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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended June 30, 2019

OR

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

For the transition period from _____ to _____

OR

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

Date of event requiring this shell company report

Commission file number 001-39059



Avita Medical Limited

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

Australia

(Jurisdiction of incorporation or organization)

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

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

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

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

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

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

The number of ordinary shares, as of June 30, 2019 is 1,871,299,575

The number of American Depositary Shares, as of June 30, 2019 is 25,518,358

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer
Emerging Growth Company

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

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

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

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

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

TABLE OF CONTENTS

INTRODUCTION	1
PART I	2
Item 1. Identity of Directors, Senior Management and Advisers	2
Item 2. Offer Statistics and Expected Timetable	2
Item 3. Key Information	2
Item 4. Information on the Company	18
Item 4A. Unresolved Staff Comments	35
Item 5. Operating and Financial Review and Prospects	35
Item 6. Directors, Senior Management and Employees	43
Item 7. Major Shareholders and Related Party Transactions	55
Item 8. Financial Information	56
Item 9. The Offer and Listing	57
Item 10. Additional Information	57
Item 11. Quantitative and Qualitative Disclosures About Market Risks	67
Item 12. Description of Securities Other than Equity Securities	67
PART II	74
Item 13. Defaults, Dividend Arrearages and Delinquencies	74
Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds	74
Item 15. Controls and Procedures	74
Item 16. Reserved	74
Item 16A. Audit Committee Financial Expert	75
Item 16B. Code of Ethics	75
Item 16C. Principal Accountant Fees and Services	75
Item 16D. Exemptions from the Listing Standards for Audit Committees	75
Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers	75
Item 16F. Change in Registrant’s Certifying Accountant	75
Item 16G. Corporate Governance	76
Item 16H. Mine Safety Disclosure	76
PART III	77
Item 17. Financial Statements	77
Item 18. Financial Statements	77
Item 19. Exhibits	77
SIGNATURES	79

INTRODUCTION

Avita Medical Limited was incorporated under the laws of the Commonwealth of Australia on December 21, 1992. The principal listing of our ordinary shares and to purchase our ordinary shares is the Australian Securities Exchange, or ASX. Since October 1, 2019 our American Depositary Share (“ADS”) securities have traded on the NASDAQ Capital Market under the symbol “RCEL”. We have appointed Bank of New York Mellon to act as our American Depositary Share (“ADS”) registrar and transfer agent to register and deliver our ADS in the United States for the Nasdaq Stock Market. As used in this annual report, the terms “we,” “us,” “our,” “Avita,” and the “Company” mean Avita Medical Limited and its subsidiaries, unless otherwise indicated.

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

In this annual report, all references to “U.S. dollars” or “US\$” are to the currency of the United States of America, and all references to “Australian dollars” or “A\$” are to the currency of Australia.

Statements made in this annual report on Form 20-F concerning the contents of any contract, agreement or other documents are summaries of such contracts, agreements or documents and are not complete descriptions of all of their terms. If we filed any of these documents as an exhibit to this annual report or to any registration statement or annual report that we previously filed, you may read the document itself for a complete description of its terms.

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

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. Directors and Senior Management

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

B. Advisers

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

C. Auditors

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

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

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

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

[Table of Contents](#)

We derived the summary consolidated statements of financial position data as of June 30, 2019 and 2018 and the summary consolidated statements of profit or loss or other comprehensive income data for the fiscal years ended June 30, 2019, 2018 and 2017 from our audited consolidated financial statements included elsewhere in this annual report on Form 20-F. We derived the summary consolidated statements of financial position data as of June 30, 2017 and 2016 and the summary consolidated statements of profit or loss or other comprehensive income data for the fiscal year ended June 30, 2017 from our audited consolidated financial statements not included in this annual report on Form 20-F. The summary financial data included in this section are not intended to replace the financial statements and related notes included elsewhere in this annual report.

	Years ended June 30,			
	2019	2018	2017	2016
Consolidated statements of profit or loss or other comprehensive income:				
Sale of goods	A\$ 7,705,398	A\$ 1,198,861	A\$ 901,376	A\$ 1,002,376
Cost of sales	(1,697,823)	(511,646)	(463,285)	(401,568)
Gross profit	6,007,575	687,215	438,091	600,439
BARDA income	8,259,152	10,104,081	6,886,236	2,424,357
Other income	456,695	68,617	344,734	120,160
Total other income	8,715,847	10,172,698	7,230,970	2,544,517
Operating costs				
Sales and marketing expenses	(17,576,754)	(8,936,441)	(5,201,761)	(5,042,189)
Product development expenses	(14,361,995)	(12,606,127)	(11,161,970)	(6,018,184)
Corporate and administrative expenses	(15,398,177)	(5,360,553)	(2,264,594)	(2,371,747)
Share-based payment expenses	(2,688,817)	(1,835,157)	(1,587,243)	(956,658)
Finance costs	(37,769)	(26,586)	(12,754)	(21)
Total operating costs	(50,063,512)	(28,764,864)	(20,228,322)	(14,388,799)
Loss from continuing operations before income tax benefit	(35,340,090)	(17,904,951)	(12,559,261)	(11,243,843)
Profit for the period from discontinued operations	—	—	—	2,493,947
Income tax benefit	179,863	1,385,796	1,048,237	971,881
Loss for the period	(35,160,227)	(16,519,155)	(11,511,024)	(7,778,015)
Other comprehensive income (loss)				
Foreign currency translation	1,783,222	563,279	(83,293)	(169,100)
Fair value gain (loss) on available for sale financial assets	—	—	(265,261)	265,261
Other comprehensive income (loss) for the period, net of tax	1,783,222	563,279	(348,554)	96,161
Total other comprehensive loss for the period	<u>A\$ (33,377,005)</u>	<u>A\$ (15,955,876)</u>	<u>A\$ (11,859,578)</u>	<u>A\$ (7,681,854)</u>
Earnings per share				
Basic and diluted loss per share from continuing operations	A\$ (2.78) cents	A\$ (1.77) cents	A\$ (1.72) cents	A\$ (1.56) cents
Basic and diluted loss per share from discontinued operations	—	—	—	A\$ (0.05) cents

[Table of Contents](#)

	As of June 30,			
	2019	2018	2017	2016
Consolidated statements of financial position data:				
Cash and cash equivalents	A\$28,983,491	A\$14,825,532	A\$3,790,491	A\$4,171,879
Total current assets	34,578,882	22,274,431	7,280,541	8,508,418
Total assets	36,738,073	23,017,014	7,667,921	8,602,909
Total current liabilities	6,283,921	3,883,117	2,546,089	1,750,392
Total equity	29,789,421	18,999,559	5,121,832	6,852,517

Exchange Rate Information

We publish our consolidated financial statements in Australian dollars. In this annual report, references to dollars, "\$" or "A\$" are to Australian dollars currency and references to "U.S. dollars" or "US\$" are to U.S. currency. Solely for informational purposes, this annual report contains translations of certain Australian dollars into or from U.S. dollars at specified rates. These translations should not be construed as representations that the Australian dollars amounts actually represent such U.S. dollar amounts or could be converted into or from U.S. dollars at the rate indicated or at any other rate. Unless otherwise stated herein, the translations of Australian dollars into or from U.S. dollars have been made at A\$1.00 to US\$0.7015, the Buying Rate on June 30, 2019.

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

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

Year Ended June 30,	At Period End	Average Ratio	High	Low
2015	A\$ 0.7680	A\$ 0.8382	A\$0.9452	A\$0.7590
2016	A\$ 0.7426	A\$ 0.7283	A\$0.7812	A\$0.6867
2017	A\$ 0.7692	A\$ 0.7545	A\$0.7724	A\$0.7202
2018	A\$ 0.7399	A\$ 0.7753	A\$0.8105	A\$0.7355
2019	A\$ 0.6877	A\$ 0.7138	A\$0.7425	A\$0.6867

[Table of Contents](#)

Month	High	Low
July 2018	A\$0.7467	A\$0.7360
August 2018	A\$0.7441	A\$0.7213
September 2018	A\$0.7296	A\$0.7103
October 2018	A\$0.7200	A\$0.7034
November 2018	A\$0.7316	A\$0.7130
December 2018	A\$0.7375	A\$0.7051
January 2019	A\$0.7268	A\$0.6945
February 2019	A\$0.7260	A\$0.7072
March 2019	A\$0.7145	A\$0.7009
April 2019	A\$0.7200	A\$0.7025
May 2019	A\$0.7040	A\$0.6866
June 2019	A\$0.7015	A\$0.6855
July 2019	A\$0.7055	A\$0.6877

B. Capitalization and Indebtedness

The table below sets forth our total indebtedness and shows our capitalization as of June 30, 2019. You should read this table in conjunction with our consolidated financial statements included in this annual report on Form 20-F, together with the accompanying notes and the other information appearing under the heading “Item 5. Operating and Financial Review and Prospects”.

	As of June 30, 2019
Cash and cash equivalents	A\$ 28,983,491
Long-term debt	A\$ —
Contributed equity	204,279,078
Accumulated losses	(183,753,106)
Reserves	9,263,449
Total	29,789,421
Total capitalization	A\$ 29,789,421

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business faces significant risks. You should carefully consider all of the information set forth in this 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 ordinary shares, which underlie our ADSs, 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 “Special Note Regarding Forward-Looking Statements” at the beginning of Item 5.

Risks Related to Our Business

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

Although we have begun full scale marketing and sales of our RECELL® System in the U.S. and other jurisdictions, such sales have been limited to date and we have not yet obtained profitability. We had a total comprehensive loss of A\$35,160,227, A\$16,519,155 and A\$11,511,024 for our fiscal years ended June 30, 2019, 2018 and 2017, respectively. We have incurred a cumulative deficit of A\$183,753,106 through June 30, 2019. We anticipate that we may continue to incur losses at least until margins from U.S. sales of the RECELL System are adequate to fund operating expenses. We may not be able to successfully achieve or sustain profitability. Successful transition to profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure.

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

Although our Premarket Approval (PMA) application for the RECELL System was approved by the U.S. Food and Drug Administration (FDA) for use the treatment of acute thermal burn wounds in patients 18 years and older in September 2018, it has not been approved for additional indications such as pediatric burns or trauma wounds, or for the treatment of vitiligo. We plan to expand into each of these indications and will need to apply for a supplement to our PMA approval with the FDA in connection with each proposed additional indication. While clinical trials for such uses are presently underway or planned, there can be no assurance that we will ever receive approval by the FDA for the use of our RECELL System for such additional applications. Such a failure of approval would have a material negative effect to our future prospects.

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

We have a contract with BARDA valued currently at US\$50.4 million (approximately A\$68.1 million) related to funding for the development of the RECELL System and future use of the product to assist disaster preparedness and response in the U.S. for mass casualties involving burn victims. As of June 30, 2019, we had received cumulative payments of US\$20.24 million (A\$26.75 million) under the BARDA contract. Under the contract BARDA has agreed to fund and provide technical support for the development of the RECELL System including two randomized, controlled pivotal clinical trials, Compassionate Use and Continued Access programs, development of the health economic model demonstrating the cost savings associated with the RECELL System, and two randomized, controlled clinical trials in pediatric burn patients. Also included in the BARDA contract is a provision for the future procurement of the RECELL System by BARDA under a vendor-managed inventory system to bolster disaster preparedness. There can be no assurances that BARDA will not terminate the contract and changes in government agenda and annual budgets may result in changing priorities and funding mandates at BARDA. Any reduction or delay in BARDA funding may force us to seek alternative funding, which may not be available on non-dilutive terms, terms favorable to us or at all, or cease our development programs related to the BARDA contract.

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

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

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

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 today. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U.S., a medical device must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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

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

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

- delays in raising, or inability to raise, sufficient capital to fund the planned trials;
- delays in reaching a consensus with regulatory agencies on trial design;
- changes in trial design;
- inability to identify, recruit and train suitable clinical investigators;
- inability to add new clinical trial sites;
- delays in reaching agreement on acceptable terms for the performance of the trials with prospective clinical research organizations and clinical trial sites;
- delays in recruiting suitable clinical sites and patients (i.e., subjects) to participate in clinical trials;
- imposition of a clinical hold by regulatory agencies for any reason, including negative clinical results, safety concerns or as a result of an inspection of manufacturing or clinical operations or trial sites;
- failure by any relevant parties to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's current Good Clinical Practices, or cGCP, or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;

Table of Contents

- delays caused by clinical trial sites not completing a trial;
- failure to demonstrate adequate effectiveness;
- occurrence of serious adverse events in clinical trials that are associated with the product candidates that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- disagreements with regulatory agencies in the interpretation of the data from our clinical trials.

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

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

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

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

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

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

If we are unable to achieve profitability sufficient to permit us to fund our operations and other planned actions, we may be required to raise additional capital. There can be no assurance that such capital would be available on favorable terms, or at all. If we raise additional capital through the issuance of equity or convertible debt securities, the percentage ownership held by existing shareholders may be reduced, and the market price of our ordinary shares which underlie our ADSs could fall due to an increased number of shares available for sale in the market. Debt financing, if available, may involve restrictive covenants, which may limit our operating flexibility with respect to certain business matters. If we are unable to secure additional capital as circumstances require, we may not be able to fund our planned activities or continue our operations.

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

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

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

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

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

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

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

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

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

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

Our products are manufactured, stored and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture, storage and distribution of our product candidates, subjects us to risks. In addition, process

deviations or unanticipated effects of approved process changes may result in production runs of our RECELL System not complying with stability requirements or specifications. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches. In the event our production efforts require a recall or result in an inventory loss, our operating results and financial condition may be adversely affected.

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

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

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

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

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

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

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

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

Risks Relating to our Industry and Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the Health Care Reform Law, was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. healthcare industry. The Health Care Reform Law, among other things, (i) subjects biologic products to potential competition by lower-cost biosimilars, (ii) addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected, (iii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and (v) promotes a new Medicare Part D coverage gap discount program.

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

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

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

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

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

Risks Relating to Our Ordinary Shares and ADSs

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

We do not anticipate paying cash dividends on our ordinary shares in the foreseeable future and intend to retain all earnings, if any, for our operations. If we decided to pay dividends at some future time, we may not have sufficient funds legally available to do so. Even if funds are legally available for distribution, we may be unable to pay any dividends to our shareholders because of limitations imposed by a lack of liquidity. Accordingly, our shareholders may have to sell some or all of their ordinary shares in order to generate cash flow from their investment. Our shareholders may not receive a gain on their investment when they sell their ordinary shares and may lose some or all of their investment. Any determination to pay dividends in the future on our ordinary shares will be made at the discretion of our board of directors and will depend on our results of operations, financial conditions, contractual restrictions, restrictions imposed by applicable law, capital requirements, and other factors that our board of directors deems relevant.

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

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

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

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

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

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

[Table of Contents](#)

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

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

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

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

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

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

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

Such Australian home-country practices may afford less protection to holders of our ordinary shares than would be available to our shareholders if we were incorporated in the U.S., governed by U.S. law and subject to all applicable NASDAQ regulations. At any general meeting of shareholders, a resolution put to the vote of the meeting must be decided on a show of hands unless a poll is effectively demanded, and the demand is not withdrawn. On a show of hands, each member present in person and each other person present as a proxy, attorney or representative of a member has one vote. On a poll, each member present in person has one vote for each share held by the member and each person present as proxy, attorney or representative of a member has one vote for each share held by such member that the person represents. Voting based on a show of hands may make it more difficult for shareholders to influence our management. NASDAQ rules require that the quorum required for a meeting of shareholders be not be less than 33 1/3 percent of the outstanding shares of the Company's ordinary shares, however, we intend to follow our home-country corporate governance practices with respect to quorum, and as a result, the quorum required for an ordinary meeting of shareholders will consist of at least three shareholders present in person, or by proxy, attorney or representative appointed pursuant to our Constitution. As required for foreign private issuers, each NASDAQ requirement with which we do not intend to comply is listed below under Item 6.C, together with a description of our applicable home-country practice.

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

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

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

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

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

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

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

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

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

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

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

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

Holders of ADSs may be subject to transfer limitations.

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

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

The deposit agreement governing the ADSs representing our shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs, including in respect of claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court.

[Table of Contents](#)

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

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

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

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

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

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

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

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

[Table of Contents](#)

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

Risks Relating to Takeovers

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

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

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

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

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

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

B. Business Overview

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

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

[Table of Contents](#)

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

Markets and Limitations of Standard of Care

Acute Thermal Burns

Acute thermal burns are life-threatening and debilitating injuries that are among the most expensive traumatic injuries to manage because of complex surgical procedures, long and costly hospitalization, rehabilitation and scar treatment. In the U.S., the largest market for the treatment of burns, approximately 486,000 people seek treatment for burns each year. Of these, at least 40,000 have burn injuries severe enough to require 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 markets for the treatment of burns. For example, in Japan, the second largest healthcare market in the world, approximately 6,000 patients with severe burns treated in hospitals each year.

The severity of the burn injury is generally assessed based on the extent of the area burned, and the depth of the injury. The extent of the patient's burn injury is typically described in terms of percent of total body surface area, or "TBSA." For example, a burn covering an average sized adult arm would be roughly 9% TBSA, while a burn covering an entire leg would be roughly 18% TBSA. The depth of the burn, referred to in terms of "degree" is generally classified into four categories:

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

Burn treatment is determined in large part by the depth and extent of the injury. and Deeper (e.g., deep partial-thickness) are commonly treated with autologous split-thickness skin grafts (STSGs) to achieve definitive closure of the burn wound. In a STSG, or autograft, the 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 that can be expanded and transferred to the burn injury that has been prepared (debrided or cleaned).

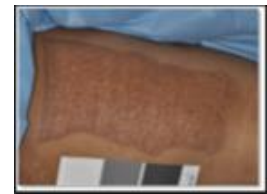
Harvesting of Donor Skin for Use in Autografting



Harvesting skin from donor site for autograft



Donor site wound created while harvesting skin for autograft



Typical donor site scar 52 weeks post procedure

Treatment with STSG creates additional trauma for the patient due to the harvesting of healthy donor skin. Although the use of STSG has been a standard treatment for more than 50 years, 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 injuries with traditional grafting techniques. The lack of available healthy donor skin in patients with high TBSA burn injuries is often the central problem impacting time to autografting and definitive closure of the wounds. In severely burned patients, doctors often must wait until the donor sites have healed so that they can reharvest from the site, resulting in delays in treatment and healing, requiring multiple procedures and

Table of Contents

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 approximately US\$579,000 and 59.4 days in hospital for a patient with a 40% TBSA mixed or full-thickness burn.

Because of the limited donor skin available for harvest in patients with high TBSA injuries, researchers have developed alternatives such as cultured epidermal autografts (CEA) in which a skin biopsy is taken from a patient and the cells are grown into sheets of skin in a laboratory and then returned for autografting onto the patient. Limitations associated with CEAs, including Epicel® from Vericel Corporation, include the time to grow the sheets of skin (approximately three weeks), the fact that the skin grown contains only keratinocytes and therefore lack the melanocytes that provide pigmentation, and the high cost. As a result, CEAs have been lifesaving in very high TBSA patients (> 30% TBSA) but in the U.S. the use of CEAs have been limited to approximately 100 patients per year.

Trauma Wounds (Soft Tissue Injuries)

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

Vitiligo and Other Dermatological Indications

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

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

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

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

Survey results reveal a low level of patient satisfaction with current treatment options. The majority of vitiligo patients in the U.S. are treated by dermatologists. In 2019, China accounted for the highest prevalence in the world with 7.7 million cases, followed by the U.S. 6.5 million cases, Japan with 1.3 million and the EU with 3.3 million.

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

Chronic Wounds

The chronic and other hard-to-heal wound market consists of a broad population of more than 6 million patients in the U.S. suffering from 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 US\$25 billion burden to the U.S. healthcare system. Chronic and hard-to-heal wounds are

[Table of Contents](#)

caused by impairment in the biochemical and cellular healing processes due to local or systemic conditions and generally can take weeks or months to heal, if not longer. Such wounds can lead to significant morbidity, including pain, infection, impaired mobility, hospitalization, reduced productivity, amputation and mortality.

Venous Leg Ulcers:

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

Diabetic Foot Ulcers:

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

The RECELL System

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

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

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



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



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

In the U.S., the RECELL System is approved by the FDA for use in the treatment of acute thermal burn wounds in patients 18 years 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 U.S., 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. In China, the RECELL System is NMPA-cleared for the treatment of burns, acute wounds, scars and vitiligo. The RECELL System is produced in a configuration that allows for treatment of up to 320 cm² for the markets in Australia and China. In Europe, the RECELL System received CE-mark approval for the treatment of burns, chronic wounds, scars and vitiligo. In February 2019 a Japan's Pharmaceuticals and Medical Devices Act ("JPMDA") application for approval to market the RECELL System in Japan was filed for use in the treatment of burns and other wounds.

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

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.

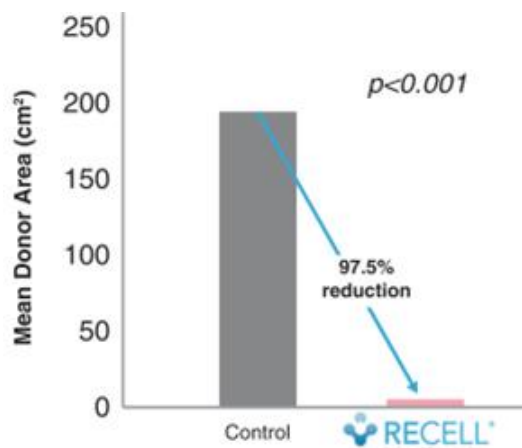
The RECELL System Clinical Results in Thermal Burns

RECELL Pivotal Clinical Trial in Second-Degree Acute Thermal Burns

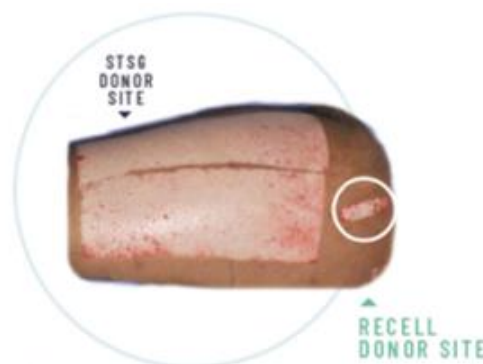
One of the two randomized, controlled clinical trials of the RECELL System supporting the September 2018 FDA approval was a study of patients with partial thickness (second-degree burns) conducted at 12 U.S. burn centers. The pivotal trial evaluated 101 adult patients with thermal, partial-thickness 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 ($p \leq 0.0025$)
- Significantly higher patient satisfaction with donor-site appearance ($p \leq 0.0025$)
- Significantly better donor-site scarring results ($p \leq 0.0025$)
- Significantly greater incidence of donor-site healing at two weeks ($p < 0.001$), with an odds ratio of 4:3

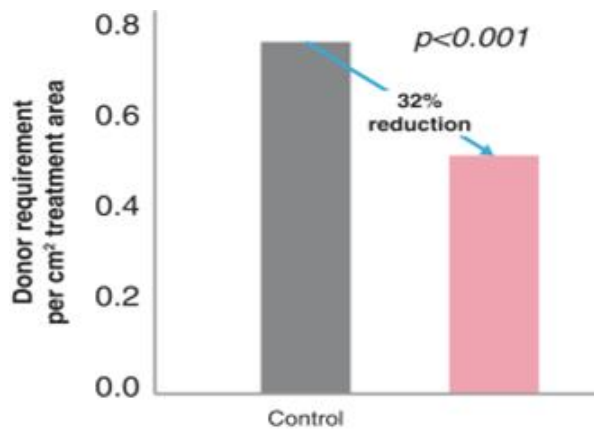
In the clinical trial, use of the RECELL System in the trial was safe and well tolerated with adverse experiences typical for the type of burn injury sustained. The results of this trial were published in a peer-reviewed scientific publication, the *Journal of Burn Care & Research*, in September 2018.

RECELL Pivotal Clinical Trial in Third-Degree Acute Thermal Burns

The second randomized, controlled clinical trial of the RECELL System supporting the September 2018 FDA approval was a study of patients with mixed and full-thickness (third-degree burns) conducted at seven U.S. burn centers. The pivotal trial evaluated 30 patients ranging in age from nine to 68 years old with thermal, mixed-thickness burns, including full-thickness burns, covering 5% to 46% of their total body surface area. Patients served as their own control, and two comparable burn sites were selected for comparative testing on each patient. One burn site was treated with the standard treatment, meshed autograft, while the other was treated with Spray-On-Skin Cells prepared using the RECELL System combined with more widely meshed autografts (for example, if a 2:1 meshed autograft was used to treat the control burn site, then a 3:1 meshed autograft used in combination with Spray-On Skin Cells was used to treat the RECELL site). The co-primary endpoints of the pivotal trial were reduction in donor skin requirements 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 donor skin required to be harvested to treat burn sites with the RECELL System was 32% less than the amount harvested to treat burn sites with the standard of care ($p < 0.001$). Despite the statistically significant reduction in donor skin required to treat using the RECELL System, eight weeks post treatment 92% of the burn sites treated using the RECELL System achieved complete healing versus 85% for the sites treated with the standard of care, demonstrating non-inferiority.

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



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

Use of the RECELL System was safe and well tolerated with no device-related adverse events. The results of this trial were published online ahead of print in a peer-reviewed scientific publication, *Burns*, in December 2018, and will appear in the print version of the journal in 2019 (Holmes IV JH, Molnar JA, Shupp JW, Hickerson WL, King BT, Foster KN, Cairns BA, Carter JE. Demonstration of the safety and effectiveness of the RECELL[®] System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. *Burns*. 2019 Jun 1;45(4):772-82).

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

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

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

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

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

Table of Contents

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

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

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

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

The peer-reviewed, published (Kowal S, Kruger E, Bilir P, Holmes JH, Hickerson W, Foster K, Nystrom S, Sparks J, Iyer N, Bush K, Quick A. Cost-Effectiveness of the Use of Autologous Cell Harvesting Device Compared to Standard of Care for Treatment of Severe Burns in the United States. *Advances in therapy*. 2019 May 7;1-5.) BEACON model highlights the potential of the RECELL System to improve patient care in the treatment of severe burns, while also reducing the total cost of care.

Additional RECELL Clinical Results in Severe Burns

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

RECELL in Treatment of Facial Burns (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.

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

A representative patient in the trial was a 12-year-old girl with 2nd-degree facial burn and widespread 3rd-degree burns, with total injuries encompassing a 62% TBSA. The patient had insufficient donor skin available for standard autografts. The healing of the patient's facial burns is highlighted in the progressions of photographs included below.

Facial Burn Case Study



Treatment Day



Day 7



Day 21



3 months



1 year

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

RECELL in Treatment of Pediatric Patients (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 U.S., one-third of burn injuries occur in children, and the availability of donor skin for traditional meshed autografts is even more limited in pediatric patients with extensive injuries. The use of the RECELL System, a donor skin sparing technology that enables rapid definitive closure of burn wounds, has the potential to improve patient outcomes.

Interim results describing clinical outcomes for pediatric patients treated using the RECELL System were presented at the American Burn Association (ABA) 51st Annual Meeting in April 2019. The study included a total of 33 pediatric patients with a median age of 6.7 years old (ranging from 0.8 to 14.2) treated under FDA IDE Compassionate Use and Continued Access programs with mixed-depth and full-thickness (third-degree) burns. The presentation was selected as a “Best of the Best Abstract” out of more than 500 abstract submissions to the ABA meeting.

In this 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. A total of 195 burn wounds were treated in the study, and 88.1% achieved definitive healing within four weeks of treatment. Importantly, for patients with greater than 50% TBSA burns, treatment with the combination of Spray-On Skin Cells and widely meshed split-thickness autografts achieved the same high rate of healing at week four as patients with smaller burns (burns equal to or less than 50% TBSA) treated with the same combination. In addition, in the study the donor sites on all patients were treated with Spray-On Skin Cells, and 62.2% of the donor sites were healed within a week of treatment, and 100% were completely healed within two weeks of treatment. Researcher reported that the majority of burn sites had cosmetic outcomes rated as satisfactory or equivalent compared to uninjured skin and that the early healing of donor sites contributed to a decrease between harvest times for patients with limited donor skin availability.

Two additional randomized, controlled clinical trials using the RECELL System in the treatment of pediatric patients are currently underway, and a third trial in this population is expected to begin in fiscal 2020.

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

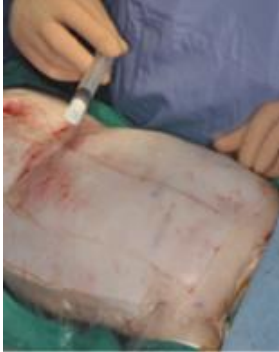
In large TBSA injuries a patient may not have enough donor skin available to allow for immediate treatment of the entire area of burn injuries with traditional autografting techniques. In severely burned patients with extensive injuries, surgeons often must wait until the donor sites have healed so that 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, 426 donor sites wounds were treated with Spray-On Skin Cells prepared using the RECELL System. The mean TBSA of the patients in the study was 54% with burns ranging from 20% to 91% TBSA. Two weeks after treatment, 91% of the donor sites had healed in this vulnerable patient population, and 98% had healed by week eight. Donor sites treated using the RECELL System were able to be reharvested as early as seven days after treatment. No infection or delayed

Table of Contents

healing were reported for donor sites treated with Spray-On Skin Cells. Researchers noted that the ability to reharvest additional donor skin from a site in as little one week after treatment with the RECELL System is extremely beneficial in this population of patients with extensive life-threatening injuries and limited available donor skin.

A representative patient in the study was a 16-month-old female with a 30% TBSA mixed depth thermal burn with donor sites taken from her back. Medical professionals applied Spray-On Skin Cells to her donor site wound. The donor sites were 100% re-epithelialized by within two weeks of treatment. At one-year follow-up the donor site wound had matching color, pigment, and texture to the surrounding skin. Treatment and healing of the patient's donor site is highlighted in the photographs included below.



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



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

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

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

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 CO₂ laser ablation followed by the application of Spray-On Skin Cells, CO₂ laser ablation alone, or no treatment.

The median repigmentation six months after treatment was 78% in the sites treated with the combination of CO₂ laser ablation followed by the application of Spray-On Skin Cells, compared to zero median repigmentation in the control groups consisting of treatment with CO₂ laser ablation alone or no treatment. The repigmentation for the sites treated with the combination of CO₂ 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 CO₂

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

Vitiligo Patient Pre- and Six-Months Post Treatment



Baseline (pre-treatment)

Six months after treatment

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

The RECELL System Clinical 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 control (14 versus 20 days, respectively)
- Fewer complications ($p=0.047$) were seen in the RECELL System group versus control (4 versus 11, respectively)
- The RECELL System group had good elasticity and texture, similar color, and less scar tissue growth at borders versus control group
- Scarring was significantly less ($p=0.005$) in the RECELL System group versus control
- Patients had no recurrent ulcers in the RECELL System group but there were three new wounds in control group (one diabetic wound, one pressure wound, and one vascular wound). Secondary surgical intervention was required for these patients.

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

[Table of Contents](#)

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

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. When ulcers were broken out into groups by size, ulcers >10-80 cm² achieved a significantly higher incidence of healing, whereas ulcers 2-10 cm² showed no significant difference from Control. 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 feasibility study presented at the *Japanese Society of Limb Salvage & Podiatric Medicine* 2019, (Tawqeer Rashid, MD. A Feasibility Study of the RECELL® Autologous Cell Harvesting Device for Diabetic Foot Ulcers. *Japanese Society of Limb Salvage & Podiatric Medicine*; 2019 June 28-29; Kobe, Japan), 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. Comparable healing outcomes were obtained independent of ulcer duration, depth, or presence of infection. All ulcers reduced in size after RECELL treatment and 30.8% of ulcers fully healed in 26 weeks. Adverse events observed were typical for the diabetic foot ulcer patient population.

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

Ongoing and Planned Clinical Trials

U.S. Pediatric Donor Site Study:

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

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

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

Table of Contents

Patients will be followed for one-year after treatment. The pediatric donor-site study is being funded by Biomedical Advanced Research and Development Authority (BARDA) under the ongoing program. This study is intended to support U.S. regulatory approval for marketing of the RECELL System for donor site treatment in patients aged 1–16 years.

Australian Pediatric Scalds Study:

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

U.S. Pediatric Early Intervention Pediatric Study:

In fiscal 2020, we plan to initiate a randomized, controlled clinical study to investigate the safety and effectiveness of Spray-On Skin Cells, prepared with the RECELL System, compared to standard of care dressings for treatment of partial-thickness burns in pediatric patients (infants, children and adolescents aged one to 16 years). The study will evaluate 160 patients in up to 18 U.S. burn centers with burns of 5% to 30% TBSA. Half of the patients will be randomized to be treated using Spray-On Skin Cells. The other half will be randomized to serve in the control group and will be treated using standard dressings.

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

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

Patients will be followed for one-year after treatment. The pediatric early intervention study is being funded by Biomedical Advanced Research and Development Authority (BARDA) under the ongoing program. This study is intended to support U.S. regulatory approval for marketing of the RECELL System for patients 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. We announced on September 17, 2019 that the FDA approved an IDE application to conduct a trauma (soft-tissue reconstruction) pivotal clinical trial. We plan to commence a U.S. clinical trial within the next six months in the use of the RECELL System for the treatment of trauma injuries under a program designed to support a supplement to the existing PMA approval.

The RECELL System in Other Indications

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

BARDA Contract

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

Under the contract, BARDA 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 two randomized, controlled clinical trials in pediatric patients. The pediatric donor site study commenced in September 2018 and the pediatric early intervention study will commence in fiscal 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 US\$7.6 million (approximately A\$10.3 million), although BARDA also has the option of increasing the amount of the procurement. In connection with the BARDA contract, we anticipate that with respect to vendor-managed inventory systems, our margins may be lower. As the vendor-managed system is solely at BARDA's option, we are unable to predict when the Company will recognize revenue on this portion, if at all. As of June 30, 2019, we had received cumulative payments of A\$26.75 million under the BARDA contract.

Research and Development

Our research and development efforts are focused on:

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

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

Manufacturing, Supply and Production

We operate a production plant in Ventura, California, in a 23,040 square foot facility that we lease through September 30, 2021. We have the right to extend the lease, at our sole option, as a result of three, three-year, options that allow us to extend the lease up to an additional nine years in total. We produce the RECELL System in this facility under the current Good Manufacturing Practices (cGMP) requirements of the FDA and the regulatory agencies of other jurisdictions in which we sell the RECELL System. As we seek regulatory approval in Japan and other new international countries for the RECELL System, the regulatory authorities of these countries are likely to review our manufacturing process, inspect our plant, and confirm that we meet all regulatory requirements. Any material future changes to our production processes for the RECELL System will have to be approved by the FDA and regulatory authorities in other jurisdictions.

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

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

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

Marketing Sales and Distribution

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

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

The objective of our field sale team is to build upon burn community awareness resulting from the extensive series of burn conference presentations and scientific publications to further expand the interest in clinical and economic benefits of the RECELL System among burn surgeons and other professionals who are not already experienced with the product. In addition, we have set a policy of not providing the RECELL System to a burn center or other institution until their site has been certified by us, which includes training in the use of the product and in the proper aftercare of the patient. Training of the burn sites is undertaken by the clinical training specialist component of our sales team, augmented from personnel by our Medical Affairs team. In general, we expect most U.S. burn centers will follow the industry standard process of evaluating the RECELL System and then taking it through their hospital's Value Analysis Committees (VAC) prior to purchasing the product. This process can sometimes be a lengthy one taking six months to complete. As a result of the training requirements and the VAC process, we expect that the adoption of the RECELL System among U.S. burn centers will occur on a staggered basis over multiple years.

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

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

Intellectual Property

We seek to protect our intellectual property, core technologies and other know-how through a combination of patents, trademarks, trade secrets, non-disclosure and confidentiality agreements, licenses, assignments of invention and other contractual arrangements with our employees, consultants, partners, suppliers, customers and others. Additionally, we rely on our research and development program, clinical trials, know-how and marketing and distribution programs to advance our products and product candidates, and to expand our intellectual property rights. As of June 30, 2019, we have been granted a total of 35 patents and have 15 pending patent applications worldwide.

The U.S. patents and patent applications provide coverage with expected expiration dates ranging from 2022 to 2033. U.S. patents covering the composition of matter related to the current RECELL System expire in 2022. We have filed a Patent Term Extension (PTE) application with the U.S. Patent and Trademark Office requesting an extension of the patent term of U.S. Patent No. 9,029,140, "Cell suspension preparation technique and device" as a result of the time required for the FDA regulatory process. If

Table of Contents

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 will provide additional claims, including composition of matter, for which we will be able to pursue additional U.S. and international patent applications. Patents and patent applications in key international markets parallel those in the U.S.

In addition to patent protection, we also rely on trade secrets, including unpatented know-how, technology innovation, drawings, technical specifications and other proprietary information in attempting to develop and maintain our competitive position. We also rely on protection available under trademark laws, and we currently hold various registered trademarks and pending trademark applications, including the “RECELL,” “Spray-On Skin Cells,” and “REGENERATIVE EPIDERMAL SUSPENSION (RES),” in the U.S. and international markets.

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

Competition

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

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

Government Regulations

FDA and International Regulation

The production and marketing of the RECELL System and any additional product candidates developed in the future ongoing research and development activities are subject to regulation by numerous governmental authorities including the FDA in the United States and similar agencies in other countries throughout the world.

Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) the FDA has jurisdiction over medical devices in the U.S. The FDA regulates, among other things, the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion and sales and distribution of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. The FD&C Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device are categorized as Class III. These devices typically require submission and approval of a Premarket Approval Application, or PMA. The

Table of Contents

RECELL System is categorized as a Class III medical device, and in September 2018 the FDA approved our PMA for use in the treatment of acute thermal burns in patients 18 years and older. Approval of the RECELL System for use in the treatment of additional indications in the U.S. will require the submission to the FDA of a supplement to our PMA.

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

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

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

The Foreign Corrupt Practices Act

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

Environmental, Health and Safety Matters

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, primarily in the United States, governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, air, water and ground contamination; air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage. Our operations at our Ventura manufacturing facility use biologic agents and produce waste materials and sewage. Our activities require permits from various governmental authorities including, local municipal authorities. Local authorities and the municipal water and sewage company conduct periodic inspections in order to review and ensure our compliance with the various regulations. We are 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.

Legal and Administrative Proceedings

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

C. Organizational Structure

We have a total of five subsidiaries and their corporate details and business activities are listed below:

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

D. Property, Plant and Equipment

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

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

Special Note Regarding Forward Looking Statements

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

Background

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

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

In this annual report, all references to “U.S. dollars” or “US\$” are to the currency of the U.S., and all references to “Australian dollars”, “A\$” or “AUD\$” are to the currency of Australia.

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

Critical Accounting Policies

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

Revenue Recognition

Revenue is recognized at a point in time based on the fixed invoice price when the Company satisfies performance obligations by transferring the promised goods or services to its customers.

To determine whether to recognize revenue, the Company follows a 5-step process:

1. Identifying the contract with a customer
2. Identifying the performance obligations
3. Determining the transaction price
4. Allocating the transaction price to the performance obligations
5. Recognizing revenue when/as performance obligation(s) are satisfied.

The Company recognizes contract liabilities for consideration received in respect of unsatisfied performance obligations and reports these amounts as contract liabilities in the statement of financial position. Similarly, if the Company satisfies a performance obligation before it receives the consideration, the Company recognizes either a contract asset or a receivable in its statement of financial position, depending on whether something other than the passage of time is required before the consideration is due.

Sale of goods – RECELL

Revenue is earned (constrained by variable considerations, which include returns and volume rebates) from the sale of RECELL products. Sales are recognized when performance obligations are satisfied at a point in time. Generally, the supply of product under a contract will represent the satisfaction of a performance obligation at a point in time, which is when control of the product passes to the customer.

Table of Contents

Estimates on sales returns are performed by management using inputs which include historical returns and customer sales data amongst other factors.

RECELL is often sold with respective volume rebates based on aggregated sales over a 12-month period. Revenue from these sales is recognized based on the price specified in the contract, net of estimated volume rebates. Accumulated experience is used to estimate and provide for the discounts, using the expected value method, and revenue is only recognized to the extent that it is highly probable that a significant reversal will not occur. A refund liability (trade and other payables) is recognized for expected volume rebates payable to customers in relation to sales made until the end of the reporting period. The *Company's* obligation to repair or replace faulty products under the standard warranty terms is recognized as a provision.

Government and other grants

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

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

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

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

Interest Income

Interest income is recognized as interest accrues using the effective interest method.

Share-based payments

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

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

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

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

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

Table of Contents

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

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

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

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

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

Research and Development Payments

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

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

Research and Development Tax Incentive

The Company's research and development activities are eligible under an Australian Government tax incentive for eligible expenditure from July 1, 2012. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. For the years ended June 30, 2019, 2018 and 2017, the Company recorded other income of A\$179,863, A\$1,385,796 and A\$1,048,634, respectively related to recognition of this tax incentive. The Australian R&D tax incentive scheme permits overseas activity to be claimed to the extent that the overseas activity does not exceed 50% of the total costs of activities for an eligible project.

Internal Controls

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

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

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

MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations for the years ended June 30, 2019, 2018 and 2017, should be read in conjunction with our consolidated financial statements and related notes included in this annual report in accordance with "Item 8. Financial Information".

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

Sale of goods of the RECELL System totaled A\$7,705,398 for the year ended June 30, 2019, an increase of A\$6,506,537 or 543% over the A\$1,198,861 recognized during fiscal 2018. Most of the current fiscal 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 fiscal year ended 30 June 2019 totaled A\$6,214,660 compared to zero in the prior fiscal year. Gross margin for the fiscal year ended 30 June 2019 was 78% compared to 57% for the same period in 2018, and management expects gross margins to further increase as sales ramp up within the U.S.

Other income totaled A\$8,715,847 for the year ended June 30, 2019, a decrease of A\$1,456,851 or 14% over the A\$10,172,698 recognized during fiscal 2018. As in prior periods, most of the other income consisted of funding from the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500028C. Under the BARDA contract, income of A\$8,259,152 was recognized during the year ended June 30, 2019 compared to income of A\$10,104,081 for fiscal 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 fiscal 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 A\$17,576,754, an increase of A\$8,640,313 or 97% over the A\$8,936,441 recognized during fiscal 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. Product development expenses for fiscal 2019 totaled A\$14,361,995 an increase of A\$1,755,868 or 14% over the A\$12,606,127 recognized during fiscal 2018. Corporate and administrative expenses totaled A\$15,398,177 for the year ended 30 June 2019, an increase of A\$10,037,624 or 187% over the A\$5,360,553 recognized during fiscal 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 30 June 2019 totaled A\$50,063,512, a A\$21,298,648 or 74% increase over the A\$28,764,864 incurred during fiscal 2018 and were in line with management expectations.

Net comprehensive loss after tax for the fiscal year ended 30 June 2019 was A\$33,377,005, an increase of A\$17,421,129 or 109% over A\$15,955,876 recognized during fiscal 2018. The increase in net comprehensive loss was driven by the higher operating costs described above, partially offset by the higher sale of goods during the fiscal 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 contract.

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

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

We believe that there are many factors and trends that may affect our financial condition and results of operations. Primarily and foremost, our revenue growth will be impacted most by market acceptance, adoption and penetration of our RECELL System. Pricing is not expected to be a significant factor in connection with our revenue growth. In addition, the Company is always pursuing expansion of labeling additional indications that could open new markets such as the treatment of leg and foot ulcers, vitiligo, chronic wounds and trauma injuries. With regard to the foregoing factors and additional indications, we believe that over the next several years, the most critical component of our changes of sales of goods will be market acceptance and adoption of the RECELL System for burns, followed by approval, market acceptance, adoption of the additional, and potentially other, indications noted above. We do not consider pricing to be a critical component of revenue growth, instead, as indicated above, market acceptance, adoption and penetration of the RECELL System would have a material effect on our sales of goods.

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

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

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

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

B. Liquidity and Capital Resources

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

During the year ended June 30, 2019, the Company completed a series of equity transactions totaling gross proceeds of A\$45,036,886 which were used to fund operations.

On October 11, 2017, the Company completed a placement of 100,982,978 fully paid ordinary shares at a price of A\$0.045 per share raising gross proceeds of A\$4,544,234. On November 7, 2017, the Company completed a rights offering of 276,502,853 fully paid ordinary shares at a price of A\$0.045 per share raising gross proceeds of A\$12,442,628. On June 6, 2018, the Company completed the first tranche of an institutional placement in which it issued 255,475,665 fully paid ordinary shares at a price of A\$0.050 per share raising gross proceeds of A\$12,773,783. The institutional placement included a second tranche totaling A\$3,250,000 of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on July 23, 2018, and the Company issued 65 million shares at a price of A\$0.050 per share and received gross proceeds of A\$3,250,000 on July 26, 2018. Also subsequent to year end, on December 4, 2018, the Company completed the first tranche of an institutional placement in which it issued 310,047,015 fully paid ordinary shares at a price of A\$0.080 per share raising gross proceeds of A\$24,803,761. The institutional placement included a second tranche totaling A\$15,196,000 of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on January 14, 2019, and the Company issued 189,952,985 shares at a price of A\$0.080 per share and received gross proceeds of A\$15,196,239 on January 14, 2019. In addition, on January 11, 2019 the Company completed a Share Purchase Plan under which it issued 22,061,250 shares of stock at a price of A\$0.080 per share and received gross proceeds of A\$1,764,900.

[Table of Contents](#)

The Company benefits from cash inflows from the BARDA contract, awarded to the Company in September 2015 and subsequently expanded through a series of modifications. These payments from BARDA offset costs from various activities undertaken to support the FDA regulatory approval process for RECELL in the U.S., preparation for the planned commercial launch of RECELL in the U.S., and RECELL clinical programs in the U.S. Further, there were no material expenditure commitments from the BARDA contract. With the U.S. FDA approval of RECELL for the treatment of burns in September 2018, and the U.S. market launch of the product in January 2019, sales of goods are expected to be an increasing source of revenue in the future. Another anticipated source of revenue for the Company is the BARDA contract covering the initial purchase, delivery and storage of RECELL devices in the amount of US\$7,594,620 (approximately A\$10,300,000). As the vendor-managed system is solely at BARDA's option, we are unable to predict when the Company will recognize revenue on this portion, if at all. As of June 30, 2019, we had received cumulative payments of A\$26.75 million under the BARDA contract.

The Company's research and development activities are eligible under an Australian Government tax incentive for eligible expenditure from July 1, 2012. Our management has assessed these activities and expenditure and to determine our likely eligibility under this incentive scheme. For the years ended June 30, 2019 and 2017, the Company has received A\$2,440,803 and A\$972,283, respectively related to this tax incentive.

The Australian R&D tax incentive scheme permits overseas activity to be claimed to the extent that the overseas activity does not exceed 50% of the total costs of activities for an eligible project. As of December 31, 2018, the Company evaluated the level overseas activity and concluded there was uncertainty as to the ability to meet this criteria. Additionally, at that time, the Federal Budget included a number of changes to the R&D tax incentive scheme which would place further limits on claimable amounts. These budget changes have since been formally placed on hold. The Company does not believe any reduction over time of these potential payments to have a material effect on its liquidity or capital resources.

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

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

(In Australian dollars)	As of June 30,		
	2019	2018	2017
Net cash used in operating activities	A\$(27,485,659)	A\$(16,372,024)	A\$(8,557,524)
Net cash (used in)/provided by investing activities	(1,794,610)	(498,749)	195,245
Net cash provided by financing activities	41,297,176	27,934,920	8,238,129
Net increase/(decrease) in cash and cash equivalents	12,016,907	11,064,147	(124,150)
Cash and cash equivalents at beginning of period	14,825,532	3,790,491	4,171,879
Impact of foreign exchange rate	2,141,052	(29,106)	(257,238)
Cash and cash equivalents at end of period	28,983,491	14,825,532	3,790,491

Years Ended June 30, 2019, 2018 and 2017

Net cash used in operating activities was A\$27,485,659, A\$16,372,024 and A\$8,557,524 during the years ended June 30, 2019, 2018 and 2017, respectively. Our payments to suppliers and employees during the years ended June 30, 2019, 2018 and 2017 were A\$46,420,306, A\$25,681,347 and, A\$17,676,710, respectively. The increase in payments to suppliers and employees is as the result of investments in commercial, manufacturing, leadership and system capabilities in preparation for the planned U.S. launch of the RECELL System and related research and development and corporate initiatives. Our operating activity receipts from customers for the years ended June 30, 2019, 2018 and 2017 of A\$5,826,634, A\$1,129,046 and A\$928,687 consisted of commercial sales from U.S., Europe and Asia Pacific. Our operating activity receipts from BARDA and other income for the years ended June 30, 2019, 2018 and 2017 of A\$10,056,537, A\$8,206,863 and A\$7,094,061. The BARDA program was received and began in the third quarter of fiscal year 2016 for the expansion of activities surrounding the Company's PMA submission to the FDA in September 2017 for approval to market the RECELL System in the U.S.

[Table of Contents](#)

Net cash (used in)/provided by investing activities was A\$(1,794,610), A\$(498,749) and A\$195,245 during the years ended June 30, 2019, 2018 and 2017, respectively. Cash flows used for investing activities was primarily attributable to payments for the purchase of a property and equipment. During the fiscal year 2017, the Company sold the respiratory business segment and the proceeds from the sale of financial assets was A\$627,837.

Net cash provided by financing activities was A\$41,297,176, A\$27,934,920 and A\$8,238,129 for the years ended June 30, 2019, 2018 and 2017. The Company completed a series of equity transactions and received proceeds from issuance of shares and exercise of options of A\$45,036,886 and A\$452,809, A\$29,760,563 and A\$9,048,102 for the years ended June 30, 2019, 2018 and 2017.

We realized a foreign exchange gain (loss) of A\$2,141,052, A\$(29,106) and A\$(257,238) for the years ended June 30, 2019, 2018 and 2017. The Australian dollar depreciated against the U.S. dollar by 8%, 3% and 4% for the years ended June 30, 2019, 2018 and 2017.

Capital management

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

For the year ended June 30, 2019, there were no dividends paid and we have no plans to commence the payment of dividends. We have no current plans to issue further shares on the market but will continue to assess market conditions and the company's cash flow requirements to ensure the Company is appropriately funded.

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

C. Research and Development, Patents and Licenses

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

Our research and development expenses consist primarily of expenses for contracted research and development activities conducted by major contract research organizations on our behalf, including personnel, testing facilities and other payments in accordance with our research and clinical agreements. Research and development expenses are included in the Product Development Expenses line item of our financial statements, and amounted to A\$3,379,346, A\$3,266,098 and A\$2,330,297 during the years ended June 30, 2019, 2018 and 2017, respectively.

D. Trend Information

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

E. Off-Balance Sheet Arrangements

During fiscal years ended June 30, 2019, 2018 and 2017, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

F. Contractual Obligations

The Company's furniture and IT equipment are held under lease arrangements. As of June 30, 2019, 2018 and 2017 the net carrying amount of the furniture and IT equipment held under lease arrangements are A\$65,369, A\$159,043 and A\$66,408, respectively. The Company's finance lease liabilities, which are secured by the related assets held under finance leases, are classified as follows:

	June 30, 2019
Finance Lease Liabilities	
Current	A\$ 48,265
Non-Current	A\$ 17,104
Total	A\$ 65,369

	Within 1 Year	Minimum Lease Payment Due 1-5 Years	After 5 Years	Total
June 30, 2019				
Lease Payments	A\$ 66,643	A\$17,165	—	A\$ 83,808
Finance Charges	(15,282)	(3,157)	—	(18,439)
Net Present Values	51,361	14,008	—	65,369

The Company leases space under operating leases. Future minimum lease payments under such leases as of June 30, 2019 are as follows:

	Within 1 Year	Minimum Lease Payment Due 1-5 Years	After 5 Years	Total
June 30, 2019	A\$ 839,673	A\$745,693	—	A\$1,585,366

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

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

Name	Age	Position
Lou Panaccio(1)	62	Non-Executive Chairman
Dr. Michael Perry	60	Executive Director and Chief Executive Officer
Erin Liberto	45	Chief Commercial Officer
Tim Rooney	53	Chief Administrative Officer and interim Chief Financial Officer
Andrew Quick	49	Chief Technology Officer
Donna Shiroma	57	General Counsel
Jeremy Curnock Cook(2)	70	Non-Executive Director
Louis Drapeau(3)(2)	75	Non-Executive Director
Damien McDonald(1)	54	Non-Executive Director
Professor Suzanne Crowe(4)	68	Non-Executive Director

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

Lou Panaccio has served as Non-Executive Chairman of the Board of Directors since July 2014. Mr. Panaccio is a successful healthcare businessman with extensive experience leading companies from concept to commercialization. Mr. Panaccio possesses more than 30 years of executive leadership experience in healthcare services and life sciences, including more than 20 years of board-level experience. Mr. Panaccio is currently a Non-Executive Director of ASX50 company and one of the world's largest medical diagnostics companies, Sonic Healthcare Limited, where he has served since 2005. In addition, Mr. Panaccio is Non-Executive Director of Unison Housing Limited, Non-Executive Chairman of Genera Biosystems Limited until June 2019, a publicly listed company (ASX) that develops and commercializes multiplexed molecular diagnostic tests, and a Non-Executive Director of Rhythm Biosciences Limited, a publicly listed (ASX) development-stage medical diagnostics company.

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

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

Tim Rooney was appointed Chief Administrative Officer in December 2017 and is responsible for operations of the Company. Mr. Rooney was also appointed as our interim Chief Financial Officer in May 2019. Mr. Rooney has served the Company in multiple roles since joining in October 2012 as Chief Financial Officer and Chief Operating Officer, including interim Chief Executive Officer from 2013 to 2015. Mr. Rooney has over 25 years of experience in senior finance and operations management in medical devices and pharmaceutical wholesale distribution, including PDI Enterprises, Inc., a pharmaceutical wholesale distributor, where he served as Chief Financial Officer and Chief Operating Officer from 1991 to 2007 and served in other roles starting in 1984. Mr., Rooney holds a B.S. degree in Business Administration, Finance from California State University, Northridge.

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

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

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

Louis Drapeau has served as Non-Executive Director of the Board since January 2016. Mr. Drapeau has considerable expertise in both the biotech sector and with the financial reporting and other requirements of U.S. public companies. Mr. Drapeau is an Independent Director at AmpliPhi Biosciences Corporation, Inc., a public (NYSE) clinical-stage biotechnology company focused on the development of bacteriophage-based therapies for the treatment of antibiotic-resistant bacterial infections from March 2011 until May 2019. Mr. Drapeau has held senior positions with Insite Vision Inc., Nektar Therapeutics and BioMarin Pharmaceutical, Inc., and served as an Audit Partner at Arthur Andersen LLP. Mr. Drapeau was previously an Independent Director at Bio-Rad Laboratories, a public (NYSE) company manufacturing products for the life science research and clinical diagnostics markets, and InterMune, Inc., a public (NASDAQ) commercial-stage biotech company. He has an MBA from Stanford University.

Damien McDonald has served as a Non-Executive Director since January 2016. Mr. McDonald has a proven track record of achieving value in the medical device space. Mr. McDonald is currently Chief Executive Officer and a Director of the Board of LivaNova plc, having previously served as Chief Operating Officer. LivaNova plc is a public (NASDAQ) company that is a leader in cardiovascular and neuromodulation solutions. Prior to that, he was a Group Executive and Corporate Vice President at NYSE-listed Danaher Corporation, a multinational science and technology innovation company that acquires and produces life science and industrial products and brands, where he led a \$1.5 billion group of dental consumable companies. Earlier in his tenure, Mr. McDonald was Group President of Kerr where he and his team focused on building a strong research and development pipeline while improving operational performance utilizing the Danaher Business System. He has also previously worked for Merck & Co, Johnson & Johnson and Zimmer. Mr. McDonald has B.S. degrees in both pharmacy and economics from the University of Queensland, a master's degree in International Economics from the University of Wales, and an MBA from IMD of Lausanne, Switzerland.

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

B. Compensation

Remuneration Principles

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

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

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

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

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

Table of Contents

Remuneration Committee

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

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

Use of Remuneration Consultants

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

Remuneration Framework, Philosophy and Policies

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

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

The main focus of executives and of performance assessment for Fiscal 2019 was related to the U.S. PMA application for the RECELL System, related activities required to support FDA approval, and preparation for the planned market launch of the RECELL System in the U.S. For the current year, the primary focus is on the successful market launch of the RECELL System in the U.S., advancement of the Company's pipeline and successful completion of the listing of our ADSs on the NASDAQ Capital Market (US Quotation). Incentives are intended to be linked to shareholder value via milestone completion, clinical trial outcomes and total shareholder return.

Non-Executive Director Remuneration

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

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

Structure: In accordance with best practice corporate governance, the structure of Non-Executive Director and Senior Management remuneration is separate and distinct. The Constitution and the ASX Listing Rules specify that the aggregate remuneration of Non-Executive Directors shall be determined from time to time by a general meeting. The latest determination was at the Annual General Meeting held on November 29, 2005 when shareholders approved an aggregate remuneration of \$450,000 per year in respect of fees payable to Non-Executive Directors. Please refer to Table 2 of this report for the allocation of Directors' fees.

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

The remuneration of Non-Executive Directors for the year ended June 30, 2019 is detailed in Table 2 of this report.

Executive Remuneration (including Executive Directors)

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

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

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

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

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

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

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

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

Fixed Remuneration Objective and Structure: The level of fixed remuneration is set so as to provide a base level of remuneration which is both appropriate to the position and is competitive in the market. During the 2019, 2018 and 2017 financial years there were no benefits paid in kind. Fixed remuneration is reviewed annually by the Remuneration Committee and the process consists of a review of Company-wide and individual performance and relevant comparative remuneration in the market.

Variable Remuneration – Short Term Incentive (STI) Objective and Structure: The objective of variable remuneration is to link the achievement of the Company's operational targets with the remuneration received by the Executives charged with meeting those targets. The Company's operational targets are set by the remuneration committee and the targets are based upon financial and non-financial measures. In the current financial year STI objectives consisted mainly of non-financial measures, primarily based around FDA approval and company readiness of commercialization. The target range is 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 remuneration 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.

Variable Remuneration – Long Term Incentive (LTI) Objective and Structure: The objective of the LTI plan is to reward Executives in a manner that aligns remuneration with the creation of shareholder value and to create an element of remuneration that supports the executive team working together to achieve this outcome over the long term. The LTI plan is also a key component of the Company’s retention strategy. The Company has two LTI plans available for use with senior executives and staff. At the 2014 AGM, shareholders approved a Performance Rights Plan. At the General Meeting of shareholders on August 24, 2015, shareholders approved a share loan plan for senior executives.

LTI for 2019 financial year

In addition to the aforementioned CEO Long Term Incentive Plan (Table 2, Operating and Financial Review), 82,391,668 share options were granted during fiscal 2019.

Remuneration of Key Management Personnel

Table 1: Employment Contracts

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

<u>Role</u>	<u>Name</u>	<u>Contract duration</u>	<u>Period of notice</u>	<u>Termination payments provided for by contract</u>
Chief Executive Officer (CEO and Executive Director)	Dr. Michael Perry	Open ended contract	12-month notice period	12 months
Chief Administrative Officer (CAO) and Interim Chief Financial Officer (CFO)	Timothy Rooney	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

Table 2: Remuneration for the year ended June 30, 2019

	Short-term Benefits				Post-employment Benefits	Equity-settled Share-based Payments		Total	Proportion of Element of Remuneration Related to Performance (Other than Options Issued – Note 2)		Proportion of Element of Remuneration Not Related to Performance (Note 3)
	Salary, fees and leave A\$	Profit share and bonuses (Note 1) A\$	Non-monetary benefits A\$	Other benefits A\$	Pension and superannuation A\$	Shares/ Units A\$	Options/ Rights A\$	A\$	Non-salary Cash-based Incentives %	Shares/ Units %	%
Non-Executive Directors											
Lou Panaccio Non-Executive Chairman	58,758	—	—	—	7,481	19,992	—	86,231	0%	0%	100%
Jeremy Curnock Cook	61,040	—	—	—	—	—	—	61,040	0%	0%	100%
Louis Drapeau Damien	60,811	—	—	—	—	—	—	60,811	0%	0%	100%
McDonald	—	—	—	—	—	61,128	—	61,128	0%	0%	100%
Suzanne Crowe	45,989	—	—	—	5,296	9,755	—	61,040	0%	0%	100%
Sub-total	226,598	—	—	—	12,777	90,875	—	330,250			
Other Key Management Personnel & Executives											
Michael Perry CEO (Note 4)	663,926	515,159	27,608	—	43,148	536,679	598,357	2,384,877	22%	27%	31%
Timothy Rooney CAO and Interim CFO	441,683	147,893	16,550	—	23,106	—	136,647	765,879	19%	0%	63%
Dale Sander CFO (Note 5)	379,908	246,299	31,660	270,450	23,193	—	80,727	1,032,237	24%	0%	68%
Erin Liberto CCO	398,353	147,893	41,897	—	22,530	—	207,097	817,770	18%	0%	57%
Andrew Quick CTO	403,853	119,723	36,807	—	23,592	—	181,914	765,889	16%	0%	61%
Donna Shiroma GC	419,319	117,519	13,632	—	27,075	—	230,284	807,829	13%	0%	52%
Sub-total	2,707,042	1,294,486	168,154	270,450	162,644	536,679	1,311,052	6,574,481			
Totals	2,933,640	1,294,486	168,154	270,450	175,421	627,554	1,311,052	6,904,731			

- (1) Profit share and bonuses are based upon the achievement of corporate goals, which are approved by the Board of Directors.
- (2) Non-salary cash-based incentives % is equal to profit share and bonuses divided by total compensation. Shares or units % is equal to shares or units divided by total compensation.
- (3) The percentage disclosed does not include the value of options expensed during the year or pension and superannuation benefits paid per the requirements of Corporations Act 2001. Thus, the sum of the percentages for compensation related to performance and compensation not related to performance disclosed for certain individuals may be less than 100%. Proportion of elements of remuneration not related to performance is equal to the sum of salary, fees and leave, non-monetary benefits, pension and superannuation and other compensation, divided by total compensation. As an example, for Dr. Michael Perry, this calculation would be as follows: (A\$663,926+A\$27,608+A\$43,148) / A\$2,384,877 = 31%.
- (4) On November 30, 2017, 50,000,000 Restrictive Stock Units, issued as part of a long-term incentive, or “LTI,” each equal to one ordinary share, were issued to Dr. Michael Perry based on the following milestones:
 - a. Tenure – a total of 16,666,666 LTIs issued but to vest over the three-year period commencing July 1, 2017;
 - b. Company Share Price – a total of 16,666,666 LTIs issued but to vest in three equal tranches subject to the Volume Weighted Average Price (VWAP) of Company share price (as at close of trade on the ASX on relevant date) achieving multiples of 2x, 3x and 4x the Company’s share price at the time of shareholder approval; and

Table of Contents

- c. Milestone performance – a total of 16,666,668 LTIs issued, but to vest in two equal tranches with one tranche to vest upon the achievement of the following milestones: (1) FDA PMA approval of RECELL for burns, and (2) Initial BARDA procurement under CLIN2 of the BARDA Contract.
- (5) Mr. Sander resigned as Chief Financial Officer effective May 15, 2019.

Table 3: Compensation of Key Management Personnel

	2019 A\$	2018 A\$	2017 A\$
Short-term employee benefits	4,396,280	3,770,141	2,933,510
Post-employment employee benefits	445,871	90,512	112,034
Share-based payment	2,062,580	1,596,368	1,215,809
Total compensation	6,904,731	5,457,021	4,261,353

Table 4: Option Holdings of Key Management Personnel

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

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

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

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

Other Equity-related Transactions with Key Management Personnel

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

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

- (a) *Tenure* – a total of 7,499,999 options issued for immediate vesting and over the two-year period commencing July 1, 2017;
- (b) *Company Share Price* – a total of 5,000,001 options issued but to vest in three equal tranches subject to the Volume Weighted Average Price (VWAP) of Company share price (as at close of trade on the ASX on relevant date) achieving multiples of 2x, 3x and 4x the Company's share price at the time of shareholder approval; and
- (c) *Milestone performance* – a total of 2,500,000 options issued, but to vest upon the achievement of initial BARDA procurement under CLIN2 of the BARDA Contract.

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

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

C. Board Practices

Introduction

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

Election of Directors

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

Corporate Governance

ASX Corporate Governance Principles

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

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

[Table of Contents](#)

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

1. Lay solid foundations for management and oversight. Companies should clearly delineate the respective roles and responsibilities of board and management and regularly review their performance.
2. Structure the Board to be effective and add value. Listed companies should have a board of an appropriate size and collectively have the skills, commitment and knowledge of the entity and the industry in which it operates, to enable it to discharge its duties effectively and to add value. During the year ended June 30, 2019, we did not follow this Recommendations in the following area:
 - a. No formal performance evaluation of the Board was conducted for the year ended June 30, 2018 as the Board believes that the Company is not of a size, nor is its our financial affairs of such complexity, to warrant such an exercise. The Board recognizes the importance of performance evaluations and will continually assess the necessity and timing of future performance evaluation.
3. Instill a culture of acting lawfully, ethically and responsibly. A listed entity should instill and continually reinforce a culture across the organization of acting lawfully, ethically and responsibly.
4. Safeguard the integrity of corporate reports. A listed entity should have appropriate processes to verify the integrity of its corporate reports
5. Make timely and balanced disclosure. A listed entity should promote timely and balanced disclosure of all material matters concerning it that a reasonable person would expect to have a material effect on the price or value of its securities. We adopted written policies designed to promote timely and balanced disclosure in accordance with ASX Listing Rule disclosure requirements for the year ending June 30, 2019. Our executive officers and members of our Board of Directors are aware of the obligations for continuous disclosure under the ASX Listing Rules and meet on a regular basis to ensure compliance.
6. Respect the rights of security holders. A listed entity should provide its security holders with appropriate information and facilities to allow them to exercise their rights as security holders effectively.
7. Recognize and manage risk. A listed entity should establish a sound system of risk management and periodically review the effectiveness of that framework.
8. Remunerate fairly and responsibly. A listed entity should pay director remuneration sufficient to attract and retain high quality directors and design its executive remuneration to attract, retain and motivate high quality senior executives and to align their interests with the creation of value for security holders and with the entity's values and risk appetite.

Non-Executive and Independent Directors

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

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

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

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

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

Committees of the Board of Directors

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

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

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

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

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

Directors’ Service Contracts

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

Indemnification of Directors and Officers

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

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

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

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

D. Employees

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

E. Share Ownership

Beneficial Ownership of Senior Management and Directors

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

F. Stock Option Plan

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

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

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

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

A summary of the status of the 2016 Plans and predecessor plans, as of June 30, 2019, 2018 and 2017, and the changes for the years ended on those dates, is presented below:

	2019		As of June 30, 2018		2017	
	Amount	Weighted average exercise price	Amount	Weighted average exercise price	Amount	Weighted average exercise price
Options outstanding at the beginning of the year	\$ 2,278,230	\$ 0.08	\$2,281,533	\$ 0.09	\$1,606,936	\$ 0.14
Granted	11,737,718	0.06	584,800	0.06	1,760,497	0.08
Exercised	(481,550)	0.07	—	—	—	—
Expired	—	—	(521,036)	0.13	(700,900)	0.14
Forfeiture	—	—	(67,067)	0.08	(385,000)	0.15
Options outstanding at the end of the year	<u>\$13,534,398</u>	<u>\$ 0.12</u>	<u>\$2,278,230</u>	<u>\$ 0.08</u>	<u>\$2,281,533</u>	<u>\$ 0.08</u>
Options exercisable at the end of the year	<u>\$ 2,264,774</u>	<u>\$ 0.07</u>	<u>\$ 914,139</u>	<u>\$ 0.09</u>	<u>\$ 438,639</u>	<u>\$ 0.09</u>

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information regarding shares of our common stock beneficially owned as of July 12, 2019 by: (i) each of our executive officers and directors; (ii) all the executive officers and directors as a group; and (iii) each person known by us to beneficially own five percent or more of the outstanding ordinary shares.

<u>Name of Beneficial Owner</u>	<u>Ordinary Shares</u>	<u>Options to Purchase Ordinary Shares Exercisable Within 60 Days</u>	<u>Restricted Security Units (RSUs) Vested or Vesting Within 60 Days</u>	<u>Total Share and Share-Based Holdings(1)</u>	<u>% Ownership(2)</u>
5% or more shareholders					
Redmile Group, LLC(1)	232,590,853	—	—	232,590,853	12.42%
Karst Peak Capital Limited(2)	156,015,827	—	—	156,015,827	8.3%
Blackcrane Capital, LLC(3)	164,724,549	—	—	164,724,549	8.81%
Names executive officers and directors					
Lou Panaccio	2,006,536	—	—	2,006,536	*
Dr. Michael Perry(4)	61,654	10,833,333	36,111,109	47,006,096	2.5%
Erin Liberto	—	2,050,000	—	2,050,000	*
Timothy Rooney	—	5,552,500	—	5,552,500	*
Andrew Quick	—	4,341,563	—	4,341,563	*
Donna Shiroma	—	—	—	—	*
Jeremy Curnock Cook(4)	—	—	—	—	*
Louis Drapeau	33,938	—	—	33,938	*
Damien McDonald	1,631,074	—	—	1,631,074	*
Professor Suzanne Crowe	304,617	—	—	304,617	*
All executive officers and directors as a group (10 persons)	4,037,819	22,777,396	36,111,109	62,926,324	3.4%

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

- (1) Consists of 79,317,007 ordinary shares held by Redmile Offshore II Master Fund Ltd., 84,138,646 ordinary shares held by Redmile Strategic Master Fund LP. Redmile Group, LLC is the investment manager/adviser of Redmile Offshore II Master Fund Ltd. and Redmile Strategic Master Fund LP. 45,385,600 ordinary shares held by Redmile Capital Offshore Master Fund Ltd, 18,076,000 ordinary shares held by Redmile Capital Fund LP and 5,673,600 ordinary shares held by a segregated portfolio of LMA SPC. Based solely on disclosures provided by Redmile Group, LLC to the ASX, these ordinary shares are owned by certain investment limited partnerships, pooled investment vehicle(s), separately managed accounts, etc. for which Redmile Group, LLC serves as the general partner and/or investment manager. Jeremy Green, as the majority managing member and owner of Redmile Group, LLC, may be deemed to beneficially own securities owned by such investment limited partnerships, pooled investment vehicle(s), separately managed accounts, etc. The principal business address of each of Redmile Group, LLC and Mr. Green is One Letterman Drive, Bldg. D, Ste D3-300, San Francisco, CA 94129.
- (2) Consists of 92,049,522 ordinary shares held by Karst Peak Asia Master Fund and 63,966,305 ordinary shares held by Vermilion Peak Fund. Karst Peak Capital Limited is the discretionary investment manager to Karst Peak Asia Master Fund and Vermilion Peak Fund. Based solely on disclosures provided by Karst Peak Capital Limited (KCPL) to the ASX, Adam Leitzes is the director of KPCL and may be deemed to have both voting power and disposal power over the shares. The address for KPCL is Kinwick Centre, Suite 1705, 32 Hollywood Road, Central, Hong Kong.
- (3) Consists of 64,137,329 ordinary shares and 5,029,361 ADSs, each ADS representing 20 ordinary shares or 100,587,220 ordinary shares in total underlying the ADSs. Blackcrane Capital, LLC holds 63,937,019 ordinary shares and 4,941,021 ADSs, Blackcrane Overseas Alpha Fund, LLC holders 570,650 ordinary shares and 11,099 ADSs, with 221,980 ordinary shares underlying the ADSs. Blackcrane Capital, LLC is the discretionary investment manager of Blackcrane Overseas Alpha Fund, LLC. Daniel Kim holds 49,823 ADSs with 996,460 ordinary shares underlying the ADSs. Mr. Kim has a relevant interest in the securities held by Blackcrane Capital, LLC and Blackcrane Overseas Alpha Fund as he holds voting power of more than 20% in Blackcrane Capital, LLC. The address of Blackcrane Capital, LLC is 500 108th Avenue NE, STE 960, Bellevue, WA 98004.
- (4) Excludes 69,147,669 ordinary shares held in the name of One Funds Management Limited (Asia Pac Health Fund II A/C) which is managed and beneficially owned by BioScience Managers Pty Ltd of which Mr. Curnock Cook is an officer and Dr. Perry is a Director.

[Table of Contents](#)

As of July 12, 2019, 17.1% of our ordinary shares were held in Australia, 10% of our ordinary shares were held in Hong Kong, 53.3% of our ordinary shares were held in the United States including ordinary shares underlying ADSs.

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

B. Related Party Transactions

Other than employment matters and indemnification agreements between our directors and executive officers, related party transactions were limited to director fees, consultancy fees and travel reimbursements paid under normal terms and conditions to Bioscience Managers Pty Ltd of which Jeremy Curnock Cook is an officer and Dr. Michael Perry is a director. Consultancy services provided were assistance in product development, customer relations, recruitment and sales by Dr. Perry prior to becoming an officer of the Company in June 2017, as well as one other employee of Bioscience Managers Pty Ltd. Total fees paid to Bioscience Managers Pty Ltd were A\$85,374, A\$157,728 and A\$128,987 for the years ended June 30, 2019, 2018 and 2017, respectively.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

Our audited financial statements for the fiscal years ending June 30, 2019, 2018, and 2017 are included in Item 18 of this annual report on Form 20-F.

Legal Proceedings

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

Dividend Distribution Policy

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

B. Significant Changes

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

Subsequent to June 30, 2018 the Company completed a series of equity transactions in which the Company received a total of A\$45,014,900 in gross proceeds. During the year ended June 30, 2018 the Company completed an institutional placement of shares to international and Australian institutional and sophisticated investors. The institutional placement included a second tranche totaling A\$3,250,000 of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on July 23, 2018, and the net proceeds of A\$3,041,000 were received by the Company on July 26, 2018. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on July 23, 2018, and the Company issued 65,000,000 shares at a price of A\$0.050 per share and received gross proceeds of A\$3,250,000 on July 26, 2018. Also subsequent to year end, on December 4, 2018 the Company completed the first tranche of an institutional placement of in which it issued 310,047,015 fully paid ordinary shares at a price of A\$0.080 per share raising gross proceeds of A\$24,803,761. The institutional placement included a second tranche totaling A\$15,196,000 of gross proceeds, contingent upon shareholder approval. Shareholder approval for Tranche 2 was received at an Extraordinary General Meeting held on January 14, 2019, and the Company issued 189,952,985 shares at a price of A\$0.080 per share and received gross proceeds of A\$15,196,239 on January 14, 2019. In addition, on January 11, 2019 the Company complete a Share Purchase Plan under which it issued 22,061,250 shares of stock at a price of A\$0.080 per share and received gross proceeds of A\$1,764,900.

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

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ordinary shares have traded on the Australian Securities Exchange Ltd., or ASX, under the ticker symbol “AVH” since our initial public offering on September 8, 1993. Our ADSs traded over the counter in the U.S. on the OTCQX under the ticker symbol “AVMXY” from May 14, 2012 through September 30, 2019. Beginning on October 1, 2019 our ADSs trade on the NASDAQ Capital Market under the ticker symbol “RCEL”.

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares have traded on the Australian Securities Exchange Ltd., or ASX, under the ticker symbol “AVH” since our initial public offering on September 8, 1993. Our ADSs traded over the counter in the U.S. on the OTCQX under the ticker symbol “AVMXY” from May 14, 2012 through September 30, 2019. Beginning on October 1, 2019 our ADSs trade on the NASDAQ Capital Market under the ticker symbol “RCEL”. Our ADSs each represent 20 Ordinary Shares and are evidenced by American Depositary Receipts, or ADRs. The ADRs were issued pursuant to a Depositary Agreement entered into with The Bank of New York Mellon.

D. Selling Shareholders

Not Applicable.

E. Dilution

Not Applicable.

F. Expenses of the Issue.

Not Applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

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

As at June 30, 2019 and 2018, we had 1,871,299,575 and 934,312,458 Ordinary Shares issued, outstanding and fully paid, respectively.

Ordinary Shares

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

Options

The Company has 113,679,371 share options outstanding at the date of this annual report and 280,932,725 share options available for future grant.

[Table of Contents](#)

History of Share Capital

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

Date	Description of Issuance	Number of Ordinary Shares Issued	Total (A\$)
January 11, 2019	We sold 22,061,250 Ordinary Shares under a Share Purchase Plan at a price of A\$0.080 per share, raising gross proceeds of A\$1,764,900.	22,061,250	A\$ 1,764,900
December 4, 2018	We sold 500,000,000 Ordinary Shares to institutional investors at a price of A\$0.080 per share, raising gross proceeds of A\$40,000,000 and incurring A\$2,923,858 in expenses.	500,000,000	A\$40,000,000
June 6, 2018	We sold 320,475,665 Ordinary Shares to institutional investors at a price of A\$0.050 per share, raising gross proceeds of A\$16,023,783 and incurring A\$1,042,720 in expenses.	320,475,665	A\$16,023,783
November 7, 2017	We sold 276,502,853 Ordinary Shares in a rights offering at a price of A\$0.045 per share raising gross proceeds of A\$12,442,628 and incurring A\$636,067 in expenses.	276,502,853	A\$12,442,628
October 11, 2017	We sold 100,982,978 Ordinary Shares at a price of A\$0.045 per share raising gross proceeds of A\$4,544,234 and incurring A\$248,720 in expenses.	100,982,978	A\$ 4,544,234
July 11, 2016	We sold 100,164,831 Ordinary Shares at a price of A\$0.09 per share raising gross proceeds of A\$9,048,102 and incurring A A\$506,452 in expenses.	100,164,831	A\$ 9,048,102

B. Memorandum and Articles of Association

General

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

Objects and Purposes

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

The Powers of the Directors

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

Management of Company

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

Specific powers of Directors

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

Other Provisions in the Constitution with Respect to the Directors

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

[Table of Contents](#)

Under the provisions of our Constitution, the non-executive directors may be remunerated for their services as directors (up to a maximum aggregate amount as determined approved by the Shareholders in general meeting) in individual amounts as determined by the Board. The remuneration of both non-executive and executive directors must comply with the Corporations Act and the Listing Rules. The Listing Rules provide that a company must not increase the total amount of non-executive directors' fees payable by it without the approval of its shareholders. The Corporations Act places a limit upon the level of termination benefits that can be paid to a person who holds a managerial or executive office upon that person's retirement from that office or position.

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

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

Members to Approve Significant Changes to Company Activities

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

Rights, Preferences and Restrictions Attached to Our Ordinary Shares

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

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

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

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

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

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

Changing Rights Attached to Shares

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

Annual and Extraordinary General Meetings

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

Limitations on the Rights to Own Securities in Our Company

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

Ownership Threshold Above Which Shareholder Ownership Must be Disclosed

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

Changes in Our Capital

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

C. Material Contracts

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

BARDA Contract

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

Under the contract, we have agreed to undertake, and BARDA have agreed to fund and provide technical support for, the development of the RECELL System including two randomized, controlled pivotal clinical trials, Compassionate Use and Continued Access programs, development of the health economic model demonstrating the cost savings associated with the RECELL System, and two randomized, controlled clinical trials in pediatric burn patients. Also included in the BARDA contract is provision for the future procurement of the RECELL System by BARDA under a vendor-managed inventory system to bolster disaster preparedness in the amount of US\$7.6 million (approximately A\$10.3 million), although BARDA has the option of increasing the amount of the procurement. As of June 30, 2019, we had received cumulative payments of A\$20.24 million under the BARDA contract.

D. Exchange Controls and Australian Tax Matters

Exchange Controls

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

The Foreign Acquisitions and Takeovers Act 1975

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

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

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

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

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

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

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

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

[Table of Contents](#)

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

The Financial Transactions Reports Act 1988

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

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

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

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

Taxation of Dividends for Non-Australian Resident Shareholders

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

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

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

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

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

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

Capital Gains Tax

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

[Table of Contents](#)

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

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

Stamp Duty

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

Australian Death Duty

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

Goods and Services Tax

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

E. U.S. Federal Income Tax Considerations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we are a passive foreign investment company for any taxable year during which a U.S. Holder has an equity interest in our company, unless the U.S. Holder makes a mark-to-market election as discussed below, such U.S. Holder will be subject to special tax rules in any future taxable year regardless of whether we are classified as a passive foreign investment company in such future years with respect to (a) "excess distributions" and (b) gain from the disposition of stock. Excess distributions are defined generally as the excess of the amount received with respect to the equity interests in the taxable year over 125% of the average annual distributions received in the shorter of either the three previous years or a U.S. Holder's holding period before the taxable year and must be allocated pro-rata to each day of the U.S. Holder's holding period. The amount allocated to the current taxable year or any year before we became a passive foreign investment company will be included as ordinary income in a U.S. Holder's gross income for that year. The amount allocated to other prior taxable years will be taxed as ordinary income at the highest rate in effect for a U.S. Holder in that prior year and the tax is subject to an interest charge at the rate applicable to deficiencies in income taxes. The entire amount of any gain realized upon the sale or other disposition of the equity interests will be treated as an excess distribution made in the year of sale or other disposition and as a consequence will be treated as ordinary income and, to the extent allocated to years prior to the year of sale or disposition with respect to which we were a passive foreign investment company, will be subject to the interest charge described above.

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

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

[Table of Contents](#)

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

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

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

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

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

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

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

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

[Table of Contents](#)

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

I. Subsidiary Information

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

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Please see the Company’s audited financial statements for the year ended June 30, 2019, at Item 18 under Note 19 “Financial Risk management Objectives and Policies” for a description of interest rate risk, foreign currency risk, credit risk and liquidity risk and how such risks affect the Company.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. American Depositary Shares

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

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

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

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

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

Dividends and Other Distributions

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

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

[Table of Contents](#)

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

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

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

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

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

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

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

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

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

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

Voting Rights

How do you vote?

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

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

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

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

Fees and Expenses

*Persons depositing or withdrawing shares
or ADS holders must pay:*

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$.05 (or less) per ADS

A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

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

Registration or transfer fees

For:

Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property

Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates

Any cash distribution to ADS holders

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

Depositary services

Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares

Table of Contents

Persons depositing or withdrawing shares or ADS holders must pay:

Expenses of the depositary

For:

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

Converting foreign currency to U.S. dollars

Taxes and other governmental charges the depositary or the custodian have to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

As necessary

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

As necessary

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

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

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

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

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

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

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

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

[Table of Contents](#)

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

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

Amendment and Termination

How may the deposit agreement be amended?

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

How may the deposit agreement be terminated?

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

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

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

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

Limitations on Obligations and Liability

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

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

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe, or it believes in good faith to be genuine and to have been signed or presented by the proper person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

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

Requirements for Depositary Actions

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

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

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

Your Right to Receive the Shares Underlying your ADSs

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

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

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

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depository of prior authorization from the ADS holder to register that transfer.

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

Shareholder communications; inspection of register of holders of ADSs

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

Jury Trial Waiver

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

D. Other Securities

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

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

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, including our chief executive officer and our chief financial officer, is responsible for establishing and maintaining our disclosure controls and procedures (within the meaning of Rule 13a-15(e) of the Exchange Act). These controls and procedures were designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC and that such information was accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. A material weakness was identified in our internal control over financial reporting relating to the application of tax legislation across jurisdictions, specifically our controls over tracking and monitoring the disclosures related to accumulated tax losses by jurisdiction.

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

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

Management's Annual Report on Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of June 30, 2019 has not been audited by our registered public accounting firm due to an exemption for emerging growth companies provided in the JOBS Act.

Changes in Internal Control over Financial Reporting

During the year ended June 30, 2019, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. RESERVED

Not applicable.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our Board of Directors has determined that Mr. Louis Drapeau is an “audit committee financial expert” as defined in Item 16A of Form 20-F and qualifies as an “independent director” in accordance with applicable Exchange Act rules and Nasdaq rules. For a brief listing of Mr. Drapeau’s relevant experience, see Item 6.A. “Directors, Senior Management and Employees—Directors and Senior Management.”

ITEM 16B. CODE OF ETHICS

We have adopted a Code of Conduct, or the Code, that applies to our executive officers and persons performing similar functions. The Code has been posted on our website, 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 or 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.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Grant Thornton Audit Pty Ltd, independent registered public accountants has served as our independent public accountant for each of the years in the two-year period ended June 30, 2019. The following table presents the aggregate fees for professional audit services and other services rendered by Grant Thornton in the years indicated.

	Year Ended June 30,	
	2019	2018
Audit fees (1)	A\$256,462	A\$ 82,440
Tax service fees(2)	65,318	46,811
Total	<u>A\$321,780</u>	<u>A\$ 229,251</u>

- (1) Audit fees consist of fees billed for the annual audit of the Company’s consolidated financial statements and the statutory financial statements of the Company. They also include fees billed for other audit services, which are those services that only the external auditor reasonably can provide, such as the provision of consents and the review of documents filed with the SEC.
- (2) Tax services fees include fees billed for tax compliance services, including professional services rendered for tax compliance and tax advice, other than in connection with tax audit. Tax compliance involves audit of original and amended tax returns, tax planning and tax advice.

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

Not applicable.

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

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT’S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

We are a foreign private issuer whose ADSs are listed on the Nasdaq Capital Market. As such, we are required to comply with U.S. federal securities laws, including the Nasdaq rules regarding corporate governance requirements. The Nasdaq rules provide that foreign private issuers may follow home country practice in lieu of certain qualitative listing requirements subject to certain exceptions and except to the extent that such exemptions would be contrary to U.S. federal securities laws, so long as the foreign issuer discloses that it does not follow such listing requirement and describes the home country practice followed in its reports filed with the SEC. Below is a concise summary of the significant ways in which our corporate governance practices differ from the corporate governance requirements of Nasdaq applicable to domestic U.S. listed companies:

NASDAQ rules require that the quorum required for a meeting of shareholders be not be less than 33 1/3 percent of the outstanding shares of the Company's ordinary shares, however, we intend to follow our home-country corporate governance practices with respect to quorum, and as a result, the quorum required for an ordinary meeting of shareholders will consist of at least three shareholders present in person, or by proxy, attorney or representative appointed pursuant to our Constitution.

We intend to follow our home country practice with respect to voting procedures at general meetings of our shareholders. At any general meeting of shareholders, a resolution put to the vote of the meeting must be decided on a show of hands unless a poll is effectively demanded, and the demand is not withdrawn. On a show of hands, each member present in person and each other person present as a proxy, attorney or representative of a member has one vote. On a poll, each member present in person has one vote for each share held by the member and each person present as proxy, attorney or representative of a member has one vote for each share held by such member that the person represents.

ITEM 16H. MINE SAFETY DISCLOSURES

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

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

- audited consolidated financial statements of the Company for the years ended June 30, 2019, 2018 and 2017, prepared in accordance with IFRS as issued by the IASB, including: consolidated statements of profits or loss and other comprehensive loss, consolidated statements of financial position, consolidated statements of cash flows, consolidated statements of changes in equity and notes to the consolidated financial statements.

ITEM 18. FINANCIAL STATEMENTS

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

ITEM 19. EXHIBITS

The following exhibits are filed as part of this annual report on Form 20-F:

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

Table of Contents

Exhibit	Description
8.1*	List of subsidiaries of the registrant
12.1**	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
12.2**	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
13.1***	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350
13.2***	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350

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

SIGNATURES

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

Avita Medical Limited

/s/ Michael Perry

By: Michael Perry

Title: Chief Executive Officer

Date: October 31, 2019

INDEX TO THE FINANCIAL STATEMENTS

Avita Medical Limited

INDEX TO AUDITED CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED JUNE 30, 2019, 2018 AND 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	F-2
CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE LOSS FOR THE YEARS ENDED JUNE 30, 2019, 2018 AND 2017	F-3
CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS OF JUNE 30, 2019 AND 2018	F-4
CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEAR ENDED JUNE 30, 2019, 2018 AND 2017	F-5
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY AS OF JUNE 30, 2019, 2018 AND 2017	F-6 to F-8
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED JUNE 30, 2019, 2018 AND 2017	F-9 to F-57

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Avita Medical Ltd.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Avita Medical Ltd. and subsidiaries (the “Company”) as of June, 30 2019 and 2018, the related consolidated statements of comprehensive income, changes in shareholders’ equity, and cash flows for each of the three years in the period ended June 30, 2019 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2019, in conformity with International Financial Reporting Standards, as issued by the International Accounting Standards Board.

Basis for opinion

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

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

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

/s/ GRANT THORNTON AUDIT PTY LTD

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

Sydney, New South Wales
October 31, 2019

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

	Notes	2019	2018	2017
Continuing operations				
Sale of goods	4	A\$ 7,705,398	A\$ 1,198,861	A\$ 901,376
Cost of sales	4	(1,697,823)	(511,646)	(463,285)
Gross profit		6,007,575	687,215	438,091
BARDA income	4	8,259,152	10,104,081	6,886,236
Other income	4	456,695	68,617	344,734
Total other income		8,715,847	10,172,698	7,230,970
Operating costs				
Sales and marketing expenses		(17,576,754)	(8,936,441)	(5,201,761)
Corporate and administrative expenses		(15,398,177)	(5,360,553)	(2,264,594)
Product development expenses		(14,361,995)	(12,606,127)	(11,161,970)
Share based payment expenses	17	(2,688,817)	(1,835,157)	(1,587,243)
Finance costs	4	(37,769)	(26,586)	(12,754)
Total operating costs		(50,063,512)	(28,764,864)	(20,228,322)
Loss from continuing operations before income tax benefit				
		(35,340,090)	(17,904,951)	(12,559,261)
Income tax benefit	6	179,863	1,385,796	1,048,237
Loss for the period	5	(35,160,227)	(16,519,155)	(11,511,024)
Other comprehensive income				
<i>Items that may be reclassified subsequently to profit and loss:</i>				
Foreign currency translation		1,783,222	563,279	(83,293)
Fair value gain on available for sale financial assets		—	—	(265,261)
Other comprehensive income for the period, net of tax		1,783,222	563,279	(348,554)
Total other comprehensive loss for the period		A\$ (33,377,005)	A\$ (15,955,876)	A\$ (11,859,578)
Loss for the period attributable to owners of the parent		(35,160,227)	(16,519,155)	(11,511,024)
Total comprehensive loss attributable to owners of the parent		A\$ (33,377,005)	A\$ (15,955,876)	A\$ (11,859,578)
Basic loss per share attributable to ordinary equity holders of the parent	5	A\$ (2.78) cents	A\$ (1.77) cents	A\$ (1.72) cents
Diluted loss per share attributable to ordinary equity holders of the parent	5	A\$ (2.78) cents	A\$ (1.77) cents	A\$ (1.72) cents

The accompanying notes form part of the consolidated financial statements.

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

	Notes	2019	2018
ASSETS			
Current Assets			
Cash and cash equivalents	7	A\$ 28,983,491	A\$ 14,825,532
Trade and other receivables	8	2,980,102	5,437,357
Prepayments and other assets		1,557,525	855,716
Inventories	9	1,057,764	1,155,826
Total Current Assets		34,578,882	22,274,431
Non-Current Assets			
Plant and equipment	10	1,838,515	742,583
Patents-in-progress		320,676	—
Total Non-Current Assets		2,159,191	742,583
TOTAL ASSETS		A\$ 36,738,073	A\$ 23,017,014
LIABILITIES			
Current Liabilities			
Trade and other payables	11	5,633,562	3,487,582
Provisions	12	650,359	395,535
Total Current Liabilities		6,283,921	3,883,117
Non-Current liabilities			
Contract liability		610,674	—
Finance lease		54,057	134,338
Total Non-Current liabilities		664,731	134,338
TOTAL LIABILITIES		A\$ 6,948,652	A\$ 4,017,455
NET ASSETS		A\$ 29,789,421	A\$ 18,999,559
EQUITY			
Equity attributable to equity holders of the parent:			
Contributed equity	13	204,279,078	162,801,028
Accumulated losses	14	(183,753,106)	(148,592,879)
Reserves		9,263,449	4,791,410
TOTAL EQUITY		A\$ 29,789,421	A\$ 18,999,559

The accompanying notes form part of the consolidated financial statements.

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

	Notes	2019	2018	2017
Cash flows from operating activities				
Payments to suppliers and employees		A\$ (46,420,307)	A\$ (25,681,347)	A\$ (17,676,710)
Interest paid		—	(26,586)	(12,754)
BARDA receipts and other income received		10,056,537	8,206,863	7,094,061
Receipts from customers		5,826,634	1,129,046	928,687
R&D tax refund received		2,440,803	—	972,283
Contract liability		610,674	—	—
Interest received		—	—	123,709
Government grants received		—	—	13,200
Net cash flows used in operating activities	15	(27,485,659)	(16,372,024)	(8,557,524)
Cash flows from investing activities				
Payments for plant and equipment	10	(1,473,934)	(498,749)	(432,592)
Payments for intellectual property		(320,676)	—	—
Proceeds from the sale of financial assets		—	—	627,837
Net cash flows (used in) provided by investing activities		(1,794,610)	(498,749)	195,245
Cash flows from financing activities				
Proceeds from issuance of shares and options		45,036,886	29,760,563	9,048,102
Proceeds from exercise of share options		452,809	—	—
Capital raising expenses		(4,192,519)	(1,825,643)	(506,452)
Purchase of finance leased asset		—	—	(303,521)
Net cash flows provided by financing activities		41,297,176	27,934,920	8,238,129
Net increase (decrease) in cash and cash equivalents		12,016,907	11,064,147	(124,150)
Cash and cash equivalents at beginning of period		14,825,532	3,790,491	4,171,879
Impact of foreign exchange		2,141,052	(29,106)	(257,238)
Cash and cash equivalents at end of period	7	A\$ 28,983,491	A\$ 14,825,532	A\$ 3,790,491

The accompanying notes form part of the consolidated financial statements.

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

	Contributed equity	Accumulated losses	Share-based payment reserve	Foreign currency translation reserve	Total
At July 1, 2018	A\$ 162,801,028	A\$ (148,592,879)	A\$ 4,505,148	A\$ 286,262	A\$ 18,999,559
Loss for the period	—	(35,160,227)	—	—	(35,160,227)
Other comprehensive income					
Foreign currency translation	—	—	—	1,783,222	1,783,222
Total comprehensive loss for the year	—	(35,160,227)	—	1,783,222	(33,377,005)
<i>Transactions with owners in their capacity as owners</i>					
Expired options	—	—	(32,362)	—	(32,362)
Share based payments	—	—	2,721,179	—	2,721,179
New shares	45,580,570	—	—	—	45,580,570
Cost of share placement	(4,102,520)	—	—	—	(4,102,520)
Balance at June 30, 2019	A\$ 204,279,078	A\$ (183,753,106)	A\$ 7,193,965	A\$ 2,069,484	A\$ 29,789,421

The accompanying notes form part of the consolidated financial statements.

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

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

The accompanying notes form part of the consolidated financial statements.

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

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

The accompanying notes form part of the consolidated financial statements.

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

1. CORPORATE INFORMATION

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

The nature of the operations and principal activities of the Company are described in the Directors' Report.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

a) Basis of preparation and statement of compliance

The consolidated financial statements are general purpose consolidated financial statements that have been prepared in accordance with the requirements of the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). The Company's consolidated financial statements include the assets and liabilities of all subsidiaries of the Company as at June 30, 2019 and the results of the subsidiaries for the year then ended. Inter-entity transactions with, or between, subsidiaries are eliminated in full on consolidation.

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

b) New Standards adopted as at July 1, 2018

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

IFRS 15 Revenue from Contracts with Customers

IFRS 15 Revenue from Contracts with Customers and the related Clarifications to IFRS 15 Revenue from Contracts with Customers (hereinafter referred to as 'IFRS 15') replace IFRS 118 Revenue, IFRS 111 Construction Contracts, and several revenue-related Interpretations. The new Standard has been applied retrospectively without restatement, with the cumulative effect of initial application recognized as an adjustment to the opening balance of retained earnings at July 1, 2018. In accordance with the transition guidance, IFRS 15 has only been applied to contracts that are incomplete as at January 1, 2018.

While this represents significant new guidance, the implementation of this new guidance did not have a significant impact on the timing or amount of revenue recognized by the Company in any year.

IFRS 9 Financial Instruments

IFRS 9 replaces IFRS 139 'Financial Instruments: Recognition and Measurement'. It makes major changes to the previous guidance on the classification and measurement of financial assets and introduces an 'expected credit loss' model for the impairment of financial assets.

When adopting IFRS 9, the Company has applied transitional relief and opted not to restate prior periods. Differences arising from the adoption of IFRS 9 in relation to classification, measurement, and impairment are recognized in retained earnings.

The adoption of IFRS 9 has impacted the impairment of financial assets applying the expected credit loss model. This affects the Company's trade receivables and investments in debt-type assets measured at amortized cost. For contract assets arising from IFRS 15 and trade receivables, the Company applies a simplified model of recognizing lifetime expected credit losses as these items do not have a significant financing component.

While this represents significant new guidance, the implementation of this new guidance did not have an impact on the recognition and measurement of financial instruments outside the areas described above.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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

At the date of authorization of these financial statements, several new, but not yet effective, Standards, amendments to existing Standards, and Interpretations have been published by the IASB. None of these Standards, amendments or Interpretations has been adopted early by the Company.

Management anticipates that all relevant pronouncements will be adopted for the first period beginning on or after the effective date of the pronouncement. New Standards, amendments and Interpretations neither adopted nor listed below have not been disclosed as they are not expected to have a material impact on the Company's financial statements.

IFRS 16 Leases

IFRS 16 will replace IFRS 117 'Leases' and three related Interpretations. It completes the IASB's long-running project to overhaul lease accounting. Leases will be recorded in the statement of financial position in the form of a right-of-use asset and a lease liability. There are two important reliefs provided by IFRS 16 for assets of low value and short-term leases of less than 12 months.

IFRS 16 is effective from periods beginning on or after July 1, 2019. Early adoption is permitted; however, the Company have decided not to early adopt.

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

- lease assets and financial liabilities on the balance sheet will increase by A\$1,599,724 and A\$1,725,540 respectively (based on the facts at the date of the assessment),
- there will be a reduction in the reported equity as the carrying amount of lease assets will reduce more quickly than the carrying amount of lease liabilities,
- Loss for the period in the statement of profit or loss and other comprehensive income will be higher as the implicit interest in lease payments for former off-balance sheet leases will be presented as part of finance costs rather than being included in operating expenses,
- operating cash outflows will be lower and financing cash flows will be higher in the statement of cash flows as principal repayments on all lease liabilities will now be included in financing activities rather than operating activities. Interest can also be included within financing activities.

The Company will adopt IFRS 16 effective July 1, 2019 using the Standard's modified retrospective approach. Under this approach, the cumulative effect of initially applying IFRS 16 is recognized as an adjustment to equity at the date of initial application. Comparative information is not restated.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(c) Basis of consolidation

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

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

(d) Segment reporting

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

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

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

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

(e) Revenue recognition

Revenue is recognized at a point in time based on the fixed invoice price when the Company satisfies performance obligations by transferring the promised goods or services to its customers.

To determine whether to recognize revenue, the Company follows a 5-step process:

1. Identifying the contract with a customer
2. Identifying the performance obligations
3. Determining the transaction price
4. Allocating the transaction price to the performance obligations
5. Recognizing revenue when/as performance obligation(s) are satisfied.

The Company recognizes contract liabilities for consideration received in respect of unsatisfied performance obligations and reports these amounts as contract liabilities in the statement of financial position. Similarly, if the Company satisfies a performance obligation before it receives the consideration, the Company recognizes either a contract asset or a receivable in its statement of financial position, depending on whether something other than the passage of time is required before the consideration is due.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(e) Revenue recognition (continued)

Sale of goods – RECELL

Revenue is earned (constrained by variable considerations, which include returns and volume rebates) from the sale of RECELL products. Sales are recognized when performance obligations are satisfied at a point in time. Generally, the supply of product under a contract will represent the satisfaction of a performance obligation at a point in time, which is when control of the product passes to the customer.

Estimates on sales returns are performed by management using inputs which include historical returns and customer sales data amongst other factors.

RECELL is often sold with respective volume rebates based on aggregated sales over a 12-month period. Revenue from these sales is recognized based on the price specified in the contract, net of estimated volume rebates. Accumulated experience is used to estimate and provide for the discounts, using the expected value method, and revenue is only recognized to the extent that it is highly probable that a significant reversal will not occur. A refund liability (trade and other payables) is recognized for expected volume rebates payable to customers in relation to sales made until the end of the reporting period. The Company's obligation to repair or replace faulty products under the standard warranty terms is recognized as a provision.

Revenue recognition (Comparative period June 30, 2018)

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

Sale of goods

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

Interest income

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

(f) Government and other grants

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

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

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

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(g) Leases

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

Company as a lessee

Finance leases, which transfer to the Company substantially all the risks and benefits incidental to ownership of the leased item, are capitalized at the inception of the lease at the fair value of the leased asset or, if lower, at the present value of the minimum lease payments. Lease payments are apportioned between the finance charges and reduction of the lease liability to achieve a constant rate of interest on the remaining balance of the liability. Finance charges are recognized as an expense in profit or loss.

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

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

(h) Cash and cash equivalents

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

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(i) Inventories

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

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

(j) Foreign currency translation

Functional and presentational currency

Both the functional and presentational currency of Avita Medical Limited and its Australian subsidiaries is Australian dollars (A\$). The United Kingdom's subsidiary's functional currency is Pound Sterling and the United States' subsidiary's functional currency is United States Dollars. These are translated to the presentational currency (see below).

Transactions and balances

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

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

Translation of the Company functional currency to presentational currency

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

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

(k) Income tax and other taxes

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

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

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

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(k) Income tax and other taxes (continued)

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

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

The carrying amount of deferred income tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilized.

Unrecognized deferred income tax assets are reassessed at each reporting date and are recognized to the extent that it has become probable that future taxable profit will allow the deferred tax asset to be recovered.

Deferred income tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realized, or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax assets and deferred tax liabilities are offset only if a legally enforceable right exists to set off current tax assets against current tax liabilities and the deferred tax assets and liabilities relate to the same taxable entity and the same taxation authority.

Tax consolidation legislation

Avita Medical Limited and its wholly owned Australian controlled entities implemented the tax consolidation legislation as of July 1, 2003.

The parent entity, Avita Medical Limited, and the controlled entities in the tax consolidated company continue to account for their own current and deferred tax amounts. The Company has applied the company allocation approach in determining the appropriate amount of current taxes and deferred taxes to allocate to members of the tax consolidated company.

In addition to its own current and deferred tax amounts, Avita Medical Limited also recognizes the current tax liabilities (or assets) and the deferred tax assets arising from unused tax losses and unused tax credits assumed from controlled entities in the tax consolidated company.

Assets or liabilities arising under tax funding agreements with the tax consolidated entities are recognized as amounts receivable from or payable to other entities in the Company.

Any difference between the amounts assumed and amounts receivable or payable under the tax funding agreement are recognized as a contribution to (or distribution from) wholly owned tax consolidated entities.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(k) Income tax and other taxes (continued)

Other Taxes

Revenues, expenses and assets are recognized net of the amount of GST except:

- when the GST incurred on a purchase of goods and services is not recoverable from the taxation authority, in which case the GST is recognized as part of the cost of acquisition of the asset or as part of the expense item as applicable; and
- receivables and payables, which are stated with the amount of GST included.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the consolidated statement of financial position.

Cash flows are included in the consolidated statement of cash flows on a gross basis and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the taxation authority is classified as part of operating cash flows.

Commitments and contingencies are disclosed net of the amount of GST recoverable from, or payable to, the taxation authority.

(l) Plant and equipment

The Company's fixed assets are stated at cost less accumulated depreciation and any accumulated impairment losses. Depreciation is computed based on the straight-line method over the estimated useful lives of the various classes of assets. The ranges of estimated useful lives for the principal classes of assets are as follows:

Laboratory equipment – 5 years

Computer equipment – 5 years

Fixtures and fittings – 7 years

The Company reviews its long-lived assets for impairment annually, or when events or changes in circumstances indicate that the carrying amount is greater than the recoverable amount. Recoverable amount is the "higher of" (i) fair value less costs of disposal and (ii) value-in-use. The excess of the carrying amount over its fair value is charged as impairment loss to profit and loss account.

Repairs and maintenance are recognized in profit or loss during the financial period in which they are incurred. Gains and losses on disposal are determined by comparing the proceeds on disposal with the carrying amount and are included in profit or loss.

(m) Interest-bearing loans and borrowings

All loans and borrowings are initially recognized at the fair value of the consideration received less directly attributable transaction costs.

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest method. Fees paid on the establishment of loan facilities that are yield related are included as part of the carrying amount of the loans and borrowings.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(n) Interest-bearing loans and borrowings (continued)

Borrowings are classified as current liabilities unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the reporting date.

Borrowing costs

Borrowing costs, other than borrowing costs relating to qualifying assets, are recognized as an expense when incurred.

(o) Financial Instruments

Recognition and derecognition

Financial assets and financial liabilities are recognized when the Company becomes a party to the contractual provisions of the financial instrument.

Financial assets are derecognized when the contractual rights to the cash flows from the financial asset expire, or when the financial asset and substantially all the risks and rewards are transferred. A financial liability is derecognized when it is extinguished, discharged, cancelled or expires.

Classification and initial measurement of financial assets

Except for those trade receivables that do not contain a significant financing component and are measured at the transaction price in accordance with IFRS 15, all financial assets are initially measured at fair value adjusted for transaction costs (where applicable).

Financial assets, other than those designated and effective as hedging instruments, are classified into the following categories:

- amortized cost
- fair value through profit or loss (FVTPL)
- fair value through other comprehensive income (FVOCI).

In the periods presented the Company does not have any financial assets categorized as FVTPL or FVOCI.

The classification is determined by both:

- the entity's business model for managing the financial asset
- the contractual cash flow characteristics of the financial asset.

All income and expenses relating to financial assets that are recognized in profit or loss are presented within finance costs, finance income or other financial items, except for impairment of trade receivables which is presented within other expenses.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(o) Financial Instruments (continued)

Impairment of financial assets

IFRS 9's impairment requirements use more forward-looking information to recognize expected credit losses – the 'expected credit loss (ECL) model'. This replaces IFRS 139's 'incurred loss model'. Instruments within the scope of the new requirements included loans and other debt-type financial assets measured at amortized cost and FVOCI, trade receivables, contract assets recognized and measured under IFRS 15 and loan commitments and some financial guarantee contracts (for the issuer) that are not measured at fair value through profit or loss.

Recognition of credit losses is no longer dependent on the Company first identifying a credit loss event. Instead, the Company considers a broader range of information when assessing credit risk and measuring expected credit losses, including past events, current conditions, reasonable and supportable forecasts that affect the expected collectability of the future cash flows of the instrument.

In applying this forward-looking approach, a distinction is made between:

- financial instruments that have not deteriorated significantly in credit quality since initial recognition or that have low credit risk ('Stage 1') and
- financial instruments that have deteriorated significantly in credit quality since initial recognition and whose credit risk is not low ('Stage 2').

'Stage 3' would cover financial assets that have objective evidence of impairment at the reporting date.

'12-month expected credit losses' are recognized for the first category while 'lifetime expected credit losses' are recognized for the second category.

Financial asset impairment under IFRS 139 (Comparative periods June 30, 2018)

In the prior year, the impairment of trade receivables was based on the incurred loss model. Individually significant receivables were considered for impairment when they were past due or when other objective evidence was received that a specific counterparty will default. Receivables that were not considered to be individually impaired were reviewed for impairment in groups, which are determined by reference to the industry and region of the counterparty and other shared credit risk characteristics. The impairment loss estimate was then based on recent historical counterparty default rates for each identified group.

Trade and other receivables and contract assets

The Company makes use of a simplified approach in accounting for trade and other receivables as well as contract assets and records the loss allowance as lifetime expected credit losses. These are the expected shortfalls in contractual cash flows, considering the potential for default at any point during the life of the financial instrument. In calculating, Company uses its historical experience, external indicators and forward-looking information to calculate the expected credit losses using a provision matrix.

Trade and other receivables (Comparative period June 30, 2018)

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

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

The Company assess impairment of trade receivables on a collective basis as they possess shared credit risk characteristics, they have been grouped based on the days past due.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(o) Financial Instruments (continued)

Classification and measurement of financial liabilities

As the accounting for financial liabilities remains largely the same under IFRS 9 compared to IFRS 139, the Company's financial liabilities were not impacted by the adoption of IFRS 9. However, for completeness, the accounting policy is disclosed below.

The Company's financial liabilities include trade and other payables. Financial liabilities are initially measured at fair value, and, where applicable, adjusted for transaction costs unless the Company designated a financial liability at fair value through profit or loss.

Subsequently, financial liabilities are measured at amortized cost using the effective interest method except for derivatives and financial liabilities designated at FVPL, which are carried subsequently at fair value with gains or losses recognized in profit or loss.

All interest-related charges and, if applicable, changes in an instrument's fair value that are reported in profit or loss are included within finance costs or finance income.

Trade and other payables (Comparative period June 30, 2019)

Trade payables and other payables are carried at amortized cost and due to their short-term nature, they are not discounted. They represent liabilities for goods and services provided to the Company prior to the end of the financial year that are unpaid and arise when the Company becomes obliged to make future payments in respect of the purchase of these goods and services. The amounts are unsecured and are usually paid within 30 days of recognition.

Financial Instruments (Comparative period June 30, 2018)

Recognition, Initial Measurement and Derecognition

Financial assets and financial liabilities are recognized when the Company becomes a party to the contractual provisions of the financial instrument and are measured initially at fair value adjusted by transactions costs, except for those carried at fair value through profit or loss, which are measured initially at fair value. Subsequent measurement of financial assets and financial liabilities are described below.

Financial assets are derecognized when the contractual rights to the cash flows from the financial asset expire, or when the financial asset and all substantial risks and rewards are transferred. A financial liability is derecognized when it is extinguished, discharged, canceled or expires.

Classification and Subsequent Measurement of Financial Assets

For the purpose of subsequent measurement, financial assets other than those designated and effective as hedging instruments are classified into the following categories upon initial recognition:

- Loans and receivables;
- Financial assets at Fair Value Through Profit or Loss ('FVTPL');
- Held-To-Maturity ('HTM') investments; or
- Available-For-Sale ('AFS') financial assets.

All financial assets except for those at FVTPL are subject to review for impairment at least at each reporting date to identify whether there is any objective evidence that a financial asset or a group of financial assets is impaired. Different criteria to determine impairment are applied for each category of financial assets, which are described below.

All income and expenses relating to financial assets that are recognized in the Statement of Profit or Loss and Other Comprehensive Income are presented within finance costs, finance income or other financial items, except for impairment of trade receivables which is presented within other expenses.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(o) Financial Instruments (continued)

Loans and Receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. After initial recognition, these are measured at amortized cost using the effective interest method, less provision for impairment. Discounting is omitted where the effect of discounting is immaterial. The Company's cash and cash equivalents, trade and most other receivables fall into this category of financial instruments.

Individually significant receivables are considered for impairment when they are past due or when other objective evidence is received that a specific counterparty will default. Receivables that are not considered to be individually impaired are reviewed for impairment in groups, which are determined by reference to the industry and region of a counterparty and other shared credit risk characteristics. The impairment loss estimate is then based on recent historical counterparty default rates for each identified group.

AFS financial assets

AFS financial assets are non-derivative financial assets that are either designated to this category or do not qualify for inclusion in any of the other categories of financial assets.

All AFS financial assets are measured at fair value. Gains and losses are recognized in other comprehensive income and reported within the AFS reserve within equity, except for impairment losses and foreign exchange differences on monetary assets, which are recognized in profit or loss. When the asset is disposed of or is determined to be impaired the cumulative gain or loss recognized in other comprehensive income is reclassified from the equity reserve to profit or loss and presented as a reclassification adjustment within other comprehensive income. Interest calculated using the effective interest method and dividends are recognized in profit or loss within 'finance income'.

Reversals of impairment losses for AFS debt securities are recognized in profit or loss if the reversal can be objectively related to an event occurring after the impairment loss was recognized. For AFS equity investments impairment reversals are not recognized in profit or loss and any subsequent increase in fair value is recognized in other comprehensive income.

Classification and subsequent measurement of financial liabilities

The Company's financial liabilities include borrowings, trade and other payables.

Financial liabilities are measured subsequently at amortized cost using the effective interest method, except for financial liabilities held for trading or designated at FVTPL, that are carried subsequently at fair value with gains or losses recognized in profit or loss.

(p) Provisions and employee leave benefits

Provisions are recognized when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

When the Company expects some or all of a provision to be reimbursed, for example under an insurance contract, the reimbursement is recognized as a separate asset but only when the reimbursement is virtually certain. The expense relating to any provision is presented in profit or loss net of any reimbursement.

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the reporting date using a discounted cash flow methodology. The risks specific to the provision are factored into the cash flows and as such a risk-free government bond rate relative to the expected life of the provision is used as a discount rate. If the effect of the time value of money is material, provisions are discounted using a current pre-tax rate that reflects the time value of money and the risks specific to the liability. The increase in the provision resulting from the passage of time is recognized in finance costs.

Employee leave benefits

Liabilities for wages and salaries, including non-monetary benefits, annual leave and accumulating sick leave expected to be settled within 12 months of the reporting date are recognized in respect of employees' services up to the reporting date. They are measured at the amounts expected to be paid when the liabilities are settled. Expenses for non-accumulating sick leave are recognized when the leave is taken and are measured at the rates paid or payable.

(q) Share-based payment transactions

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

The Company has in place an Employee Share Option Plan (ESOP) which provides benefits to employees.

The cost of these equity-settled transactions with employees is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by an external valuer using a binomial model.

The cost of equity-settled transactions is recognized, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled (the vesting period), ending on the date on which the relevant employees become fully entitled to the award (the vesting date).

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

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(q) Share-based payment transactions (continued)

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

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

Until an award has vested, any amounts recorded are contingent and will be adjusted if more or fewer awards vest than were originally anticipated to do so. Any award subject to a market condition is considered to vest irrespective of whether or not that market condition is fulfilled, provided that all other conditions are satisfied.

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

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

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

(r) Contributed equity

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

Basic loss per share is calculated as net loss attributable to members of the parent, adjusted to exclude any costs of servicing equity (other than dividends), divided by the weighted average number of ordinary shares, adjusted for any bonus element.

Diluted loss per share is calculated as net loss attributable to members of the parent, adjusted for:

- costs of servicing equity (other than dividends);
- the after-tax effect of dividends and interest associated with dilutive potential ordinary shares that have been recognized as expenses; and
- other non-discretionary changes in revenues or expenses during the year that would result from the dilution of potential ordinary shares;
- divided by the weighted average number of ordinary shares and dilutive potential ordinary shares, adjusted for any bonus element.

(s) Research and development costs

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

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

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

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(t) Intangible assets

Separately acquired patents are initially measured at cost. Following initial recognition, it is carried at cost less any amortization and impairment. They have a finite useful life and are subsequently carried at cost less accumulated amortization and impairment losses.

(u) Going Concern

These financial statements have been prepared on the basis of going concern, which contemplates the continuity of normal business activities and the realization of assets and settlement of liabilities in the ordinary course of business. During the financial year ended June 30, 2019 and 2018, the Company has generated a loss for the period of A\$35,160,227 and A\$16,519,155 and the Company has used cash in operations of A\$27,485,659 and A\$16,372,024, respectively.

During the year ended June 30, 2019, the Company completed a series of equity transactions totaling gross proceeds of A\$45,036,886 which were used to fund operations.

During the year ended June 30, 2019, the Company completed a series of equity transactions. The Company issued 65,000,000 shares at a price of A\$0.050 per share and received gross proceeds of A\$3,250,000 on July 26, 2018. The Company completed the first tranche of an institutional placement in which it issued 310,047,015 fully paid ordinary shares at a price of A\$0.080 per share raising gross proceeds of A\$24,803,761 on December 4, 2018. The institutional placement included a second tranche in which it issued 189,952,985 shares at a price of A\$0.080 per share and received gross proceeds of A\$15,196,239. In addition, on January 11, 2019 the Company completed a Share Purchase Plan under which it issued 22,061,250 shares of stock at a price of \$0.080 per share and received gross proceeds of A\$1,764,900.

The Company benefits from cash inflows from the series of BARDA contracts, the first of which was awarded to the Company in September 2015. These payments from BARDA offset costs from various activities undertaken to support the FDA regulatory approval process for RECELL in the U.S., preparation for the planned commercial launch of RECELL in the U.S., and RECELL clinical programs in the U.S. With the U.S. FDA approval of RECELL for the treatment of burns in September 2018, and the U.S. market launch of the product in January 2019, sales of goods are expected to be an increasing source of revenue in the future. Another anticipated source of revenue for the Company is the BARDA contract line item covering the initial purchase, delivery and storage of the RECELL System in the amount of US\$7,594,620 (approximately A\$10,300,000).

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

As a result of the above, the directors are satisfied that there is enough working capital to support the committed research and development programs and other activities over the next 12 months and the Company can realize its assets and pay its liabilities and commitments in the normal course of business. Accordingly, the directors have prepared the financial report on a going concern basis.

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

3. SIGNIFICANT ACCOUNTING JUDGEMENTS, ESTIMATES AND ASSUMPTIONS

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the reported amounts in the financial statements. Management continually evaluates its judgements and estimates in relation to assets, liabilities, contingent liabilities, revenue and expenses. Management bases its judgements and estimates on historical experience and on other various factors it believes to be reasonable under the circumstances, the result of which form the basis of the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

Management has identified the following critical accounting policies for which significant judgements, estimates and assumptions are made. Actual results may differ from these estimates under different assumptions and conditions and may materially affect financial results or the financial position reported in future periods.

Share-based payment transactions

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by using a binomial model, using the assumptions detailed in note 17. The accounting estimates and assumptions relating to equity-settled share-based payments would have no impact on the carrying amounts of assets and liabilities within the next annual reporting period but may impact expenses and equity.

Estimation of useful lives of assets

The estimation of the useful lives of assets has been based on historical experience. In addition, the condition of the assets is assessed at least once per year and considered against the remaining useful life. Adjustments to useful lives are made when considered necessary. Depreciation charges are included in note 4(d).

Impairment of non-financial assets other than goodwill

The Company assesses impairment of all assets at each reporting date by evaluating conditions specific to the Company and to the particular asset that may lead to impairment. These include product and manufacturing performance, technology, economic and political environments and future product expectations. If an impairment trigger exists, the recoverable amount of the asset is determined. This involves value in use calculations, which incorporate several key estimates and assumptions.

Taxation

The Company's accounting policy for taxation requires management's judgement as to the types of arrangements considered to be a tax on income in contrast to an operating cost. Judgement is also required in assessing whether deferred tax assets and certain deferred tax liabilities are recognized on the consolidated statement of financial position. Deferred tax assets, including those arising from unrecouped tax losses, capital losses and temporary differences, are recognized only where it is considered more likely than not that they will be recovered, which is dependent on the generation of enough future taxable profits.

Assumptions about the generation of future taxable profits depend on management's estimates of future cash flows. These depend on estimates of future production and sales volumes, operating costs, capital expenditure, dividends and other capital management transactions. Judgements are also required for the application of income tax legislation. These judgements and assumptions are subject to risk and uncertainty, hence there is a possibility that changes in circumstances will alter expectations, which may impact the amount of deferred tax assets and deferred tax liabilities recognized on the consolidated statement of financial position and the amount of other tax losses and temporary differences not yet recognized. In such circumstances, some or all the carrying amounts of recognized deferred tax assets and liabilities may require adjustment, resulting in a corresponding credit or charge to profit or loss.

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

4. REVENUES AND EXPENSES

	<u>2019</u>	<u>2018</u>	<u>2017</u>
(a) Revenue			
Sale of goods	A\$ 7,705,398	A\$ 1,198,861	A\$ 901,376
Total revenue	<u>A\$ 7,705,398</u>	<u>A\$ 1,198,861</u>	<u>A\$ 901,376</u>
(b) Other income			
BARDA income	A\$ 8,259,152	A\$ 10,104,081	A\$ 6,886,236
Interest income	456,695	68,617	344,734
Total other income	<u>A\$ 8,715,847</u>	<u>A\$ 10,172,698</u>	<u>A\$ 7,230,970</u>

The Company had been granted a BARDA contract in September 2015, wherein BARDA will fund the Company to support the ongoing U.S. clinical regulatory program towards FDA Premarket Approval, Compassionate Use program, clinical and health economics research, and in U.S. pediatric burn programs. The objectives support BARDA's overarching goal of building burn care preparedness, by securing effective medical countermeasures for burn injuries for use in case of a mass casualty event.

	<u>2019</u>	<u>2018</u>	<u>2017</u>
(c) Finance costs			
Interest expense	A\$ 37,769	A\$ 26,586	A\$ 12,754
	<u>A\$ 37,769</u>	<u>A\$ 26,586</u>	<u>A\$ 12,754</u>
(d) Depreciation included in profit or loss			
Depreciation	A\$ 378,002	A\$ 143,546	A\$ 139,703
Profit on disposal of plant and equipment	—	—	(1,347)
	<u>A\$ 378,002</u>	<u>A\$ 143,546</u>	<u>A\$ 138,356</u>
(e) Cost of sales			
	<u>A\$ 1,697,823</u>	<u>A\$ 511,646</u>	<u>A\$ 463,285</u>

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

4. REVENUES AND EXPENSES (continued)

	<u>2019</u>	<u>2018</u>	<u>2017</u>
(f) Lease payments and other expenses included in profit or loss	<u>A\$ 950,399</u>	<u>A\$ 463,095</u>	<u>A\$ 418,193</u>
	<u>2019</u>	<u>2018</u>	<u>2017</u>
(g) Employee benefits expense			
Salaries and wages	A\$ 15,472,511	A\$ 8,057,869	A\$ 6,143,458
Share-based expenses	2,688,817	1,835,157	1,587,243
Defined contribution superannuation expense	831,558	374,435	341,586
	<u>A\$18,992,886</u>	<u>A\$10,267,461</u>	<u>A\$8,072,287</u>

5. LOSS PER SHARE

Basic loss per share amounts are calculated by dividing the net loss for the year by the weighted average number of ordinary shares outstanding during the year.

Diluted earnings per share amounts are calculated by dividing the net loss for the year by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on the conversion of all the dilutive potential ordinary shares into ordinary shares.

The following reflects the income and share data used in the basic and diluted loss per share computations:

	<u>2019</u>	<u>2018</u>	<u>2017</u>
Net loss for the period	<u>A\$ 35,160,227</u>	<u>A\$ 16,519,155</u>	<u>A\$ 11,511,024</u>
Weighted average number of ordinary shares for basic and diluted loss per share	<u>1,266,654,166</u>	<u>934,312,458</u>	<u>669,930,538</u>

Transactions involving ordinary shares or potential ordinary shares that would change the number of ordinary shares or potential ordinary shares outstanding between the reporting date and the date of the completion of these financial statements are disclosed in Note 17 to the consolidated financial statements.

A total of 111,523,332 employee stock options (2018: 29,131,664 and 2017: 24,797,286) were not included in the dilutive loss per share calculation as they are anti-dilutive.

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

6. INCOME TAX

(a) Income tax expense	2019	2018	2017
The major components of income tax benefit are:			
<i>Current income tax benefit:</i>			
Current income tax benefit – R&D Claim	A\$ (179,863)	A\$ (1,420,752)	A\$ (1,048,634)
Adjustment for prior year tax	—	34,956	—
Income tax benefit reported in profit or loss – R&D Claim	<u>A\$ (179,863)</u>	<u>A (1,385,796)</u>	<u>A\$ (1,048,634)</u>
(b) Numerical reconciliation of income tax expense to prima facie tax payable			
Loss from continuing operations before income tax expense	<u>(35,340,090)</u>	<u>(17,904,569)</u>	<u>(12,559,261)</u>
	A\$ (35,340,090)	A\$ (17,904,569)	(12,559,261)
Tax at the Australian rate of 27.5% (2018: 27.5% and 2017: 27.5%)	A\$ (9,718,525)	A\$ (4,923,756)	A\$ (3,767,778)
Tax effect of amounts which are not deductible/(taxable) in calculating taxable income:			
Other	4,847,621	1,464,746	792,798
Tax losses not brought to account	5,196,259	3,537,629	2,974,980
Research and development tax offset	(179,863)	(1,420,751)	(1,048,634)
Adjustment for prior year research and development tax offset	—	34,955	—
Adjustment due to change in tax rate	—	66,341	—
	<u>145,492</u>	<u>(1,240,836)</u>	<u>(1,048,634)</u>
Movement in deferred tax asset	—	—	41,629
Deferred tax assets not brought to account as realization is not considered probable	<u>(325,355)</u>	<u>(144,960)</u>	<u>(41,629)</u>
Income tax benefit	A\$ (179,863)	A\$ (1,385,796)	(1,048,634)
(c) Non-current assets – Deferred tax assets			
The balance comprises temporary differences attributable to:			
Provisions	A\$ 21,008	A\$ 122,243	A\$ 48,513
Property, plant and equipment	10,672	10,155	12,945
Intangible assets	802,179	1,025,616	735,400
Other	1,178	2,378	(766)
Total deferred tax assets	A\$ 835,037	A\$ 1,160,392	A\$ 796,092
Set off deferred tax liabilities pursuant to set-off provisions	—	—	—
	<u>A\$ 835,037</u>	<u>1,160,392</u>	<u>796,092</u>
Deferred tax assets not brought to account as realization is not considered probable	<u>(835,037)</u>	<u>(1,160,392)</u>	<u>(796,092)</u>
Deferred tax assets recognized	A\$ —	A\$ —	A\$ —

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

6. INCOME TAX (continued)

Movements – Consolidated	<u>Provisions</u>	<u>Plant and equipment</u>	<u>Intangible assets</u>	<u>Other</u>	<u>Total</u>
At June 30, 2016	A\$ 81,984	A\$ 13,905	A\$ 611,343	A\$ —	A\$ 707,232
(Charged) / credited to the consolidated statement of profit or loss and other comprehensive income	(33,471)	(960)	124,057	(766)	88,770
At 30 June 2017	A\$ 48,513	A\$ 12,945	A\$ 735,400	A\$ (766)	A\$ 796,092
(Charged) / credited to the consolidated statement of profit or loss and other comprehensive income	73,730	(2,790)	(219,044)	3,144	(144,960)
(Charged) / credited directly to equity	—	—	509,260	—	509,260
At 30 June 2018	122,243	10,155	1,025,616	2,378	1,160,392
(Charged) / credited to the consolidated statement of profit or loss and other comprehensive income	(101,235)	517	(223,437)	(1,200)	(325,355)
(Charged) / credited directly to equity	—	—	—	—	—
At 30 June 2019	21,008	10,672	802,179	1,178	835,037

Unrecognized temporary differences

At June 30, 2019, there is no recognized or unrecognized deferred income tax liability (2018 and 2017: A\$nil) for taxes that would be payable on the unremitted earnings of certain of the Company's subsidiaries. The Company has no liability for additional taxation should unremitted earnings be remitted (2018 and 2017: A\$nil).

Tax consolidation*(i) Members of the tax consolidated company and the tax sharing arrangement*

Avita Medical Limited and its 100% owned Australian resident subsidiaries formed a tax consolidated group with effect from July 1, 2003. Avita Medical Limited is the parent entity of the tax consolidated group. Members of the group have not entered into a tax sharing arrangement or a tax funding arrangement.

(ii) Tax effect accounting by members of the tax consolidated group

No amounts have been recognized as tax consolidation contribution adjustments in preparing the accounts of Avita Medical Limited.

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

7. CURRENT ASSETS – CASH AND CASH EQUIVALENTS

	2019	2018
Cash at bank and in hand	A\$28,701,791	A\$14,825,532
Short-term deposits	281,700	—
Cash and cash equivalents	<u>A\$28,983,491</u>	<u>A\$14,825,532</u>

8. CURRENT ASSETS – TRADE AND OTHER RECEIVABLES

	2019	2018
Trade receivables	A\$2,143,889	A\$ 263,421
Allowance for doubtful debts	(25,155)	(23,452)
	2,118,734	239,969
R&D Tax claim	179,863	2,434,430
BARDA and other receivables	681,505	2,762,958
Carrying amount of trade and other receivables	<u>A\$2,980,102</u>	<u>A\$5,437,357</u>

(a) Allowance for impairment loss

Trade receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. They are generally due for settlement within 30 days and therefore are all classified as current. Trade receivables are recognized initially at the amount of consideration that is unconditional unless they contain significant financing components, when they are recognized at fair value. The company holds the trade receivables with the objective to collect the contractual cash flows and therefore measures them subsequently at amortized cost using the effective interest method.

The expected loss rates are based on the payment profiles of sales over a period of 6 months before June 30, 2019, prior to commercialization in the United States, and the corresponding historical credit losses experienced within this period. The historical loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors affecting the ability of the customers to settle the receivables.

On that basis, the loss allowance as at June 30, 2019 (on adoption of IFRS 9) was determined as follows for trade receivables:

	Current	31-60 days	61-90 days	91-120 days	>120 days	Total
Expected loss rate	0%	0%	0%	0%	100%	1.17%
Gross carrying amount – trade receivables	A\$1,532,187	A\$365,458	A\$202,260	A\$18,829	A\$25,155	A\$2,143,889
Allowance for impairment loss	<u>A\$ —</u>	<u>A\$ —</u>	<u>A\$ —</u>	<u>A\$ —</u>	<u>A\$25,155</u>	<u>A\$ 25,155</u>

Movements in the allowance for impairment loss were as follows:

	2019	2018
At July 1	A\$23,452	A\$ 88,859
Write off during the year	(7,099)	(88,859)
Charge for the year	8,802	23,452
At June 30	<u>A\$25,155</u>	<u>A\$ 23,452</u>

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

8. CURRENT ASSETS – TRADE AND OTHER RECEIVABLES (continued)

At June 30, the ageing analysis of trade receivables is as follows:

		Total	0-30 days	31-60 days	61-90 days	+91 days PDNI*	+91 days CI**
2019	Consolidated	2,143,452	1,532,046	365,459	202,260	18,532	25,155
2018	Consolidated	263,421	129,979	82,406	6,173	42,792	2,071

* Past due not impaired (“PDNI”)

** Considered impaired (“CI”)

The Company’s trade receivables past due but not considered impaired amounted to A\$25,155 at June 30, 2019 (2018: A\$23,452). Payment terms on these amounts have not been re-negotiated however each operating unit has been in direct contact with the relevant debtor and is satisfied that payment will be received in full.

Other balances within trade and other receivables which have similar terms as trade receivables do not contain impaired assets and are not past due. It is expected that these other balances will be received when due.

(b) Fair value and credit risk

Due to the short-term nature of these receivables, their carrying value is assumed to approximate their fair value. The maximum exposure to credit risk is the fair value of receivables. Collateral is not held as security, nor is it the Company’s policy to transfer (on-sell) receivables to special purpose entities.

(c) Foreign exchange and interest rate risk

Detail regarding foreign exchange and interest rate risk exposure is disclosed in Note 19.

9. CURRENT ASSETS – INVENTORIES

	2019	2018
Raw materials and components at cost	A\$ 869,016	A\$ 778,947
Finished goods at cost	188,748	376,879
Total inventories at cost	A\$ 1,057,764	A\$ 1,155,826

A provision of \$ A\$125,159 (2018: A\$42,412) has been allocated against inventory to reduce the carrying amount of certain inventory items to nil net realisable value. The change in provision of inventory has been included in the cost of sales line item as a cost of inventories in the consolidated statement of profit or loss and other comprehensive income.

Inventory expense

Inventories recognized as an expense as a result of expiration for the year ended June 30, 2019 totaled A\$97,029 (2018: A\$38,107 and 2017: A\$408,052).

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

10. NON-CURRENT ASSETS – PLANT AND EQUIPMENT

Reconciliation of carrying amounts at the beginning and end of the period

	<i>Plant and Equipment</i>
Year ended June 30, 2019	
At July 1, 2018, net of accumulated depreciation	A\$ 742,583
Additions	1,532,656
Disposals	(58,722)
Depreciation charge for the year	(378,002)
At June 30, 2019, net of accumulated depreciation	<u>A\$ 1,838,515</u>
At June 30, 2019	
Cost	A\$ 2,787,761
Accumulated depreciation	(949,246)
Net carrying amount	<u>A\$ 1,838,515</u>
	<i>Plant and Equipment</i>
Year ended June 30, 2018	
At July 1, 2017, net of accumulated depreciation	A\$ 387,380
Additions	498,749
Depreciation charge for the year	(143,546)
At June 30, 2018, net of accumulated depreciation	<u>A\$ 742,583</u>
At June 30, 2018	
Cost	A\$ 1,448,142
Accumulated depreciation	(705,559)
Net carrying amount	<u>A\$ 742,583</u>

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

11. CURRENT LIABILITIES – TRADE AND OTHER PAYABLES

	<u>2019</u>	<u>2018</u>
Trade payables	A\$ 679,106	A\$ 271,913
Bonus payable	1,198,063	1,317,188
Accruals and other payables	3,756,393	1,898,481
Carrying amount of trade and other payables	<u>A\$ 5,633,562</u>	<u>A\$3,487,582</u>

(a) Fair value

Due to the short-term nature of these payables, their carrying value is assumed to approximate their fair value.

(b) Interest rate, foreign exchange and liquidity risk

Information regarding interest rate, foreign exchange and liquidity risk exposure is set out in Note 19.

12. CURRENT LIABILITIES – PROVISIONS

	<u>2019</u>	<u>2018</u>
Provision for annual leave (i)	A\$ 627,928	A\$ 376,535
Provision for long service leave (ii)	22,431	19,000
	<u>A\$ 650,359</u>	<u>A\$ 395,535</u>

Employee benefits

- (i) A provision is recognized for annual leave due to employees at the end of the year.
- (ii) A provision is recognized for long service leave due to employees at the end of the year.

13. CONTRIBUTED EQUITY

	<u>2019</u>	<u>2018</u>
<i>Ordinary shares</i>		
Authorised, issued and fully paid	<u>A\$ 204,279,078</u>	<u>A\$ 162,801,028</u>

Fully paid ordinary shares carry one vote per share and carry the right to dividends.

<i>Movement in ordinary shares on issue</i>	<u>Number</u>	<u>Amount</u>
At July 1, 2017	673,219,854	A\$ 134,806,022
New shares	633,658,471	29,846,859
Cancelled shares	(29,500,000)	—
Capital issue costs	—	(1,851,853)
At July 1, 2018	1,277,378,325	A\$ 162,801,028
New shares	593,921,250	45,580,570
Capital issue costs	—	(4,102,520)
At June 30, 2019	<u>1,871,299,575</u>	<u>A\$ 204,279,078</u>

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

13. CONTRIBUTED EQUITY (continued)

Capital management

When managing capital, management's objective is to ensure the entity continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. Management also aims to maintain a capital structure that ensures the lowest cost of capital available to the entity.

The Company regularly reviews the capital structure and seeks to take advantage of available opportunities to improve outcomes for the Company and its shareholders.

For the year ended 30 June 2019, there were no dividends paid and management has no plans to commence the payment of dividends. Management will continue to assess market conditions and the company's cash flow requirements to ensure the company is appropriately funded.

The Company monitors capital based on the gearing ratio, however, there is no significant external borrowing at the reporting date. Neither the Company nor any of the subsidiaries are subject to externally imposed capital requirement.

14. ACCUMULATED LOSSES AND RESERVES

(a) Movements in accumulated losses were as follows:

	<u>2019</u>	<u>2018</u>
Balance 1 July	A\$(148,592,879)	A\$(132,218,352)
Net loss attributable to owners of Avita Medical Limited	(35,160,227)	(16,519,155)
Transfer from expired / lapsed options	—	141,188
Forfeited options	—	3,440
Balance 30 June	<u>A\$ (183,753,106)</u>	<u>A\$ (148,592,879)</u>

(b) Nature and purpose of reserves

Employee equity benefits reserve

The employee equity benefits reserve is used to record the value of share-based payments provided to employees, including Key Management Personnel, as part of their remuneration. Refer to note 17 for further details of these plans.

Foreign currency translation reserve

The foreign currency translation reserve is used to record exchange differences arising from the translation of the financial statements of foreign subsidiaries.

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

15. CONSOLIDATED STATEMENT OF CASH FLOWS RECONCILIATION

	2019	2018	2017
Reconciliation of net loss after tax to net cash flows from operations			
Loss from ordinary activities after tax	A\$(35,160,227)	A\$(16,519,155)	A\$ (11,511,024)
Adjustments for non-cash items:			
Depreciation	378,002	143,546	139,703
Share based payments expensed	2,779,694	1,835,157	1,587,243
Share options canceled classified as financing activities	—	62,681	—
Capital raising costs classified as financing activities	(90,000)	—	—
R&D claim accrual	179,863	(1,385,414)	—
Foreign exchange differences	(357,830)	592,385	—
Changes in assets and liabilities:			
Decrease/(increase) in inventories	98,063	(118,336)	333,132
Decrease/(increase) in trade and other receivables	2,457,255	(1,980,566)	(49,040)
Increase in prepayments and other assets	(701,809)	(473,690)	(156,756)
Increase in trade and other payables	2,065,833	1,258,186	1,125,116
Increase/(decrease) in provisions	254,824	213,182	(25,898)
Increase in contract liability	610,673	—	—
Net cash used in operating activities	A\$ (27,485,659)	A\$ (16,372,024)	A\$ (8,557,524)

16. RELATED PARTY DISCLOSURE

(a) Subsidiaries

The consolidated financial statements include the financial statements of Avita Medical Limited and the subsidiaries listed in the following table:

<i>Name</i>	<i>Country of Incorporation</i>	<i>% Equity interest at June 30, 2018</i>	<i>% Equity interest at June 30, 2017</i>	<i>Investment at June 30, 2019</i>	<i>Investment At June 30, 2018</i>
C3 Operations Pty Ltd	Australia	100%	100%	A\$ —	A\$ —
Avita Medical Europe Ltd	United Kingdom	100%	100%	—	—
Avita Medical Americas LLC	United States	100%	100%	—	—
Infamed Pty Limited	Australia	100%	100%	—	—
Visiomed Group Pty Ltd	Australia	100%	100%	4,643,888	4,643,888
				A\$4,643,888	A\$4,643,888

(b) Ultimate parent

Avita Medical Limited is the ultimate parent entity in the wholly-owned company.

(c) Key Management Personnel

The total remuneration paid to key management personnel of the Company during the year is detailed below

	2019	2018	2017
Short-term employee benefits	A\$ 4,396,280	A\$ 3,770,141	A\$ 2,933,510
Post-employment employee benefits	445,871	90,512	112,034
Share-based expenses	2,062,580	1,596,368	1,215,809
Total compensation	A\$ 6,904,731	A\$ 5,457,021	A\$ 4,261,353

Refer to the remuneration report contained the Directors' Report for details of the remuneration paid or payable to each member of the Company's key management personnel for the year ended June 30, 2019.

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

16. RELATED PARTY DISCLOSURE (continued)

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. Total fees paid to Bioscience Managers Pty Ltd for the year ended June 30, 2019 were A\$85,374 (2018: A\$128,987 and 2017: A\$128,987).

(d) Transactions with related parties

Subsidiaries of the Company:

During the reporting period, inter-company other revenue was made of A\$ nil (2018: A\$2,819,592 and 2017: A\$2,087,051) by Avita Medical Europe Ltd and Avita Medical Americas LLC to Avita Medical Limited. These have been eliminated on consolidation.

Employees

Contributions to superannuation funds on behalf of employees are disclosed in note 4(g).

Terms and conditions of transactions with related parties

Outstanding balances are unsecured, interest free and settlement occurs in cash. At June 30, 2019 there were no outstanding balances.

17. SHARE-BASED PAYMENT PLANS

(a) Recognized share-based payment expenses

The expense recognized for employee services received during the year is shown in the table below:

	2019	2018	2017
Expenses arising from equity-settled share-based payment transactions	A\$ 2,688,817	A\$ 1,835,157	A\$ 1,587,243
Total expense arising from share-based payment transactions	A\$ 2,688,817	A\$ 1,835,157	A\$ 1,587,243

The share-based payment plans are described below. There have been no share-based plan forfeitures during fiscal 2019 and there has been forfeiture of one share-based plan during fiscal 2018. Further, there have been no cancellations to any of the plans during fiscal 2019.

(b) Types of share-based payment plans

Employee Share Option Plan (ESOP)

Share options are granted to employees under the Employee Share Option Plan at the discretion of the Board. The exercise price of the options is based on a weighted average market price of the shares preceding the date of grant. The options vest at the time of grant and the contractual life of each option granted is ten years. There are no cash settlement alternatives.

Subject to shareholder approval, options may also be granted to Directors at the discretion of the Board. The exercise price of the options is based on a weighted average market price of the shares preceding the date of grant. The options vest either at the time of grant or are subject to performance conditions at the discretion of the Board and the contractual life of each option granted is 10 years. There are no cash settlement alternatives.

(c) Summaries of options granted under ESOP arrangements

The following table illustrates the number (No) and weighted average exercise price (WAEP) of, and movements in, share options issued during the year:

	2019 <i>No</i>	2019 <i>WAEP</i>	2018 <i>No</i>	2018 <i>WAEP</i>	2017 <i>No</i>	2017 <i>WAEP</i>
Outstanding at the beginning of the year	29,131,664	A\$ 0.08	24,797,286	A\$ 0.09	11,147,289	A\$ 0.14
Expired during the year	—	—	(3,937,289)	0.13	(4,710,000)	0.14
Forfeited during the year	—	—	(838,333)	0.08	(2,500,000)	0.15
Granted during the year	89,251,668	0.13	9,110,000	0.06	20,859,997	0.08
Exercised during the year	(6,860,000)	(0.07)	—	—	—	—
Outstanding at the end of the year	111,523,332	A\$ 0.121	29,131,664	A\$ 0.078	24,797,286	A\$ 0.084

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

17. SHARE-BASED PAYMENT PLANS (continued)

As at the reporting date, there were 111,523,332 unissued ordinary shares under options represented by:

16,160,415 exercisable at A\$0.085 expiring May 18, 2027 issued to employees on May 18, 2017.
1,072,916 exercisable at A\$0.082 expiring May 26, 2027 issued to an employee on May 26, 2017.
1,038,333 exercisable at A\$0.080 expiring June 27, 2027 issued to employees on June 27, 2017.
4,000,000 exercisable at A\$0.063 expiring September 6, 2027 issued to an employee on September 6, 2017.
9,000,000 exercisable at A\$0.057 expiring April 16, 2028 issued to employees on April 16, 2018.
3,000,000 exercisable at A\$0.057 expiring April 18, 2028 issued to employees on April 18, 2018.
2,000,000 exercisable at A\$0.056 expiring June 12, 2028 issued to an employee on June 12, 2018.
700,000 exercisable at A\$0.057 expiring June 14, 2028 issued to employees on June 14, 2018.
3,000,000 exercisable at A\$0.059 expiring June 25, 2028 issued to an employee on June 25, 2018.
14,430,000 exercisable at A\$0.089 expiring November 1, 2028 issued to employees on November 1, 2018.
18,881,250 exercisable at A\$0.082 expiring November 30, 2028 issued to employees on November 30, 2018.
15,000,000 exercisable at A\$0.082 expiring November 30, 2028 issued to an employee on November 30, 2018.
360,000 exercisable at A\$0.082 expiring November 30, 2028 issued to employees on November 30, 2018.
1,080,000 exercisable at A\$0.082 expiring January 2, 2029 issued to employees on January 2, 2019.
4,910,000 exercisable at A\$0.082 expiring January 2, 2029 issued to employees on January 2, 2019.
380,000 exercisable at A\$0.089 expiring January 2, 2029 issued to employees on January 2, 2019.
6,866,250 exercisable at A\$0.30 expiring April 1, 2029 issued to employees on April 1, 2019.
9,644,168 exercisable at A\$0.42 expiring June 28, 2029 issued to employees on June 28, 2019.

Option holders do not have any right, by virtue of the option, to participate in any share issue of the Company or any related corporate body.

Shares issued as a result of the exercise of options

During the financial year and up to the date of this report, there were 6,860,000 options exercised to acquire fully paid ordinary shares in the Company.

(d) Weighted average remaining contractual life

The weighted average remaining contractual life for the share options outstanding as at June 30, 2019 is 10 years (2018: 9.52 years and 2017: 9.39 years).

(e) Range of exercise price

The range of exercise prices for options outstanding at the end of the year was A\$0.056 – A\$0.420 (2018: A\$0.061 – A\$0.126 and 2017: A\$0.079—A\$0.14).

As the range of exercise prices is wide, refer to Section (c) above for further information in assessing the number and timing of additional shares that may be issued and the cash that may be received upon exercise of those options.

(f) Weighted average fair value

The weighted average fair value of options granted during the year was A\$2,594,883 (2018: A\$247,089 and 2017: A\$578,879). The total fair value of the options granted during the year is A\$2,594,883 (2018: A\$247,089 and 2017: A\$578,879).

(g) Option pricing model: ESOP and Investor

Equity-settled transactions

The fair value of the equity-settled share options granted under the ESOP is estimated at the date of grant using a Binomial Model considering the terms and conditions upon which the options were granted.

The options issued in the period have vesting criteria based on the following performance conditions:

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

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

17. SHARE-BASED PAYMENT PLANS (continued)

i) On May 18, 2017, 17,910,415 options were granted to employees at an exercise price of A\$0.085 expiring on May 18, 2027.

The following table lists the inputs to the models used for the options granted to employees each year:

Grant date	05/18/2017	
Share price at date of grant	A\$	0.08
Dividend yield (%)	0%	
Expected volatility (%)	90%	
Risk-free interest rate (%)	1.5%	
Expected life of option	3,650	
Fair value at date of grant	A\$	0.0754
Option exercise price (A\$)	A\$	0.085

At year end, 5,304,166 options were unvested.

ii) On May 26, 2017, 1,072,916 options were granted to employees at an exercise price of A\$0.082 expiring on May 26, 2027.

The following table lists the inputs to the models used for the options granted to employees each year:

	<u>Tranche 1</u>	<u>Tranche 2</u>
Grant date	05/26/2017	05/26/2017
Share price at date of grant	A\$ 0.086	A\$ 0.086
Dividend yield (%)	0%	0%
Expected volatility (%)	90%	90%
Risk-free interest rate (%)	1.5%	1.50%
Expected life of option	3,650	3,650
Fair value at date of grant	A\$ 0.070	A\$ 0.0754
Option exercise price (A\$)	A\$ 0.082	A\$ 0.082

At year end, 469,166 options were unvested.

iii) On June 27, 2017, 1,038,333 options were granted to employees at an exercise price of A\$0.08 expiring on June 27, 2027.

The following table lists the inputs to the models used for the options granted to employees each year:

	<u>Tranche 1</u>	<u>Tranche 2</u>
Grant date	06/27/2017	06/27/2017
Share price at date of grant	A\$ 0.067	A\$ 0.067
Dividend yield (%)	0%	0%
Expected volatility (%)	90%	90%
Risk-free interest rate (%)	1.50%	1.50%
Expected life of option	3,650	3,650
Fair value at date of grant	A\$ 0.0621	A\$ 0.0754
Option exercise price (A\$)	A\$ 0.080	A\$ 0.080

At year end, 361,500 options were unvested.

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

17. SHARE-BASED PAYMENT PLANS (continued)

iv) On September 6, 2017, 4,000,000 options were granted to an employee at an exercise price of A\$0.063 expiring on September 6, 2027.

The following table lists the inputs to the models used for the options granted to employees each year:

Grant date		09/06/2017
Share price at date of grant	A\$	0.056
Dividend yield (%)		0%
Expected volatility (%)		90%
Risk-free interest rate (%)		1.5%
Expected life of option		3,650
Fair value at date of grant	A\$	0.0523
Option exercise price (A\$)	A\$	0.063

At year end, 1,700,000 options were unvested.

v) On April 16, 2018, 9,000,000 options were granted to employees at an exercise price of A\$0.057 expiring on April 16, 2028.

The following table lists the inputs to the models used for the options granted to employees:

Grant date		04/16/2018
Share price at date of grant	A\$	0.055
Dividend yield (%)		0%
Expected volatility (%)		90%
Risk-free interest rate (%)		2.65%
Expected life of option (days)		3,650
Option exercise price (A\$)	A\$	0.057

This represents tranches 1-6, the fair value at date of grant for each tranche is as follows:

Tranche 1	A\$ 0.0343
Tranche 2	A\$ 0.0373
Tranche 3	A\$ 0.0398
Tranche 4	A\$ 0.0417
Tranche 5	A\$ 0.0495
Tranche 6	A\$ 0.0471

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 4,440,000 options were unvested.

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

17. SHARE-BASED PAYMENT PLANS (continued)

vi) On April 18, 2018, 3,000,000 options were granted to an employee at an exercise price of A\$0.057 expiring on April 18, 2028.

The following table lists the inputs to the models used for the options granted to employees:

Grant date	04/18/2018
Share price at date of grant	A\$ 0.057
Dividend yield (%)	0%
Expected volatility (%)	90%
Risk-free interest rate (%)	2.65%
Expected life of option (days)	3,650
Option exercise price (A\$)	A\$ 0.057

This represents tranches 1-9, the fair value at date of grant for each tranche is as follows:

Tranche 1	A\$ 0.0493
Tranche 4	A\$ 0.0358
Tranche 5	A\$ 0.0390
Tranche 6	A\$ 0.0417
Tranche 7	A\$ 0.0437
Tranche 8	A\$ 0.0493
Tranche 9	A\$ 0.0493

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 2,250,000 options were unvested.

vii) On June 12, 2018, 2,000,000 options were granted to an employee at an exercise price of A\$0.056 expiring on June 12, 2028.

The following table lists the inputs to the models used for the options granted to employee each year:

Grant date	06/12/2018
Share price at date of grant	A\$ 0.056
Dividend yield (%)	0%
Expected volatility (%)	90%
Risk-free interest rate (%)	2.65%
Expected life of option (days)	3,650
Option exercise price (A\$)	A\$ 0.056

This represents tranches 1-9, the fair value at date of grant for each tranche is as follows:

Tranche 1	A\$ 0.0485
Tranche 2	A\$ 0.0485
Tranche 3	A\$ 0.0485
Tranche 4	A\$ 0.0352
Tranche 5	A\$ 0.0384
Tranche 6	A\$ 0.0409
Tranche 7	A\$ 0.0430
Tranche 8	A\$ 0.0485
Tranche 9	A\$ 0.0485

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 975,000 options were unvested.

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

17. SHARE-BASED PAYMENT PLANS (continued)

viii) On June 14, 2018, 700,000 options were granted to an employee at an exercise price of A\$0.057 expiring on June 14, 2028.

The following table lists the inputs to the models used for the options granted to employees:

Grant date	06/14/2018
Share price at date of grant	A\$ 0.058
Dividend yield (%)	0%
Expected volatility (%)	90%
Risk-free interest rate (%)	2.65%
Expected life of option (days)	3,650
Option exercise price (A\$)	A\$ 0.057

This represents tranches 1-9, the fair value at date of grant for each tranche is as follows:

Tranche 1	A\$ 0.0502
Tranche 2	A\$ 0.0502
Tranche 3	A\$ 0.0502
Tranche 4	A\$ 0.0365
Tranche 5	A\$ 0.0399
Tranche 6	A\$ 0.0425
Tranche 7	A\$ 0.0446
Tranche 8	A\$ 0.0502
Tranche 9	A\$ 0.0502

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 350,000 options were unvested.

ix) On June 25, 2018, 3,000,000 options were granted to an employee at an exercise price of A\$0.059 expiring on June 25, 2028.

The following table lists the inputs to the models used for the options granted to employees:

Grant date	06/25/2018
Share price at date of grant	A\$ 0.059
Dividend yield (%)	0%
Expected volatility (%)	90%
Risk-free interest rate (%)	2.65%
Expected life of option (days)	3,650
Option exercise price (A\$)	A\$ 0.059

This represents tranches 1-9, the fair value at date of grant for each tranche is as follows:

Tranche 1	A\$ 0.0504	Tranche 6	A\$ 0.0448
Tranche 2	A\$ 0.0504	Tranche 7	A\$ 0.0504
Tranche 3	A\$ 0.0368	Tranche 8	A\$ 0.0504
Tranche 4	A\$ 0.0401	Tranche 9	A\$ 0.0504
Tranche 5	A\$ 0.0427		

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 1,480,000 options were unvested.

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

17. SHARE-BASED PAYMENT PLANS (continued)

x) On November 1, 2018, 17,200,000 options were granted to employees at an exercise price of A\$0.089 expiring on November 1, 2028.

The following table lists the inputs to the models used for the options granted to employees each year:

	Tranche 1		Tranche 2		Tranche 3		Tranche 4	
Grant date	11/1/2018		11/1/2018		11/1/2018		11/1/2018	
Share price at date of grant	A\$	0.093	A\$	0.093	A\$	0.093	A\$	0.093
Dividend yield (%)		0%		0%		0%		0%
Expected volatility (%)		90%		90%		90%		90%
Risk-free interest rate (%)		2.65%		2.65%		2.65%		2.65%
Expected life of option (days)		3,650		3,650		3,650		3,650
Fair value at date of grant	A\$	0.0587	A\$	0.0641	A\$	0.683	A\$	0.0716
Option exercise price (A\$)	A\$	0.089	A\$	0.089	A\$	0.089	A\$	0.089

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 14,430,000 options were unvested, and 2,770,000 options were forfeited.

xi) On November 30, 2018, 24,851,250 options were granted to employees at an exercise price of A\$0.082 expiring on November 30, 2028.

The following table lists the inputs to the models used for the options granted to employees each year:

	Tranche 1		Tranche 2		Tranche 3		Tranche 4	
Grant date	11/30/2018		11/30/2018		11/30/2018		11/30/2018	
Share price at date of grant	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082
Dividend yield (%)		0%		0%		0%		0%
Expected volatility (%)		90%		90%		90%		90%
Risk-free interest rate (%)		2.65%		2.65%		2.65%		2.65%
Expected life of option (days)		3,650		3,650		3,650		3,650
Fair value at date of grant	A\$	0.0514	A\$	0.0561	A\$	0.0599	A\$	0.0628
Option exercise price (A\$)	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 18,881,250 options were unvested, and 5,970,000 options were forfeited.

xii) On January 2, 2019, 1,180,000 options were granted to employees at an exercise price of A\$0.082 expiring on January 2, 2023.

The following table lists the inputs to models used for the options granted to employees each year:

	Tranche 1		Tranche 2		Tranche 3		Tranche 4	
Grant date	01/02/2019		01/02/2019		01/02/2019		01/02/2019	
Share price at date of grant	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082
Dividend yield (%)		0%		0%		0%		0%
Expected volatility (%)		90%		90%		90%		90%
Risk-free interest rate (%)		2.65%		2.65%		2.65%		2.65%
Expected life of option (days)		3,650		3,650		3,650		3,650
Fair value at date of grant	A\$	0.045	A\$	0.0488	A\$	0.0519	A\$	0.0543
Option exercise price (A\$)	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 1,180,000 options were unvested.

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

17. SHARE-BASED PAYMENT PLANS (continued)

xiii) On January 2, 2019, 4,910,000 options were granted to employees at an exercise price of A\$0.082 expiring on January 2, 2023.

The following table lists the inputs to the models used for the options granted to employees each year:

	Tranche 1		Tranche 2		Tranche 3		Tranche 4	
Grant date	01/02/2019		01/02/2019		01/02/2019		01/02/2019	
Share price at date of grant	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082
Dividend yield (%)	0%		0%		0%		0%	
Expected volatility (%)	90%		90%		90%		90%	
Risk-free interest rate (%)	2.65%		2.65%		2.65%		2.65%	
Expected life of option (days)	3,650		3,650		3,650		3,650	
Fair value at date of grant	A\$	0.0462	A\$	0.0497	A\$	0.0526	A\$	0.0551
Option exercise price (A\$)	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 4,910,000 options were unvested.

xiv) On January 2, 2019, 380,000 options were granted to employees at an exercise price of A\$0.082 expiring on January 2, 2029.

The following table lists the inputs to the models used for the options granted to employees each year:

	Tranche 1		Tranche 2		Tranche 3		Tranche 4	
Grant date	01/02/2019		01/02/2019		01/02/2019		01/02/2019	
Share price at date of grant	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082
Dividend yield (%)	0%		0%		0%		0%	
Expected volatility (%)	90%		90%		90%		90%	
Risk-free interest rate (%)	2.65%		2.65%		2.65%		2.65%	
Expected life of option (days)	3,650		3,650		3,650		3,650	
Fair value at date of grant	A\$	0.0455	A\$	0.0488	A\$	0.0519	A\$	0.0543
Option exercise price (A\$)	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 380,000 options were unvested.

xv) On April 1, 2019, 6,866,250 options were granted to employees at an exercise price of A\$0.300 expiring on April 1, 2029.

The following table lists the inputs to the models used for the options granted to employees each year:

Grant date	04/01/2019
Share price at date of grant	A\$ 0.300
Dividend yield (%)	0%
Expected volatility (%)	90%
Risk-free interest rate (%)	2.65%
Expected life of option (days)	3,650
Option exercise price (A\$)	A\$ 0.300

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

17. SHARE-BASED PAYMENT PLANS (continued)

This represents tranches 1-20, the fair value at date of grant for each tranche is as follows:

Tranche 1	A\$0.1706	Tranche 8	A\$0.2026	Tranche 15	A\$0.1688
Tranche 2	A\$0.1834	Tranche 9	A\$0.1936	Tranche 16	A\$0.1812
Tranche 3	A\$0.1945	Tranche 10	A\$0.2030	Tranche 17	A\$0.1926
Tranche 4	A\$0.2037	Tranche 11	A\$0.1677	Tranche 18	A\$0.2022
Tranche 5	A\$0.1694	Tranche 12	A\$0.1806	Tranche 19	A\$0.2033
Tranche 6	A\$0.1823	Tranche 13	A\$0.1922	Tranche 20	A\$0.1682
Tranche 7	A\$0.1931	Tranche 14	A\$0.2014		

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 6,866,250 options were unvested.

xvi) On November 30, 2018, 360,000 options were granted to employees at an exercise price of A\$0.082 expiring on November 30, 2028.

The following table lists the inputs to the models used for the options granted to employees each year:

	Tranche 1		Tranche 2		Tranche 3		Tranche 4	
Grant date	11/30/2018		11/30/2018		11/30/2018		11/30/2018	
Share price at date of grant	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082
Dividend yield (%)		0%		0%		0%		0%
Expected volatility (%)		90%		90%		90%		90%
Risk-free interest rate (%)		2.65%		2.65%		2.65%		2.65%
Expected life of option (days)		3,650		3,650		3,650		3,650
Fair value at date of grant	A\$	0.0514	A\$	0.0561	A\$	0.0599	A\$	0.0628
Option exercise price (A\$)	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 360,000 options were unvested.

xvii) On June 28, 2019, 9,644,168 options were granted to employees at an exercise price of A\$0.42 expiring on June 28, 2029.

The following table lists the inputs to the models used for the options granted to employees each year:

	Tranche 1		Tranche 2		Tranche 3		Tranche 4	
Grant date	06/28/2019		06/28/2019		06/28/2019		06/28/2019	
Share price at date of grant	A\$	0.42	A\$	0.42	A\$	0.42	A\$	0.42
Dividend yield (%)		0%		0%		0%		0%
Expected volatility (%)		90%		90%		90%		90%
Risk-free interest rate (%)		2.65%		2.65%		2.65%		2.65%
Expected life of option (days)		3,650		3,650		3,650		3,650
Option exercise price (A\$)	A\$	0.42	A\$	0.42	A\$	0.42	A\$	0.42

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

17. SHARE-BASED PAYMENT PLANS (continued)

This represents tranches 1-21, the fair value at date of grant for each tranche is as follows:

Tranche 1	A\$0.2389	Tranche 8	A\$0.2868	Tranche 15	A\$0.2751
Tranche 2	A\$0.2567	Tranche 9	A\$0.2413	Tranche 16	A\$0.2421
Tranche 3	A\$0.2732	Tranche 10	A\$0.2591	Tranche 17	A\$0.2757
Tranche 4	A\$0.2862	Tranche 11	A\$0.2745	Tranche 18	A\$0.2430
Tranche 5	A\$0.2397	Tranche 12	A\$0.2878	Tranche 19	A\$0.2606
Tranche 6	A\$0.2575	Tranche 13	A\$0.2884	Tranche 20	A\$0.2764
Tranche 7	A\$0.2738	Tranche 14	A\$0.2598	Tranche 21	A\$0.2889

The above valuation includes varied vesting periods and assumes an early exercise multiple. At year end, 9,644,168 options were unvested.

xviii) On the November 30, 2018, 15,000,000 options were granted to Dr Michael Perry at an exercise price of A\$0.082 expiring on November 30, 2028 based on the following milestones:

1. *Tenure* – a total of 3,333,333 options issued but to vest over the two-year period commencing June 1,2019;
2. *Company Share Price* – a total of 5,000,001 options issued but to vest in three equal tranches subject to the Volume Weighted Average Price (VWAP) of Company share price (as at close of trade on the ASX on relevant date) achieving multiples of 2x, 3x and 4x the Company's share price at the time of shareholder approval; and
3. *Milestone performance* – a total of 2,500,000 options issued, but to vest upon the achievement of initial BARDA procurement under CLIN2 of the BARDA Contract.
4. *Vested Due to Milestone Achievement* – a total of 4,166,666 options, fully vested due to prior achievement of a milestone related to FDA approval of RECELL for burns.

Grant date	Tranche 1		Tranche 2		Tranche 3		Tranche 4	
	11/30/2018		11/30/2018		11/30/2018		11/30/2018	
Share price at date of grant	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082
Dividend yield (%)		0%		0%		0%		0%
Expected volatility (%)		90%		90%		90%		90%
Risk-free interest rate (%)		2.59%		2.59%		2.59%		2.59%
Expected life of option (days)		3,650		3,650		3,650		3,650
Fair value at date of grant	A\$	0.049	A\$	0.054	A\$	0.048	A\$	0.052
Option exercise price (A\$)	A\$	0.082	A\$	0.082	A\$	0.082	A\$	0.082

Grant date	Tranche 5		Tranche 6		Tranche 7	
	11/30/2018		11/30/2018		11/30/2018	
Share price at date of grant	A\$	0.082	A\$	0.082	A\$	0.082
Dividend yield (%)		0%		0%		0%
Expected volatility (%)		90%		90%		90%
Risk-free interest rate (%)		2.59%		2.59%		2.59%
Expected life of option (days)		3,650		3,650		3,650
Fair value at date of grant	A\$	0.058	A\$	0.071	A\$	0.048
Option exercise price (A\$)	A\$	0.082	A\$	0.082	A\$	0.082

At year end, 4,166,667 options were unvested.

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

17. SHARE-BASED PAYMENT PLANS (continued)

(h) Long-term incentive rights

On the November 30, 2017, 50,000,000 LTI's were issued to Dr Michael Perry based on the following milestones:

5. *Tenure* – a total of 16,666,666 LTIs issued but to vest over the three-year period commencing July 1,2017;
6. *Company Share Price* – a total of 16,666,666 LTIs issued but to vest in three equal tranches subject to the Volume Weighted Average Price (VWAP) of Company share price (as at close of trade on the ASX on relevant date) achieving multiples of 2x, 3x and 4x the Company's share price at the time of shareholder approval; and
7. *Milestone performance* – a total of 16,666,668 LTIs issued, but to vest in two equal tranches with one tranche to vest upon the achievement of the following milestones:
 - a. FDA PMA approval of RECELL for burns
 - b. Initial BARDA procurement under CLIN2 of the BARDA Contract

	<u>Tranche 1</u>		<u>Tranche 2</u>		<u>Tranche 3</u>		<u>Tranche 4</u>	
Grant date	11/30/2017		11/30/2017		11/30/2017		11/30/2017	
Share price at date of grant	A\$	0.061	A\$	0.061	A\$	0.061	A\$	0.061
Exercise price	A\$	nil	A\$	nil	A\$	nil	A\$	nil
Vesting hurdle		n/a		n/a		n/a	A\$	0.122
Expiry period	11/30/2027		11/30/2027		11/30/2027		11/30/2027	
Dividend yield (%)		0%		0%		0%		0%
Expected volatility (%)		70%		70%		70%		70%
Risk-free interest rate (%)		2.47%		2.47%		2.47%		2.47%

	<u>Tranche 5</u>		<u>Tranche 6</u>		<u>Tranche 7</u>		<u>Tranche 8</u>	
Grant date	11/30/2017		11/30/2017		11/30/2017		11/30/2017	
Share price at date of grant	A\$	0.061	A\$	0.061	A\$	0.061	A\$	0.061
Exercise price	A\$	nil	A\$	nil	A\$	nil	A\$	nil
Vesting hurdle	A\$	0.183	A\$	0.244		n/a		n/a
Expiry period	11/30/2027		11/30/2027		11/30/2027		11/30/2027	
Dividend yield (%)		0%		0%		0%		0%
Expected volatility (%)		70%		70%		70%		70%
Risk-free interest rate (%)		2.47%		2.47%		2.47%		2.47%

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

18. SEGMENT INFORMATION

Operating segments are identified based on internal reports about components of the Company that are regularly reviewed by the chief operating decision maker to allocate resources to the segment and to assess its performance.

The Company's chief operating decision maker has been identified as the Chief Executive Officer.

The Chief Executive Officer reviews the financial and operating performance of the business primarily from a geographic perspective. On this basis, management have identified three reportable operating segments being the Asia Pacific, Europe and Americas including Canada. The Chief Executive Officer monitors the performance of all these segments separately. The Company does not operate in any other geographic segment.

The Americas, Europe, and Asia Pacific operating segments derived its revenues from the sale of RECELL Devices.

The Chief Executive Officer assesses the performance of the operating segments based on a measure of gross margin and net profit before tax.

Unallocated

The following items of income and expense and associated assets are not allocated to operating segments as they are not considered part of the core operations of any segment:

- Corporate revenue
- Corporate charges
- Amortisation of intellectual property

The segment information provided to the Chief Executive Officer for the reportable segments for the year ended June 30, 2019 is as follows:

Year ended June 30, 2019	<i>Asia Pacific</i>	<i>Continuing Operations</i>		<i>Total</i>
		<i>Europe</i>	<i>Americas</i>	
Revenue				
Sale of goods	A\$ 1,126,407	A\$ 364,331	A\$ 6,214,660	A\$ 7,705,398
Other income	11,970	543	8,703,335	8,715,848
Total revenue and other income per consolidated statement of profit or loss and other comprehensive income	A\$ 1,138,377	A\$ 364,874	A\$ 14,917,995	A\$ 16,421,246
Segment net loss before tax benefit	A\$ (734,835)	A\$ (919,932)	A\$ (27,919,276)	A\$ (29,574,043)
Reconciliation of segment net result before tax to loss before income tax benefit				
Corporate charges including share-based expenses				(5,766,047)
Loss before income tax				A\$ (35,340,090)

The Company's other income in its Americas including Canada operating segment includes \$8,259,152 from BARDA, representing 95% of the Americas operating segment's total other income from external customers for the year ended June 30, 2019.

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

18. SEGMENT INFORMATION (Continued)

Revenue is attributed to geographic location based on the location of the customers. The percentages of external revenues from external customers that are attributable to foreign countries are as shown below:

	<u>2019</u>	<u>2018</u>
Australia	14.6%	6.8%
Americas and other	85.4%	93.2%
Total revenue	<u>100.0%</u>	<u>100.0%</u>

	<i>Asia Pacific</i>	<i>EMEA</i>	<i>Americas</i>	<i>Total</i>
Year ended June 30, 2019				
Segment assets				
Segment operating assets	A\$ 870,041	A\$ 284,424	A\$32,455,556	A\$ 33,610,021
Segment non-current assets	324,456	5,862	1,828,873	2,159,191
Unallocated assets	A\$ —	A\$ —	A\$ —	A\$ 968,861
Total assets per the consolidated statement of financial position				<u>A\$ 36,738,073</u>
Segment liabilities				
Segment operating liabilities	A\$ 172,815	A\$ 196,908	A\$ 5,777,373	A\$ 6,147,096
Unallocated liabilities	—	—	—	801,556
Total liabilities per the consolidated statement of financial position				<u>A\$ 6,948,652</u>
Year ended June 30, 2018				
Revenue				
Sale of goods	A\$ 709,907	A\$ 488,954	A\$ —	A\$ 1,198,861
Other income	—	2,961	10,104,081	10,107,042
Interest received	59,552	438	5,666	65,656
Total revenue and other income per consolidated statement of profit or loss and other comprehensive income	<u>A\$ 769,459</u>	<u>A\$ 492,353</u>	<u>A\$10,109,747</u>	<u>A\$ 11,371,559</u>
Segment net loss before tax benefit	<u>A\$(1,341,200)</u>	<u>A\$(2,181,622)</u>	<u>A\$ (9,539,296)</u>	<u>A\$ (13,062,118)</u>
Reconciliation of segment net result before tax to loss before income tax benefit:				
Corporate charges including share-based expenses				<u>A\$ (4,842,833)</u>
Loss before income tax				<u>A\$(17,904,951)</u>

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

18. SEGMENT INFORMATION (continued)

	<i>Asia Pacific</i>	<i>EMEA</i>	<i>Americas</i>	<i>Total</i>
Year ended June 30, 2018				
Segment assets				
Segment operating assets	A\$ 532,926	A\$ 579,081	A\$ 17,079,653	A\$ 18,191,660
Segment non-current assets	5,662	18,215	703,100	726,977
Unallocated assets	A\$ —	A\$ —	A\$ —	A\$ 4,098,377
Total assets per the consolidated statement of financial position				<u>A\$ 23,017,014</u>
Segment liabilities				
Segment operating liabilities	A\$ 189,531	A\$ 176,461	A\$ 3,314,423	A\$ 3,680,415
Unallocated liabilities	—	—	—	337,040
Total liabilities per the consolidated statement of financial position				<u>A\$ 4,017,455</u>
Year ended June 30, 2017				
Revenue				
Sale of goods	A\$ 452,662	A\$ 448,714	A\$ —	A\$ 901,376
Other revenues from external customers	197,488	23,537	6,886,236	7,107,261
Interest received	116,559	1,218	5,932	123,709
Total revenue and other income per consolidated statement of profit or loss and other comprehensive income	<u>A\$ 766,709</u>	<u>A\$ 473,469</u>	<u>A\$ 6,892,168</u>	<u>A\$ 8,132,346</u>
Segment net operating loss before tax	A\$(1,559,592)	A\$(2,836,165)	A\$ (2,373,062)	A\$ (6,768,819)
Reconciliation of segment net result before tax to loss before income tax:				
Corporate charges including share-based expenses				(5,790,442)
Loss before income tax				<u>A\$ (12,559,261)</u>
Year ended June 30, 2017				
Segment assets				
Segment operating assets	A\$ 227,359	A\$ 1,166,946	A\$ 2,342,846	A\$ 3,737,150
Segment non-current assets	6,624	20,375	360,380	387,380
Unallocated assets	—	—	—	3,156,011
Total assets per the consolidated statement of financial position				<u>A\$ 7,280,541</u>
Segment liabilities				
Segment operating liabilities	A\$ 153,502	A\$ 468,996	A\$ 1,743,657	A\$ 2,366,155
Unallocated liabilities	—	—	—	179,934
Total liabilities per the consolidated statement of financial position				<u>A\$ 2,546,089</u>

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

19. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Company's principal financial instruments comprise receivables, payables, cash and short-term deposits.

The Company manages its exposure to key financial risks, including interest rate and foreign currency risk in accordance with the Company's financial risk management policy. The objective of the policy is to support the delivery of the Company's financial targets whilst protecting future financial security.

The main risks arising from the Company's financial instruments are interest rate risk, foreign currency risk, credit risk and liquidity risk. The Company uses different methods to measure and manage different types of risk to which it is exposed. These include monitoring levels of exposure to interest rate and foreign exchange risk and assessments of market forecasts for interest rates and foreign exchange. Aging analyses and monitoring of specific credit allowances are undertaken to manage credit risk, and liquidity risk is monitored through the development of future rolling cash flow forecasts. The Board reviews and agrees on policies for managing each of these risks as summarized below.

Primary responsibility for identification and control of financial risks rests with the Chief Financial Officer under the authority of the Board. The Board reviews and agrees on policies for managing each of the risks identified below including foreign currency and interest rate risk, credit allowances and future cash flow forecast projections.

At the reporting date, the Company had the following financial assets and liabilities:

	<u>2019</u>	<u>2018</u>
Financial Assets		
Cash and cash equivalents	A\$28,983,491	A\$14,825,532
Trade and other receivables	2,980,102	5,437,357
Financial Liabilities		
Trade and other payables	(5,633,562)	(3,487,582)
Provisions	(650,359)	(395,535)
Net	<u><u>A\$25,679,672</u></u>	<u><u>A\$16,379,772</u></u>

Risk Exposures and Responses

Interest rate risk

The Company's exposure to market interest rates relates primarily to short-term deposits with a floating interest rate.

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

19. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

At reporting date, the Company had the following mix of financial assets exposed to interest rate risk:

	2019	2018
Financial Assets		
Cash and cash equivalents	A\$28,983,491	A\$14,825,532
Net exposure	A\$28,983,491	A\$14,825,532

The Company's policy is to manage its finance costs and revenue using a mix of fixed and variable interest rates depending on the forecast funding requirements of the Company. At June 30, 2019 and 2018, there were no cash and cash equivalents recorded at a fixed rate of interest.

The following sensitivity analysis is based on the interest rate exposures in existence at the reporting date. The 1% sensitivity is based on reasonably possible changes over a financial year, using the observed range of historical rates for the preceding two-year period.

At June 30, 2019, if interest rates had moved, as illustrated in the table below with all other variables held constant, post tax loss and equity would have been affected as follows:

Judgements of reasonably possible movements:

	Post Tax Loss (Higher)/Lower		Equity Higher/(Lower)	
	2019	2018	2019	2018
+1% (100 basis points)	A\$ 289,835	A\$ 148,255	A\$ 289,835	A\$ 148,255
-1% (100 basis points)	(289,835)	(148,255)	(289,835)	(148,255)

The movements in loss are due to higher/lower finance revenue from variable rate cash balances.

Foreign currency risk

The Company has investment operations in Europe and the United States. The Company's consolidated statement of financial position can be affected by movements in exchange rates and the Company does not currently hedge this exposure.

The Company also has transactional currency exposures. Such exposures arise from sales or purchases by an operating entity in currencies other than the functional currency.

Approximately 85% (2018: 93%) of the Company's sales are denominated in currencies other than the functional currency, whilst approximately 70% (2018: 74%) of costs are denominated in the functional currency.

At June 30, 2019, the Company had the following exposure to foreign currencies:

	2019	2018
Financial Assets		
Cash and cash equivalents	A\$28,539,291	A\$13,046,513
Trade and other receivables	2,350,457	2,847,542
	30,889,748	15,894,055
Financial Liabilities		
Trade and other payables	(4,718,118)	(3,356,546)
Net exposure	A\$26,171,630	A\$12,537,509

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

19. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

The following sensitivity is based on the foreign currency risk exposures in existence at the reporting date. The percentage sensitivity is based on reasonably possible changes over a financial year, using the observed range of historical rates for the preceding two-year period.

At June 30, 2019, had the Australian Dollar moved, as illustrated in the table below, with all other variables held constant, post-tax loss and equity would have been affected as follows:

Judgments of reasonably possible movements:

	2019	Post Tax Loss (Higher)/Lower 2018	2017	2019	Equity (Higher)/(Lower) 2018	2017
AUD/GBP +10%	A\$ 29,701	A\$ 54,761	A\$(62,731)	A\$ 29,701	A\$ 54,761	A\$(62,731)
AUD/GBP -5%	14,851	27,380	31,366	14,851	27,380	31,366
AUD/USD +10%	3,509,311	1,827,003	(67,791)	3,509,311	1,827,003	(67,791)
AUD/USD -5%	1,754,656	913,502	33,895	1,754,656	913,502	33,895
AUD/EUR +10%	12,762	8,663	(13,795)	12,762	8,663	(13,795)
AUD/EUR -5%	6,381	4,332	6,897	6,381	4,332	6,897

Management believe the reporting date risk exposures are representative of the risk exposure inherent in the financial instruments. The Company has no processes and objectives for managing foreign exchange risks.

Credit risk

Credit risk arises from the financial assets of the Company, which comprise cash and cash equivalents and trade and other receivables. The Company's exposure to credit risk arises from potential default of the counterparty, with a maximum exposure equal to the carrying amount of these instruments.

The Company does not hold any credit derivatives to offset its credit exposure.

The Company trades only with recognized, creditworthy third parties, and as such collateral is not requested nor is it the Company's policy to securitize its trade and other receivables.

It is the Company's policy that all customers who wish to trade on credit terms are subject to credit verification procedures including an assessment of their independent credit rating, financial position, experience and industry reputation. Risk limits are set for each individual customer in accordance with parameters set by the Board. These risk limits are regularly monitored.

In addition, receivable balances are monitored on an on-going basis with the result that the Company's exposure to bad debts is not significant.

A significant balance of cash is held in Silicon Valley Bank. This is a highly rated institution which effectively manages its risk profile and therefore the company considers its cash balances to be secure.

There is no concentration of debt amongst the creditors.

Liquidity risk

The Company's objective is to maintain a balance between continuity of funding and flexibility using bank overdrafts, bank loans and finance leases.

The table below reflects all contractually fixed payoffs and receivables for settlement, repayments and interest resulting from recognized financial assets and liabilities. For all obligations, the respective undiscounted cash flows for the respective upcoming fiscal years are presented. Cash flows for financial assets and liabilities without fixed amount or timing are based on the conditions existing at June 30, 2019.

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

19. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

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

	2019	2018
6 months or less	A\$ 5,633,562	A\$ 3,487,582
6-12 months	—	—
1-3 years	—	—
	<u>A\$ 5,633,562</u>	<u>A\$ 3,487,582</u>

Maturity analysis of financial assets and liabilities are based on management's expectation.

The risk implied from the values shown in the table below reflects a balanced view of cash inflows and outflows. Trade payables and other financial liabilities mainly originate from the financing of assets used in our on-going operations such as property, plant, equipment and investments in working capital including inventories and trade receivables. These assets are considered in the Company's overall liquidity risk.

Year ended June 30, 2019	< 6 months	6-12 months	1-5 years	Total
Financial Assets				
Cash and cash equivalents	A\$28,983,491	A\$ —	A\$ —	A\$28,983,491
Trade and other receivables	2,980,102	—	—	2,980,102
	<u>31,963,593</u>	<u>—</u>	<u>—</u>	<u>31,963,593</u>
Financial Liabilities				
Trade and other payables	(5,633,562)	—	—	(5,633,562)
Net maturity	<u>A\$26,330,031</u>	<u>A\$ —</u>	<u>A\$ —</u>	<u>A\$26,330,031</u>
Year ended June 30, 2018	< 6 months	6-12 months	1-5 years	Total
Financial Assets				
Cash & cash equivalents	A\$14,825,532	A\$ —	A\$ —	A\$14,825,532
Trade & other receivables	5,437,357	—	—	5,437,357
	<u>20,262,889</u>	<u>—</u>	<u>—</u>	<u>20,262,889</u>
Financial Liabilities				
Trade & other payables	(3,487,582)	—	—	(3,487,582)
Net maturity	<u>A\$16,775,307</u>	<u>A\$ —</u>	<u>A\$ —</u>	<u>A\$16,775,307</u>

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

20. COMMITMENTS AND CONTINGENCIES

Finance Leases as Lessee

The Company's furniture and IT equipment are held under lease arrangements. As of June 30, 2019, the net carrying amount of the furniture and IT equipment held under lease arrangements is A\$65,369.

The Company's finance lease liabilities, which are secured by the related assets held under finance leases, are classified as follows:

Finance Lease liabilities	2019
Current:	A\$48,265
Non-current:	17,104
	<u>A\$65,369</u>

	Minimum Lease Payment Due			Total
	Within 1 Year	1-5 Years	After 5 Years	
June 30, 2019				
Lease Payments	66,643	17,165	—	83,808
Finance charges	(15,282)	(3,157)	—	(18,439)
Net Present Values	51,361	14,008	—	65,369

Operating Leases as Lessee

The Company leases space under operating leases. Future minimum lease payments as of June 30, 2019 are as follows:

	Minimum Lease Payment Due			Total
	Within 1 Year	1-5 Years	After 5 Years	
June 30, 2019	839,673	745,693	—	1,585,366
June 30, 2018	525,919	856,541	—	1,382,460
June 30, 2017	344,431	879,079	—	1,223,509

21. AUDITORS' REMUNERATION

The auditors of Avita Medical Limited and its subsidiaries are Grant Thornton Audit Pty Ltd.

	2019	2018	2017
<i>Amounts received or due and receivable by Grant Thornton Pty Ltd.</i>			
An audit or review of the financial report of the Company and any other entity in the Group	A\$ 256,462	A\$ 182,440	A\$ 120,366
Other services in relation to the entity and any other entity in the Group – Taxation services	65,318	46,811	62,635
	<u>A\$ 321,780</u>	<u>A\$ 229,251</u>	<u>A\$ 183,001</u>

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

22. PARENT ENTITY INFORMATION

Information relating to Avita Medical Limited:

	<u>2019</u>	<u>2018</u>
Current assets	A\$ 968,862	A\$ 4,098,378
Total assets	968,862	4,098,378
Current liabilities	(801,555)	(337,040)
Total liabilities	<u>(801,555)</u>	<u>(337,040)</u>
Net assets	167,307	3,761,338
Issued capital	204,279,078	162,801,028
Accumulated losses	(211,334,455)	(163,541,196)
Share option reserves	<u>7,222,684</u>	<u>4,501,506</u>
Total shareholders' equity	A\$ 167,307	A\$ 3,761,338
Loss of parent entity after income tax	A\$ (5,586,183)	A\$ (3,258,675)
Total comprehensive loss of the parent entity	A\$ (5,586,183)	A\$ (3,258,675)
Details of any contingent liabilities of the parent entity	None	None
Details of any contractual commitments by the parent entity for the acquisition of plant and equipment	None	None

During the period, the parent entity impaired A\$40,806,526 (2018: A\$21,368,073) of intercompany loans to subsidiaries and investments in subsidiaries. The impairment charges are eliminated on consolidation.

23. DEED OF CROSS GUARANTEE

The following entities are party to a deed of cross guarantee under which each company guarantees the debts of the others:

Avita Medical Limited
C3 Operations Pty Ltd
Visiomed Group Pty Ltd
Infamed Pty Limited

By entering into the deed, the wholly owned entities have been relieved from the requirement to prepare a financial report and Directors' Report under Australian Securities and Investments Commission ('ASIC') Corporations (Wholly owned Companies) Instrument 2016/785.

The above companies represent a 'Closed Company' for the purposes of the Class Order, and as there are no other parties to the Deed of Cross guarantee that are controlled by Avita Medical Limited, they also represent the 'Extended Closed Company'.

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

23. DEED OF CROSS GUARANTEE (continued)

Set out below is a consolidated statement of profit or loss and other comprehensive income and consolidated statement of financial position of the 'Closed Company'.

	2019	2018	2017
Continuing operations			
Sale of goods	A\$ 1,126,407	A\$ 709,907	A\$ 452,662
Other income	11,972	59,552	129,958
Total revenue and other income	1,138,379	769,459	582,620
Cost of sales	(511,345)	(331,244)	(243,708)
Gross profit	627,034	438,215	338,912
Other income	—	—	184,088
Operating costs			
Sales and marketing expenses	(1,286,323)	(1,250,976)	(834,600)
Product development expenses	(352,186)	(43,048)	(2,365,647)
Corporate and administrative expenses	(5,480,845)	(4,660,971)	(3,085,503)
Impairment of inter-company loans	(40,806,526)	(21,368,073)	(5,983,551)
Finance costs	(8,558)	—	(41)
Total operating costs	(47,934,438)	(27,323,068)	(12,269,342)
Loss from continuing operations before income tax benefit	(47,307,404)	(26,884,853)	(11,746,342)
Income tax benefit	179,863	1,385,796	1,048,634
Total comprehensive loss for the period	A\$ (47,127,541)	A\$ (25,499,057)	A\$ (10,697,708)

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

23. DEED OF CROSS GUARANTEE (continued)

	2019	2018
Current assets		
Cash and cash equivalents	A\$ 444,200	A\$ 1,779,019
Trade and other receivables	629,646	2,589,816
Prepayments and other assets	708,635	130,055
Inventories	56,422	132,414
Total current assets	1,838,903	4,631,304
Non-current assets		
Plant and equipment	3,780	5,662
Patents-in-progress	320,676	—
Total non-current assets	324,456	5,662
TOTAL ASSETS	A\$ 2,163,359	A\$ 4,636,966
LIABILITIES		
Current liabilities		
Trade and other payables	916,619	477,366
Provisions	57,751	49,205
Total current liabilities	974,370	526,571
TOTAL LIABILITIES	A\$ 974,370	A\$ 526,571
NET ASSETS	A\$ 1,188,989	A\$ 4,110,395
EQUITY		
Contributed equity	204,279,078	162,801,028
Accumulated losses	(210,313,036)	(163,194,156)
Reserves	7,222,947	4,503,523
TOTAL EQUITY	A\$ 1,188,989	A\$ 4,110,395

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

24. SUBSEQUENT EVENTS

On September 19, 2019 AVITA filed a registration statement on Form 20-F under the Securities Exchange Act of 1934 with the Securities and Exchange Commission (“SEC”) relating to the proposed registration in the United States of its class of American Depositary Shares representing ordinary shares of the Company. The registration statement was declared effective by the SEC on September 27, 2019, and the Company started trading of its American Depositary Shares on Nasdaq Capital Market on October 1, 2019 under the ticker symbol “RCEL.” This disclosure does not constitute an offer to sell, or the solicitation of an offer to buy, any securities of the Company.

CERTIFICATION
pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended

I, Dr. Michael Perry, certify that:

1. I have reviewed this annual report on Form 20-F of Avita Medical Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: October 31, 2019

/s/ Dr. Michael Perry

Dr. Michael Perry
Chief Executive Officer

CERTIFICATION
pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended

I, Timothy Rooney, certify that:

1. I have reviewed this annual report on Form 20-F of Avita Medical Limited;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) [paragraph omitted in accordance with Exchange Act Rule 13a-14(a)];
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: October 31, 2019

/s/ Timothy Rooney

Timothy Rooney
Chief Financial Officer

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report of Avita Medical Limited (the "Company") on Form 20-F for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dr. Michael Perry, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, that, to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Dr. Michael Perry

Dr. Michael Perry
Chief Executive Officer

Date: October 31, 2019

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350

In connection with the Annual Report of Avita Medical Limited (the "Company") on Form 20-F for the period ended June 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Timothy Rooney, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, that, to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Timothy Rooney

Timothy Rooney
Chief Financial Officer

Date: October 31, 2019