting to achieve healing

Patients will be followed for one year after treatment. The pediatric early intervention study is being funded by BARDA under the ongoing program. This study is intended to support U.S. regulatory approval for marketing of the RECELL System for patients ages 1–16 with partial-thickness thermal burn injuries.

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

Case reports of the use of the RECELL System in the treatment of trauma injuries (soft-tissue reconstruction) 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.

U.S. Trauma (Soft-Tissue Reconstruction) Study:

We announced on September 17, 2019 that the FDA approved an IDE application to conduct a trauma (soft-tissue reconstruction) pivotal clinical trial. Subsequently, in March 2020, we initiated the pivotal study for soft tissue reconstruction with the enrollment of the first patient at the Arizona Burn Center at Valleywise Medical Health Center in Phoenix, AZ. This study will evaluate the safety and effectiveness of the RECELL System when used as an adjunct to meshed autografts in patients undergoing reconstruction of skin defects not associated with a burn injury. The primary measure of effectiveness is non-inferior healing at (or prior to) 8 weeks following treatment, with healing defined as complete closure characterized by 100% skin re-epithelialization without drainage confirmed at two consecutive visits at least two weeks apart, thickness thermal burn injuries. Enrollment of this pivotal study is ongoing.

BARDA Contract

We have a contract with BARDA, under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, valued at least $53.4 million. 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 United States 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, September 18, 2017 and June 30, 2020. The options to the contract terminate between September 28, 2022 and December 31, 2023, and may be terminated earlier at the option of BARDA.

Under the contract, BARDA has provided 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 a randomized, controlled clinical trial for a pediatric early intervention study which commenced enrollment in March 2020. 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 $7.6 million, although BARDA also has the option of increasing the amount of the procurement. On July 13, 2020, we announced that BARDA will procure the RECELL System and agreed to the purchase, storage and delivery of RECELL Systems utilizing a vendor-managed inventory ("**VMI**") plan valued at $7.6 million. Further, BARDA has expanded the awarded contract to provide supplemental funding of $1.6 million to support emergency deployment of RECELL Systems for use in mass casualty or other emergency situations. Delivery of RECELL Systems under the VMI plan is expected to commence in the second half of the 2020 calendar year. As of June 30, 2020, we had received cumulative payments of $24.4 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, trauma wounds, vitiligo, and, potentially, chronic wounds. These activities are generally characterized by additional pivotal studies such as the studies for which FDA has issued us with na IDE (e.g. pediatric scalds, sofft tissue reconstruction 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.

Manufacturing, Supply and Production

We operate a production plant in Ventura, California, in a 23,040 square foot facility that we have leased 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 for the RECELL System or endeavor to maintain our existing foreign regulatory approvals, foreign 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 and leased the facility.

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 that will need 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 critical raw materials are procured from single source suppliers. We continue to evaluate methods of removing risk from the supply chain for the RECELL System.

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 United States through our own commercial organization consisting of 21 field sales personnel (consisting of Regenerative Tissue Specialists, Clinical Training specialists and regional

directors) 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 premarket approval and were trained prior to our U.S. market launch of the RECELL System in January 2019. 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 United States is highly concentrated, with approximately 134 burn centers and approximately 300 burn surgeons. Accordingly, we believe that our sales organization is generally of an appropriate size to reach the burn surgeons and other key decision makers associated with our current target market of patients 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 (permanent) distribution or warehousing structure and ship the RECELL System directly from our Ventura facility to U.S. burn centers. From time-to-time we also store small quantities of the RECELL System at satellite distribution sites on the east or west coast of the United States so as to support access of the RECELL System to our customers.

The objective of our field sales 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 generally 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. 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 or more 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 gradual basis over multiple years.

In the United States, 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 DRG (Diagnosis Related Group) 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 of the use of the RECELL System for the treatment of burns in the outpatient setting will require us to successfully obtain incremental reimbursement coverage for use of the RECELL System in that setting. In August 2020, we filed a Transitional Pass-through Payment Application ("**TPT**") with The Centers for Medicare & Medicaid Services ("**CMS**") to support separate additional Medicare payment for the RECELL System. If approved CMS would create a new "C code" and would allow the RECELL System to be billed and paid separately in hospital outpatient facilities and ambulatory surgical centers. The Company presently expects to be informed of CMS's decision on our TPT submission during December 2020, or early 2021.

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. We continue to work with COSMOTEC to advance our application for approval to market the RECELL System in Japan pursuant to Japan's Pharmaceuticals and Medical Devices Act.

Given the size and concentration of the U.S. Market, our commercialization efforts are almost exclusively focused on that market. Our highly limited 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 United States, 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 we no longer actively promote the RECELL System and have

limited our commercialization efforts to filling sales orders as received from a small group of customers who have already been trained to use the product. As additional pivotal trial data for the RECELL System is generated in additional indications, we may seek to commercialize the RECELL System in countries outside the United States 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 June 30, 2020, we have been granted a total of 50 patents and have 17 pending patent applications worldwide.

The U.S. patents and patent applications provide coverage with expected expiration dates ranging from 2022 to 2034. 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 April 9, 2024. 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 may provide additional claims, including composition of matter, for which we will be able to pursue additional U.S. and international patent applications in key international markets, parallel to 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, "REGENERATIVE EPITHELIAL SUSPENSION," and "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 1A. 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, together with other skin replacement offerings such as Epicel, which is manufactured by Vericel Inc. 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 sustainable competitive clinical and economic advantages over the current standard of care.

Government Regulations

FDA and International Regulation

The production and marketing of the RECELL System and any additional product candidates developed in 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 United States. 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 United States 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 United States will require the submission to the FDA of a supplement to our PMA following successful completion of clinical studies.

To support a PMA supplement or other application for approval in the United States or other regions, the completion of additional clinical and non-clinical studies and supporting development activities will likely be required. Clinical trials can take many years to complete and require the expenditure of substantial resources. The length of time varies substantially according to the type, complexity, novelty and intended use of the product candidate. We cannot make any assurances that once clinical trials are completed by us or a collaborative partner, we will be able to submit as scheduled a marketing approval request to the applicable governmental regulatory authority, or that such request and application will be reviewed and cleared by such governmental authority in a timely manner, or at all. Although we intend to make use of fast-track and abbreviated regulatory approval programs when possible and commercially appropriate, we cannot be certain that we will be able to obtain the clearances and approvals necessary for clinical testing or for manufacturing and marketing our product candidates. Delays in obtaining regulatory approvals could adversely affect the development and

commercialization of our product candidates and could adversely impact our business, financial condition and results of operations. During the course of clinical trials and non-clinical studies, product candidates may exhibit unforeseen and unacceptable safety considerations. If any unacceptable side effects were to occur, we may, or regulatory authorities may require us to, interrupt, limit, delay or abort the development of our potential products.

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

The RECELL System is TGA-registered in Australia for use in the treatment of burns, acute wounds, scars and vitiligo. In the European Union, 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 the review is ongoing with approval expected to occur during 2021.

The Foreign Corrupt Practices Act

The U.S. 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 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; and 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 not 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.

Organizational Structure

The Company has a total of six subsidiaries and their corporate details and business activities are listed below:

Subsidiary Name	Place of Incorporation	% Held	Business Purpose
AVITA Medical Limited	Australia	100	Operating Company
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

Employees

As of June 30, 2020, we had 98 full time employees. Our employees are not members of any labor union, and we have never experienced business interruptions due to labor disputes.

Available Information

The Company files annual, quarterly, and current reports, proxy statements and other documents with the Securities and Exchange Commission ("**SEC**") under the Exchange Act. The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The public can obtain any documents that we file with the SEC at *www.sec.gov*. In addition, copies of announcements made by the Company to ASX are available on the ASX website (www.asx.com.au) and also under the heading "Investors: Press Releases" at the following link on our website (https://ir.avitamedical.com/press-releases).

We maintain a website at www.avitamedical.com. Since becoming a domestic, U.S. issuer on July 1, 2020, our filings with the SEC, including without limitation, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge through a link maintained on our website under the heading "Investor Relations—SEC Filings," as soon as reasonably practicable after we file or furnish them electronically with the SEC. Information contained on our website is not incorporated by reference into this report.

Item 1A. RISK FACTORS

Our business faces significant risks. You should carefully consider all of the information set forth in this Annual Report, 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 common stock would likely decline and you might lose all or part of your investment. This Annual Report 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 "*Forward-Looking Statements*" included elsewhere within this Annual Report for a discussion of certain risks, uncertainties and assumptions associated with these statements.

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 United States and other jurisdictions, such sales have been limited to date and we have not yet obtained profitability. We had a total comprehensive loss of $42 million, $25 million, and $12.7 million for our fiscal years ended June 30, 2020, 2019 and 2018, respectively. We have incurred a cumulative deficit of $194.9 million through June 30, 2020. 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, including in new markets for which we are not presently approved.

Our operations are overseen directly by management. Our management oversees all responsibilities in the areas of corporate administration, business development, and research. We have successfully expanded our current management to retain skilled employees with experience to our business and intend to continue with this initiative.

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 PMA application for the RECELL System was approved by the FDA for use in 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 be successful in those clinical trials or 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 on 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 $53.4 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 United States for mass casualties involving burn victims. As of June 30, 2020, we had received cumulative payments of $24.4 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 a randomized, controlled clinical trial in pediatric scald 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 which BARDA initiated procurement for in July 2020. There can be no assurances that BARDA will take shipment of the RECELL System under the contract nor that BARDA will perform under 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.

Provisions in our U.S. government contracts, including our contracts with BARDA, may affect our intellectual property rights.

Certain of our activities have been funded, and may in the future be funded, by the U.S. government, including through our contracts with BARDA. When new technologies are developed with U.S. government funding, the government obtains certain rights in any resulting patents, including the right to a nonexclusive license authorizing the government to use the invention and rights that may permit the government to disclose our confidential information to third parties and to exercise "march-in" rights. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government, U.S. government funding must be disclosed in any resulting patent applications, and our rights in such inventions may be subject to certain requirements to manufacture products in the United States.

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

In the United States, 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 United States, 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 Australia, the RECELL System is approved to use for the treatment of burns, acute wounds, scars and repigmentation (vitiligo). In the EU the product has been approved for the treatment of burns, chronic wounds, scars and vitiligo. We will require additional clinical data or 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 be unsuccessful or otherwise 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 United States 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.

Finally, per FDA regulations, changes made to products, specifications, or test data evaluation methodology would generally require communication with the FDA. There are several pathways for communicating with the FDA of such changes. As part of such review, the FDA may request additional information, at which time the product may become temporarily unavailable.

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. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, 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 United States, 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 are highly dependent on our regulatory approval ("PMA") in the United States and failure to maintain that approval would materially impact our business and prospects.

Our business is highly dependent on the PMA we received in September 2018 from the FDA. This PMA allows us to sell our RECELL System in the United States, our current primary market. In addition, maintaining this PMA also increases the probability of approval of secondary indications for the PMA outside of trauma burns. While we intend to take every action and precaution to ensure that our PMA remains effective, it is possible that the FDA could take a position in the future that requires a modification, temporary suspension or revocation of our PMA. Any such action by the FDA would have a material adverse effect on our business.

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 in a clinical study or regulatory application can occur at any stage. Events that may prevent successful or timely commencement, enrollment or completion of clinical development or a regulatory application 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 GCP, 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;
- adverse events, safety issues, product recalls, manufacturing or supply chain interruptions, or poor clinical outcomes where the RECELL System is being used commercially; and
- 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 United States, can also vary widely from one health system or hospital to the next. In some foreign jurisdictions, including the EU, 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.

For example, we presently benefit from various reimbursement codes, including the following:

- Medicare reimburses hospitals for inpatient services using MS-DRGs (Medicare Severity Diagnosis-Related Groups).
- Specific ICD-10-PCS code series describing our "cell suspension technique" for the use of the RECELL System.
- Current Procedural Terminology ("**CPT**") for physicians to support reimbursement for physician rendered healthcare services.

There can be no guarantee that the above reimbursement codes will not be withdrawn, reduced, consolidated or otherwise be altered in a manner which is not supportive of ongoing commercial use of the RECELL System. In addition, we are also seeking a Transitional Pass-through Application ("**TPT**") to support additional Medicare payment in the outpatient and the ambulatory surgical setting, and there can be no guarantee that the TPT will be approved or we will be available in an amount or manner that supports our commercialization efforts.

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 stockholders 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 stockholders may be reduced, and the market price of our common stock or CDIs could fall due to an increased number of shares or CDIs 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 in 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, suffer 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, we are 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 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.

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 expose 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 therefore 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 may compete, such as China, may not protect our intellectual property to the same extent as do the laws of the United States. 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 United States 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 and 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 United States, 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 United States 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 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.

We could be negatively impacted by the outbreak of coronavirus ("COVID-19").

In light of the continuing uncertain and rapidly evolving situation relating to the spread of COVID-19, this public health concern poses a risk to the ability of medical facilities to focus on the treatment of acute burns should they be overwhelmed, our employees, our partners and suppliers and the communities in which we operate, which could negatively impact our business. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted at this time. We could experience employee impacts from illness, school closures and other community response measures, all of which could negatively impact our business. Timing of the development on any vaccine against COVID-19 is uncertain and when any such vaccine will be determined to be effective and made widely available, if ever, cannot be predicted. We intend to continue to monitor the situation and may adjust our current policies and practices as more information and guidance become available.

Risks Relating to Our Common Stock

We have never paid a dividend on our common stock 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 common stock.

We do not anticipate paying cash dividends on our common stock 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 stockholders because of limitations imposed by a lack of liquidity. Accordingly, our stockholders may have to sell some or all of their common stock in order to generate cash flow from their investment. Our stockholders may not receive a gain on their investment when they sell their common stock and may lose some or all of their investment. Any determination to pay dividends in the future on our common stock 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 ASX and of 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, 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 in aggregate would exceed 15% of the number of ordinary securities on issue at the commencement of that 12-month period.

Our equity issuances will be limited by ASX Listing Rule 7.1 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.

In addition to ASX Listing Rule 7.1, we are also 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 common stock (or securities convertible into or exercisable for common stock) equal to 20% or more of the common stock, 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, the operation of the NASDAQ 20% rule could limit our ability to raise capital through issuance of common stock or convertible securities without jeopardizing our listing status. If we were to violate the NASDAQ 20% rule, our company would be subject to delisting from NASDAQ and share prices and trading volumes would likely suffer.

There has been relatively limited trading volume in the markets for our common stock and CDIs, and more active, liquid trading markets for such securities may never develop.

Trading in our common stock on NASDAQ and our CDIs on the ASX is often thin and susceptible to wide fluctuations in trading prices due to such limited trading volume and other factors, some of which may have little to do with our operations or business prospects. Limited liquidity in the trading markets for our common stock and CDIs may adversely affect a stockholder's ability to sell its shares of our common stock or our CDIs at the time it wishes to sell them or at a price that it considers acceptable. In addition, if a more active, liquid public trading market does not develop we may be limited in our ability to raise capital by selling shares of common stock or CDIs. We cannot assure you that more active, liquid public trading markets for our common stock and CDIs will develop or, if developed, will be sustained.

The market price and trading volume of our common stock may be volatile and may be affected by variability in our performance from period to period and economic conditions beyond management's control.

The market price of our common stock (including common stock represented by CDIs) may be highly volatile and could be subject to wide fluctuations. This means that our stockholders could experience a decrease in the value of their common stock or CDIs 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 common stock and CDIs may fluctuate and cause significant price variations to occur. If the market price of our common stock or CDIs declines significantly, our stockholders may be unable to resell our common stock or CDIs at or above their purchase price, if at all. There can be no assurance that the market price of our common stock and CDIs will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of our common stock and CDIs 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;

- 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 common stock or CDIs by us, our directors, senior management or our stockholders 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;
- economic and social effects of the COVID-19 virus or other pandemics;
- 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; and
- conditions in the financial markets in general or changes in general economic conditions.

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

As a public company, we are subject to the reporting requirements of the Exchange Act, the U.S. Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**") the Dodd-Frank Act and the listing standards and the rules and regulations of NASDAQ. We are also subject to the reporting requirements under the ASX Listing Rules due to the listing of our CDIs on 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 our disclosure of information in 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, stockholders 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.

We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("**JOBS Act**"). For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions and relief from various U.S. reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) having the option of delaying the adoption of certain new or revised financial accounting standards, (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iv) exemptions from the requirements of holding

a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We have taken, and in the future may take, advantage of these exemptions until such time that we are no longer an emerging growth company. Accordingly, the information contained herein and in other reports we file with the SEC may be different than the information our investors receive from other public companies in which they hold stock. Further, we have elected to take advantage of the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards. It is possible that some investors will find our common stock and CDIs less attractive as a result, which may result in a less active trading market for our common stock and CDIs and higher volatility in our stock and CDI price.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the U.S. Securities Act of 1933, as amended (the "Securities Act"), (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

If research analysts publish unfavorable commentary or downgrade our common stock and CDIs it could adversely affect our share price and trading volume.

The trading market for our common stock and CDIs depends, 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 or CDIs, publish unfavorable commentary about the Company or cease publishing reports about us or our business, the price of our common stock and CDIs 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 common stock and CDIs could decrease, which could cause our share price or trading volume to decline.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

Our principal corporate office is located at 28159 Avenue Stanford, Suite 220, Valencia, California 91355. We lease the 17,465 square foot facility under two lease agreements that, as amended, expire on January 31, 2021. 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. We do not own any real property. We believe that leased facilities are adequate to meet current needs and that additional facilities will, if required, be available for lease to meet future needs.

Item 3. LEGAL PROCEEDINGS

We are not currently involved in any significant legal, arbitration or governmental proceedings. From time to time, as an operating business, we are involved in disputes (both formal and informal) with customer, manufacturing partners and employees.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Following the completion of our Redomicile Transaction on June 29, 2020, our shares of common stock are listed on NASDAQ under ticker symbol "RCEL", and our CDIs are quoted on ASX under ticker symbol "AVH". Five CDIs on ASX represent one share of common stock on NASDAQ.

Prior to the completion of our Redomicile Transaction, the ordinary shares of AVITA Medical (the AVITA Group's former parent company prior to redomiciliation) traded on the ASX, under the same ticker symbol of "AVH" since June 17, 2008. In the United States, the American Depositary Shares, or ADSs, of AVITA Medical traded over the counter on the OTCQX under the ticker symbol "AVMXY" from May 14, 2012 through September 30, 2019. Beginning on October 1, 2019 (and until completion of our redomiciliation) the ADSs of AVITA Medical traded on NASDAQ under the ticker symbol "RCEL" with each of these ADSs representing 20 ordinary shares in AVITA Medical. These ADSs were evidenced by American Depositary Receipts ("**ADRs**") and the ADRs were issued pursuant to a Depositary Agreement entered into with The Bank of New York Mellon.

Holders

As of August 14, 2020, we had approximately 22,731 stockholders of record of our common stock (which includes CHESS Depositary Nominees Pty Ltd, who holds all of the outstanding common stock underlying the CDIs of the Company).

Dividends

We have never paid cash dividends to our stockholders, or prior to the Redomicile Transaction, holders of our ordinary shares. We intend to retain future earnings for use in our business and do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future dividend policy will be determined by our 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 our board of directors may deem relevant.

Recent Sales of Unregistered Securities

During the year ended June 30, 2020, we completed an institutional placement to raise $81.7 million (through our former parent company, AVITA Medical). We sold 2,033,898 shares at an issue price of $40.17 per share for total net proceeds of $76.6 million, after deducting commission and offering expenses. In addition, an aggregate of 15,853 shares were issued to our directors in lieu of their director fees during the year ended June 30, 2020 under the Director Share Plan that was approved by shareholders in December 2017. Each transaction was exempt from the registration requirements of the Securities Act as a transaction not involving a public offering pursuant to Section 4(2) of the Securities Act.

Item 6. SELECTED FINANCIAL DATA

(In thousands, except share and per share data)	Year Ended June 30, 2020	2019	2018
Revenues	$ 14,263	$ 5,474	$ 929
Cost of sales	2,973	1,271	546
Gross profit	11,290	4,203	383
BARDA income	3,926	5,921	7,734
Operating Expenses:			
Sales and marketing expenses	14,813	12,253	4,875
General and administrative expenses	18,135	13,581	9,403
Research and development expenses	8,461	7,872	6,257
Share-based compensation	16,486	1,946	1,423
Total operating expenses	57,895	35,652	21,958
Operating loss	(42,679)	(25,528)	(13,841)
Interest expense	33	27	21
Other income	686	332	53
Loss before income taxes	(42,026)	(25,223)	(13,809)
Income tax benefit (expense)	(4)	121	1,074
Net loss	$ (42,030)	$ (25,102)	$ (12,735)
Net loss per common share:			
Basic	$ (2.07)	$ (1.56)	$ (1.37)
Diluted	$ (2.07)	$ (1.56)	$ (1.37)
Weighted-average common shares:			
Basic	20,290,966	16,064,588	9,326,810
Diluted	20,290,966	16,064,588	9,326,810

	Year Ended June 30, 2020	2019
	(in thousands)	
Balance Sheet Data		
Cash	$73,639	$20,174
Total current assets	78,387	24,125
Total assets	82,462	25,784
Total current liabilities	7,709	4,481
Total long term liabilities	2,352	471
Total equity	72,401	20,832

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations for the years ended June 30, 2020 and 2019, should be read in conjunction with our consolidated financial statements and related notes included in this Annual Report.

Results of Operations

The table below summarizes the results of our continuing operations for each of the periods presented.

Statement of Operations Data:	Year Ended June 30, 2020	Year Ended June 30, 2019	$ Change	% Change
Revenues	$ 14,263	$ 5,474	$ 8,789	161%
Cost of sales	2,973	1,271	1,702	134%
Gross profit	11,290	4,203	$ 7,087	169%
BARDA income	3,926	5,921	(1,995)	(34%)
Operating Expenses:				
Sales and marketing expenses	14,813	12,253	2,560	21%
General and administrative expenses	18,135	13,581	4,554	34%
Research and development expenses	8,461	7,872	589	7%
Share-based compensation	16,486	1,946	14,540	747%
Total operating expenses	57,895	35,652	22,243	62%
Operating loss	(42,679)	(25,528)	$(17,151)	67%
Interest expense	33	27	6	22%
Other income	686	332	354	107%
Loss before income taxes	(42,026)	(25,223)	$(16,803)	67%
Income tax benefit (expense)	(4)	121	(125)	(103%)
Net loss	$(42,030)	$(25,102)	$(16,928)	67%

Year Ended June 30, 2020 compared to Year Ended June 30, 2019

Revenue of the RECELL System totaled $14.3 million for the year ended June 30, 2020, an increase of $8.8 million or 161% over the $5.5 million for the year ended June 30, 2019. Similar to prior years, most of the current year increase in sales occurred in the United States as a result of the September 2018 FDA approval and commencement of the U.S. national market launch of the RECELL System in January 2019. U.S. sales during the year ended June 30, 2020 totaled $13.8 million compared to $4.4 million in the prior year. Gross margin for the year ended June 30, 2020 was 79% compared to 77% for the same period in 2019.

BARDA 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 ongoing USG Contract No. HHSO100201500028C. Under the BARDA contract, income of $3.9 million was recognized during the year ended June 30, 2020 compared to income of $5.9 million for the year ended June 30, 2019. BARDA income declined as a result of wind-down of certain activities associated with supporting the U.S. FDA approval of the RECEL System as well as the compassionate use and continued access programs.

Operating costs for the year ended June 30, 2020 totaled $57.9 million, a $22.2 million or 62% increase over the $35.7 million incurred during the year ended June 30, 2019. Sales and marketing expenses for the year ended June 30, 2020 totaled $14.8 million, an increase of $2.6 million or 21% over the $12.3 million recognized during the year ended June 30, 2019. This increase was primarily attributed to commercialization activities being provided for the entire fiscal year ended June 30, 2020 versus the prior fiscal year where those activities were rendered for less than twelve months. General and administrative expenses totaled $18.1 million for the year

ended June 30, 2020, an increase of $4.6 million or 34% over the $13.6 million recognized during the year ended June 30, 2019. The increase was primarily a result of the costs related to the Redomicile Transaction, together with additional headcount associated with the growth of the Company and the Company' status as a cross listed entity on NASDAQ and the ASX. Research and development expenses for the year ended June 30, 2020 totaled $8.5 million, an increase of $0.6 million or 7% over the $7.9 million recognized during the year ended June 30, 2019. Share-based compensation also increased to $16.5 million for the year ended June 30, 2020, an increase of $14.6 million or 747% over the $1.9 million recognized during the year ended June 30, 2019 primarily due to the increase in the grant date fair value of awards granted during the year. The increase in the grant date fair value of the awards is due to the increase in the Company's stock price.

Net loss after tax for the year ended June 30, 2020 was $42 million, an increase of $16.9 million or 67% over the $25.1 million recognized during the year ended June 30, 2019. The increase in net loss was driven by the higher operating costs described above, partially offset by the higher revenue during the year. As a result of the U.S. national launch of the RECELL System in January 2019, and the expansion of research and development including multiple pivotal clinical studies seeking premarket approval from the FDA, operating expenses are expected to increase in future periods. These expenses are expected to be partially offset by increased commercial sales of the RECELL System as well as income under the BARDA contract.

The table below summarizes the results of our continuing operations for each of the periods presented.

Statement of Operations Data:	Year Ended June 30, 2019	Year Ended June 30, 2018	$ Change	% Change
Revenues	$ 5,474	$ 929	$ 4,545	489%
Cost of sales	1,271	546	725	133%
Gross profit	4,203	383	$ 3,820	997%
BARDA income	5,921	7,734	(1,813)	(23%)
Operating Expenses:				
Sales and marketing expenses	12,253	4,875	7,378	151%
General and administrative expenses	13,581	9,403	4,178	44%
Research and development expenses	7,872	6,257	1,615	26%
Share-based compensation	1,946	1,423	523	37%
Total operating expenses	35,652	21,958	13,694	62%
Operating loss	(25,528)	(13,841)	$(11,687)	84%
Interest expense	27	21	6	29%
Other income	332	53	279	526%
Loss before income taxes	(25,223)	(13,809)	$(11,414)	83%
Income tax benefit (expense)	121	1,074	(953)	(89%)
Net loss	$(25,102)	$(12,735)	$(12,367)	97%

Year Ended June 30, 2019 compared to Year Ended June 30, 2018

Revenue of the RECELL System totaled $5.5 million for the year ended June 30, 2019, an increase of $4.6 million or 489% over the $0.9 million for the year ended June 30, 2018. Most of the current year increase in sales occurred in the U.S. as a result of the September 2018 FDA approval and commencement of the U.S. national market launch of the RECELL System in January 2019. U.S. sales during the year ended June 30, 2019

totaled $4.4 million compared to zero in the prior year. Gross margin for the year ended June 30, 2019 was 77% compared to 41% for the same period in 2018, and management expects gross margins to further increase as sales ramp up within the U.S.

BARDA income of $5.9 million was recognized during the year ended June 30, 2019 compared to income of $7.7 million for the year ended June 30, 2018. The decrease was the result of wind-down of certain activities associated with supporting the U.S. FDA approval of the RECELL System as well as the compassionate use and continued access programs.

Operations for the first half of the year ended June 30, 2019 were focused primarily on preparation for the January 2019 U.S. market launch of the RECELL System. Sales and marketing expenses for the year ended June 30, 2019 totaled $12.3 million, an increase of $7.4 million or 151% over the $4.9 million recognized during the year ended June 30, 2018. This increase was primarily attributed to the recruitment, hiring and training of a U.S. sales force and the associated product launch sales and marketing materials and activities. Research and development expenses for the year ended June 30, 2019 totaled $7.9 million an increase of $1.6 million or 26% over the $6.3 million recognized during the year ended June 30, 2018. General and administrative expenses totaled $13.6 million for the year ended June 30, 2019, an increase of $4.2 million or 44% over the $9.4 million recognized during the year ended June 30, 2018. 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 year ended June 30, 2019 totaled $35.7 million, a $13.7 million or 62% increase over the $22 million incurred during the year ended June 30, 2018 and were in line with management expectations.

Net loss after tax for the year ended June 30, 2019 was $25.1 million, an increase of $12.4 million or 97% over $12.7 million recognized during the year ended June 30, 2018. The increase in net loss was driven by the higher operating costs described above, partially offset by the higher sale of goods during the year. As a result of the U.S. national launch of the RECELL System 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 commercial sales of goods as well as income under the BARDA grant.

B. Liquidity and Capital Resources

We expect to utilize cash reserves until U.S. sales of our products reach a level sufficient to fund ongoing operations. The AVITA Group 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, 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, 2020, we raised additional capital via a private placement in the amount of $81.7 million (through our former parent company, AVITA Medical). We sold the equivalent of 2,033,898 shares at an issue price of $40.17 per share for total net proceeds of $76.6 million, after deducting commission and offering expenses.

During the year ended June 30, 2019, we completed a series of equity transactions (through our former parent company, AVITA Medical). The second tranche of the June 2018 Placement (defined below) closed on July 27, 2018, raising an aggregate of $2.4 million through the issuance of the equivalent of 650,000 shares in the Company at $3.70 per share. During December 2018, we completed a placement to raise $28.8 million over two tranches. We completed the first tranche on December 10, 2018 and issued the equivalent of 3,100,471 shares in the Company at a price of $5.76 per share raising gross proceeds of $17.9 million. The settlement of the second tranche for $10.9 million was approved by the shareholders at an extraordinary meeting held during January 2019. The second tranche closed on January 18, 2019 and raised gross proceeds of $10.9 million through the sale of the equivalent of 1,899,530 shares in the Company at the same price as the first tranche, being $5.76 per share.

In addition, on January 10, 2019, we completed a Share Purchase Plan under which we effectively offered existing eligible shareholders the opportunity to purchase shares in the Company at a purchase price of $5.74 per share pursuant to a Share Purchase Plan. As part of the Share Purchase Plan we received gross proceeds of $1.3 million for the issuance of the equivalent of 220,612 shares in the Company.

During the year ended June 30, 2018, the Company completed a series of equity transactions (through our former parent company, AVITA Medical). During October 2017, we announced a capital raising in aggregate to raise $13.2 million over two tranches; the first a private placement and the second a rights offering to existing shareholders. On October 17, 2017, we completed the private placement of the equivalent of 1,009,830 shares at a price of $3.53 per share raising gross proceeds of $3.6 million. On November 2, 2017, we completed the rights offering resulting in a total issue of the equivalent of 2,765,029 shares to raise a gross total of $9.6 million. During June 2018, we announced an institutional placement to raise an aggregate of $13.3 million over two tranches ("**June 2018 Placement**"). The first tranche closed on June 13, 2018 and raised an aggregate of $9.7 million by issuing the equivalent of 2,554,756 shares at a price of $3.79 per share. The second tranche for an aggregate of $2.4 million (referenced above) was issued on July 27, 2018.

During December 2017, the board of directors approved the 2016 Director Share Plan which previously allowed directors to convert their compensation into our shares.

The AVITA Group also benefits from cash inflows from the BARDA contract, awarded to the AVITA Group in September 2015 and subsequently expanded through a series of modifications. These payments from BARDA offset operating costs from various activities undertaken to support the FDA regulatory approval process for RECELL in the United States, preparation for the planned commercial launch of RECELL in the United States, and RECELL clinical programs in the United States. 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 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. On July 13, 2020 the Company announced that BARDA will procure the RECELL System and agreed to the purchase, storage and delivery of RECELL Systems utilizing a vendor-managed inventory ("**VMI**") plan valued at $7.6 million. Further, BARDA has expanded the awarded contract to provide supplemental funding of $1.6 million to support emergency deployment of RECELL Systems for use in mass casualty or other emergency situations. Delivery of RECELL Systems under the VMI plan is expected to commence in the second half of the 2020 calendar year. As of June 30, 2020, we had received cumulative payments of $24.4 million under the BARDA contract.

The Company's research and development activities are eligible to receive an incentive under an Australian Government tax incentive for eligible expenditure incurred on or after July 1, 2012 ("**R&D Incentive**"). Our management has assessed these activities and expenditure to determine our likely eligibility under the R&D Incentive. For the years ended June 30, 2020 and 2019, the Company has received $0.1 million and $1.6 million, respectively related to this R&D Incentive.

Given the above, we believe there is presently sufficient working capital to support our committed research and development programs and other activities over the next twelve months and the Company believes it 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:

(In Thousands)	As of June 30, 2020	2019
Net cash used in operations	$(22,747)	$(19,250)
Net cash used in investing activities	(847)	(1,227)
Net cash provided by financing activities	77,057	29,709
Effect of foreign exchange rate on cash and restricted cash	3	156
Net increase in cash and restricted cash	53,466	9,388
Cash and restricted cash at beginning of year	20,374	10,986
Cash and restricted cash at end of year	73,840	20,374

Years Ended June 30, 2020, and 2019

Net cash used in operating activities was $22.7 million and $19.3 million during the years ended June 30, 2020 and 2019, respectively. The increase was primarily due to higher operating costs associated with a full year of commercialization of the RECEL System in the United States, and the expansion of research and development.

Net cash used in investing activities was $0.8 million and $1.2 million during the years ended June 30, 2020 and 2019, respectively. Cash flows used for investing activities was primarily attributable to payments for the purchase of a property and equipment.

Net cash provided by financing activities was $77.1 million and $29.7 million for the years ended June 30, 2020 and 2019, respectively. The AVITA Group completed a series of financing transactions and received proceeds from the issuance of shares and exercise of options.

Capital management

We aim to manage capital so that the Company continues as a going concern while also maintaining optimal returns to s tockholders 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 stockholders.

For the year ended June 30, 2020, there were no dividends paid and we have no plans to commence the payment of dividends. We have no committed 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 in order to pursue its various opportunities.

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 institutions based primarily in the United States but also in Australia, Japan 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 which may be suitable for use with the 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, including clinical studies, 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 were $8.5 million, and $7.9 million, during the years ended June 30, 2020, and 2019, respectively.

D. Trend Information

While our RECELL System has reached commercialization for specific applications in certain jurisdictions, the United States remains our primary point of commercial and clinical focus. In addition, we are currently seeking to expand the breadth of clinical indications for which the RECELL System is approved for use in the United States ut have no plans to conduct clinical studies outside of the United States at this time. While we seek to advance the commercial opportunities for the RECELL System, 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

We have no off-balance sheet arrangements (as defined in the rules and regulations of the SEC) that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material investors.

F. Contractual Obligations and Commitments

The following summarizes our contractual obligations and commitments as of June 30, 2020:

	Payments due by period				
Contractual Obligations (in thousands)	**Total**	**Less than 1 year**	**2-3 years**	**4-5 years**	**More than 5 years**
Operating lease obligations (1)	$607	$530	$77	$—	$—
Total	$607	$530	$77	$—	$—

(1) - *Operating lease obligations are primarily for corporate office space and warehouse facilities.*

G. Critical Accounting Policies and Estimates

The SEC defines “critical accounting policies” as those that require the application of management’s most difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

The preparation of consolidated financial statements in conformity with U.S. Generally Accepted Accounting Practices, or U.S. GAAP, requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base those estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ from those estimates.

The following listing is not intended to be a comprehensive list of all of our accounting policies. Our significant accounting policies are described in Note 2 to our consolidated financial statements contained elsewhere in this Annual Report. In many cases, the accounting treatment of a particular transaction is dictated by U.S. GAAP, with no need for our judgment in its application. There are also areas in which our judgment in selecting an available alternative would not produce a materially different result. We have identified the following as our critical accounting policies.

Revenue Recognition

Revenues are recognized as control of the product is transferred to customers, at an amount that reflects the consideration expected to be received in exchange for the product. Revenues are recognized net of volume discounts. As such revenue is recognized only to the extent a significant reversal of revenues is not expected to occur in subsequent periods. Effective July 1, 2018, the Company adopted ASC 606, Revenue from Contracts with Customers, using the modified retrospective method applicable to all contracts that were not completed at the date of initial application. This update outlined a comprehensive new revenue recognition model designed to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new standard also required additional qualitative disclosures. Upon adoption, the ASC 606 did not have a material impact on the financial statements. Refer to Note 12 – Revenues for further information. For the Company's contracts that have an original duration of one year or less, the Company used the practical expedient applicable to such contracts and does not consider the time value of money. Further, because of the short duration of these contracts, the Company has not disclosed the transaction price for the remaining performance obligations as of each reporting period or when the Company expects to recognize this revenue. The Company has further applied the practical expedient to exclude sales tax in the transaction price and expense contract fulfilment costs such as commissions and shipping and handling expenses as incurred.

See Note 12 to our Consolidated Financial Statements included in this Annual Report for additional detail on revenue recognition.

Government Grants / BARDA Income and Receivables

The AVITA Group was granted a BARDA contract in September 2015, wherein BARDA provided funding to the AVITA Group to support the ongoing U.S. clinical regulatory program towards FDA premarket approval, Compassionate Use program, clinical and health economics research, and U.S. pediatric burn programs.

Income under the BARDA contract is earned under a cost-plus-fixed-fee arrangement in which the Company is reimbursed for direct costs incurred plus allowable indirect costs and a fixed-fee earned. Billings under the contracts are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, general and administrative expenses and a fixed fee.

The Company has concluded that grants are not within the scope of ASC 606, as they do not meet the definition of a contract with a "customer". The Company has further concluded that Subtopic 958-605, Not-for-Profit-Entities-Revenue Recognition also does not apply, as the Company is a business entity and the grants are with governmental agencies. Government grants and related receivables 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. 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 installments.

Stock Based Compensation

The Company records compensation expense for stock options based on the fair market value of the awards on the date of grant. The fair value of stock-based compensation awards is amortized over the vesting period of the award. Compensation expense for performance-based awards is measured based on the number of shares ultimately expected to vest, estimated at each reporting date based on management's expectations regarding the relevant performance criteria.

For certain awards, the Company estimates the fair value of share options and other equity-based compensation using a Binomial option pricing model on the date of grant.

See Note 13 to our Consolidated Financial Statements included in this Annual Report for additional detail on stock based compensation.

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that a portion of the deferred tax asset will not be realized.

The Company reviews its uncertain tax positions regularly. An uncertain tax position represents the Company's expected treatment of a tax position taken in a filed return, or planned to be taken in a future tax return or claim that has not been reflected in measuring income tax expense for financial reporting purposes. The Company recognizes the tax benefit from an uncertain tax position when it is more-likely-than-not that the position will be sustained upon examination on the basis of the technical merits or the statute of limitations for the relevant taxing authority to examine and challenge the tax position has expired.

See Note 14 to our Consolidated Financial Statements included in this Annual Report for additional detail on income taxes.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Please see the Company's audited financial statements for the year ended June 30, 2020, beginning at page F-1 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements and supplementary data are attached hereto beginning on Page F-1, and are incorporated by reference herein.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its chief executive officer and chief financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) under the Exchange Act, our management, with the participation of our chief executive officer and chief financial officer,

conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2020. Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2020.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company, as this term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As required by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2020, based on the criteria set forth in the Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our disclosure controls and procedures were effective as of June 30, 2020.

This report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting, in accordance with applicable SEC rules that permit us to provide only management's report in this report.

Changes in Internal Control over Financial Reporting

Remediation of Material Weakness

Throughout the year ended June 30, 2020, the Company undertook remediation measures related to the previously reported material weaknesses in internal control over financial reporting. We completed these remediation measures during the year ended June 30, 2020, including testing of the design and implementation of the related controls. Specifically, we implemented 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. Based on these procedures, we believe that the previously reported material weakness has been remediated.

Other than described above, there was no change in our internal control over financial reporting during the year ended June 30, 2020, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Disclosure Controls and Procedures

Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of these inherent limitations, our disclosure controls and procedures may not prevent or detect all instances of fraud, misstatements, or other control issues. In addition, projections of any evaluation of the effectiveness of disclosure or internal controls to future periods are subject to risks, including, among others, that controls may become inadequate because of changes in conditions or that the degree of compliance with policies or procedures may deteriorate.

Item 9B. OTHER INFORMATION

None

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The following table sets forth our directors and executive officers, their ages and the positions they held as of the date of this Annual Report. All of our directors and executive officers may be contacted at our registered office located at 28159 Avenue Stanford, Suite 220, Valencia, CA 91355.

Any references in this section to a director's role prior to completion of the Redomicile Transaction are references to that director's role as a director of AVITA Medical (being the former parent company of the AVITA Group).

Name	Position	Age	Date First Elected or Appointed
Lou Panaccio	Non-Executive Chairman	62	July 2014
Jeremy Curnock Cook	Non-Executive Director	70	October 2012
Louis Drapeau	Non-Executive Director	75	January 2016
Damien McDonald	Non-Executive Director	54	January 2016
Professor Suzanne Crowe	Non-Executive Director	68	January 2016
Dr. Michael Perry	Executive Director and Chief Executive Officer	60	June 2017
David McIntyre	Chief Financial Officer	49	November 2019
Erin Liberto	Chief Commercial Officer	45	August 2017
Andrew Quick	Chief Technology Officer	49	April 2019
Donna Shiroma	General Counsel	57	June 2018

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, was Non-Executive Chairman of Genera Biosystems Limited until June 2019, and a Non-Executive Director of Rhythm Biosciences Limited, a publicly listed (ASX) development-stage medical diagnostics company.

We believe Mr. Panaccio is qualified to serve on our board of directors based on his extensive experience in the healthcare services and life sciences and his experience serving on boards.

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 formerly 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. From November 2005, he also serves as a Director for AmpliPhi Biosciences Corporation, Inc. (which merged to Armata Pharmaceuticals, Inc. in May 2019), 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 a 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.

We believe Mr. Curnock Cook is qualified to serve on our board of directors based on his extensive experience in the life sciences.

Louis Drapeau has served as Non-Executive Director of our 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. From March 2011 until May 2019, Mr. Drapeau served as 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.

We believe Mr. Drapeau is qualified to serve on our board of directors based on his experience with financial reporting and other requirements of U.S. public companies, and considerable expertise in the biotech sector.

Damien McDonald has served as a Non-Executive Director of our board of directors 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.

We believe Mr. McDonald is qualified to serve on our board of directors based on his extensive experience in the biotech and medical device industries, and his proven track record of achieving value in the medical device space.

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.

We believe Professor Crowe is qualified to serve on our board of directors based on her technical experience and extensive expertise in supporting companies with their medical and scientific strategies.

Dr. Michael Perry was appointed Chief Executive Officer and Executive Director in June 2017. Prior to this appointment, Dr. Perry 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 U.S. 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 genes. He is also a Director at BioScience Managers Pty Ltd.

We believe Dr. Perry is qualified to serve on our board of directors based on our review of his experience, qualifications, attributes and skills, including his executive leadership experience in the healthcare and biotechnology industries.

David McIntyre was appointed Chief Financial Officer in November 2019. Mr. McIntyre has more than 20 years of executive experience having held senior financial, legal and operational roles across multinational and growth-stage entities. Most recently, Mr. McIntyre served as a Partner with Apple Tree Partners (ATP), a multibillion-dollar venture capture and growth equity fund focused exclusively on life sciences. At ATP, Mr. McIntyre was responsible for the medical device portfolio, together with various operating and board functions, including acting as Executive Vice President, Chief Financial Officer and Head of Technical Operations at Braeburn, Inc. Prior to ATP, Mr. McIntyre was Executive Vice President, Chief Financial Officer and Chief Operating Officer at HeartWare® International, Inc. (previously ASX:HIN; NASDAQ: HTWR) where he oversaw HeartWare's financial, supply chain and operating functions as it transitioned from pre-clinical stage through commercialization across more than 20 countries. Prior to HeartWare, Mr. McIntyre practiced as a senior attorney in private practice specializing in corporate, mergers and acquisitions and equity capital markets with Baker & McKenzie and KPMG as well as holding various senior financial roles in multi-national companies, including within the Rio Tinto Group of companies.

Mr. McIntyre holds a Bachelor of Economics (Accounting) from the University of Sydney (Australia), a Bachelor of Law from the University of Technology, Sydney (Australia) and a Master of Business Administration (Fuqua Scholar) from Duke University. He is also a Certified Practicing Accountant (CPA) and is admitted as a Legal Practitioner of the Supreme Court of New South Wales (in Australia).

Erin Liberto has served as Chief Commercial Officer since August 2017. Ms. Liberto has more than 19 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 United States, 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.

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.

Term of Office

Our directors are elected for a term of one year and until their respective successors are elected and qualified, or until their earlier resignation, disqualification or removal.

Our executive officers are appointed by our board of directors and hold office for such terms as may be prescribed by our board of directors and until their successors are appointed, or until their earlier resignation or removal.

Family Relationships

There are no family relationships between our directors or executive officers.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any of the following events during the past ten years:

a) any bankruptcy petition filed by or against any business or property of such person or any partnership or business in which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

b) any conviction in a criminal proceeding or being a named subject of a pending criminal proceeding (excluding traffic violations and other minor offences);

c) being the subject of any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities;

d) being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

e) being the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of: (i) any federal or state securities or commodities law or regulation; or (ii) any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease- and-desist order, or removal or prohibition order; or (iii) any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

f) being the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(40) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Gender Diversity

Under the 4th Edition of the ASX's Corporate Governance Principles and Recommendations the Company is required to set measurable objectives for achieving gender diversity in the composition of its board, senior executives and workforce generally.

As a newly incorporated company, the Company is in the process of developing measurable objectives for achieving gender diversity in the composition of its board, senior executives and workforce generally in accordance with its Code of Ethics and Business Conduct. However, the Company has a target to have at least 30% of its directors of each gender by 2024. The Company will disclose its measurable objectives, the time period for achieving those objectives and the Company's progress towards achieving those objectives in future reporting periods.

Performance Evaluations

As a newly incorporated entity, the Company has not yet undertaken an evaluation of the performance of the board of directors or of the Company's senior executive team in respect of the fiscal year ended June 30, 2020.

Code of Ethics

We have adopted a Code of Conduct, or the Code, that constitutes a "codes of ethics" as that term is defined in paragraph (b) of Item 406 of Regulation S-K and that applies to our executive officers and persons performing similar functions, including our chief executive officer, chief financial officer, chief accounting officer and controller. A copy of the Code is included as Exhibit 14.1 to this Annual Report and is available on our website at www.avitamedical.com.

If we make any amendment to the Code or grant any waivers, including any implicit waiver, from a provision of the Code, which applies to our chief executive officer, chief financial officer, chief accounting officer and controller, or persons performing similar functions, we will disclose the nature of such amendment or waiver on our website. The information on our website is not incorporated by reference into this Annual Report.

Election of Directors

Our board of directors consists of six members. Directors are elected at our annual general meeting of stockholders, and hold office for a term of one year and until their successors have been elected and qualified or until the earlier of their resignation or removal. Any newly created directorship or any vacancy occurring on our board of directors may be filled only by a majority of the remaining members of our board, even if such majority is less than a quorum, and each director so elected shall hold office until the expiration of the term of office of the director whom he or she has replaced or until his or her successor is elected and qualified.

Under ASX Listing Rule 14.4, any directors of the Company (except a managing director) must not hold office without re-election past the third annual general meeting following the director's appointment or three years, whichever is longer.

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominations and corporate governance committee, each of which operates pursuant to a written charter adopted by our board of directors. Our board of directors may also establish other committees from time to time to assist the board of directors. The composition and functioning of all of our committees comply with all applicable requirements of the Sarbanes-Oxley Act, NASDAQ and SEC rules and regulations and the ASX Listing Rules and also align with the ASX Corporate Governance Council's 4th Edition Corporate Governance Principles and Recommendations. Each committee has a charter, which is available on our website at www.avitamedical.com. As of the date of this report, the composition of our audit, compensation and nominations and corporate governance committees were as follows:

Director	Independent	Compensation Committee	Audit Committee	Nomination Committee
Lou Panaccio	X		Member	
Jeremy Curnock Cook	X	Member		Member
Louis Drapeau	X	Member	Chair	Member
Damien McDonald	X		Member	
Professor Suzanne Crowe	X	Chair		Chair

During the fiscal year ended June 30, 2020, the Board of Directors met a total of twelve times (July 29, 2019, September 10, 2019, October 30, 2019, November 4, 2019, February 13, 2020, March 9, 2020, April 8, 2020, April 16, 2020, April 19, 2020, May 4, 2020, May 29, 2020, and June 22, 2020) and had full attendance of each Board of Directors member (six Board of Directors members) at nine of those meetings, as well as attendance by at least four Board of Directors members at all twelve meetings.

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 SEC and NASDAQ and one of whom has accounting or related financial management expertise at senior levels within a company. In addition, the ASX Listing Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations require us to have an audit committee comprised of at least three members, all of whom are non-executive directors and a majority of whom are "independent" directors and which is chaired by an independent director who is not the chair of the board.

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. 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 registered public accounting firm's qualifications and independence, and registered public accounting firm, and such other duties as may be directed by our board of directors. The Audit Committee is also required to assess risk management in conjunction with the board.

Our Audit Committee currently consists of three board members, each of whom satisfies the "independence" requirements of the SEC, NASDAQ Marketplace Rules, the ASX Listing Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. Our Audit Committee is currently composed of Louis Drapeau, Lou Panaccio and Damien McDonald. Each qualifies as an "independent director" within the meaning of NASDAQ Marketplace Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. Mr. Drapeau is the chairman of the audit committee (being an independent director who is not the chair of the board). The audit committee meets at least two times per year. During the fiscal year ended June 30, 2020, the audit committee met a total of four times (August 21, 2019, September 18, 2019, September 26, 2019, and February 12, 2020) and had full attendance at two of the meetings (three audit committee members) and two of the meetings had two audit committee members attending as well as all four meetings had the Chief Executive Officer in attendance. Our board of directors has determined that Louis Drapeau is an "audit committee financial expert," as defined in item 407(d)(5)(ii) of Regulations S-K.

Compensation Committee. Our board of directors has established a Compensation Committee, which is comprised of independent directors, within the meaning of NASDAQ Marketplace Rules and also the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. The Compensation Committee must be comprised solely of non-executive directors in accordance with the ASX Listing Rules and must also be chaired by an independent director in accordance with the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. The Compensation 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 Compensation Committee is also responsible for overseeing and advising our board of directors with regard to the adoption of policies that govern our compensation programs. Suzanne Crowe, Louis Drapeau, and Jeremy Cook are the current members of the Compensation Committee and each qualifies as an "independent director" within the meaning of NASDAQ Marketplace Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. Professor Crowe is the chairman of this committee (being an independent director who is not the chair of the board). During the fiscal year ended June 30, 2020, the Compensation Committee met a total of seven times (July 29, 2019, August 29, 2019, September 9, 2019, October 10, 2019, October 14, 2019, February 12, 2020, and March 11, 2020) and had full attendance of each Compensation Committee member (three Compensation Committee members) at five of those meetings, as well as attendance by at least two Compensation Committee members at all seven meetings.

Nomination and Corporate Governance Committee. Our board of directors has established a Nomination and Corporate Governance Committee. Under the 4th Edition of the ASX's Corporate Governance Principles and Recommendations, our Nomination and Corporate Governance Committee should have at least three members, a majority of whom are independent director and should also be chaired by an independent director. Suzanne Crowe, Louis Drapeau, and Jeremy Cook are the current members of the Nomination and Corporate Governance Committee and each qualifies as an "independent director" within the meaning of NASDAQ Marketplace Rules and the 4th Edition of the ASX's Corporate Governance Principles and Recommendations. Professor Crowe is the chairman of this committee (being an independent director). The Nomination and Corporate Governance 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 stockholders 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. In addition, the Nomination and Corporate Governance Committee is responsible for leading the board of directors to complete a self-evaluation of the board, its committees, and the individual directors. During the fiscal year ended June 30, 2020, the Nomination and Corporate Governance Committee met one time on February 12, 2020 and had full attendance of each Nomination and Corporate Governance Committee member (three Nomination and Corporate Governance Committee members) at that meeting.

Item 11. EXECUTIVE COMPENSATION

The particulars of the compensation paid to our "named executive officers" of our company are set out in the summary compensation below. For the fiscal year ended June 30, 2020, our "named executive officers" and their positions were as follows:

- Michael Perry, *Chief Executive Officer*
- David McIntyre, *Chief Financial Officer*
- Andrew Quick, *Chief Technology Officer*
- Erin Liberto, *Chief Commercial Officer*
- Donna Shiroma, *General Counsel*
- Tim Rooney, *Former Chief Administrative Officer*

SUMMARY COMPENSATION TABLE

Name and Position	Year	Salary (1) ($)	Bonus (2) ($)	Stock Awards (3) ($)	Option Awards (4) ($)	Incentive Plan Compensation ($)	Compensation Earnings ($)	All Other Compensation (6) ($)	Total ($)
Michael Perry ..... *Chief Executive Officer*	2020	475,000	415,625	15,424,774	—	—	—	991,473(9)	17,306,872
	2019	475,000	365,750	—	594,425	—	—	50,746	1,485,921
	2018	514,584(5)	252,146	2,236,469	—	—		14,538	3,017,737
David McIntyre ... *Chief Financial Officer*	2020	242,079	25,062	1,804,073	3,702,477	—	—	59,659(10)	5,833,349
	2019	—	—	—	—	—	—	—	—
	2018	—	—	—	—	—	—	—	—
Erin Liberto, ... *Chief Commercial Officer*	2020	310,539	114,548	—	—	—	—	50,452	475,540
	2019	285,000	105,000	—	350,162	—	—	46,030	786,192
	2018	241,884	178,500		222,995	—		30,704	674,083
Andrew Quick ..... *Chief Technology Officer*	2020	314,717	97,231	—	—	—	—	42,319	454,267
	2019	288,750	85,000	—	691,617	—	—	43,194	1,108,560
	2018	265,000	53,000			—		40,701	358,701
Donna Shiroma ... *General Counsel*	2020	313,064	103,022	60,136	—	—	—	36,090	512,312
	2019	300,000	83,000	—	570,754	—	—	28,981	982,734
	2018	5,769	—	—	—	—	—	156	5,925
Timothy Rooney, former ..... *Chief Administrative Officer and Former Chief Financial Officer (7)*	2020	315,716	143,280	100,226	—	—	—	24,319	583,542
	2019	316,000	105,000	—	229,459	—	—	28,390	678,848
	2018	316,000	75,840	—	—	—	—	34,433	426,273
Dale Sander .. *Former Chief Financial Officer (8)*	2020	—	—	—	—	—	—	—	—
	2019	273,239	175,500	—	350,162	—	—	227,231(11)	1,026,131
	2018	182,740	50,000	—	215,722	—	—	20,837	469,299

(1) Amounts in this column represent dollar value of base salary (cash and non-cash) earned by the named executive officer during the fiscal year covered.

(2) Amounts in this column represent dollar value of bonus (cash and non-cash) earned by the named executive officer during the fiscal year covered.

(3) Amounts in this column represent awards of stock with the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. The fair value determined at the date of grant in accordance with U.S. GAAP based on the closing price of our common stock on the applicable grant date. See Note 13- Share-Based Payment Plans to our Consolidated Financial Statements included in Part II, Item 8. “Financial Statements and Supplementary Data” of this Annual Report for additional detail for the assumptions used in determining the grant date fair value of stock awards. The vesting of these stock award are subject to various performance or related criteria, including continuation of employment over the relevant vesting period.

(4) Amounts in this column represent awards of options with the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. Amounts in this column represent option awards issued to the individuals noted, based on the fair value determined at the date of grant in accordance with U.S. GAAP. See Note 13- Share-Based Payment Plans to our Consolidated Financial Statements included in Part II, Item 8. “Financial Statements and Supplementary Data” for the assumptions used in determining the grant date fair value of option awards. The vesting of these option award are subject to various performance or related criteria, including continuation of employment over the relevant vesting period.

(5) Includes retroactive pay from the prior year of $39,584.

(6) Amounts in this column represent all other compensation for the covered fiscal year that the smaller reporting company could not properly report in any other column of the Summary Compensation Table. This includes the 401-k Match, superannuation (pension) and health care benefits.

(7) Mr. Rooney’s employment with the Company ended on July 31, 2020.

(8) Mr. Sander resigned as Chief Financial Officer as of May 15, 2019.

(9) Comprises (a) $204,682 in relation to the travel, flight and accomodoation costs associated with the executive commuting from his home on Colorado to our offices in Valencia, California (including an amount necessary to gross up these cost for income tax purposes under U.S. federal, California and Colorado State laws); (b) $723,620 associated with profession legal, financial and tax advice associated with the conclusion of various employment, financial and income tax issues in connection with the executive’s revised employment arrangement (including an amount necessary to gross up these cost for income tax purposes under U.S. federal, California and Colorado State laws); and (c) $50,419 associated with medical benefits (including an amount necessary to gross up these cost for income tax purposes under U.S. federal, California and Colorado State laws), and (d) $12,752 associated with 401-k matching contributions.

(10) Comprises (a) $35,945 in relation to the travel, flight and accomodation costs associated with the executive commuting from his home in New Jersey to our offices in Valencia, California (including an amount necessary to gross up these costs for income tax purposes under relevant U.S. federal, California and New Jersey income tax laws); $16,712 associated with health care benefits pursuant to the Company’s health care plan; and (b) $9,001 associated with 401-k matching contributions.

(11) Includes severance payments of $187,788, and health care benefits of $39,443 pursuant to the Company’s health care plan.

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
Chief Executive Officer (CEO)	Dr. Michael Perry	Open ended contract	12-month notice period	12 months
Chief Financial Officer	David McIntyre	Open ended contract	12-month notice period	12 months
Chief Commercial Officer (CCO)	Erin Liberto	Open ended contract	6-month notice period	6 months
Chief Technology Officer (CTO)	Andrew Quick	Open ended contract	3-month notice period	Payment in lieu of notice only, no other benefits specified
General Counsel (GC)	Donna Shiroma	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

Compensation Principles

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

- A revised Compensation Committee Charter which now mandates the development and maintenance of other Compensation Governance Framework elements;
- A Senior Executive Compensation Policy;
- A Short-Term Incentive ("**STI**") Policy & Procedure document; and
- A Long-Term Incentive ("**LTI**") Policy & Procedure document.

Compensation Committee: The Compensation Committee of the Board of Directors of the Company is responsible for determining and reviewing compensation arrangements for the board and our executives. The

Compensation Committee assesses the appropriateness of the nature and amount of compensation of our 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. In addition, the Compensation Committee is responsible for evaluating the performance of the Company's key senior executives.

Use of Compensation Consultants: The Company did not make use of any external compensation consultants during the fiscal year ended June 30, 2020, although it did obtain from third parties industry benchmarking information.

Compensation 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 compensation framework:

- Provide competitive rewards to attract and retain high caliber executives;
- Acceptability to stockholders through transparency and engagement, and ensuring that compensation 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 compensation.

The main focus of executives and of performance assessment for fiscal year ended June 30, 2020 was the commercialization of the RECELL® System within the United States, together with the approval by the FDA of various Investigational Device Exemptions which would support the commencement of additional pivotal clinical studies. Other important activities, including advancement of the Company's pipeline and successful completion of the listing of our ADSs on NASDAQ were items of key focus in the fiscal year. Incentives are intended to be linked to shareholder value via milestone completion and clinical trial outcomes.

Executive Compensation

Objective: The Company aims to reward executives with a level and mix of compensation 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 stockholders; and
- ensure total compensation is competitive by market standards.

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

- executive compensation 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' compensation is structured in a manner designed to link reward to corporate and individual performances; and
- recommendations are made to our board with respect to the quantum of bonuses to be paid to executives.

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

Structure: The Compensation Committee determines the level and make-up of the Chief Executive Officer's compensation. The Compensation Committee reviews and approves the corporate goals and objectives relevant to the Chief Executive Officer's compensation and evaluates the Chief Executive Officer's performance in light of those goals and objectives, on an annual basis. The Compensation Committee takes advice from the Chief Executive Officer with input from industry benchmarking data to set and approve all other executive compensation. To assist in achieving the Company's objectives, the Compensation Committee links the nature and number of officers' emoluments to the Company's performance. Compensation may consist of the following key elements:

- Fixed Compensation
- Variable Compensation
- Short Term Incentive ("**STI**") and/or
- Long Term Incentive ("**LTI**")

The proportion of fixed compensation and variable compensation (potential short term and long-term incentives) is established for each executive by the Compensation Committee annually.

Fixed Compensation Objective and Structure: The level of fixed compensation is set so as to provide a base level of compensation which is both appropriate to the position and is competitive in the market. Fixed Compensation is reviewed annually by the Compensation Committee and the process consists of a review of Company-wide and individual performance and relevant comparative compensation in the market.

Variable Compensation –STI Objective and Structure: The objective of variable compensation is to link the achievement of the Company's operational targets with the compensation received by the executives charged with meeting those targets. The Company's operational targets are set by the Compensation Committee and the targets are based upon financial and non-financial measures. For fiscal year ended June 30, 2020, STI objectives consisted mainly of non-financial measures, primarily based around commercialization of the RECELL System in the United States. The target range was between 25-75% of base salary for the key management personnel. The Company's STI objectives are designed to:

- 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.

All key objectives were assessed by the Compensation Committee as being fully met. All key management personnel achieved 100% of the maximum bonus available to them under the STI plan and were paid in the current year.

Resignation, Retirement, Other Termination, or Change in Control Arrangements

The Company does not have any agreements or plans in place for the named executive officers that would provide additional compensation in connection with a resignation, retirement or other termination or a change in control.

Outstanding Equity Awards at Fiscal Year End

The following table presents information regarding outstanding equity awards held by our named executive officers as of June 30, 2020.

	Option awards					Stock awards			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares of units of stock that have not vested ($)	Equity incentive plan awards: Number of unearned shares, units or other rights have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights have not vested ($) (1)
Michael Perry, Chief Executive Officer **(3)**	125,000	—	25,000	$ 6.00	11/30/2028	—	—	294,359	$8,989,729
David McIntyre, Chief Financial Officer and Board Member **(4)**	45,000	—	90,000	$ 37.99	11/25/2029	—	—	45,000	$1,374,300
Erin Liberto, Chief Commercial Officer and Board Member	43,200	—	114,800	$5.04 - $6.41 (2)	9/6/2027 -11/30/2028(2)	—	—	—	$ —
Andrew Quick, Chief Technology Officer and Board Member	53,516	—	67,284	$6.00 - $21.33 (2)	5/18/2027 - 4/1/2029 (2)	—	—	—	$ —
Donna Shiroma, General Counsel and Board Member	26,900	—	80,900	$4.37 - $6.41 (2)	6/25/2028 - 11/30/2028(2)	—	—	—	$ —

(1) Amounts in this column are calculated by multiplying the closing market price of the Company's stock at the end of the last completed fiscal year by the number of shares or units of stock or the amount of equity incentive plan awards, respectively.

(2) Represents range of exercise price and expiration dates for all of Erin Liberto, Andrew Quick, and Donna Shiroma stock options. Options were granted on different dates throughout their tenure.

(3) On November 26, 3019 shareholders approved 395,543 long term incentives that vest over tenure and performance metrics

(4) David McIntyre was granted 135,000 stock options and 45,000 long term incentives which vest based upon continued employment, tenure and performance metrics determined by the board.

Approval for the issue of the above mentioned equity awards to Mr. Perry was obtained under ASX Listing Rule 10.14.

Compensation of Directors

Objective: Our board seeks to set aggregate compensation 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 stockholders.

Policy: The amount of aggregate compensation sought to be approved by stockholders and the fee structure is to be commercially acceptable, competitive and subject to an annual review. Our 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 compensation is separate and distinct. The Constitution of our former parent company AVITA Medical Limited and the ASX Listing Rules specify that the aggregate compensation 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 compensation of A$450,000 per year in respect of fees payable to Non-Executive Directors.

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 following table sets forth certain information regarding the compensation earned by or awarded to each non-employee director who served on our board during the fiscal year ended June 30, 2020. We do not provide separate compensation to our executive directors, such as Dr. Michael Perry, our Chief Executive Officer. Dr. Perry's compensation is reported in this Annual Report under "Item 11. Executive Compensation."

	Short-term Benefits	**Post-employment Benefits**	**Equity-settled Share-based Payments**	**Total**	**Proportion of Element of Compensation Related to Performance (Other than Options Issued)(1)**		**Proportion of Elements of Compensation Not Related to Performance**
	Salary, fees and leave	401K Match and Superannuation	Shares/Units		Non-salary Cash based Incentives	Shares/Units	
	$	$	$	$	%	%	%
Non-Executive Directors							
L Panaccio - Chairman	48,492	5,029	4,442	**57,963**	0%	0%	100%
J Curnock Cook	37,546			**37,546**	0%	0%	100%
L Drapeau	43,600			**43,600**	0%	0%	100%
D McDonald	32,700		10,900	**43,600**	0%	0%	100%
S Crowe	34,326	3,560	3,144	**41,030**	0%	0%	100%
Total Non-Executive Directors	**196,664**	**8,588**	**18,486**	**223,739**			

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

Compensation Committee Interlocks and Insider Participation

During fiscal year ended June 30, 2020, Suzanne Crowe, Louis Drapeau, and Jeremy Cook served as members of our Compensation Committee. None of the members of our Compensation Committee was, during fiscal year ended June 30, 2020, an officer or employee of the Company and none of the members of our Compensation Committee was formerly an officer of the Company. None of the members of our Compensation Committee had any relationship requiring disclosure by us under any paragraph of Item 404 of Regulation S-K. None of our executive officers currently serves, nor in the past fiscal year has served, as a member of the board of directors or Compensation Committee of any entity that has one or more executive officers serving on our board of directors or Compensation Committee.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Principal Stockholders and Management

The following table provides certain information regarding the ownership of our common stock, as of August 20, 2020 by each person or group of affiliated persons known to us to be the beneficial owner of more than 5% of our common stock; each of our named executive officers; each of our directors; and all of our executive officers and directors as a group. The table also sets out the names of all persons (of which the Company is aware) who have disclosed pursuant to the *Corporations Act 2001* (Cth) to be "substantial shareholders" of the Company and carry 5% or more of the voting rights attached to the issued securities of the Company.

Title of Class	Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership[1]	Percentage of Class[2]
	More than 5% stockholders:		
Common Stock	Redmile Group, LLC One Letterman Drive, Bldg. D, Ste D3-300 San Francisco, CA 94129.	2,001,787[3]	9.32%
Common Stock	Vanguard Group P.O. Box 2600 V26 Valley Forge, PA 19482	1,119,918[4]	5.20%
Common Stock	Blackcrane Capital, LLC 500 108th Avenue NE, STE 960 Bellevue, WA 98004	1,261,938[5]	5.92%
	Directors and named executive officers:		
Common Stock	Lou Panaccio 28159 Avenue Stanford Suite 220 Valencia, CA 91355	20,064[6]	*
Common Stock	Dr. Michael Perry 28159 Avenue Stanford Suite 220 Valencia, CA 91355	473,239[7]	2.20%
Common Stock	Erin Liberto 28159 Avenue Stanford Suite 220 Valencia, CA 91355	43,200[8]	*
Common Stock	David McIntyre 28159 Avenue Stanford Suite 220 Valencia, CA 91355	46,393[9]	*
Common Stock	Andrew Quick 28159 Avenue Stanford Suite 220 Valencia, CA 91355	53,516[10]	*
Common Stock	Donna Shiroma 28159 Avenue Stanford Suite 220 Valencia, CA 91355	26,900[11]	*
Common Stock	Jeremy Curnock Cook 28159 Avenue Stanford Suite 220 Valencia, CA 91355	—	*
Common Stock	Louis Drapeau 28159 Avenue Stanford Suite 220 Valencia, CA 91355	339[12]	*
Common Stock	Damien McDonald 28159 Avenue Stanford Suite 220 Valencia, CA 91355	16,310[13]	*
Common Stock	Professor Suzanne Crowe 28159 Avenue Stanford Suite 220 Valencia, CA 91355	3,046[14]	*
			*
Common Stock	**All executive officers and directors as a group (10 persons)**	683,007	3.18%

* Represents beneficial ownership of less than 1% of the outstanding common stock.

(1) Except as otherwise indicated, we believe that the beneficial owners of the common stock listed above, based on information furnished by such owners, have sole investment and voting power with respect to such shares, subject to community property laws where applicable. Beneficial ownership is determined in

accordance with the rules of the SEC and generally includes voting or investment power with respect to securities.

(2) Percentage of ownership is based on 21,467,911 shares of our common stock issued and outstanding as of August 10, 2020. Common stock subject to options or warrants exercisable within 60 days of August 20, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such option or warrants, but are not deemed outstanding for purposes of computing the percentage ownership of any other person.

(3) Consists of 554,939 CHESS Depositary Interests, CDIs, held by Redmile Offshore II Master Fund Ltd., 63,800 CDIs 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. 503,671 CDIs held by Redmile Capital Offshore Master Fund Ltd, 210,329 CDIs held by Redmile Capital Fund LP, 63,063 CDIs held by a segregated portfolio of LMA SPC, and 31,785 CDIs held by Remile Capital Offshre Fund (ERISA), Ltd. Based solely on disclosures provided by Redmile Group, LLC to the ASX on January 28, 2020, these CDIs 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 serves as the managing member of Redmile Group, LLC, and as such has a deemed relevant interest in the shares under section 608(3) of the Corporations Act.

(4) Consists of 8,956 CDIs held by Brown Brothers Harriman, 75,864 shares of common stock held by BNY Mellon, 622,960 shares of common stock held by JP Morgan Chase Bank, N.A., 142,736 shares of common stock held by State Street Bank and Trust Company, and 269,400 shares of common stock held by various other. Vanguard Group is the manager of various Mutual funds and accounts and that capacity has the power to dispose of the shares. The other members of Vanguard Group have a relevant interest under section 608(3) of the Corporations Act.

(5) Consists of 824,824 common shares, and 437,114 CDIs. 3,888 common shares held by Blackcrane Overseas Alpha Fund, LLC; 1,410 common shares and 59 CDIs held by Blackcrane Partners Fund, LLC; 805,565 ordinary shares and 434,248 CDIs held by Blackcrane Capital LLC; 13,964 ordinary shares held by Daniel Kim. 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.

(6) Reflects 70,460 CDIs, which translates into 14,092 shares of the common stock. . Includes 29,860 CDIs which translates into 5,972 shares of common stock. These CDI's are held by The Panaccio Superannuation Fund.

(7) Includes of 1,266,125 CDI's which translates into 348,239 shares of common stock. In addition amount includes stock options to acquire 125,000 shares of our common stock exercisable within 60 days of August 20, 2020.

(8) Includes stock options to acquire 43,200 shares of our common stock exercisable within 60 days of August 20, 2020.

(9) Includes 4,966 CDIs which translates into 1,393 shares of our common stock. In addition includes stock options to acquire 45,000 shares of our common stock exercisable within 60 days of August 20, 2020.

(10) Includes stock options to acquire 53,516 shares of our common stock exercisable within 60 days of August 20, 2020.

(11) Includes stock options to acquire 26,900 shares of our common stock exercisable within 60 days of August 20, 2020.

(12) Includes of 1,695 CDIs which translates into 339 shares of our common stock.

(13) Includes of 81,550 CDIs which translates into 16,310 shares of our common stock.

(14) Includes of 15,230 CDIs which translates into 3,046 shares of our common stock.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets out equity compensation plan information as at June 30, 2020.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the second column) (1)
Equity compensation plans approved by security holders (2)	1,260,524	$14.72	0
Equity compensation plans not approved by security holders	—	—	—
Total	1,260,524	$14.72	0

(1) Upon closing of the Redomicile Transaction, the 2016 Plans were terminated with respect to future grants and accordingly, there are no more shares available to be issued under the 2016 Plans. At the 2020 annual meeting of stockholders that the Company intends to hold in late September or early October, the Company intends to seek stockholder approval of a new employee stock option plan.

(2) The 2016 Plans were previously approved and adopted by the shareholders of Avita Medical Limited, our predecessor company.

Australian Disclosure Requirements

In addition to the Company's primary listing on the NASDAQ Global Market, the Company's shares of common stock are also quoted in the form of CHESS Depositary Interests ("**CDIs**") on the Australian Securities Exchange ("**ASX"**) and trade under ticker symbol "AVH". As part of our ASX listing, we are required to comply with the various disclosure requirements as set out under the ASX Listing Rules. The following information is intended to comply with the ASX Listing Rules (where that information has not been provided elsewhere in this Annual Report).

Jurisdiction of incorporation and restrictions on the acquisition of securities

The Company is incorporated in the State of Delaware in the United States of America.

As a foreign company registered in Australia, the Company is not subject to Chapters 6, 6A, 6B and 6C of the *Corporations Act 2001* (Cth) dealing with the acquisition of its shares (including substantial holdings and takeovers).

Under the Delaware General Corporation Law, the Company's shares are generally freely transferable, subject to restrictions imposed by United States federal or state securities laws, by the Company's certificate of incorporation or by-laws or by an agreement signed with the holders of shares on issue. The Company's certificate of incorporation and by-laws do not impose any specific restrictions on the transfer of its shares. Repurchases of the Company's securities are governed by the safe harbor provisions set forth in Rule 10b-18 of the Securities Exchange Act or 1934.

However, provisions of the Delaware General Corporation Law, the Company's certificate of incorporation and the Company's by-laws could make it more difficult to acquire the Company by means of a tender offer (takeover), a proxy contest or otherwise, or to remove incumbent officers and directors of the Company. These provisions could discourage certain types of coercive takeover practices and takeover bids that the Company's board may consider inadequate and encourage persons seeking to acquire control of the Company to first negotiate with the board.

Australian Corporate Governance Statement

The board of directors and employees of the Company are committed to developing, promoting and maintaining a strong culture of good corporate governance and ethical conduct.

The board of directors confirm that the Company's corporate governance framework is generally consistent with the ASX's Corporate Governance Council's "Corporate Governance Principles and Recommendations" (4th Edition) ("**ASX Governance Recommendations**"). The Company's Corporate Governance Statement is available for viewing at https://ir.avitamedical.com/corporate-governance. The Corporate Governance Statement sets out the ASX Governance Recommendations and the Company's response as to how and whether it follows those recommendations. Where the Company's practices depart from a recommendation, the board of directors have disclosed in the Corporate Governance Statement the departure along with reasons for adoption of its own practices.

The Company's Corporate Governance Statement is accurate and up to date as at August 24, 2020 and has been approved by the board of directors.

Issued capital

As at August 14, 2020, the Company's issued share capital was as follows:

- 21,468,494 shares of common stock, of which:
  - 8,043,445 shares of common stock were held by 13,215 stockholders and quoted on NASDAQ; and
  - 13,430,049 shares of common stock were held by CHESS Depositary Nominees Pty Limited ("**Authorised Nominee**") (on behalf of 22,731 CDI holders) underpinning 67,150,245 CDIs quoted on ASX.

In addition, the following unquoted securities in AVITA Medical are on issue, which entitle the holders of those securities, upon vesting of their conversion rights, to be issued shares of our common stock in the Company rather than shares in AVITA Medical on a 100:1 consolidation ratio in accordance with, and pursuant to, their terms of issue and the deed poll entered into by the Company on or about May 6, 2020 in favor of, amongst others, the holders of those securities:

- 1,259,662 unquoted options in the Company held by 99 option holders. Specifically:
  - 150,000 options are on issue to Dr Michael Perry, CEO;
  - 1,101,900 options were granted (and are on issue) to 96 employees of the AVITA Group under AVITA Medical's Employee Incentive Option Plan; and
  - 7,761 options are on issue to 3 warrant holders.
- 339,359 unquoted restricted stock units ("**RSUs**") held by:
  - Dr Michael Perry, CEO (294,359 RSUs); and
  - David McIntyre, CFO (45,000 RSUs).

Voting Rights

The Company's by-laws provide that each stockholder has one vote for every share of common stock entitled to vote held of record by such stockholder.

If holders of CDIs wish to attend and vote at the Company's general meetings, they will be able to do so. Under the ASX Listing Rules and ASX Settlement Operating Rules, the Company must allow CDI holders to attend any meeting of the holders of the underlying securities, unless relevant United States laws at the time of the meeting prevent CDI holders from attending those meetings.

In order to vote as such meetings, CDI holders have the following options:

- instruct the Authorised Nominee (as the legal owner of the shares of common stock) to vote the common stock represented by their CDIs in a particular manner. A voting instruction form will be sent to CDI holders with the notice of meeting or proxy statement for the meeting and that instruction form must be completed and returned to the Company's registry prior to the record date fixed for the relevant meeting ("**CDI Voting Instruction Receipt Time**"), which is notified to the CDI holder in the voting instructions included in the notice of meeting; or
- inform the Company that they wish to nominate themselves or a third party to be appointed as the Authorised Nominee's proxy with respect to their common stock underlying their CDIs for the purposes of attending and voting at the meeting. The instruction form must be completed and returned to the Company's registry prior to the CDI Voting Instruction Receipt Time.

Alternatively, a CDI holder can convert their CDIs into a holding of common stock and vote those shares of common stock at a meeting of stockholders. Such a conversion must be undertaken prior to the record date fixed by the Company's board of directors for determining the entitlement of stockholders to attend and vote at the meeting. However, if the former CDI holder later wishes to sell their investment on the ASX, it would be necessary to convert those shares of common stock back to CDIs.

As CDI holders will not appear on the Company's register as the legal holders of the underlying common stock, they will not be entitled to vote at a stockholder meeting unless one of the above steps is undertaken. As each CDI represents 1/5 of a share of common stock, if the CDI holder takes one of the steps noted above to allow it to vote at a stockholder meeting, the CDI holder will be entitled to one vote for every five CDIs it holds.

Holders of options, warrants and RSUs are not entitled to vote.

Substantial Shareholders

The information required in relation to the substantial shareholders of the Company is included in this Annual Report at Item 12 of Part III.

Distribution of Common Stock and CDI Holders at August 14, 2020

Below is a distribution schedule of the number of holders of CDIs, categorised by the size of their holdings, based on the Company's registers as at August 14, 2020 (assuming all issued shares of common stock are held as CDIs).

	CDIs	
	Number of Holders	Number of CDIs
1 - 1000	17,769	5,519,187
1,001 - 5,000	3,965	8,984,196
5,001 - 10,000	518	3,785,787
10,001 - 100,000	444	10,662,775
100,001 - and over	35	38,198,300
	22,731	67,150,245

The number of stockholders and/or CDI holders holding less than a marketable parcel of shares of common stock and/or CDIs (where a "marketable parcel" means a parcel of securities worth at least A$500, pursuant to the ASX Operating Rules) was ten based on the closing market price as of August 14, 2020.

There is no current on-market buy-back of our securities.

Twenty Largest CDI Holders as at August 14, 2020

Below is a statement of the 20 largest holders of CDIs, and the number and percentage of issued CDIs held by those holders, based on the Company's registers as at August 14, 2020 (assuming all shares of common stock of the Company are held as CDIs, with 5 CDIs representing a beneficial ownership interest in one share of common stock in the Company).

Rank	Name	Number of CDIs Held	% of CDIs Outstanding
1	CEDE & CO	40,188,890	37.44%(1)
2	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	7,253,182	6.76%
3	CITICORP NOMINEES PTY LIMITED	7,045,639	6.56%
4	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	6,687,839	6.23%
5	NATIONAL NOMINEES LIMITED	5,395,728	5.03%
6	MERRILL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED	1,816,130	1.69%
7	MR MICHAEL PERRY	1,263,045	1.18%
8	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSCO ECA	1,252,369	1.17%
9	CS FOURTH NOMINEES PTY LIMITED <HSBC CUST NOM AU LTD 11 A/C>	1,097,835	1.02%
10	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	735,579	0.69%
11	ATEQ INVESTMENTS PTY LTD	590,000	0.55%
12	BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAILCLIENT DRP>	490,104	0.46%
13	BNP PARIBAS NOMINEES PTY LTD <AGENCY LENDING DRP A/C>	412,302	0.38%
14	WARBONT NOMINEES PTY LTD <UNPAID ENTREPOT A/C>	403,116	0.38%
15	BRISPOT NOMINEES PTY LTD <HOUSE HEAD NOMINEE A/C>	359,195	0.33%
16	MR ADRIAN SIMUN PULJICH	271,765	0.25%
17	BNP PARIBAS NOMINEES PTY LTD HUB24 CUSTODIAL SERV LTD <DRP A/C>	244,938	0.23%
18	DIBBENS DEVELOPMENTS PTY LIMITED <DIBBENS SUPER BEN FUND A/C>	225,000	0.21%
19	MR ANTHONY MARK SAIA & MRS CARMEN SAIA <SAIA FAMILY SUPER FUND A/C>	217,500	0.20%
20	CITICORP NOMINEES PTY LIMITED <COLONIAL FIRST STATE INV A/C>	213,979	0.20%

(1) Represents shares of common stock converted into CDIs.

General Information

The name of our Secretary is Donna Shiroma.

The Company's ASX liaison officer who is responsible for communications with the ASX is Mark Licciardo.

The complete mailing address, including zip code, of our principal executive office is 28159 Avenue Stanford, Suite 220, Valencia, CA 91355, USA. The telephone number is +1(661) 367-9170.

The address of the principal registered office in Australia is c/- Mertons Corporate Services Pty Ltd, Level 7, 330 Collins Street, Melbourne VIC 3000, Australia and our telephone number there is +61 3 8689 9997.

Registers of securities are held as follows:

- for CDIs in Australia at Computershare Investor Services Pty Limited, Level 2, 45 St Georges Terrace, Perth WA 6000 Australia, Investor Enquiries +61 8 9323 2000 (within Australia) +61 3 9415 4677 (outside Australia); and
- for common stock in the United States at Computershare Investor Services, 250 Royall Street, Canton, MA 02021 USA, Tel: 866-644-4127.

Application of funds

The Company advises that it has used the cash and assets in a form readily convertible to cash that it had at the time of the Company's admission to the Official List of ASX in a way that is consistent with its business objectives.

Directors' Declaration

As at the date of this report, the directors confirm that they are of the opinion that there are reasonable grounds to believe that the members of the "extended closed group" identified in Note 17, being the Company and the Australian Subsidiaries that are party to the deed of cross guarantee that is detailed in Note 17, will be able to meet any liabilities to which they are, or may become, subject, by virtue of the deed of cross guarantee.

Item 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Persons

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. Such transactions have been reviewed and approved by our board of directors after review and approval by our Audit Committee and Nominating Committee.

Director Independence

Our board of directors has determined that all members of our board of directors, except Dr. Michael Perry, are independent directors for purposes of the rules of NASDAQ and the SEC and for the purposes of the ASX Listing Rules and the ASX Corporate Governance Council's 4th Edition Corporate Governance Principles and Recommendations. In making this determination, our board of directors considered the relationships that each non-executive director has with us and all other facts and circumstances that our board of directors deemed relevant, including the beneficial ownership of our common stock by each non-executive director and Mr Perry's executive role within the Avita Group.

The composition and functioning of our board of directors and each of our committees complies with all applicable requirements of NASDAQ and the rules and regulations of the SEC as well as the ASX Listing Rules and the ASX Corporate Governance Council's 4th Edition Corporate Governance Principles and Recommendations.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Principal Accounting Fees and Services

Grant Thornton Audit Pty Ltd, a subsidiary of Grant Thornton Australia Ltd, independent registered public accountants served as our independent public accountant for the years ended June 30, 2020 and 2019. Grant Thornton LLP, the U.S. member of Grant Thornton International Ltd, independent registered public accountants have served as our independent public accountant for the period ended June 30, 2020. The following table sets forth fees billed or accrued by our independent registered public accountants during the fiscal years ended June 30, 2020 and 2019:

	Year Ended June 30,	
	2020	2019
Audit fees - Grant Thornton LLP (1)	$265,423	$ —
Audit fees - Grant Thornton Audit Pty Ltd (1)	212,147	86,785
Audit related fees	—	—
Tax fees - Grant Thornton LLP (2)	90,737	—
Tax fees - Grant Thornton Audit Pty Ltd (2)	20,815	73,308
All other fees (3)	—	—
Total fees	$589,122	$160,093

(1) Audit fees consist of fees billed for the professional services rendered by the principal accountant for the audit of the registrant's annual financial statements and review of financial statements included in the registrant's Form 10-Q or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements.

(2) Tax fees include the aggregate fees billed in each of the last two fiscal years for professional services rendered by the principal accountant for tax compliance, tax advice, and tax planning.

(3) All other fees consists of products and services provided by the principal accountant, other than the services reported in Audit Fees, Audit Related Fees, or Tax Fees.

Pre-Approval Policies and Procedures

The Audit Committee's policy is for the Audit Committee to approve all audit and non-audit services prior to such services being performed by the independent registered public accounting firm. Before engaging an independent registered public accountant firm to render audit or non-audit services, the engagement is approved by our audit committee or the engagement to render services is entered into pursuant to pre-approval policies and procedures established by the audit committee.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report:

(1) All Financial Statements

See Index to Financial Statements in Part II, Item 8 of this Annual Report.

(2) Financial Statement Schedules

all financial statement schedules have been omitted since the required information was not applicable or was not present in amounts sufficient to require submission of the schedules, or because the information required is included in the financial statements or the accompanying notes.

(3) Exhibits

The exhibits listed in the following Index to Exhibits are filed, furnished or incorporated by reference as part of this Annual Report

EXHIBITS

Exhibit Number	Exhibit Description
2.1	Scheme Implementation Agreement (incorporated by reference to Exhibit 99.2 of Form 6-K of Avita Medical Limited dated April 20, 2020)
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K12B filed on June 30, 2020)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the registrant's Form 8-K12B filed on June 30, 2020)
4.1	Description of Capital Stock (incorporated by reference to the registrant's Form 8-K12B filed on June 30, 2020)
10.1	Employee Incentive Option Plan (incorporated by reference to Exhibit 4.1 of the Form 20-F of Avita Medical Limited filed September 27, 2019)†
10.2	Employee Share Plan (incorporated by reference to Exhibit 4.2 of the Form 20-F of Avita Medical Limited filed September 27, 2019)†
10.3	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) (incorporated by reference to Exhibit 4.3 of the Form 20-F of Avita Medical Limited filed September 27, 2019)*
10.4	Award Contract dated September 29, 2015 by and between the registrant and BARDA (incorporated by reference to Exhibit 4.4 of the Form 20-F of Avita Medical Limited filed September 27, 2019) *
10.5	Amendment of Solicitation/Modification of Contract dated June 24, 2016 by and between the registrant and BARDA (incorporated by reference to Exhibit 4.5 of the Form 20-F of Avita Medical Limited filed September 27, 2019) *
10.6	Amendment of Solicitation/Modification of Contract dated September 28, 2017 by and between the registrant and BARDA (incorporated by reference to Exhibit 4.6 of the Form 20-F of Avita Medical Limited filed September 27, 2019) *
10.7	Amendment of Solicitation/Modification of Contract dated July 2, 2018 by and between the registrant and BARDA (incorporated by reference to Exhibit 4.7 of the Form 20-F of Avita Medical Limited filed September 27, 2019) *
10.8	Lease Agreement between the registrant and Hartco Ventura Inc. dated January 25, 2018 (incorporated by reference to Exhibit 4.8 of the Form 20-F of Avita Medical Limited filed September 27, 2019)
10.9	Lease Agreement between the registrant and RIF-Avenue Stanford LLC, dated October 3, 2016, as amended (incorporated by reference to Exhibit 4.9 of the Form 20-F of Avita Medical Limited filed September 27, 2019)
14.1	Code of Ethics **

Exhibit Number	Exhibit Description
21.1	Subsidiaries of the Registrant **
31.1	Certification of CEO pursuant to Section 302 of The Sarbanes-Oxley Act of 2002 **
31.2	Certification of CFO pursuant to Section 302 of The Sarbanes-Oxley Act of 2002 **
32.1	Certification of CEO and CFO pursuant to Section 906 of The Sarbanes-Oxley Act of 2002**
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

† Management contract or compensation plan or arrangement.
* 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.
** Filed herewith

Item 16. Form 10-K Summary

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AVITA Therapeutics, Inc.
(Registrant)

Date: August 27, 2020

/s/ Dr. Michael Perry
Dr. Michael Perry
Chief Executive Officer (Principal Executive Officer)

Date: August 27, 2020

/s/ David McIntyre
David McIntyre
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Dr. Michael Perry Dr. Michael Perry	Chief Executive Officer and Director (Principal Executive Officer)	August 27, 2020
/s/ David McIntyre David McIntyre	Chief Financial Officer (Principal Financial and Accounting Officer)	August 27, 2020
/s/ Lou Pannaccio Lou Panaccio	Director	August 27, 2020
/s/ Jeremy Curnock Cook Jeremy Curnock Cook	Director	August 27, 2020
/s/ Louis Drapeau Louis Drapeau	Director	August 27, 2020
/s/ Damien McDonald Damien McDonald	Director	August 27, 2020
/s/ Suzanne Crowe Suzanne Crowe	Director	August 27, 2020

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
AVITA Therapeutics, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of AVITA Therapeutics, Inc. (a Delaware corporation) and subsidiaries (the "**Company**") as of June 30, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for each of the three years in the period ended June 30, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2020, in conformity with accounting principles generally accepted in the United States of America.

Adoption of new accounting standard

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leasing arrangements effective July 1, 2019 due to the adoption of the guidance in Accounting Standards Codification Topic 842, Leases, using the current period adjustment method.

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 regarding 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 LLP

We have served as the Company's auditor since 2020.

Los Angeles, California
August 27, 2020

AVITA THERAPEUTICS, INC.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	June 30, 2020	June 30, 2019
ASSETS		
Cash	$ 73,639	$ 20,174
Accounts receivable, net	2,076	1,403
BARDA receivables	356	382
R&D tax credits	—	126
Prepaids and other current assets	990	1,098
Restricted cash	201	200
Inventory	1,125	742
Total current assets	78,387	24,125
Plant and equipment, net	1,363	1,309
Operating lease right-of-use assets	2,347	—
Intangible assets	364	225
Other long term assets	1	125
Total assets	$ 82,462	$ 25,784
LIABILITIES AND SHAREHOLDERS' EQUITY		
Accounts payable and accrued liabilities	$ 4,333	$ 1,916
Accrued wages and fringe benefits	2,816	2,127
Other current liabilities	560	438
Total current liabilities	7,709	4,481
Contract liabilities	435	429
Operating lease liabilities, long term	1,917	—
Other long term liabilities	—	42
Total liabilities	10,061	4,952
Contingencies (Note 10)		
Shareholders' Equity:		
Common stock, $0.0001 par value per share, 200,000,000 shares authorized, 21,467,912 and 18,712,996 shares issued and outstanding at June 30, 2020 and 2019, respectively	3	3
Preferred stock, $0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at June 30, 2020 and 2019	—	—
Additional paid-in capital	259,165	165,473
Accumulated other comprehensive income	8,146	8,184
Accumulated deficit	(194,913)	(152,828)
Total shareholders' equity	72,401	20,832
Total liabilities and shareholders' equity	$ 82,462	$ 25,784

The accompanying notes form part of the consolidated financial statements

AVITA THERAPEUTICS, INC.
Consolidated Statements of Operations
(In thousands, except share and per share data)

	Year Ended June 30,		
	2020	**2019**	**2018**
Revenues	$ 14,263	$ 5,474	$ 929
Cost of sales	2,973	1,271	546
Gross profit	11,290	4,203	383
BARDA income	3,926	5,921	7,734
Operating Expenses:			
Sales and marketing expenses	14,813	12,253	4,875
General and administrative expenses	18,135	13,581	9,403
Research and development expenses	8,461	7,872	6,257
Share-based compensation	16,486	1,946	1,423
Total operating expenses	57,895	35,652	21,958
Operating loss	(42,679)	(25,528)	(13,841)
Interest expense	33	27	21
Other income	686	332	53
Loss before income taxes	(42,026)	(25,223)	(13,809)
Income tax benefit (expense)	(4)	121	1,074
Net loss	$ (42,030)	$ (25,102)	$ (12,735)
Net loss per common share:			
Basic	$ (2.07)	$ (1.56)	$ (1.37)
Diluted	$ (2.07)	$ (1.56)	$ (1.37)
Weighted-average common shares:			
Basic	20,290,966	16,064,588	9,326,810
Diluted	20,290,966	16,064,588	9,326,810

The accompanying notes form part of the consolidated financial statements

AVITA THERAPEUTICS, INC.
Consolidated Statements of Shareholders' Equity
(In thousands, except shares)

	Common Stock Shares	Common Stock Amount	Additional Paid-in-Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Shareholders' Equity
Balance at July 1, 2017	**6,732,198**	**$ 1**	**$ 110,861**	**$ 8,058**	**$(114,991)**	**$ 3,929**
Net loss	—	—	—	—	(12,735)	(12,735)
Issuance of common stock under direct placement	6,329,615	1	22,791	—	—	22,792
Issuance costs associated with direct placement	—	—	(1,435)	—	—	(1,435)
Share-based compensation	—	—	1,423	—	—	1,423
Issuance of common stock to director in lieu of directors fees	6,970	—	33	—	—	33
Cancelled shares	(295,000)	—	—	—	—	—
Translation gain	—	—	—	25	—	25
Balance at June 30, 2018	**12,773,783**	**2**	**133,673**	**8,083**	**(127,726)**	**14,032**
Net loss	—	—	—	—	(25,102)	(25,102)
Issuance of common stock under direct placement	5,870,613	1	32,453	—	—	32,454
Issuance costs associated with direct placement	—	—	(2,934)	—	—	(2,934)
Share-based compensation	—	—	1,946	—	—	1,946
Exercise of stock options	68,600	—	335	—	—	335
Translation gain	—	—	—	101	—	101
Balance at June 30, 2019	**18,712,996**	**3**	**165,473**	**8,184**	**(152,828)**	**20,832**
Net loss	—	—	—	—	(42,030)	(42,030)
Issuance of common stock under direct placement	2,033,898	—	81,702	—	—	81,702
Issuance costs associated with direct placement	—	—	(5,077)	—	—	(5,077)
Share-based compensation	—	—	16,486	—	—	16,486
Exercise of stock options	99,982	—	474	—	—	474
Vesting of RSU options	605,183	—	—	—	—	—
Issuance of common stock to director in lieu of directors fees	15,853	—	107	—	—	107
Beginning balance adjustment related ot the adoption of ASC 842	—	—	—	—	(55)	(55)
Translation loss	—	—	—	(38)	—	(38)
Balance at June 30, 2020	**21,467,912**	**$ 3**	**$ 259,165**	**$ 8,146**	**$(194,913)**	**$ 72,401**

The accompanying notes form part of the consolidated financial statements

AVITA THERAPEUTICS, INC.

Consolidated Statements of Comprehensive Loss

(In thousands)

	June 30,		
	2020	**2019**	**2018**
Net Loss	$ (42,030)	$ (25,102)	$ (12,735)
Other comprehensive income gain/(loss):			
Foreign currency translation gain/(loss)	(38)	101	25
Comprehensive loss	$ (42,068)	$ (25,001)	$ (12,710)

The accompanying notes form part of the consolidated financial statements

Avita Therapeutics, Inc.

Consolidated Statement of Cash Flows

(in thousands)

	Years Ended June 30,		
	2020	**2019**	**2018**
Cash flow from operating activities:			
Net loss	$(42,030)	$(25,102)	$(12,735)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	465	269	110
Non-cash lease expense	502	—	—
Loss on fixed assset disposal	259	2	
Loss on foreign currency transactions	7	397	95
Provision for bad debt expense	43	6	15
Provision for inventory obsolesence	84	89	31
Share based compensation	16,486	1,946	1,423
Issuance of common stock to directors in lieu of directors fees	107	—	33
R&D tax credit benefit	—	(129)	(1,101)
Changes in operating assets and liabilities:			
Trade and other receivables	(729)	(1,291)	(27)
BARDA receivables	26	1,522	(1,889)
R&D tax credits	121	1,742	26
Prepaids and other current assets	219	(315)	174
Inventory	(468)	17	(94)
Operating lease liability	(476)	—	—
Other long term assets	—	(4)	(1)
Accounts payable and accrued expenses	2,308	69	280
Accrued wages and fringe benefits	693	737	700
Other current liabilities	(366)	384	5
Contract liabilities	6	429	—
Other long term liabilities	(4)	(18)	(5)
Net cash used in operations	(22,747)	(19,250)	(12,960)
Cash flows from investing activities:			
Cash paid for property and equipment	(590)	(1,021)	(365)
Cash paid for patent filing fees	(257)	(206)	—
Net cash used in investing activities	(847)	(1,227)	(365)
Cash flow from financing activities:			
Proceeds from direct placement of common stock	81,702	32,453	22,791
Issuance cost associated with direct placement	(5,077)	(2,934)	(1,435)
Principal repayment of finance lease	(42)	(62)	(61)
Proceeds from exercise of stock options	474	252	—
Net cash provided by financing activities	77,057	29,709	21,295
Effect of foreign exchange rate on cash and restricted cash	3	156	102
Net increase in cash and restricted cash	53,466	9,388	8,072
Cash and restricted cash at beginning of year	20,374	10,986	2,914
Cash and restricted cash end of year	$ 73,840	$ 20,374	$ 10,986
Supplemental Disclosure of Cash Flow Information			
Cash paid for:			
Interest	$ 42	$ 27	$ 21
Fixed assets in accounts payable	$ 85	$ 15	$ 9

The accompanying notes form part of the consolidated financial statements

AVITA THERAPEUTICS, INC.
Notes to Consolidated Financial Statements

1. The Company

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("**U.S. GAAP**"). These financial statements include the assets, liabilities, revenues and expenses of all wholly-owned subsidiaries.

Nature of the Business

The AVITA group of companies (comprising AVITA Therapeutics, Inc. ("AVITA Therapeutics" or the "Company") and its subsidiaries, including AVITA Medical Limited ("AVITA Medical")) (collectively, "AVITA Group" or "we", "us", or "our") is a commercial-stage regenerative tissue company focused on the treatment of burns, trauma and other acute injuries, including vitiligo. The Company's lead product is the RECELL System, a device that enables healthcare professionals to produce a suspension of Spray-On Skin™ Cells using a small sample of the patient's own skin. In September 2018, the United States Food & Drug Administration ("**FDA**") granted premarket approval (PMA) to the RECELL System for use in the treatment of acute thermal burns in patients eighteen years and older. Following receipt of our PMA, we commenced commercializing the RECELL System in January 2019 in the United States. In addition, the FDA has granted the Company three Investigational Device Exemptions ("**IDEs**") which enable the Company to initiate pivotal clinical investigational studies to seek expanded FDA (supplementary) PMA of the RECELL System for each of soft tissue reconstruction, pediatric scalds, and vitiligo. Enrollment of those clinical studies is ongoing and, if successful, those studies would enable the Company to commence commercializing the RECELL System in the United States in each of those indications.

In March 2020, the World Health Organization declared the outbreak of a novel strain of the coronavirus ("**COVID-19**") a pandemic. During the last two quarters of fiscal year 2020, the pandemic had minor effects on the Company's consolidated results of operations. With respect to future operating results, it is not possible at this time to predict, with any degree of precision, the effects of the pandemic. Consequently, accounting estimates and assumptions, particularly those relating to the recoverability of certain intangible assets and estimates of expected credit losses on accounts receivable, require management judgments concerning the effects of the economic downturn and recovery, which are inherently imprecise.

Redomiciliation

On June 29, 2020, the Company, a newly formed Delaware corporation, acquired all of the issued share capital of AVITA Medical Limited ("**AVITA Medical**"), a public company incorporated under the laws of the Commonwealth of Australia and former parent company of the AVITA Group. The acquisition was completed pursuant to a scheme of arrangement under Australian law, and was approved by the Federal Court of Australia on June 22, 2020, and by shareholders of AVITA Medical on June 15, 2020 (the Redomiciliation). Under the Redomiciliation, all of the issued and outstanding ordinary shares of AVITA Medical, including those ordinary shares held in the form of American Depositary Shares ("**ADSs**"), were exchanged for newly issued shares of common stock of the Company or CHESS Depositary Interests ("**CDIs**"). This exchange was conducted on the basis of one share of common stock of AVITA Therapeutics for every 100 ordinary shares of AVITA Medical, effecting an 'implicit consolidation' or 'reverse split'. The holders of ordinary shares of AVITA Medical received one CDI for every 20 ordinary shares held in AVITA Medical, and the holders of AVITA Medical **ADSs** (each of which represented 20 ordinary shares in AVITA Medical) received one share of common stock in AVITA Therapeutics for every five ADSs held. The Company's common stock began trading on The NASDAQ Stock Exchange LLC ("**NASDAQ**") upon market open on July 1, 2020 under the same ticker code, "RCEL" as AVITA Medical's ADSs were traded under prior to the Redomiciliation.

As part of the exchange of shares under the Redomiciliation, a reverse split was also simultaneously implemented such that the number of shares of common stock on issue in the Company (as set out in the

consolidated financial statements) is less than the number of ordinary shares in AVITA Medical that was previously set out in the consolidated financial statements of AVITA Medical.

The Redomiciliation resulted in the domicile of the AVITA Group moving from Australia to the United States of America, with AVITA Therapeutics becoming the ultimate parent company of the AVITA Group. In addition, the existing listing of AVITA Medical ordinary shares on the Australian Securities Exchange ("**ASX**") (as its primary listing) and AVITA Medical ADSs on NASDAQ (as its secondary listing) was inverted and replaced with a new listing of AVITA Therapeutics common stock on NASDAQ (as its primary listing) under the existing ticker symbol, "RCEL" and AVITA Therapeutics CDIs on the ASX (as its secondary listing) under the existing ticker symbol, AVH. Five CDIs traded on ASX are equivalent to one share of common stock traded on NASDAQ.

As a result of the Redomiciliation, the reporting currency of the AVITA Group has changed from the Australian dollar to the U.S. dollar. In accordance with SEC regulation, SX Rule 320 (e), the impact of the change in the reporting currency was included in a component of other comprehensive income (loss).

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. As a result of the redomiciliation described above, the parent company of the AVITA group changed from AVITA Medical to AVITA Therapeutics, Inc. All intercompany transactions and balances have been eliminated on consolidation.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts (including doubtful accounts, carrying value of long-lived asset, the useful lives of long-lived assets, accounting for income taxes and stock-based compensation) and related disclosures. Estimates have been prepared on the basis of the current and available information. However, actual results could differ from estimated amounts.

Foreign Currency Translation

The financial position and results of operations of the Company's non-U.S. subsidiaries were generally determined using the respective local currency as the functional currency. Assets and liabilities of these subsidiaries are translated at the exchange rate in effect at each year end. Income statement accounts are translated at the average rate of exchange prevailing during the year. Adjustments arising from the use of differing exchange rates from period to period are included in accumulated other comprehensive gain (loss) in shareholders' equity. Gains and losses resulting from foreign currency transactions, which are not material, are included in general and administrative expenses in the consolidated statements of operations.

Revenue Recognition

Revenues are recognized as control of the product is transferred to customers, at an amount that reflects the consideration expected to be received in exchange for the product. Revenues are recognized net of volume discounts. As such revenue is recognized only to the extent a significant reversal of revenues is not expected to occur in subsequent periods. Effective July 1, 2018, the Company adopted ASC 606, *Revenue from Contracts with Customers*, using the modified retrospective method applicable to all contracts that were not completed at the date of initial application. This update outlined a comprehensive new revenue recognition model designed to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to

which the entity expects to be entitled in exchange for those goods or services. The new standard also required additional qualitative disclosures. Upon adoption, the ASC 606 did not have a material impact on the financial statements. Refer to Note 12 – Revenues for further information.

For the Company's contracts that have an original duration of one year or less, the Company used the practical expedient applicable to such contracts and does not consider the time value of money. Further, because of the short duration of these contracts, the Company has not disclosed the transaction price for the remaining performance obligations as of each reporting period or when the Company expects to recognize this revenue. The Company has further applied the practical expedient to exclude sales tax in the transaction price and expense contract fulfilment costs such as commissions and shipping and handling expenses as incurred.

Cost of Sales

Cost of sales related to products includes costs to manufacture or purchase, package and ship the Company's products. Costs also include relevant production overhead and depreciation and amortization. These costs are recognized when control of the product is transferred to the customer and revenue is recognized.

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income or loss in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that a portion of the deferred tax asset will not be realized. We recognize interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheet.

The Company reviews its uncertain tax positions regularly. An uncertain tax position represents the Company's expected treatment of a tax position taken in a filed return, or planned to be taken in a future tax return or claim that has not been reflected in measuring income tax expense for financial reporting purposes. The Company recognizes the tax benefit from an uncertain tax position when it is more-likely-than-not that the position will be sustained upon examination on the basis of the technical merits or the statute of limitations for the relevant taxing authority to examine and challenge the tax position has expired.

Cash

Cash consists of cash held at deposit institutions. The Company holds cash denominated in foreign currencies in foreign institutions of approximately $466,000 and $476,000 as of June 30, 2020 and 2019, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, and trade and other receivables. As of June 30, 2020, and 2019, substantially all of the Company's cash was deposited in accounts at financial institutions, and amounts may exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institutions in which its cash is held.

As of June 30, 2020, no single customer accounted for more than 10% of total revenues or net accounts receivable. As of June 30, 2019, one customer accounted for approximately 10.5% of total revenues and three

customers accounted for more than 10% of net accounts receivable, each representing approximately 14.6%, 10.3% and 10.1% of total net accounts receivable. As of June 30, 2018, four customers accounted for more than 10% of total revenues, each representing approximately 17%, 14.5%, 12.8% and 10.4% of total revenues.

Restricted Cash

Pursuant to a contractual agreement with American Express to maintain the business credit card, the Company must maintain restricted cash deposits which amounted to approximately $201,000 and $200,000 as of June 30, 2020 and 2019, respectively.

Fair Value of Financial Instruments

The carrying values of the Company's financial instruments, consisting of cash, trade receivables, prepaids and other receivables, accounts payable, accrued liabilities and contract liabilities, approximate fair value due to the relative short-term nature of these instruments.

Accounts Receivable

Accounts receivable are recorded net of customer allowances for doubtful accounts. The Company estimates an allowance for expected credit losses (i.e., the inability of our customers to make required payments). These estimates are based on a combination of past experience and current trends. In estimating the allowance for expected credit losses, consideration is given to the current aging of receivables, a specific review for potential bad debts and an evaluation of historic write-offs. The resulting bad debt expense is included in sales and marketing expenses in the consolidated statement of operations. Receivables are written-off when deemed uncollectible. As of June 30, 2020, and 2019 the allowance for doubtful accounts was $18,000 and $18,000, respectively.

A rollforward of the activity in the Company's allowance for doubtful account is as follows (in thousands):

	June 30,		
	2020	**2019**	**2018**
Allowance for doubtful accounts at beginning of the year	$ 18	$17	$ 68
Bad debt expense	43	6	15
Deductions	(43)	(5)	(66)
Allowance for doubtful accounts at end of the year	$ 18	$18	$ 17

BARDA Income and Receivables

The AVITA Group was awarded a Biomedical Advance Research and Development Authority ("**BARDA**") grant in September 2015. Under this grant BARDA supports the Company's research and development for the Company's product, including the ongoing U.S. clinical regulatory program targeted towards FDA PMA, our compassionate use program, clinical and health economics research, and U.S. pediatric burn programs.

Consideration received under the BARDA grant is earned and recognized under a cost-plus-fixed-fee arrangement in which the Company is reimbursed for direct costs incurred plus allowable indirect costs and a fixed-fee earned. Billings under the contracts are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, general and administrative expenses and a fixed fee.

The Company has concluded that grants under the BARDA grantt are not within the scope of ASC 606, as they do not meet the definition of a contract with a "customer." The Company has further concluded that Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* also does not apply, as the Company is a business entity and the grants are with governmental agencies or units. With respect to the BARDA grant, we

considered the guidance in IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance,* by anology. BARDA income and related receivables are recognized when there is reasonable assurance that the grant will be received, and all attaching conditions have been complied with. When the grant relates to an expense item, the grant received is recognized as income over the period when the expense was incurred.

Inventory

Inventory is valued at the lower of cost or estimated net realizable value and is reflected in cost of sales. 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 ("**FIFO**"). The Company capitalizes inventory costs associated with the Company's products when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. Inventory is evaluated for impairment periodically to identify inventory obsolescence when an inventory item's cost basis is in excess of its net realizable value. These adjustments are based upon multiple factors, including inventory levels, projected demand, and product shelf life.

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

Leases

Effective July 1, 2019, operating leases give rise to operating lease right-of-use assets and operating lease liabilities on the consolidated balance sheets, see Note 3– Accounting Standards Update. Prior to July 1, 2019, the Company accounted for leases in accordance with ASC 840 Leases.

Property, Plant and Equipment

The Company's property, plant and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is computed based on the straight-line method over the estimated useful lives of the various asset classes, generally three to seven years. Leasehold improvements are amortized over the shorter of the life of the related asset or the remaining term of the lease. Costs associated with customized internal-use software systems that have reached the application development stage and meet recoverability tests are capitalized and include external direct costs utilized in developing or obtaining the applications and payroll and payroll-related expenses for employees who are directly associated with the application development. Maintenance and repairs are expensed as incurred.

Intangible Assets

The Company maintains definite-lived intangible assets related to patents initially measured at cost and amortized over estimated useful lives of approximately 3—20 years. The Company had capitalized patent costs of $483,000 and $225,000 as of June 30, 2020 and 2019, respectively, related to regulatory approval of the RECELL System, and are being amortized over their estimated useful lives.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the sum of the estimated, undiscounted future cash flows is less than the carrying amount of the asset, then an impairment is recognized for the amount by which the carrying value of the asset exceeds its estimated fair value. Fair value is determined using the market, income or cost approaches as appropriate for the asset. Any write-downs are treated as permanent reductions in the carrying amount of the asset and recognized as an operating loss. There were no impairments of long-lived assets in the years ended June 30, 2020, 2019 and 2018.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of compensation and employee benefits of sales and marketing personnel and related sales support teams, marketing events, advertising costs, travel, trade shows and other marketing materials. The Company expenses all selling and marketing costs as incurred.

Research and Development Expenses

Research and development expenses represent costs incurred to develop the Company's products. Research and development expenses consist primarily of salaries and other personnel costs, clinical trial costs, regulatory costs and manufacturing costs for non-commercial products. The Company expenses all research and development costs in the periods in which they are incurred.

Stock-Based Compensation

The Company records compensation expense for stock options based on the fair market value of the awards on the date of grant. The fair value of stock-based compensation awards is amortized over the vesting period of the award. Compensation expense for performance-based awards is measured based on the number of shares ultimately expected to vest, estimated at each reporting date based on management's expectations regarding the relevant performance criteria.

For certain awards, the Company estimates the fair value of share options and other equity-based compensation using a Binomial option pricing model on the date of grant. The Binomial model requires multiple subjective inputs, which are discussed further in Note 13 — Share-Based Payment Plans.

Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, assuming potentially dilutive ordinary shares from option exercises, employee share awards, and other dilutive instruments that have been issued. For periods where the Company has presented a net loss, potentially dilutive securities are excluded from the computation of diluted net loss per share as they would be anti-dilutive. The loss per share incorporates the impact of the reverse stock split that was effectuated in conjunction with the redomicilation. In accordance with ASC 260, the impact of the reverse stock split was retrospectively applied for all periods presented.

Segment Reporting

Operating segments are defined as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer. To date, the Company has viewed its operations and manages its business as one segment.

3. Accounting Standards Update

Recently Adopted

Effective July 1, 2018, the Company adopted ASU 2014-09 *Revenue from Contracts with Customers*, and all related amendments (collectively codified as ASC 606) utilizing the modified retrospective method. The adoption of ASC 606 did not have a significant impact on the recognition of revenues and therefore the Company did not recognize an opening retained earnings adjustment. See Note 12 – Revenue and Note 9 – Reporting Segment and Geographic Information.

Effective July 1, 2019, the Company adopted ASU 2016-02, *Leases* ("**ASC 842**"*)*, which requires lessees to recognize operating leases on the balance sheet as a right-of-use asset and lease liability. The Company recognized and measured the right-of-use asset and lease liability from operating leases on the consolidated balance sheet using the current-period adjustment method without revising comparative period information. Upon the adoption on July 1, 2019, the impact on total assets and total liabilities was an increase of $2.8 million and $2.9 million, respectively. See Note 4—Leases for further information.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows* ("**ASC 230**"*)*: *Restricted Cash*. The amendments in this update require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. As a result, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown in the statements of cash flows. The amendments do not provide a definition of restricted cash or restricted cash equivalents. The Company adopted this standard effective July 1, 2018. The adoption of this ASU resulted in the inclusion of $201,000, $200,000 and $0 of restricted cash in the cash and cash equivalents totals in the Company's statements of cash flows for the years ended June 30, 2020, 2019 and 2018, respectively.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation* ("**ASC 718**"*) Improvements to Employee Share-Based Payment Accounting*, ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016. Under the new ASU 2016-09 guidance, companies can continue to estimate forfeitures, or they can elect to account for forfeitures as they occur by reversing compensation cost when the award is forfeited. The Company adopted this ASU as of July 1, 2018 and will record the impact of forfeitures as they occur.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments Credit Losses* ("**ASC 326**"*) Measurement of Credit Losses on Financial Instruments*. For public business entities that meet the definition of an U.S. Securities and Exchange (SEC) filer, the amendments in this update are effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. This guidance requires a financial asset (or a group of financial assets) that is measured at amortized cost basis to be presented at the net amount expected to be collected. The financial assets of the Company in scope of ASU 2016-13 were primarily accounts receivable. Effective July 1, 2018, the Company early adopted and applied this guidance to its methodology for estimating the accounts receivable allowance for doubtful accounts. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements. The Company estimates an allowance for expected credit losses on accounts receivable that result from the inability of customers to make required payments. These estimates are based on a combination of historical loss statistics, current business conditions and macro-economic trends. In estimating the allowance for expected credit losses, consideration is given to the current aging of receivables and a specific review for potential bad debts. The resulting bad debt expense is included in sales and marketing expense in the consolidated statements of operations. Receivables are written-off when deemed uncollectible. The Company evaluates the adequacy of its allowance for credit losses on accounts receivable on a regular basis. The accounts receivable allowance was $18,000 and $18,000 at June 30, 2020 and 2019, respectively.

Recent Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB Issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that Is a Service Contract* (a consensus of the FASB Emerging Issues Task Force). Effective for public business entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The amendments in this update should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The guidance will be adopted for the fiscal year beginning on July 1, 2020. The Company is currently evaluating the potential impact that the adoption of ASU 2018-15 will have on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, or ASU 2019-12, which includes amendments to simplify the accounting for income taxes by removing certain exceptions to the general principles in ASC 740, *Income Taxes*, or ASC 740. The amendments also improve consistent application of and simplify U.S. GAAP for other areas of ASC 740 by clarifying and amending existing guidance. The new guidance is effective for the Company for annual periods beginning after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. Early adoption of the amendments is permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2019-12 will have on its consolidated financial statements.

4. Leases

On July 1, 2019, the Company adopted Accounting Standards Codification No. 842, *Leases*, ("**ASC 842**"), which requires lessees to recognize operating leases on the balance sheet as a right-of-use asset and lease liability. ASC 842 provides an optional transition method that allows entities to apply the standard prospectively, versus recasting the prior periods presented. The Company adopted the standard effective July 1, 2019, using the current period adjustment method and did not adjust prior periods.

The Company elected the practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs for our leases which existed and expired prior to the adoption date. For existing or expired contracts as of the adoption date, the conclusions made for these items under previous accounting standards (ASC 840) were retained at transition as allowed by the guidance.

The Company has also made accounting policy elections, including a short-term lease exception policy, permitting the Company to not apply the recognition requirements of this standard to short-term leases (i.e. leases with expected terms of 12 months or less), and an accounting policy to account for lease and certain non-lease components as a single component for certain classes of assets. The portfolio approach, which allows a lessee to account for its leases at a portfolio level, was elected for certain equipment leases in which the difference in accounting for each asset separately would not have been materially different from accounting for the assets as a combined unit.

At contract inception, the Company determines whether the contract is a lease or contains a lease. A contract contains a lease if the Company is both able to identify an asset and can conclude it has the right to control the identified asset for a period of time. Leases with an initial term of twelve months or less are not recorded on the condensed consolidated balance sheet.

The Company has operating leases for corporate office space, manufacturing and warehouse facility. The Company has finance leases for equipment and furniture. The Company's leases have remaining lease terms of less than one year to five years, some of which include options to renew the lease. On July 1, 2019, the Company recorded operating lease right-of-use ("ROU") assets of $2.8 million and operating lease liabilities of $2.9 million. The difference between the ROU assets and lease liabilities is due to deferred rent resulting from historical straight-line recognition of operating leases that were reclassified as a component of the ROU asset. Finance leases as of July 1, 2019 were approximately $53,000 and are not considered material to the consolidated financial statements. As of June 30, 2020, approximately $11,000 in finance leases was included Other current liabilities.

ROU assets represent the Company's right to control an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company used its incremental borrowing rate ("**IBR**") based on the information available at commencement date in determining the discount rate used to present value lease payments. The Company used the IBR on July 1, 2019 for its operating leases that commenced on or prior to that date. In determining the IBR, the Company considered its credit rating and

current market interest rates. The IBR used approximates the interest that the Company would be required to pay for a collateralized loan over a similar term. Additionally, the Company used the portfolio approach when applying the discount rate selected based on the dollar amount and term of the obligation. Certain leases for equipment and furniture contain bargain purchase options and are classified as finance leases. The Company's leases typically do not include any residual value guarantees or asset retirement obligations.

The Company's lease terms are only for periods in which it has enforceable rights. A lease is no longer enforceable when both the lessee and the lessor each have the right to terminate the lease without permission from the other party with no more than an insignificant penalty. The Company has options to renew some of these leases for three years after their expiration. The Company considers these options, which may be elected at the Company's sole discretion, in determining the lease term on a lease-by-lease basis.

The Company's agreements may contain variable lease payments. The Company includes variable lease payments that depend on an index or a rate and excludes those which depend on facts or circumstances occurring after the commencement date, other than the passage of time. Additionally, for certain equipment leases, the Company applies a portfolio approach to effectively account for the finance lease ROU assets and finance lease liabilities.

Some leases require variable payments for common area maintenance, property taxes, parking, insurance, and other variable costs. The variable portion of lease payments is not included in operating lease ROU assets or operating lease liabilities. Variable lease costs are expensed when incurred.

The following table sets forth the Company's operating lease expense which are included in general and administrative expenses in the consolidated statements of operations (in thousands):

	Year Ended June 30,
	2020
Operating lease cost	$ 701
Variable lease cost	47
Total lease cost	$ 748

Supplemental cash flow information related to operating leases for the year ended June 30, 2020 was as follows (in thousands):

	Year Ended June 30,
	2020
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash outflows due to operating leases	$ 675
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	—

Supplemental balance sheet information, as of June 30, 2020, related to operating leases was as follows (in thousands):

	June 30, 2020
Reported as:	
Operating lease right-of-use assets	$ 2,347
Total right-of-use assets	2,347
Other current liabilities:	
Operating lease liability, short-term	533
Operating lease liabiltiies, long term	1,917
Total operating lease liabilities	$ 2,450
Operating lease weighted average remaining lease term (years)	3.91
Operating lease weighted average discount rate	7.50%

As of June 30, 2020, maturities of the Company's operating lease liabilities are as follows (in thousands):

Years Ending June 30,	Operating Leases
2021	$ 695
2022	717
2023	740
2024	588
2025	87
Total lease payments	$ 2,827
Less imputed interest	377
Total operating lease liabilities	$ 2,450

At June 30, 2020, there were no leases entered into that had not yet commenced.

Under legacy lease accounting ("**ASC 840**"), future minimum lease payments under non-cancellable leases for the year ended June 30, 2020 was as follows (in thousands):

Years Ending June 30,	Operating Leases
2021	$ 530
2022	77
Total operating lease liabilities	$ 607

5. Inventory

The composition of inventories is as follows (in thousands):

	Year Ended June 30,	
	2020	2019
Raw materials and components	$ 947	$ 638
Finished goods	178	104
Total inventory	$ 1,125	$ 742

The Company has reduced the carrying value of its inventories to reflect the lower of cost or market value. Charges for estimated excess and obsolescence are recorded in cost of sales in the consolidated statement of operations. Inventory impairments recognized in cost of sales are a result of expired product and were $306,000, $36,000, and $0 for the years ended June 30, 2020, 2019 and 2018, respectively.

6. Intangible Assets

The composition of intangible assets is as follows (in thousands):

		As of June 30, 2020			As of June 30, 2019		
	Weighted Average Life	Gross Amount	Accumulated Amortization	Net Carry Amount	Gross Amount	Accumulated Amortization	Net Carry Amount
Patent 1	3	$ 235	$ (101)	$ 134	$ 151	$ —	$ 151
Patent 2	14	74	(9)	65	22	—	22
Patent 3	15	125	(9)	116	52	—	52
Patent 5	20	26	—	26	—	—	—
Trademarks	Indefinite	23	—	23	—	—	—
Total intangible assets		$ 483	$(119)	$ 364	$ 225	$ —	$ 225

During the years ended June 30, 2020 and 2019, the Company did not identify any events or changes in circumstances that indicated the carrying value of its intangibles may not be recoverable. As such, there was no impairment of intangibles assets recognized for the years ended June 30, 2020, 2019 and 2018. Amortization expense of intangibles included in the consolidated statements of operations was $119,000, $0 and $0 for the years ended June 30, 2020, 2019 and 2018, respectively.

The Company expects the future amortization of amortizable intangible assets held at June 30, 2020 to be (in thousands):

	Estimated Amortization Expense
2021	$ 100
2022	70
2023	16
2024	15
2025	15
2026 and thereafter	125
Total	**$ 341**

7. Property, Plant and Equipment

The composition of property, plant and equipment, net is as follows (in thousands):

	Useful Lives	Year Ended June 30, 2020	2019
Computer equipment	3-5 years	$ 802	$ 462
Computer software	3 years	369	219
Construction in progress		138	470
Furniture and fixtures	7 years	425	399
Laboratory equipment	5 years	194	143
Leasehold improvements	Lesser of life or lease term	216	155
RECELL moulds	5 years	100	128
Less: accumulated amortization and depreciation		(881)	(667)
Total property, plant and equipment, net		$ 1,363	$ 1,309

Depreciation expense related to plant and equipment was $346,000, $269,000 and $110,000 for the years ended June 30, 2020, 2019 and 2018, respectively.

8. Prepaids and Other Current Assets

Prepaids and Other current assets consisted of the following (in thousands):

	Year Ended June 30, 2020	2019
Prepaid expenses	$ 792	$ 933
Lease deposits	123	40
Other receivables	75	125
Total prepaids and other current assets	$ 990	$ 1,098

Prepaid expenses primarily consist of prepaid benefits and insurance.

9. Reporting Segment and Geographic Information

The Company views its operations and manages its business in one reporting segment. Long-lived assets were primarily located in the United States as of June 30, 2020 and 2019 with an insignificant amount located in Australia and the United Kingdom. Revenue by region for the years ended June 30, 2020, 2019 and 2018 were as follows (in thousands):

	Year Ended June 30, 2020	2019	2018
Revenue:			
United States	$ 13,800	$ 4,404	$ —
Foreign:			
Australia	292	806	550
United Kingdom	171	264	379
Total	$ 14,263	$ 5,474	$ 929

10. Contingencies

The Company is subject to certain contingencies arising in the ordinary course of business. The Company records accruals for these contingencies to the extent that a loss is both probable and reasonably estimable. If some amount within a range of loss appears to be a better estimate than any other amount within the range, that amount is accrued. Alternatively, when no amount within a range of loss appears to be a better estimate than any other amount, the lowest amount in the range is accrued. The Company expenses legal costs associated with loss contingencies as incurred. As of June 30, 2020, the Company does not have any outstanding or threatened litigation that would have a material impact to the financial statements.

11. Common and Preferred Stock

On June 29, 2020, a statutory scheme of arrangement under Australian law to effect a redomiciliation of the AVITA Group from Australia to the United States of America was implemented ("the Scheme"). The Scheme was approved by shareholders on June 15, 2020 and approved by the Federal Court of Australia on June 22, 2020.

Pursuant to the Scheme, all ordinary shares in AVITA Medical, the former parent company of the AVITA Group, were exchanged for shares of common stock in AVITA Therapeutics. As a result, AVITA Therapeutics became the sole shareholder of AVITA Medical and the new parent company of the AVITA Group. In conjunction with the Scheme, an implicit reverse split on a 1 for 100 basis was implemented whereby shareholders of AVITA Medical received one share of common stock in AVITA Therapeutics for every 100 shares held in AVITA Medical.

Under the Scheme, eligible shareholders in AVITA Medical Limited received consideration in the form of:

- five **CDIs** in the Company for every 100 ordinary shares in AVITA Medical that were held by them; or
- one share of common stock in the Company for every 5 ADS**s** in AVITA Medical that were held by them.

The Company's CDIs are quoted on the ASX under AVITA Medical's existing ASX ticker code, "AVH". The Company's shares of common stock are quoted on NASDAQ under AVITA Medical's existing NASDAQ ticker code, "RCEL". One share of common stock on NASDAQ is equivalent to five CDIs on the ASX.

As a result of the 'implicit consolidation' that occurred under the Scheme, the number of shares of common stock on issue in the Company (as set out in the consolidated financial statements) is less than the number of ordinary shares in AVITA Medical that was previously set out in the consolidated financial statements of AVITA Medical. All common share amounts included in these financial statements have been retroactively reduced by a factor of one hundred and all per share amounts have been increased by a factor or one hundred, with the exception of the Company's common stock par value.

The Company is authorized to issue 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share, issuable in one or more series as designated by the Company's board of directors. No other class of capital stock is authorized. As of June 30, 2020, and 2019, 21,467,912 and 18,712,996 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

During the year ended June 30, 2020, the AVITA Group raised additional capital via a private placement in the amount of $81.7 million (through our former parent company, AVITA Medical). The Company sold 2,033,898 ordinary shares at an issue price of $40.17 per share for total net proceeds of $76.6 million, after deducting commission and offering expenses. An aggregate 15,853 ordinary shares were issued to the directors of the Company in lieu of director fees during the year ended June 30, 2020 under the Director Share Plan that was approved in December 2017.

During the year ended June 30, 2019, the AVITA Group completed a series of equity transactions (through our former parent company, AVITA Medical). The second tranche of the June 2018 Placement (defined below) closed on July 27, 2018, raising an aggregate of $2.4 million through the issuance of the equivalent of 650,000 shares at $3.70 per share. During December 2018, AVITA Medical entered into a placement agreement to raise $28.8 million over two tranches. AVITA Medical completed the first tranche on December 10, 2018 and issued the equivalent of 3,100,471 shares at a price of $5.76 per share raising gross proceeds of $17.9 million. The settlement of the second tranche for $10.9 million was approved by the shareholders at an extraordinary meeting held during January 2019. The second tranche closed on January 18, 2019 and raised gross proceeds of $10.9 million through the sale of the equivalent of 1,899,530 shares at the same price as the first tranche, being $5.76 per share. In addition, on January 10, 2019, AVITA Medical completed a Share Purchase Plan under which AVITA Medical offered to existing eligible shareholders the opportunity to purchase shares at a purchase price equivalent to $5.74 per share. As part of the Share Purchase Plan AVITA Medical received gross proceeds of $1.3 million for the issuance of the equivalent of 220,612 shares.

During the year ended June 30, 2018, the AVITA Group completed a series of equity transactions (through its former parent company, AVITA Medical). During October 2017, AVITA Medical announced that it was undertaking a capital raising in aggregate to raise $13.2 million. The capital raise was split over two tranches; the first being a private placement and the second a rights offering to existing shareholders. On October 17, 2017, AVITA Medical completed the private placement of the equivalent of 1,009,830 shares at a price of $3.53 per share raising gross proceeds of $3.6 million. On November 2, 2017, AVITA Medical completed the rights offering resulting in a total issue of the equivalent of 2,765,029 shares to raise a gross total of $9.6 million. During June 2018, AVITA Medical announced an institutional placement to raise an aggregate of $12.1 million over two tranches ("**June 2018 Placement**"). The first tranche closed on June 13, 2018 and raised an aggregate of $9.7 million by issuing the equivalent of 2,554,756 shares at a price of $3.79 per share. The second tranche for an aggregate of $2.4 million (referenced above) was issued on July 27, 2018.

During December 2017, the board of directors approved the 2016 Director Share Plan which previously allowed directors to convert their compensation into ordinary shares. A total of the equivalent of 6,970 shares were issued under the Director Share Plan. Future issuances are no longer authorized under the Director Share Plan.

12. Revenue

The Company adopted ASC Topic 606 – *Revenue from Contracts with Customers*, on July 1, 2018. Under Topic 606, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services.

To determine revenue recognition for arrangements that are within the scope of Topic 606, the Company performs the following five steps:

1. Identify the contract with a customer
2. Identify the performance obligations
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations
5. Recognize revenue when/as performance obligation(s) are satisfied

In order for an arrangement to be considered a contract, it must be probable that the Company will collect the consideration to which it is entitled for goods or services to be transferred. Once the contract is determined to

be within the scope of ASC 606, the Company assesses the goods or services promised with each contract, determines whether those are performance obligations and the related transaction price. The Company then recognizes the sale of goods based on the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

Revenues

The Company's revenue consists of sale of the RECELL System to hospitals or other treatment centers ("**customers**"), predominately in the United States.

Performance Obligations

The Company's contracts typically have a single performance obligation to deliver the product to the customer. The transaction price is stated within the contract and is therefore fixed consideration. The transaction price does not include the sales tax that are imposed by governmental authority.

We identified the hospital or treatment center as the customer in Step 1 of the model above and have determined a contract exists with those customers in Step 1. As these contracts typically have a single performance obligation (i.e. product delivery), no allocation of the transaction price is required in Step 4 of the model. Control product is transferred to the customer at a point in time. Specifically, we determined the customer obtains control of the product at point in time at which the goods are either shipped or delivered to our customers' facilities, depending on the terms of the contract.

Variable Consideration

Revenue from the sale of goods is recognized net of volume discounts. The Company uses the expected value method when estimating variable consideration. Revenue is only recognized to the extent that it is probable that a significant reversal will not occur.

The Company evaluates its contracts with customers for forms of variable consideration, which may require an adjustment to the transaction price based on their estimated impact. Revenues from product sales are recorded at the sales price, net of volume discounts.

Volume Discounts — The Company generally provides contracted customers with volume discounts that are explicitly stated in the Company's customer contracts. The RECELL system is sold with respective volume discounts based on aggregated sales over a 12-month period on a customer-by-customer basis. Revenue from these sales is recognized based on the price specified in the contract, net of estimated volume discounts, and net of any sales tax charged. Goods sold are not eligible for return. The Company has determined such discounts are not distinct from the Company's sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue and as a reduction to accounts receivable, net.

Contract Assets and Contract Liabilities

The Company receives payments from customers based on contractual terms. Trade receivables are recorded when the right to consideration becomes unconditional. The Company satisfies its performance obligation on product sales when the products are shipped or delivered, depending on the terms of the sale. Payment terms on invoiced amounts are typically 30-90 days, and do not include a financing component.

Contract assets include amounts related to the Company's contractual right to consideration for both completed and partially completed performance for which the Company does not have the right to payment. As of the period ended June 30, 2020 and 2019, the Company does not have any contract assets.

Contract liabilities are recorded when the Company receives payment prior to satisfying its obligation to transfer goods to a customer. The Company had $435,000 and $429,000 of contract liabilities as of June 30, 2020 and 2019, respectively. For the years ended June 30, 2020 and 2019, revenue recognized from amounts included in the beginning balance of contract liabilities was not significant.

Cost to Obtain and Fulfill a Contract

Contract fulfillment costs include commissions and shipping expenses. The Company has opted to immediately expense the incremental cost of obtaining a contract when the underlying related asset would have been amortized over one year or less. The Company generally does not incur costs to obtain new contracts.

Remaining Performance Obligations

Since the Company's adoption of ASC 606 on July 1, 2018, revenues from remaining performance obligations are now calculated as the dollar value of the remaining performance obligations on executed contracts. The estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) pursuant to the Company's existing customer agreements is $435,000 and $429,000 as of June 30, 2020 and 2019, respectively. The Company expects to recognize these amounts upon receiving Japanese Pharmaceuticals and Medical Device Act approval of the RECELL System in Japan.

13. Share-Based Payment Plans

Overview of Employee Share-Based Compensation Plans

In November 2014, our former parent company, AVITA Medical, adopted the Employee Share Plan and the Incentive Option Plan (collectively, the "**2016 Plans**"). The Employee Share Plan was amended at the 2018 Annual General Meeting. The 2016 Plans previously authorized the issuance of stock options or other share-based instruments representing up to 7.5% of outstanding capital. Any increase in the maximum number of shares issuable under the 2016 Plans was subject to shareholder approval or to an increase in the total number of ordinary shares outstanding. The maximum shares allowed to be issued was 1,610,093, 1,403,475 and 958,034 as of June 30, 2020, 2019 and 2018 respectively. Upon redomiciliation of the AVITA Group to the United States, the 2016 Plans were terminated with respect to future grants and accordingly, there are no more shares available to be issued under the 2016 Plans. In addition, upon redomiciliation, the Company had an implicit 100-1 reverse stock split and all share information presented below has been presented on a reverse split stock basis. At the 2020 annual meeting of stockholders that will be held in late September or early October, the Company intends to seek shareholder approval for a new employee stock option plan.

The 2016 Plans were governed by the Compensation Committee. Subject to Board approval where required by applicable law, the Compensation Committee previously had 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 Compensation Committee pursuant to the provisions of the 2016 Plans were final, conclusive and binding on all persons.

The number of awards issued, the exercise price and the vesting schedule under the 2016 Plans were determined by the Compensation Committee, in accordance with the provisions of the 2016 Plans. Options granted under the 2016 Plans have an exercise price equal to the share price at the date of grant, or such other exercise price that the Compensation Committee determines to be appropriate under the circumstances. The contractual term of awards granted under the 2016 Plans is ten years from the date of its grant. Unless otherwise specified, the vesting period of awards under the 2016 Plan was: (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) subject to other performance criteria and hurdles, as determined by the Compensation Committee.

The following table summarizes information about the Company's stock-based award plans as of June 30, 2020:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance
2016 Plan	1,260,524	0	0
RSU Awards	0	339,359	0

Share-Based Payment Expenses

Share-based payment transactions are recognized as compensation cost based on the fair value of the instrument on the date of grant. The Company uses the Binomial option valuation model to estimate the grant date fair value of employee stock options.

During the years ended June 30, 2020, 2019 and 2018, the Company recorded stock-based compensation expense of $16.5 million, $1.9 million, and $1.4 million. No income tax benefit was recognized in the consolidated statement of comprehensive loss for share-based payment arrangements for June 30, 2020, 2019 and 2018.

A summary of stock option activity under the employees share option plan arrangement as of June 30, 2020 and changes during the year then ended is presented below:

	Service Only Stock Options	Performance Based Stock Options	Total Stock Options	Service Only Stock Options	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at June 30, 2019	817,077	319,717	1,136,794	$ 8.83	8.02	$24,679,478
Granted	192,133	67,500	259,633	38.16		
Exercised	(70,282)	(29,700)	(99,982)	6.37		
Expired	(9,270)	—	(9,270)	29.45		
Forfeited	(25,305)	(1,346)	(26,651)	18.14		
Outstanding at June 30, 2020	904,353	356,171	1,260,524	14.72	8.42	22,185,034
Exercisable at June 30, 2020	279,776	221,923	501,699	$10.25	8.10	$10,520,968

The weighted-average grant-date fair value of options granted during the years 2020, 2019, and 2018 was $26.56, $6.67, and $5.11, respectively. The total intrinsic value of options exercised during the years ended June 30, 2020, 2019 and 2018 was $3.1 million, $1.7 million, and $0, respectively. Intrinsic value is measured using the fair market value at the date of exercise for options exercised, or at June 30 for outstanding options, less the applicable exercise price.

Cash received from the exercise of options was approximately $474,000 and $252,000 and $0 for the year ended June 30, 2020, 2019 and 2018, respectively.

As of June 30, 2020, there was approximately $5.8 million of total unrecognized compensation cost related to stock options to be recognized over a weighted average period of 1.41 years.

Option Pricing Model

The fair value of each stock option is estimated on the date of grant using the Binomial valuation model. Expected volatilities are based on historical volatility of the Company's shares over multiple trading periods, to estimate the future volatility of the Company's shares over the contractual term of 10 years. The expected term of

options granted is derived from the output of the option valuation model and represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the contractual life of the option is based on the Reserve Bank of Australia's government bonds, not the U.S. Treasury yield curve in effect at the time of grant. As the Company has never declared dividends, no dividend yield is used in the calculation. Actual value realized, if any, is dependent on the future performance of the Company's shares and overall stock market conditions. There is no assurance the value realized by an optionee will be at or near the value estimated by the Binomial model.

Included in the following table is a summary of the grant-date fair value of stock options granted and the related assumptions used in the Binomial models for stock options granted in fiscal 2020, 2019, and 2018.

	Year Ended June 30,		
	2020	2019	2018
Expected volatility	75% - 90%	90%	90%
Weighted-average volatility	88%	90%	90%
Expected dividends	0%	0%	0%
Expected term (in years)	10.0	10.0	1.5 - 10.0
Risk-free interest rate	0.68% - 2.65%	1.50% - 2.65%	1.50%

Restricted Stock Units

Restricted stock units (RSUs) are granted to executives as part of their long-term incentive compensation. RSU awards are approved by the Compensation Committee as determined necessary. The RSU awards have a contractual term of 10 years and vest in accordance with the tenure or performance conditions as determined by the Compensation Committee. The grant date fair value is determined based on the price of the Company stock on the ASX on the date of grant. RSUs primarily consist of awards to the CEO and other executives. The terms of the awards are described below:

CEO RSUs

On November 30, 2017, 500,000 RSUs were issued to the CEO with the following vesting terms:

a) Tenure – 166,667 shares with a vesting period of three-years commencing on June 1, 2017.

b) Company Share Price – 166,667 shares 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 – 166,666 shares to vest in two equal tranches upon satisfaction of the following milestones:

    1. FDA PMA approval of RECELL for burns

    2. Initial BARDA procurement under CLIN 2 of the BARDA Grant

On November 2019, 395,542 RSUs were issued to the CEO with the following vesting terms:

a) Tenure – 142,520 shares with a vesting period of three-years commencing on June 1, 2020.

b) Milestone performance – 253,033 RSUs will vest upon satisfaction of the following milestones:

    a. First patient visit for treatment in an FDA approved U.S. soft tissue and trauma trial by the Company prior to March 3, 2020.

    b. First patient visit for treatment in an FDA approved U.S pediatric trial by the Company prior to June 30, 2020,

c. First patient visit for treatment in an FDA approved U.S pilot vitiligo trial by the Company prior to September 30, 2020.

d. FDA application submission for approval of the next generation RECELL device prior to June 30, 2021.

e. FDA approval of the next generation RECELL device prior to June 30, 2022.

Other Executive Grants

During November 2019, 49,000 RSUs were to executives.

A summary of the status of the Company's unvested shares as of June 30, 2020, and changes during the year ended June 30, 2020, is presented below:

Unvested Shares	Service Condition RSU	Performance Condition RSU	Total RSUs	Weighted Average Grant Date Fair Value per Unit
Unvested RSUs outstanding at June 30, 2019	166,667	333,333	500,000	$ 4.48
Granted	146,521	298,022	444,543	39.12
Vested	(218,175)	(387,009)	(605,184)	15.22
Forfeited	—	—	—	—
Unvested RSUs outstanding at June 30, 2020	95,013	244,346	339,359	$30.70

The weighted-average grant-date fair value of the RSUs granted during 2020, 2019 and 2018 was $39.12, $0 and $4.48 per unit, respectively. The total fair value of shares vested during the years ended June 30, 2020, 2019 and 2018 was $9.2 million, $0, and $0, respectively.

As of June 30, 2020, there was $6.6 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the RSU award agreements. This amount includes $1.9 million for performance share awards that have been determined to be not probable. The associated expense will be recognized once the performance conditions has been determined to be probable. The remaining unrecognized expense of $4.7 million is expected to be recognized over a weighted average period of 0.69 years.

14. Income Taxes

Geographic sources of income (loss) from continuing operations before income taxes are as follows:

(amounts in thousands)	Year Ended June 30, 2020	Year Ended June 30, 2019	Year Ended June 30, 2018
United States	$(20,793)	$(19,899)	$ (5,382)
Foreign	(21,233)	(5,324)	(8,427)
Income (loss) from continuing operations before income taxes	$(42,026)	$(25,223)	$(13,809)

The income tax benefit (expense) as shown in the accompanying consolidated statements of operations includes the following:

(amounts in thousands)	Year Ended June 30, 2020	Year Ended June 30, 2019	Year Ended June 30, 2018
Current:			
Federal	$—	$ —	$ —
State	4	—	—
Foreign	—	(121)	(1,074)
	4	(121)	(1,074)
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
	—	—	—
Total Income Tax Expense (Benefit)	$ 4	$(121)	$(1,074)

The provision for income taxes differs from the tax computed using the statutory United States federal income tax rate of 21%, 21% and 28% for June 30, 2020, 2019 and 2018 as a result of the following items:

(amounts in thousands)	Year Ended June 30, 2020	Year Ended June 30, 2019	Year Ended June 30, 2018
Tax expense (benefit) at U.S. statutory rate	$ (8,827)	$(5,297)	$(3,805)
State income taxes	4	—	—
Foreign rate differential	(1,389)	(299)	120
Tax Credits	—	(121)	(1,074)
Share-based compensation	(3,794)	535	391
Permanent differences	669	84	796
Change in tax rate	—	—	2,824
Net change in valuation allowance	13,341	4,977	(326)
Income tax expense (benefit)	$ 4	$ (121)	$(1,074)

A summary of deferred *income tax assets is as follows (in thousands):*

	Year Ended June 30, 2020	Year Ended June 30, 2019
Deferred tax liabilities		
ROU Asset	$ (608)	$ —
Total deferred tax liabilities	$ (608)	$ —
Deferred tax assets		
Property, plant and equipment	$ 17	$ 7
Accrued expenses	564	15
Intangible assets	255	563
Stock based compensation	2,996	—
Lease liability	634	—
Net operating loss carryforward	37,756	25,358
Other	285	1
Total deferred tax assets	$ 42,507	$ 25,944
Less valuation allowance	(41,899)	(25,944)
Net deferred tax assets	$ 608	$ —
Net deferred tax assets / (liabilities)	$ —	$ —

At June 30, 2020, the Company and its subsidiaries had net operating loss carryforwards for federal, state, United Kingdom, and Australia income tax purposes of $88.5 million, $57.5 million, $29.8 million, and $34.1 million respectively. The net operating loss carryforwards may be subject to limitation regarding their utilization against taxable income in future periods due to "change of ownership" provisions of the Internal Revenue Code and similar state and foreign provisions. Of these carryforwards, $21.7 million will expire, if not utilized, in various years through 2038. The remaining carryforwards have no expiration.

In assessing the recoverability of its deferred tax assets, the Company considers whether it is more likely than not that its deferred assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income in those periods in which temporary differences become deductible and/or net operating losses can be utilized. The Company considers all positive and negative evidence when determining the amount of the net deferred tax assets that are more likely than not to be realized. This evidence includes, but is not limited to, historical earnings, scheduled reversal of taxable temporary differences, tax planning strategies and projected future taxable income. Based upon the weight of available evidence including the uncertainty regarding the Company's ability to utilize certain net operating losses and tax credits in the future, the Company has established a valuation allowance against its net deferred tax assets of $41.9 million and $25.9 million as of June 30, 2020 and 2019, respectively. The deferred tax assets are primarily net operating loss carryforwards for which management has determined it is more likely than not that the deferred tax assets will not be realized.

The Company recognizes the tax benefit from an uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements related to a particular tax position are measured based on the largest benefit that has a greater than a 50% likelihood of being realized upon settlement. The amount of unrecognized tax benefits is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by the taxing authorities, new information obtained during a tax examination, or resolution of an examination.

The Company has not identified any uncertain tax positions as of June 30, 2020 or June 30, 2019.

The Company files income tax returns in the U.S. federal, California and certain other state and foreign jurisdictions. The Company remains subject to income tax examinations for its U.S. federal and state income taxes generally for fiscal years ended June 30, 2006 and forward. The Company also remains subject to income tax examinations for international income taxes for fiscal years ended June 30, 2016 through June 30, 2019, and for certain other U.S. state and local income taxes generally for the fiscal years ended June 30, 2016 through June 30, 2019.

The Tax Cuts and Jobs Act ("the Tax Act") was enacted on December 22, 2017 and reduced U.S. corporate income tax rates to 21% as of January 1, 2018. The rate change became effective during tax year June 30, 2018, resulting in a blended statutory tax rate of 28% and a decrease in the Company's deferred tax assets and the associated valuation allowance in tax year June 30, 2018.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("**CARES Act**") was enacted in the United States. The CARES Act provides numerous tax provisions and other stimulus measures, including temporary changes regarding the prior and future utilization of net operating losses and technical corrections from prior tax legislation for tax depreciation of certain qualified improvement property. The Company evaluated the provisions of the CARES Act and does not anticipate the associated impacts, if any, will have a material effect on our financial position.

15. Loss per Share

The following is a reconciliation of the basic and diluted loss per share computations:

	Year Ended June 30,		
	2020	2019	2018
	(in thousands)		
Net Loss	$ 42,030	$ 25,102	$ 12,735
Weighted-average common shares—outstanding, basic	20,291	16,065	9,327
Weighted-average common shares—outstanding, diluted	20,291	16,065	9,327
Net loss per common share, basic	$ 2.07	$ 1.56	$ 1.37
Net loss per common share, diluted	$ 2.07	$ 1.56	$ 1.37

The Company's basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the relevant period. For the purposes of the calculation of diluted net loss per share options to purchase common stock, restricted stock units and unvested shares of common stock issued upon the early exercise of stock options have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive. Because the Company has reported a net loss for the years ended June 30, 2020, 2019 and 2019, diluted net loss per common share is the same as the basic net loss per share for those years.

16. Retirement Plans

The Company offers a 401(k)-retirement savings plan (the "**401(k) Plan**") for its employees, including its executive officers, who satisfy certain eligibility requirements. The Internal Revenue Code of 1986, as amended, allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) Plan. The Company matches contributions to the 401(k) Plan based on the amount of salary deferral contributions the participant makes to the 401(k) Plan. The Company will match up to 6% of an employee's compensation that the employee contributes to his or her 401(k) Plan account. Total Company matching contributions to the 401(k) Plan were $713,000, $594,000 and $ 290,000 in the years ended June 30, 2020, 2019 and 2018, respectively.

17. Deed of Cross Guarantee

The Company (as the parent entity of the AVITA Group) is party to a deed of cross guarantee dated June 29, 2020 ("**Deed**") with each of its Australian wholly-owned subsidiaries, namely:

- AVITA Medical Ltd (ACN 058 466 523) ("**AVITA Medical**");
- C3 Operations Pty Ltd (ACN 090 161 505);
- Visiomed Group Pty Ltd (ACN 003 010 580); and
- Infamed Pty Limited (ACN 084 800 653),

(together, the "**Australian Subsidiaries**").

The Company and the Australian Subsidiaries were the only parties to the Deed at June 30, 2020 and comprise the "closed group" for the purposes of the Deed (and also the "extended closed group"). No parties have been added to or removed from the Deed, or are subject to a notice of disposal, since June 29, 2020. Since June 30, 2020, there has been no change in ownership in any of the Australian Subsidiaries.

By entering into the deed, the Company and the Australian Subsidiaries have guaranteed the debts of each other.

Relief under ASIC Corporations (Wholly-owned Companies) Instrument 2016/785

By entering into the Deed, the Australian Subsidiaries, except for Avita Medical, have been relieved from the requirement to prepare a financial report and directors' report for the financial year ended June 30, 2020 under *ASIC Corporations (Wholly-owned Companies) Instrument 2016/785*.

Relief under ASIC Instrument 20-0431

Avita Medical, being the former parent entity of the Avita Group, is unable to rely on the relief provided under *ASIC Corporations (Wholly-owned Companies) Instrument 2016/785* for the financial year ended June 30, 2020, because it was a disclosing entity for part of the relevant financial year. However, under subsection 340(1) of the *Corporations Act 2001* (Cth), the Australian Securities and Investments Commission ("**ASIC**") has granted separate relief to Avita Medical under ASIC Instrument 20-0431 ("**Instrument**"). Under the Instrument, ASIC has ordered that Avita Medical does not have to comply with a number of Australian reporting requirements including the requirement to prepare and file a stand-alone financial report in Australia.

In order to comply with the conditions to the relief provided in the Instrument, the Australian Subsidiaries (including Avita Medical) entered into the Deed with the Company on June 29, 2020.

Consolidated financial information of parties to the Deed

The financial statements below are additional disclosure items specifically required by ASIC and represent the consolidated financial statements of the entities that are party to the Deed only (being the 'closed group' and also the 'extended closed group' under the Deed).

(in thousands)	Year Ended June 30, 2020
Revenues	$ 292
Cost of sales	335
Gross profit	(43)
Operating Expenses:	
Sales and marketing expenses	488
General and administrative expenses	5,013
Research and development expenses	103
Share-based compensation	16,486
Total operating expenses	22,090
Operating loss	(22,133)
Interest expense	20
Other income	2
Loss before income taxes	(22,151)
Income tax benefit (expense)	—
Net loss	$ (22,151)

	June 30, 2020
ASSETS	
Cash	$ 403
Accounts receivable, net	17
R&D tax credits	—
Prepaids and other current assets	414
Inventory	23
Total current assets	857
Plant and equipment, net	1
Intangibles	364
Total assets	$ 1,222
LIABILITIES AND STOCKHOLDERS' EQUITY	
Accounts payable and accrued liabilities	$ 1,946
Accrued wages and fringe benefits	70
Other current liabilities	—
Total liabilities	$ 2,016
Contributed Equity	232,747
Reserves	31,345
Accumulated deficit	(264,886)
Total stockholders' equity (deficit)	(794)
Total liabilities and stockholders' equity (deficit)	$ 1,222

18. Quarterly Results (Unaudited)

(in thousands, except per share data)	Year Ended June 30,			
	September 30, 2019	December 31, 2019	March 31, 2020	June 30, 2020
Revenues	$ 3,250	$ 3,259	$ 3,877	$ 3,877
Cost of sales	619	846	634	874
Gross profit	2,631	2,413	3,243	3,003
BARDA income	2,051	386	1,008	481
Operating Expenses:				
Sales and marketing expenses	2,962	3,738	4,162	3,951
General and administrative expenses	3,071	4,558	4,145	6,361
Research and development expenses	1,635	2,192	2,302	2,332
Share-based compensation	672	2,903	9,048	3,863
Total operating expenses	8,340	13,391	19,657	16,507
Operating loss	(3,658)	(10,592)	(15,406)	(13,023)
Interest expense	11	9	5	8
Other income/(expense)	103	99	363	121
Loss before income taxes	(3,566)	(10,502)	(15,048)	(12,910)
Income tax benefit (expense)	—	—	—	(4)
Net loss	$ (3,566)	$ (10,502)	$ (15,048)	$ (12,914)
Net loss per common share:				
Basic	$ (0.19)	$ (0.53)	$ (0.71)	$ (0.60)
Diluted	$ (0.19)	$ (0.53)	$ (0.71)	$ (0.60)
Weighted-average common shares:				
Basic	18,719,857	19,877,676	21,215,246	21,372,892
Diluted	18,719,857	19,877,676	21,215,246	21,372,892

(in thousands, except per share data)	Year Ended June 30,			
	September 30, 2018	December 31, 2018	March 31, 2019	June 30, 2019
Revenues	$ 269	$ 1,040	$ 1,710	$ 2,455
Cost of sales	232	242	292	505
Gross profit	37	798	1,418	1,950
BARDA income	1,862	1,753	1,238	1,068
Operating Expenses:				
Sales and marketing expenses	2,163	2,840	3,309	3,941
General and administrative expenses	2,605	3,399	3,650	3,927
Research and development expenses	1,972	2,019	1,809	2,072
Share-based compensation	217	593	567	569
Total operating expenses	6,957	8,851	9,335	10,509
Operating loss	(5,058)	(6,300)	(6,679)	(7,491)
Interest expense	6	5	5	11
Other income/(expense)	37	$ 39	$ 502	$ (246)
Loss before income taxes	(5,027)	(6,266)	(6,182)	(7,748)
Income tax benefit (expense)	(7)	—	—	128
Net loss	$ (5,034)	$ (6,266)	$ (6,182)	$ (7,620)
Net loss per common share:				
Basic	$ (0.38)	$ (0.44)	$ (0.34)	$ (0.41)
Diluted	$ (0.38)	$ (0.44)	$ (0.34)	$ (0.41)
Weighted-average common shares:				
Basic	13,240,087	14,165,200	18,263,535	18,665,604
Diluted	13,240,087	14,165,200	18,263,535	18,665,604

19. Subsequent Events

The Company has considered all events occurring subsequent to June 30, 2020 and has concluded that all significant events have been disclosed in the financial statements and accompanying notes.

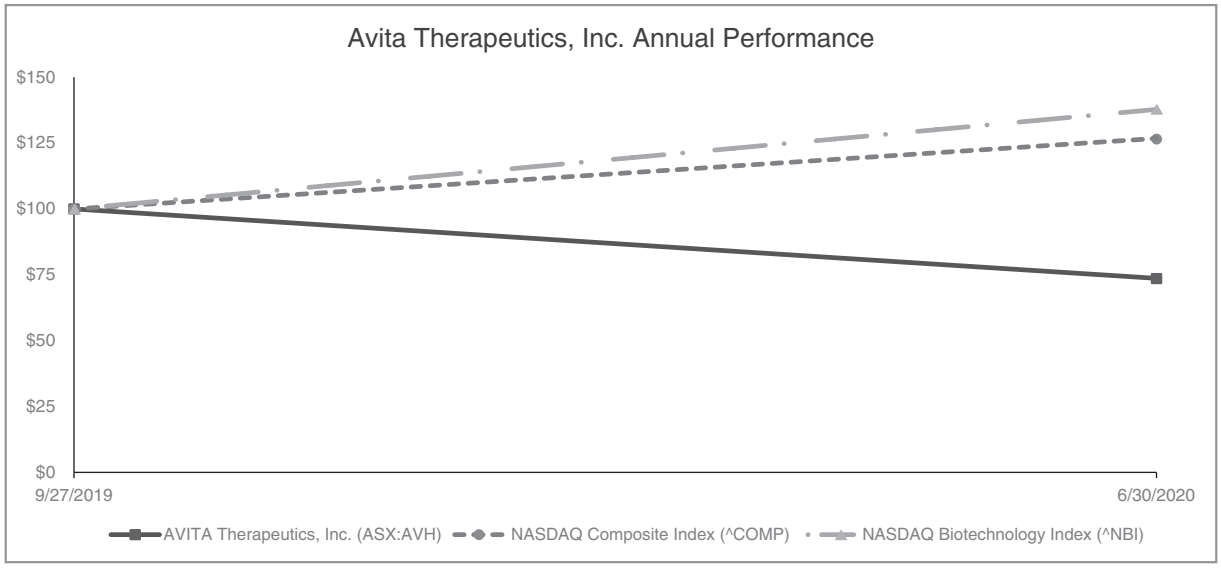
On July 7, 2020, the Company had a change in Auditors from Grant Thornton Audit Pty Ltd a subsidiary of Grant Thornton Australia Ltd to Grant Thornton LLP, the U.S. member firm of Grant Thornton Internation Ltd. Change in auditors was a result of the redomiciliation of the Company and the SEC filing requirement that resulted upon the redomiciliation.

We continue to manage the risk to our business posed by the global COVID-19 pandemic. For much of the last two quarters of 2020, our entire workforce worked from home except for employees in our Ventura facility who were essential for the commercial production of the RECELL System. As various stay-at-home orders were lifted, our office reopened, although many employees continue to work from home. Although our productivity was not significantly impacted by the global pandemic, we have suitably adapted to the changed business environment that now exists.

The COVID-19 pandemic continues to evolve rapidly and its ultimate impact remains highly uncertain. We do not yet know the full extent of potential delays or impacts on our business, commercialization efforts, healthcare systems or to the global economy as a whole. We do not expect the COVID-19 pandemic to negatively impact our near-term revenues or our operations. We will continue to monitor the COVID-19 situation closely.

Performance Comparison Graph

The following graph depicts the total return to shareholders from September 27, 2019 (the date that our securities were first registered under Section 12 of the Exchange Act) through June 30, 2020 (the end of our most recent fiscal year), relative to the performance of NASDAQ Composite Index and NASDAQ Biotechnology Index over the same period. All indices shown in the graph have been reset to a base of 100 as of September 27, 2019 and assume an investment of $100 on that date and the reinvestment of dividends paid since that date. The stock price performance shown in the graph is not necessarily indicative of future price performances.



	September 27, 2019	June 30, 2020
Avita Therapeutics, Inc	$100.00	$ 73.75
NASDAQ Composite Index	100.00	126.69
NASDAQ Biotechnology Indes	100.00	137.86