UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F

☐ **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**

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

For the transition period from _____ to _____

Commission file number 001-37626

MESOBLAST LIMITED

(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

AUSTRALIA
(Jurisdiction of incorporation or organization)

Level 38, 55 Collins Street
Melbourne, VIC, 3000, Australia
Telephone: +61 (3) 9639 6036
(Address of principal executive offices)

Silviu Itescu
Chief Executive Officer
Telephone: +61 (3) 9639 6036; Fax: +61 (3) 9639 6030
Level 38, 55 Collins Street
Melbourne, VIC, 3000, Australia
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing five Ordinary Shares*	MESO	The NASDAQ Global Select Market

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.

498,626,208 Ordinary Shares

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, or 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. (Check one):

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

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

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

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

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

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

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INTRODUCTION AND USE OF CERTAIN TERMS

Mesoblast Limited and its consolidated subsidiaries publish consolidated financial statements expressed in U.S. dollars, unless otherwise indicated. This Annual Report on Form 20-F is presented in U.S. dollars, unless otherwise indicated. Our consolidated financial statements found in Item 18 of this annual report on Form 20-F are prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board and Australian equivalents to International Financial Reporting Standards as issued by the Australian Accounting Standards Board.

Except where the context requires otherwise and for purposes of this Form 20-F only:

- "ADSs" refers to our American depositary shares, each of which represents ordinary shares, and "ADRs" refers to the American depositary receipts that evidence our ADSs.
- "Mesoblast," "we," "us" or "our" refer to Mesoblast Limited and its subsidiaries.
- "A$" or "Australian dollar" refers to the legal currency of Australia.
- "IFRS" refers to the International Financial Reporting Standards as issued by the International Accounting Standards Board, or IASB.
- "AIFRS" refers to the Australian equivalents to International Financial Reporting Standards as issued by the Australian Accounting Standards Board, or AASB.
- "U.S. GAAP" refers to the Generally Accepted Accounting Principles in the United States.
- "FDA" refers to the United States Food and Drug Administration.
- "US$" or "U.S. dollars" refers to the legal currency of the United States.
- "U.S." or "United States" refers to the United States of America.

Australian Disclosure Requirements

Our ordinary shares are primarily quoted on the Australian Securities Exchange ("ASX") in addition to our listing of our ADSs on the Nasdaq Global Select Market. As part of our ASX listing, we are required to comply with various disclosure requirements as set out under the Australian *Corporations Act 2001* and the *ASX Listing Rules*. Information furnished under the sub-heading "Australian Disclosure Requirements" is intended to comply with ASX listing and *Corporations Act 2001* disclosure requirements and is not intended to fulfill information required by this Annual Report on Form 20-F.

FORWARD-LOOKING STATEMENTS

This Form 20-F includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our current expectations, assumptions, estimates and projections about the Company, our industry, economic conditions in the markets in which we operate, and certain other matters. These statements include, among other things, the discussions of our business strategy and expectations concerning our market position, future operations, margins, profitability, liquidity and capital resources. These statements are subject to known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "target," "likely," "will," "would," "could," "should", "may", "goal," "objective" and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. Forward- looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical and clinical studies, and our research and development programs;
- our ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials;
- our ability to advance our manufacturing capabilities;
- the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any;

- our ability to take advantage of the potential benefits of the 21st Century Cures Act;
- the commercialization of our product candidates, if approved;
- regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies;
- the potential for our product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths;
- the potential benefits of strategic collaboration agreements and our ability to enter into and maintain established strategic collaborations;
- our ability to establish and maintain intellectual property on our product candidates and our ability to successfully defend these in cases of alleged infringement;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our financial performance;
- developments relating to our competitors and our industry;
- the pricing and reimbursement of our product candidates, if approved; and
- other risks and uncertainties, including those listed under the caption “Risk Factors”.

You should read thoroughly this Form 20-F and the documents that we refer to herein with the understanding that our actual future results may be materially different from and/or worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements. Other sections of this Form 20-F include additional factors which could adversely impact our business and financial performance. Moreover, we operate in an evolving environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

This Form 20-F also contains third-party data relating to the biopharmaceutical market that includes projections based on a number of assumptions. The biopharmaceutical market may not grow at the rates projected by market data, or at all. The failure of this market to grow at the projected rates may have a material adverse effect on our business and the market price of our ordinary shares and ADSs. Furthermore, if any one or more of the assumptions underlying the market data turns out to be incorrect, actual results may differ from the projections based on these assumptions. You should not place undue reliance on these forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements made in this Form 20-F relate only to events or information as of the date on which the statements are made in this Form 20-F. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1. Identity of Directors, Senior Management

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

3.A Selected Financial Data

The following selected consolidated financial data presented below has been extracted from our consolidated financial statements prepared in accordance with IFRS as issued by the IASB. Our consolidated financial statements for the years ended June 30, 2019, 2018 and 2017 are included in "Item 18. Financial Statements" in this Form 20-F.

The summary consolidated financial data should be read in conjunction with "Item 5. Operating and Financial Review and Prospects" and our consolidated financial statements and related notes thereto. Historical results are not necessarily indicative of results to be expected in the future.

	Year ended June 30,				
(in U.S. dollars, in thousands except per share information)	**2019**	**2018**	**2017**	**2016**	**2015**
Consolidated Income Statement Data:					
Revenue:					
Commercialization revenue	$ 5,003	$ 3,641	$ 1,444	$ 37,969	$ 15,004
Milestone revenue	11,000	13,334	500	3,500	2,000
Interest revenue	719	366	468	1,079	2,757
Total revenue	**16,722**	**17,341**	**2,412**	**42,548**	**19,761**
Research & development	(59,815)	(65,927)	(58,914)	(50,013)	(62,649)
Manufacturing commercialization	(15,358)	(5,508)	(12,065)	(29,763)	(23,783)
Management and administration	(21,625)	(21,907)	(23,007)	(22,500)	(29,540)
Fair value remeasurement of contingent consideration(1)	(6,264)	10,541	(130)	28,112	(15,336)
Other operating income and expenses	(1,086)	1,312	1,489	2,714	15,303
Finance costs	(11,328)	(1,829)	—	—	—
Impairment of intangible assets	—	—	—	(61,919)	—
Loss before income tax	**(98,754)**	**(65,977)**	**(90,215)**	**(90,821)**	**(96,244)**
Income tax benefit/(expense)	8,955	30,687	13,400	86,694	—
Loss attributable to the owners of Mesoblast Limited	**$ (89,799)**	**$ (35,290)**	**$ (76,815)**	**$ (4,127)**	**$ (96,244)**
Losses per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share(2)	(18.16)	(7.58)	(19.25)	(1.13)	(29.71)
Diluted - losses per share(2)	(18.16)	(7.58)	(19.25)	(1.13)	(29.71)

(1) For the year ended June 30, 2017, the Group identified an opportunity to enhance the presentation of the fair value remeasurement of contingent consideration and associated unwinding of the discount rate recorded within finance costs in the Consolidated Income Statement. The Group considered that the change in contingent consideration is primarily due to changes in assumptions about the settlement of the contingent consideration and these line items in the Consolidated Income Statement should therefore be reported in aggregate, to provide more relevant information to the users of the financial statements. This change in presentation has been retrospectively applied to the years ended June 30, 2016 and 2015.

(2) For the year ended June 30, 2018, the Group adjusted its losses per share calculations to reflect the bonus element in the fully underwritten institutional and retail entitlement offer to existing eligible shareholders which occurred in September 2017. This change has been retrospectively applied to the years ended June 30, 2017, 2016 and 2015.

(in U.S. dollars, in thousands except per share information)	As of June 30, 2019	2018	2017	2016	2015
Consolidated Balance Sheet Data:					
Cash and cash equivalents	50,426	37,763	45,761	80,937	110,701
Total current assets	62,522	101,071	63,609	88,823	122,460
Total assets	652,115	692,443	655,686	684,018	781,766
Total current liabilities	44,331	24,003	36,670	29,415	48,407
Total liabilities	171,063	146,435	138,920	155,857	313,779
Total net assets	481,052	546,008	516,766	528,161	467,987
Equity:					
Issued capital (498,626,208; 482,639,654; 428,221,398; 381,363,137 and 336,997,729 ordinary shares (no par value) issued as of June 30, 2019, 2018, 2017, 2016, and 2015 respectively)	910,405	889,481	830,425	770,272	709,191
Reserves	40,638	36,719	31,243	25,976	22,756
(Accumulated loss)/retained earnings	(469,991)	(380,192)	(344,902)	(268,087)	(263,960)
Total equity	481,052	546,008	516,766	528,161	467,987

(in U.S. dollars, in thousands)	Year ended June 30, 2019	2018	2017	2016	2015
Cash Flow Data:					
Net cash (outflows) in operating activities	(57,790)	(75,012)	(95,471)	(87,996)	(101,036)
Net cash (outflows)/inflows in investing activities	(1,000)	(1,153)	142	(1,727)	(5,064)
Net cash inflows in financing activities	71,608	68,613	60,005	62,066	45,852
Net increase/(decrease) in cash and cash equivalents	**12,818**	**(7,552)**	**(35,324)**	**(27,657)**	**(60,248)**

Exchange Rate

The Company publishes its consolidated financial statements expressed in U.S. dollars. Mesoblast Limited, the parent entity of the Group, has a functional currency of Australian dollars. For the convenience of the reader, this Annual Report contains translations of certain Australian dollar amounts into U.S. dollars at specified rates. These translations should not be construed as representations that the Australian dollar amounts actually represent such U.S. dollar amounts or could be converted into U.S. dollars at the rate indicated. Unless otherwise stated, the translations of Australian dollars into U.S. dollars have been made at the rate of US$0.7013 = A$1.00, the foreign exchange rate as issued daily by the Reserve Bank of Australia (http://www.rba.gov.au/statistics/tables/) on June 28, 2019.

Exchange rates for the six months to July 2019 A$1.00 per US$:

	High	Low
Most recent six months:		
Month ended February 28, 2019	0.7260	0.7072
Month ended March 31, 2019	0.7145	0.7009
Month ended April 30, 2019	0.7200	0.7025
Month ended May 31, 2019	0.7054	0.6875
Month ended June 30, 2019	0.7013	0.6840
Month ended July 31, 2019	0.7065	0.6894

Exchange rates for the last five fiscal years A$1.00 per US$:

	Average Rate(1)
Annual:	
Fiscal year ended	
June 30, 2015	0.8288
June 30, 2016	0.7272
June 30, 2017	0.7542
June 30, 2018	0.7736
June 30, 2019	0.7153

(1) Determined by calculating the average rate of the exchange rates on the last trading day of each month during the period.

3.B Capitalization and Indebtedness

Not applicable.

3.C Reasons for the offer and use of proceeds

Not applicable.

3.D Risk Factors

You should carefully consider the risks described below and all other information contained in this Annual Report on Form 20-F before making an investment decision. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our ordinary shares and ADSs could decline, and you may lose part or all of your investment. This Annual Report on Form 20-F also contains forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including the risks described below and elsewhere in this Annual Report on Form 20-F.

Risks Related to Our Financial Position and Capital Requirements

We have incurred operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or sustain profitability.

We are a clinical-stage biotechnology company and we have not yet generated significant revenues. We have incurred net losses during most of our fiscal periods since our inception. Our net loss for the year ended June 30, 2019 was $89.8 million. As of June 30, 2019, we have an accumulated deficit of $470.0 million since our inception. We do not know whether or when we will become profitable. Our losses have resulted principally from costs incurred in clinical development and manufacturing activities.

We anticipate that our expenses will increase as we move toward commercialization, including the scaling up of our manufacturing activities and our establishment of infrastructure and logistics necessary to support potential product launches. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. To achieve and maintain profitability, we must successfully develop our product candidates, obtain regulatory approval, and manufacture, market and sell those products for which we obtain regulatory approval. If we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve and maintain sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates in those markets. We may not succeed in these activities, and we may never generate revenue from product sales that is significant enough to achieve profitability. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations. A decline in the value of our company could cause you to lose part or all of your investment.

We have never generated any revenue from product sales and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, either alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. We do not currently generate revenues from product sales (other than licensing revenue from sales of TEMCELL® HS. Inj. (“TEMCELL”), a registered trademark of JCR Pharmaceuticals Co., Ltd. (“JCR”), by JCR in Japan, and, royalty revenue from net sales of Alofisel® a registered trademark of TiGenix NV (“TiGenix”), previously known as Cx601, an adipose-derived mesenchymal

stem cell product developed by TiGenix, now a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda") and approved for marketing in the EU), and we may never generate product sales. Our ability to generate future revenues from product sales depends heavily on our success in a number of areas, including:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical studies;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate (in amount and quality) products and services to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by collaborating with a partner or, if launched independently, by establishing a sales force, marketing and distribution capabilities and necessary supporting infrastructure to effectively seek and maintain market access and ensure compliance with legal and regulatory requirements relating to interactions with healthcare providers and healthcare organizations and to price reporting;
- obtaining market acceptance of our product candidates and stem cell therapy as a viable treatment option;
- addressing any competing technological and market developments;
- obtaining and sustaining an adequate level of reimbursement from payors;
- identifying and validating new stem cell therapy product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, know-how and trademarks;
- attracting, hiring and retaining qualified personnel; and
- implementing additional internal systems and infrastructure, as needed.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing and distributing any approved product candidate. Our expenses could increase beyond expectations if we are required by the United States Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA"), or other regulatory agencies, to perform clinical and other studies in addition to those that we currently anticipate. We may not become profitable and may need to obtain additional funding to continue operations.

We require substantial additional financing to achieve our goals, and our failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. As of June 30, 2019, our cash and cash equivalents were $50.4 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future in connection with our planned research, development and product commercialization efforts. In addition, we will require additional financing to achieve our goals and our failure to do so could adversely affect our commercialization efforts. We anticipate that our expenses will increase if and as we:

- continue the research and clinical development of our product candidates, including MPC-150-IM (Class II-IV Chronic Heart Failure ("CHF")), MPC-06-ID (Chronic Low Back Pain ("CLBP")), MSC-100-IV ("remestemcel-L") and MPC-300-IV (inflammatory conditions) product candidates;
- seek to identify, assess, acquire, and/or develop other and combination product candidates and technologies;
- seek regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical studies and identify and apply for regulatory designations to facilitate development and ultimate commercialization of our products;
- establish collaborations with third parties for the development and commercialization of our product candidates, or otherwise build and maintain a sales, marketing and distribution infrastructure and/or external logistics to commercialize any products for which we may obtain marketing approval;
- further develop and implement our proprietary manufacturing processes in both planar technology and our bioreactor programs and expand our manufacturing capabilities and resources for commercial production;
- seek coverage and reimbursement from third-party payors, including government and private payors for future products;

- make milestone or other payments under our agreements pursuant to which we have licensed or acquired rights to intellectual property and technology;
- seek to maintain, protect and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel; and
- develop the compliance and other infrastructure necessary to support product commercialization and distribution.

If we were to experience any delays or encounter issues with any of the above, including clinical holds, failed studies, inconclusive or complex results, safety or efficacy issues, or other regulatory challenges that require longer follow-up of existing studies, additional studies, or additional supportive studies in order to pursue marketing approval, it could further increase the costs associated with the above. Further, the net operating losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder or as a holder of the ADSs. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations or partnerships, or marketing, distribution or licensing arrangements with third parties, we may be required to do so at an earlier stage than would otherwise be ideal and/or may have to limit valuable rights to our intellectual property, technologies, product candidates or future revenue streams, or grant licenses or other rights on terms that are not favorable to us. Furthermore, any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

As described in Note 1(i) of our accompanying financial statements, our continuing viability and our ability to continue as a going concern and meet our debts and commitments as they fall due are dependent upon non-dilutive funding in the form of strategic and commercial transactions, equity-based or debt-based financing to fund future operations.

Management and the directors believe that we will be successful in the above matters and, accordingly, have prepared the financial report on a going concern basis, notwithstanding that there is a material uncertainty that may cast significant doubt on our ability to continue as a going concern and that we may be unable to realize our assets and liabilities in the normal course of business. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to obtain adequate funding or partnerships in the future, we may not be able to continue as a going concern, and our shareholders and holders of the ADSs may lose some or all of their investment in us.

The terms of our loan facilities with Hercules Capital, Inc. ("Hercules") and NovaQuest Capital Management, L.L.C. ("NovaQuest") could restrict our operations, particularly our ability to respond to changes in our business or to take specified actions.

On March 6, 2018, we entered into a loan and security agreement with Hercules, for a $75.0 million non-dilutive, four-year credit facility. We drew the first tranche of $35.0 million at closing, and we have subsequently drawn a further $15.0 million. On June 29, 2018, we entered into a loan and security agreement with NovaQuest for a $40.0 million non-dilutive, eight-year term credit facility, repayable from net sales of our allogeneic product candidate remestemcel-L in pediatric patients with steroid-refractory acute graft versus host disease ("SR-aGVHD"), in the United States and other geographies excluding Asia. We drew the first tranche of $30.0 million on closing. Our loan facilities with Hercules and NovaQuest contain a number of restrictive covenants that impose operating restrictions on us, which may restrict our ability to respond to changes in our business or take specified actions. Our ability to comply with the various covenants under the agreements may be affected by events beyond our control, and we may not be able to continue to meet the covenants. Upon the occurrence of an event of default, Hercules or NovaQuest could elect to declare all amounts outstanding under the loan facility to be immediately due and payable and terminate all commitments to extend further credit. If Hercules or NovaQuest accelerates the repayment, if any, we may not have sufficient funds to repay our existing debt. If we were unable to repay those amounts, Hercules or NovaQuest could proceed against the collateral granted to it to secure such indebtedness. We have pledged substantially all of our assets as collateral under the loan facility with Hercules, and a portion of our assets relating to the aGVHD product candidate as collateral under the loan facility with NovaQuest.

We are subject to risks associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations.

Historically, a substantial portion of our operating expenses has been denominated in U.S. dollars and our main currency requirements are U.S. dollars, Australian dollars and Singapore dollars. Approximately 97% of our cash and cash equivalents as of June 30, 2019 were denominated in U.S. dollars and 3% were denominated in Australian dollars. Because we have multiple functional currencies across different jurisdictions, changes in the exchange rate between these currencies and the foreign currencies of the transactions recorded in our accounts could materially impact our reported results of operations and distort period-to-period comparisons. For example, a portion of our research and clinical trials are undertaken in Australia. As such, payment will be made in Australian dollar currency, and may exceed the budgeted expenditure if there are adverse currency fluctuations against the U.S. dollar.

More specifically, if we decide to convert our Australian dollars into U.S. dollars for any business purpose, appreciation of the U.S. dollar against the Australian dollar would have a negative effect on the U.S. dollar amount available to us. Appreciation or depreciation in the value of the Australian dollar relative to the U.S. dollar would affect our financial results reported in U.S. dollar terms without giving effect to any underlying change in our business or results of operations. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

Risks Related to Clinical Development and Regulatory Review and Approval of Our Product Candidates

Our product candidates are based on our novel mesenchymal lineage adult stem cell technology, which makes it difficult to accurately and reliably predict the time and cost of product development and subsequently obtaining regulatory approval. At the moment, no industrially manufactured, non-hematopoietic, allogeneic stem cell products have been approved in the United States.

Other than with respect to sales of products by our licensees, we have not commercially marketed, distributed or sold any products. The success of our business depends on our ability to develop and commercialize our lead product candidates. We have concentrated our product research and development efforts on our mesenchymal lineage adult stem cell platform, a novel type of stem cell therapy. Our future success depends on the successful development of this therapeutic approach. There can be no assurance that any development problems we experience in the future related to our mesenchymal lineage adult stem cells platform will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays in developing sustainable, reproducible and scalable manufacturing processes or transferring these processes to collaborators, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all.

In addition, the clinical study requirements of the FDA, the EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer to develop than for other, better known or extensively studied pharmaceutical or other product candidates. In addition, adverse developments in clinical trials of cell therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

We may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory agencies.

We must conduct extensive testing of our product candidates to demonstrate their safety and efficacy, including both preclinical animal testing and evaluation in human clinical trials, before we can obtain regulatory approval to market and sell them. Conducting such testing is a lengthy, time-consuming, and expensive process and there is a high rate of failure.

Our current and completed preclinical and clinical results for our product candidates are not necessarily predictive of the results of our ongoing or future clinical trials. Promising results in preclinical studies of a product candidate may not be predictive of similar results in humans during clinical trials, and successful results from early human clinical trials of a product candidate may not be replicated in later and larger human clinical trials or in clinical trials for different indications. If the results of our or our collaborators' ongoing or future clinical trials are negative or inconclusive with respect to the efficacy of our product candidates, or if these trials do not meet the clinical endpoints with statistical significance, or if there are safety concerns or adverse events associated with our product candidates, we or our collaborators may be prevented or delayed in obtaining marketing approval for our product candidates.

Even if ongoing or future clinical studies meet the clinical endpoints with statistical significance, the FDA or other regulatory agencies may still find the data insufficient to support marketing approval based on other factors.

We may encounter substantial delays in our clinical studies.

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

- problems which may arise as a result of our transition of research and development programs from licensors or previous sponsors;
- delays in raising, or inability to raise, sufficient capital to fund the planned trials;
- delays by us or our collaborators 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 contract research organizations ("CROs"), and clinical trial sites;
- delays in obtaining required Institutional Review Board ("IRB"), approval at each clinical trial site;
- delays in recruiting suitable clinical sites and patients (i.e., subjects) to participate in clinical trials and delays in accruing medical events necessary to complete any events-driven trial;
- 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 CROs, other third parties or us or our collaborators to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's current Good Clinical Practices ("cGCP"), or applicable regulatory guidelines in other countries;
- delays in testing, validation, manufacturing and delivery of a product candidate to clinical trial sites;
- delays caused by patients not completing participation in a trial or not returning for post-treatment follow-up;
- delays caused by clinical trial sites not completing a trial;
- failure to demonstrate adequate efficacy;
- occurrence of serious adverse events in clinical trials that are associated with a product candidates and that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- disagreements between us and the FDA or other regulatory agencies regarding a clinical trial design, protocol amendments, or interpreting the data from our clinical trials.

Delays, including delays caused by the above factors, can be costly and could negatively affect our or our collaborators' ability to complete clinical trials for our product candidates. If we or our collaborators 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 and/or will not be able to commercialize our product candidates and our commercial partnering opportunities will be harmed.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. In general, if patients are unwilling to participate in our stem cell therapy trials because of negative publicity from adverse events in the biotechnology or stem cell industries or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval for our product candidates may be delayed. Additionally, we or our collaborators generally will have to run multi-site and potentially multi-national trials, which can be time consuming, expensive and require close coordination and supervision. If we have difficulty enrolling a sufficient number of patients or otherwise conducting clinical trials as planned, we or our collaborators may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

If there are delays in accumulating the required number of trial subjects or, in trials where clinical events are a primary endpoint, if the events needed to assess performance of our clinical candidates do not accrue at the anticipated rate, there may be delays in completing the trial. These delays could result in increased costs, delays in advancing development of our product candidates, including delays in testing the effectiveness, or even termination of the clinical trials altogether.

Patient enrollment and completion of clinical trials are affected by factors including:

- size of the patient population, particularly in orphan diseases;
- severity of the disease under investigation;
- design of the trial protocol;
- eligibility criteria for the particular trial;
- perceived risks and benefits of the product candidate being tested;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians and level and effectiveness of study site recruitment efforts; and
- ability to monitor patients adequately during and after treatment.

Once enrolled, patients may choose to discontinue their participation at any time during the trial, for any reason. Participants also may be terminated from the study at the initiative of the investigator, for example if they experience serious adverse clinical events or do not follow the study directions. If we are unable to maintain an adequate number of patients in our clinical trials, we may be required to delay or terminate an ongoing clinical trial, which would have an adverse effect on our business.

We may conduct multinational clinical trials, which present additional and unique risks.

We plan to seek initial marketing approval for our product candidates in the United States and in select non-U.S. jurisdictions such as Europe, Japan and Canada. Conducting trials on a multinational basis requires collaboration with foreign medical institutions and healthcare providers. Our ability to successfully initiate, enroll and complete a clinical trial in multiple countries is subject to numerous risks unique to conducting business internationally, including:

- difficulty in establishing or managing relationships with physicians, sites and CROs;
- standards within different jurisdictions for conducting clinical trials and recruiting patients;
- our ability to effectively interface with non-US regulatory authorities;
- our inability to identify or reach acceptable agreements with qualified local consultants, physicians and partners;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments, and anti-corruption/anti-bribery laws; and
- differing genotypes, average body weights and other patient profiles within and across countries from our donor profile may impact the optimal dosing or may otherwise impact the results of our clinical trials.

The complexity of conducting multinational clinical trials could negatively affect our or our collaborators' ability to complete trials as intended which could have an adverse effect on our business.

Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our product candidates, or limit the scope of any approved indication or market acceptance.

Participants in clinical trials of our investigational stem cell products may experience adverse reactions or other undesirable side effects. While some of these can be anticipated, others may be unexpected. We cannot predict the frequency, duration, or severity of adverse reactions or undesirable side effects that may occur during clinical investigation of our product candidates. If any of our product candidates, prior to or after any approval for commercial sale, cause serious adverse events or are associated with other safety risks, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend (e.g., through a clinical hold) or terminate clinical trials;
- regulatory authorities may deny regulatory approval of our product candidates;

- regulators may restrict the indications or patient populations for which a product candidate is approved;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, and/or impose restrictions on distribution in the form of a risk evaluation and mitigation strategy ("REMS"), in connection with approval, if any;
- regulatory authorities may withdraw their approval, require more onerous labeling statements or impose a more restrictive REMS than any product that is approved;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- patient recruitment into our clinical trials may suffer;
- our relationships with our collaborators may suffer;
- we could be required to provide compensation to subjects for their injuries, e.g., if we are sued and found to be liable or if required by the laws of the relevant jurisdiction or by the policies of the clinical site; or
- our reputation may suffer.

There can be no assurance that adverse events associated with our product candidates will not be observed, in such settings where no prior adverse events have occurred. As is typical in clinical development, we have a program of ongoing toxicology studies in animals for our clinical-stage product candidates and cannot provide assurance that the findings from such studies or any ongoing or future clinical trials will not adversely affect our clinical development activities.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our product candidates are unlikely to receive regulatory approval or unlikely to be successfully commercialized. In addition, regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate a clinical trial for any of our product candidates, the commercial prospects for that product as well as our other product candidates may be harmed and our ability to generate product revenue from these product candidates may be delayed or eliminated. Furthermore, any of these events could prevent us or our collaborators from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these product candidates either by us or by our collaborators.

Several of our product candidates are being evaluated for the treatment of patients who are extremely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if they are not shown to be related to our product candidates.

We are developing MPC-150-IM, which will focus on Class II-IV CHF, and remestemcel-L, which will focus on SR-aGVHD. The patients who receive our product candidates are very ill due to their underlying diseases.

Generally, patients remain at high risk following their treatment with our product candidates and may more easily acquire infections or other common complications during the treatment period, which can be serious and life threatening. As a result, it is likely that we will observe severe adverse outcomes in patients during our Phase 3 and other trials for these product candidates, including patient death. If a significant number of study subject deaths were to occur, regardless of whether such deaths are attributable to our product candidates, our ability to obtain regulatory approval for the applicable product candidate may be adversely impacted and our business could be materially harmed. Should studies of a candidate product result in regulatory approval, any association with a significant number of study subject deaths could limit the commercial potential of an approved product candidate, or negatively impact the medical community's willingness to use our product with patients.

The requirements to obtain regulatory approval of the FDA and regulators in other jurisdictions can be costly, time-consuming, and unpredictable. If we or our collaborators are unable to obtain timely regulatory approval for our product candidates, our business may be substantially harmed.

The regulatory approval process is expensive and the time and resources required to obtain approval from the FDA or other regulatory authorities in other jurisdictions to sell any product candidate is uncertain and approval may take years. Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the discretion of the regulatory authorities. For example, governing legislation, approval policies, regulations, regulatory policies, or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing or future product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval.

Further, regulatory requirements governing stem cell therapy products in particular have changed and may continue to change in the future. For example, in December 2016, the 21st Century Cures Act ("Cures Act") was signed into law in the United States. This new law is designed to advance medical innovation, and includes a number of provisions that may impact our product development programs. For example, the Cures Act establishes a new "regenerative medicine advanced therapy" designation ("RMAT"), and creates a pathway for increased interaction with FDA for the development of products which obtain designations. Although the FDA has issued guidance documents in 2018, it remains unclear how and when the FDA will fully implement all deliverables under the Cures Act.

Any regulatory review committees and advisory groups and any contemplated new guidelines may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient revenue to maintain our business.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- we may be unable to successfully complete our ongoing and future clinical trials of product candidates;
- we may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that a product candidate is safe, pure, and potent for any or all of a product candidate's proposed indications;
- we may be unable to demonstrate that a product candidate's benefits outweigh the risk associated with the product candidate;
- the FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval;
- the FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- a decision by the FDA, other regulatory authorities or us to suspend or terminate a clinical trial at any time;
- the data collected from clinical trials of our product candidates may be inconclusive or may not be sufficient to support the submission of a Biologics License Application ("BLA"), or other submission or to obtain regulatory approval in the United States or elsewhere;
- our third party manufacturers of supplies needed for manufacturing product candidates may fail to satisfy FDA or other regulatory requirements and may not pass inspections that may be required by FDA or other regulatory authorities;
- the failure to comply with applicable regulatory requirements following approval of any of our product candidates may result in the refusal by the FDA or similar foreign regulatory agency to approve a pending BLA or supplement to a BLA submitted by us for other indications or new product candidates; and
- the approval policies or regulations of the FDA or other regulatory authorities outside of the United States may significantly change in a manner rendering our clinical data insufficient for approval.

We or our collaborators may gain regulatory approval for any of our product candidates in some but not all of the territories available and any future approvals may be for some but not all of the target indications, limiting their commercial potential. Regulatory requirements and timing of product approvals vary from country to country and some jurisdictions may require additional testing beyond what is required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval.

Our drug candidates may not benefit from an expedited approval path for cellular medicines designated as Regenerative Medicine Advanced Therapies (RMATs) under the 21st Century Cures Act.

On December 21, 2017, the FDA granted RMAT designation for our novel MPC therapy in the treatment of heart failure patients with left ventricular systolic dysfunction and left ventricular assist devices. While the Cures Act offers several potential benefits to drugs designated as RMATs, including eligibility for increased agency support and advice during development, priority review on filing, a potential pathway for accelerated approval based on surrogate or intermediate endpoints, and the potential to use patient registry data and other sources of real world evidence for post approval confirmatory studies, there is no assurance that any of these potential benefits will either apply to any or all of our drug candidates or, if applicable, accelerate marketing approval. RMAT designation does not change the evidentiary standards of safety and effectiveness needed for marketing approval.

Furthermore, there is no certainty as to whether any of our product candidates that have not yet received RMAT designation under the Cures Act will receive such designation under the Cures Act. Designation as an RMAT is within the discretion of the FDA. Accordingly, even if we believe one of our products or product candidates meets the criteria for RMAT designation, the FDA may disagree. Additionally, for any product candidate that receives RMAT designation, we may not experience a faster development, review or approval process compared to conventional FDA procedures. The FDA may withdraw RMAT designation if it believes that the product no longer meets the qualifying criteria for designation.

Even if we obtain regulatory approval for our product candidates, our products will be subject to ongoing regulatory scrutiny.

Any of our product candidates that are approved in the United States or in other jurisdictions will continue to be subject to ongoing regulatory requirements relating to the quality, identity, strength, purity, safety, efficacy, testing, manufacturing, marketing, advertising, promotion, distribution, sale, storage, packaging, pricing, import or export, record-keeping and submission of safety and other post-market information for all approved product candidates. In the United States, this includes both federal and state requirements. In particular, as a condition of approval of a BLA, the FDA may require a REMS, to ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. Moreover, regulatory approval may require substantial post-approval (Phase 4) testing and surveillance to monitor the drug's safety or efficacy. Delays in the REMS approval process could result in delays in the BLA approval process. In addition, as part of the REMS, the FDA could require significant restrictions, such as restrictions on the prescription, distribution and patient use of the product, which could significantly impact our ability to effectively commercialize our product candidates, and dramatically reduce their market potential thereby adversely impacting our business, results of operations and financial condition. Post-approval study requirements could add additional burdens, and failure to timely complete such studies, or adverse findings from those studies, could adversely affect our ability to continue marketing the product.

Any failure to comply with ongoing regulatory requirements, as well as post-approval discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, may significantly and adversely affect our ability to generate revenue from our product candidates, and may result in, among other things:

- restrictions on the marketing or manufacturing of the product candidates, withdrawal of the product candidates from the market, or voluntary or mandatory product recalls;
- suspension or withdrawal of regulatory approval;
- costly regulatory inspections;
- fines, warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our collaborators, or suspension or revocation of BLAs;
- restrictions on our operations;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties by FDA or other regulatory bodies.

If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our business and our operating results will be adversely affected.

The FDA's policies, or that of the applicable regulatory bodies in other jurisdictions, may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are not able to maintain regulatory compliance, are slow or unable to adopt new requirements or policies, or effect changes to existing requirements, we or our collaborators may no longer be able to lawfully market our product, and we may not achieve or sustain profitability, which would adversely affect our business.

Ethical and other concerns surrounding the use of embryonic stem cell-based therapy may negatively affect regulatory approval or public perception of our non-embryonic stem cell product candidates, which could reduce demand for our products or depress our share price.

The use of embryonic stem cells ("ESCs"), for research and therapy has been the subject of considerable public debate, with many people voicing ethical, legal and social concerns related to their collection and use. Our cells are not ESCs, which have been the predominant focus of this public debate and concern in the United States and elsewhere. However, the distinction between ESCs and

non-ESCs, such as our mesenchymal lineage adult stem cells, may be misunderstood by the public. Negative public attitudes toward stem cell therapy and publicity and harm from stem cell usage clinically by others could also result in greater governmental regulation of stem cell therapies, which could harm our business. The improper use of cells could give rise to ethical and social commentary adverse to us, which could harm the market demand for new products and depress the price of our ordinary shares and ADSs. Ongoing lack of understanding of the difference between ESCs and non-ESCs could negatively impact the public's perception of our company and product candidates and could negatively impact us.

Additional government-imposed restrictions on, or concerns regarding possible government regulation of, the use of stem cells in research, development and commercialization could also cause an adverse effect on us by harming our ability to establish important partnerships or collaborations, delaying or preventing the development of certain product candidates, and causing a decrease in the price of our ordinary shares and ADSs, or by otherwise making it more difficult for us to raise additional capital. For example, concerns regarding such possible regulation could impact our ability to attract collaborators and investors. Also, existing and potential government regulation of stem cells may lead researchers to leave the field of stem cell research altogether in order to assure that their careers will not be impeded by restrictions on their work. This may make it difficult for us to find and retain qualified scientific personnel.

Orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed.

A product candidate that receives orphan drug designation can benefit from potential commercial benefits following approval. Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, defined as affecting (1) a patient population of fewer than 200,000 in the United States, (2) a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States, or (3) an "orphan subset" of a patient population greater than 200,000 in the United States. In the European Union ("EU"), the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 10,000 persons in the EU. Currently, this designation provides market exclusivity in the U.S. and the EU for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve a drug with similar chemical structure for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs. In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is "clinically superior" to the original orphan drug.

Our remestemcel-L product candidate has received orphan drug designation for the treatment of aGVHD by the FDA, and our CHF product candidate, rexlemestrocel-L has received orphan drug designation for prevention of post-implantation mucosal bleeding in end-stage CHF patients who require a left ventricular assist device ("LVAD"). If we seek orphan drug designations for other product candidates in other indications, we may fail to receive such orphan drug designations and, even if we succeed, such orphan drug designations may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position.

We may face competition from biosimilars due to changes in the regulatory environment.

In the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products that are demonstrated to be "highly similar," or biosimilar, to or "interchangeable" with an FDA-approved innovator (original) biological product. This pathway could allow competitors to reference data from innovator biological products already approved after 12 years from the time of approval. For several years the annual budget requests of President Obama's administration included proposals to cut this 12-year period of exclusivity down to seven years. Those proposals were not adopted by Congress. Under President Trump's administration, it is unclear if a similar change will be pursued in the future. In Europe, the European Commission has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data from biological products already approved, but will not be able to get on the market until ten years after the time of approval. This 10-year period will be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilars in other countries that could compete with our products. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars causing the price for our products and our potential market share to suffer, resulting in lower product sales.

Our ongoing BLA submission for paediatric SR-aGVHD may not be approved and even if it is approved, we will continue to be closely regulated by FDA.

As a biological product, our allogeneic cellular medicine, remestemcel-L, for the treatment of children with SR-aGVHD, requires regulatory approval from the FDA before it may legally be distributed in U.S. commerce. In particular, remestemcel-L will require FDA approval of a BLA under Section 351 of the Public Health Service Act to be commercialized. We initiated the filing of this BLA application in May 2019. The outcome of this BLA application is uncertain, and there is a risk that it may not be approved by the FDA.

We have received Fast Track designation from the FDA for remestemcel-L in children with SR aGVHD. A biologic product that receives Fast Track designation can be eligible for regulatory benefits, including rolling BLA review. Rolling review of a BLA enables individual modules of the application to be submitted to and reviewed by the FDA on an ongoing basis, rather than waiting for all sections of a BLA to be completed before submission. If FDA accepts a portion of the BLA application for rolling review, this does not necessarily mean that FDA review will commence or proceed before the complete application is submitted. We reported that FDA has agreed we can submit on a rolling basis our BLA for remestemcel-L for children with SR-aGVHD and that we have filed the first component of this rolling submission. Fast Track designation may provide for a more streamlined development or approval process but it does not change the standards for approval and may be rescinded by FDA if the product no longer meets the qualifying criteria.

The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. During the course of review of our BLA, the FDA may request or require additional preclinical, clinical, chemistry and manufacturing, controls (or CMC), or other data and information. The development and provision of these data and information may be time consuming and expensive. Our failure to comply, or the failure of our contract manufacturers to satisfy, applicable FDA CMC requirements could result in a delay or failure to obtain approval of our BLA. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in our submission and may request additional testing or information. The testing and approval process requires substantial time, effort and financial resources, and may take several years to complete. In addition, the FDA or other regulatory agencies may find the data from our clinical studies insufficient to support marketing approval. For example, our Phase 3 study for remestemcel-L, which met the primary clinical endpoint with statistical significance, was conducted as a single-arm study due to the seriousness of the condition, the rapid clinical deterioration of affected patients, the mounting literature suggesting a meaningful treatment effect, and the position in the medical community that a randomized controlled trial was neither feasible nor ethical in this patient population. While we intend to provide the FDA with comparator outcomes from control subjects, it is possible that the FDA may not find the data sufficient for approval. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

It is likely that we will have to participate in FDA Advisory Committee proceedings in connection with the FDA's review of the BLA for our aGVHD product candidate as well as potentially other of our product candidates. FDA Advisory Committees are convened to conduct public hearings on matters of importance that come before FDA, to review the issues involved, and to provide advice and recommendations to FDA. New product candidates may be referred for review by Advisory Committees whether FDA has identified issues or concerns in respect of such candidates or not. Advisory Committee input and recommendations may be used at the discretion of the FDA. Advisory Committee proceedings are in part conducted publicly. While the recommendations made by Advisory Committees in respect of marketing applications for any product are not dispositive, such determinations and recommendations are often influential, and may be made available publicly and to the advantage of our competitors. In addition, it is possible that safety findings and recommendations as well as other concerns and considerations raised by Advisory Committee members, who constitute a multi-disciplinary group of experts (including representatives and/or advocates from the consumer sector), may impact FDA's review of our product candidate submissions or labeling unfavorably. Furthermore, commentary from Advisory Committee proceedings can figure into future product and other litigation.

Even if we receive regulatory approval for our remestemcel-L product, such approval may entail limitations on the indicated uses for which such product may be marketed and/or require post-marketing testing and surveillance to monitor safety or efficacy of our product. The FDA may limit further marketing of our product based on the results of post-marketing studies, if compliance with pre- and post-marketing regulatory standards is not maintained, or if problems occur after our product reaches the marketplace such as later discovery of previously unknown problems or concerns with our product, including adverse events of unanticipated severity or frequency, or with our manufacturing processes.

Risks Related to Collaborators

We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates in a timely and cost-effective manner or at all, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party entities, including CROs, academic institutions, hospitals and other third-party collaborators, to monitor, support, conduct and/or oversee preclinical and clinical studies of our current and future product candidates. We rely on these parties for execution of our nonclinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies 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. If we or any of these third-parties fail to comply with the applicable protocol, legal, regulatory, and scientific standards, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical studies before approving our marketing applications.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative parties or do so on commercially reasonable terms. In addition, these parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our on-going nonclinical and clinical programs. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical studies may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Third parties may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with these third parties, there can be no assurance that we will not encounter similar 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.

Our existing product development and/or commercialization arrangements, and any that we may enter into in the future, may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We are a party to, and continue to seek additional, collaboration arrangements with biopharmaceutical companies for the development and/or commercialization of our current and future product candidates. We may enter into new arrangements on a selective basis depending on the merits of retaining certain development and commercialization rights for ourselves as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for each product candidate, both in the United States and internationally. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Any failure to meet our clinical milestones with respect to an unpartnered product candidate would make finding a collaborator more difficult. Moreover, collaboration arrangements are complex, costly and time consuming to negotiate, document and implement, and we cannot guarantee that we can successfully maintain such relationships or that the terms of such arrangements will be favorable to us. If we fail to establish and implement collaboration or other alternative arrangements, the value of our business and operating results will be adversely affected.

We may not be successful in our efforts to establish, implement and maintain collaborations or other alternative arrangements if we choose to enter into such arrangements. The terms of any collaboration or other arrangements that we may establish may not be favorable to us. The management of collaborations may take significant time and resources that distract our management from other matters.

Our ability to successfully collaborate with any future collaborators may be impaired by multiple factors including:

- a collaborator may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a collaborator may cease development in therapeutic areas which are the subject of our strategic alliances;
- a collaborator may change the success criteria for a particular program or product candidate thereby delaying or ceasing development of such program or candidate;
- a significant delay in initiation of certain development activities by a collaborator will also delay payments tied to such activities, thereby impacting our ability to fund our own activities;

- a collaborator could develop a product that competes, either directly or indirectly, with our current or future products, if any;
- a collaborator with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaborator with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a collaborator may exercise its rights under the agreement to terminate our collaboration;
- a dispute may arise between us and a collaborator concerning the research or development of a product candidate or commercialization of a product resulting in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources;
- the results of our clinical trials may not match our collaborators' expectations, even if statistically significant;
- a collaborator may not adequately protect or enforce the intellectual property rights associated with a product or product candidate; and
- a collaborator may use our proprietary information or intellectual property in such a way as to invite litigation from a third party.

Any such activities by our current or future collaborators could adversely affect us financially and could harm our business reputation.

Risks Related to Our Manufacturing and Supply Chain

We have no experience manufacturing our product candidates at a commercial scale. We may not be able to manufacture our product candidates in quantities sufficient for development and commercialization if our product candidates are approved, or for any future commercial demand for our product candidates.

We have manufactured clinical quantities of our mesenchymal lineage adult stem cell product candidates in manufacturing facilities owned by Lonza Walkersville, Inc. and Lonza Bioscience Singapore Pte. Ltd. (collectively referred to as "Lonza"). We do not have any direct experience in manufacturing commercial quantities of any of our product candidates. The production of any biopharmaceutical, particularly stem cell-based therapies, involves complex processes and protocols. We cannot provide assurance that such production efforts will enable us to manufacture our product candidates in the quantities and with the quality needed for clinical trials and any resulting commercialization. If we are unable to do so, our clinical trials and commercialization efforts, if any, may not proceed in a timely fashion and our business will be adversely affected. If any of our product candidates are approved for commercialization and marketing, we may be required to manufacture the product in large quantities to meet demand. Producing product in commercial quantities requires developing and adhering to complex manufacturing processes that are different from the manufacture of a product in smaller quantities for clinical trials, including adherence to additional and more demanding regulatory standards. Although we believe that we have developed processes and protocols that will enable us to consistently manufacture commercial-scale quantities of product, we cannot provide assurance that such processes and protocols will enable us to manufacture our product candidates in quantities that may be required for commercialization of the product with yields and at costs that will be commercially attractive. If we are unable to establish or maintain commercial manufacture of the product or are unable to do so at costs that we currently anticipate, our business will be adversely affected.

We are focusing on the introduction of novel manufacturing approaches with the potential to result in efficiency and yield improvements to our current process. Certain of these novel approaches include modifying the media used in cell production. Another approach includes the development of 3-dimensional ("3D") bioreactor-based production for mesenchymal lineage adult stem cells. There is no guarantee that we will successfully complete either of these processes or meet all applicable regulatory requirements. This may be due to multiple factors, including the failure to produce sufficient quantities and the inability to produce cells that are equivalent in physical and therapeutic properties as compared to the products produced using our current manufacturing processes. In the event our transition to these improved manufacturing processes is unsuccessful, we may not be able to produce certain of our products in a cost-efficient manner and our business may be adversely affected.

We rely on Lonza as our sole supplier and manufacturer of our product candidates. Our business could be harmed if Lonza fails to provide us with sufficient quantities of these product candidates or fails to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our mesenchymal lineage adult stem cell product candidates for use in the conduct of our clinical trials, and we currently lack the internal resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. As a result, we currently depend on Lonza to manufacture our mesenchymal lineage adult stem cell product candidates. Relying on Lonza as our sole source to manufacture our mesenchymal lineage adult stem cell product candidates entails risks, and Lonza may:

- cease or reduce production or deliveries, raise prices or renegotiate terms;
- be unable to meet any product specifications and quality requirements consistently;

- delay or be unable to procure or expand sufficient manufacturing capacity, which may harm our reputation or frustrate our customers;
- not have the capacity sufficient to support the scale-up of manufacturing for our product candidates;
- have manufacturing and product quality issues related to scale-up of manufacturing;
- experience costs and validation of new equipment facilities requirement for scale-up that it will pass on to us;
- fail to comply with cGMP and similar international standards;
- lose its manufacturing facility in Singapore, stored inventory or laboratory facilities through fire or other causes, or other loss of materials necessary to manufacture our product candidates;
- experience disruptions to its operations by conditions unrelated to our business or operations, including the bankruptcy or interruptions of its suppliers;
- experience carrier disruptions or increased costs that it will pass on to us;
- fail to secure adequate supplies of essential ingredients in our manufacturing process;
- experience failure of third parties involved in the transportation, storage or distribution of our products, including the failure to deliver supplies it uses for the manufacture of our product candidates under specified storage conditions and in a timely manner;
- terminate agreements with us; and
- appropriate or misuse our trade secrets and other proprietary information.

Any of these events could lead to delays in the development of our product candidates, including delays in our clinical trials, or failure to obtain regulatory approval for our product candidates, or it could impact our ability to successfully commercialize our current product candidates or any future products. Some of these events could be the basis for FDA or other regulatory action, including injunction, recall, seizure or total or partial suspension of production.

In addition, the lead time needed to establish a relationship with a new manufacturer can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new manufacturer. We are expanding our manufacturing collaborations in order to meet future demand and to provide back-up manufacturing options, which also involves risk and requires significant time and resources. Our future collaborators may need to expand their facilities or alter the facilities to meet future demand and changes in regulations. These activities may lead to delays, interruptions to supply, or may prove to be more costly than anticipated. Any problems in our manufacturing process could have a material adverse effect on our business, results of operations and financial condition.

We may not be able to manufacture or commercialize our product candidates in a profitable manner.

We intend to implement a business model under which we control the manufacture and supply of our product candidates, including but not exclusively, through our product suppliers, including Lonza. We and the suppliers of our product candidates, including Lonza, have no experience manufacturing our product candidates at commercial scale. Accordingly, there can be no assurance as to whether we and our suppliers will be able to scale-up the manufacturing processes and implement technological improvements in a manner that will allow the manufacture of our product candidates in a cost effective manner. Our or our collaborators' inability to sell our product candidates at a price that exceeds our cost of manufacture by an amount that is profitable for us will have a material adverse result on the results of our operations and our financial condition.

Our or our collaborators' ability to identify, test and verify new donor tissue in order to create new master cell banks involves many risks.

The initial stage of manufacturing involves obtaining mesenchymal lineage adult stem cell-containing bone marrow from donors, for which we currently rely on Lonza. Mesenchymal lineage adult stem cells are isolated from each donor's bone marrow and expanded to create a master cell bank. Each individual master cell bank comes from a single donor. A single master cell bank can source many production runs, which in turn can produce up to thousands of doses of a given product, depending on the dose level. The process of identifying new donor tissue, testing and verifying its validity in order to create new master cell banks and validating such cell bank with the FDA and other regulatory agencies is time consuming, costly and prone to the many risks involved with creating living cell products. There could be consistency or quality control issues with any new master cell bank. Although we believe we and our collaborators have the necessary know-how and processes to enable us to create master cell banks with consistent quality and within the timeframe necessary to meet projected demand and we have begun doing so, we cannot be certain that we or our collaborators will be able to successfully do so, and any failure or delays in creating new master cell banks may have a material adverse impact on our business, results of operations, financial conditions and growth prospects and could result in our inability to continue operations.

We and our collaborators depend on a limited number of suppliers for our product candidates' materials, equipment or supplies and components required to manufacture our product candidates. The loss of these suppliers, or their failure to provide quality supplies on a timely basis, could cause delays in our current and future capacity and adversely affect our business.

We and our collaborators depend on a limited number of suppliers for the materials, equipment and components required to manufacture our product candidates and the product candidates themselves. We rely exclusively on Lonza to supply certain of our product candidates. In addition, we rely on additional third parties to provide various "devices" or "carriers" for some of our programs (e.g., the catheter for use with MPC-150-IM, and the hyaluronic acid used for disc repair). The main consumable used in our manufacturing process is our media, which currently is sourced from fetal bovine serum ("FBS"). This material comes from limited sources, and as a result is expensive. Consequently, we or our collaborators may not be able to obtain sufficient quantities of our product candidates or other critical materials equipment and components in the future, at affordable prices or at all. A delay or interruption by our suppliers may also harm our business, and operating results. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we or our collaborators may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify for and, in some cases, obtain regulatory approval for a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Our and our collaborators' dependence on single-source suppliers exposes us to numerous risks, including the following:

- our or our collaborators' suppliers may cease or reduce production or deliveries, raise prices or renegotiate terms;
- we or our collaborators may be unable to locate suitable replacement suppliers on acceptable terms or on a timely basis, or at all; and
- delays caused by supply issues may harm our reputation, frustrate our customers and cause them to turn to our competitors for future needs.

We and our collaborators and Lonza are subject to significant regulation with respect to manufacturing our product candidates. The Lonza manufacturing facilities on which we rely may not continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing manufacturers, including Lonza, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with current international Good Manufacturing Practice and other international regulatory requirements. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates. We, our collaborators, or suppliers must supply all necessary documentation in support of a BLA on a timely basis and must adhere to current Good Laboratory Practice and current Good Manufacturing Practice regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. Lonza and other suppliers have never produced a commercially approved cellular therapeutic product and therefore have not yet obtained the requisite regulatory authority approvals to do so.

Before we can begin commercial manufacture of our products for sale in the United States, we must obtain FDA regulatory approval for the product, in addition to the approval of the processes and quality systems associated with the manufacturing of such product, which requires a successful FDA inspection of the facility handling the manufacturing of our product, including Lonza's manufacturing facilities. The novel nature of our product candidates creates significant challenges in regards to manufacturing. For example, the U.S. federal and state governments and other jurisdictions impose restrictions on the acquisition and use of tissue, including those incorporated in federal Good Tissue Practice regulations. We may not be able to identify or develop sources for the cells necessary for our product candidates that comply with these laws and regulations. Further, we may be required to conduct additional clinical trials using 3D manufacturing processes before we receive regulatory approval.

In addition, the regulatory authorities may, at any time before or after product approval, audit or inspect a manufacturing facility involved with the preparation of our product candidates or raw materials or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we oversee each contract manufacturer involved in the production of our product candidates, we cannot control the manufacturing process of, and are dependent on, Lonza for compliance with the regulatory requirements. If Lonza is unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of any approved products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions would adversely affect our business, results of operations and financial condition. If Lonza fails to maintain regulatory compliance, the FDA or other applicable regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or biologic product, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially harmed.

We will rely on third parties to perform many necessary services for the commercialization of our product candidates, including services related to the distribution, storage and transportation of our products.

We will rely upon third parties for certain storage, distribution and other logistical services. In accordance with certain laws, regulations and specifications, our product candidates must be stored and transported at extremely low temperatures within a certain range. If these environmental conditions deviate, our product candidates' remaining shelf-lives could be impaired or their efficacy and safety could become adversely affected, making them no longer suitable for use. If any of the third parties that we intend to rely upon in our storage, distribution and other logistical services process fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver product to meet commercial demand may be significantly impaired. In addition, as our cellular therapies will constitute a new form of product, experience in commercial distribution of such therapies in the United States is extremely limited, and as such is subject to execution risk. While we intend to work closely with our selected distribution logistics providers to define appropriate parameters for their activities to ensure product remains intact throughout the process, there is no assurance that such logistics providers will be able to maintain all requirements and handle and distribute our products in a manner that does not significantly impair them, which may impact our ability to satisfy commercial demand.

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

Our product candidates 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. For example, during the manufacturing process we have from time to time experienced several different types of issues that have led to a rejection of various batches. Historically, the most common reasons for batch rejections include major process deviations during the production of a specific batch and failure of manufactured product to meet one or more specifications. While product candidate batches released for the use in clinical trials or for commercialization undergo sample testing, some latent defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these product candidates 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.

Risks Related to Commercialization of Our Product Candidates

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients and healthcare payors.

Even when product development is successful and regulatory approval has been obtained, our ability to generate significant revenue depends on the acceptance of our products by physicians, payors and patients. Many potential market participants have limited knowledge of, or experience with, stem cell-based products, so gaining market acceptance and overcoming any safety or efficacy concerns may be more challenging than for more traditional therapies. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more or different resources than are required by the conventional therapies marketed by our competitors. We cannot assure you that our products will achieve the expected market acceptance and revenue if and when they obtain the requisite regulatory approvals. Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. The market acceptance of each of our product candidates will depend on a number of factors, including:

- the efficacy and safety of the product candidate, as demonstrated in clinical trials;
- the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings or contraindications that may be required on the label;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the continued projected growth of markets for our various indications;
- relative convenience and ease of administration;

- the prevalence and severity of adverse side effects;
- the effectiveness of our, and our collaborators' sales and marketing efforts; and
- sufficient third-party insurance and other payor (e.g., governmental) coverage and reimbursement.

Market acceptance is critical to our ability to generate significant revenue. Any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

If, in the future, we are unable to establish our own sales, marketing and distribution capabilities or enter into licensing or collaboration agreements for these purposes, we may not be successful in independently commercializing any future products.

We have limited sales, marketing or distribution infrastructure and experience. Commercializing our product candidates, if such product candidates obtain regulatory approval, would require significant sales, distribution and marketing capabilities. Where and when appropriate, we may elect to utilize contract sales forces or distribution collaborators to assist in the commercialization of our product candidates. If we enter into arrangements with third parties to perform sales, marketing and distribution/price reporting services for our product candidates, the resulting revenue or the profitability from this revenue to us may be lower than if we had sold, marketed and distributed that product ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute any future products or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of these third parties may fail to devote the necessary resources and attention to sell, market and distribute our current or any future products effectively.

To the extent we are unable to engage third parties to assist us with these functions, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that any of our proprietary product candidates will be approved. For any future products for which we decide to perform sales, marketing and distribution functions ourselves, we could face a number of additional risks, including:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel or to develop alternative sales channels;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the inability of account teams to obtain formulary acceptance for our products, allowing for reimbursement and hence patient access;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with multiple products; and
- unforeseen costs and expenses associated with creating and maintaining an independent sales and marketing organization.

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

The biopharmaceutical industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of our potential competitors have significantly greater development, financial, manufacturing, marketing, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in conducting clinical trials, obtaining regulatory approvals, manufacturing pharmaceutical and biologic products and commercializing such therapies. Recent and potential future merger and acquisition activity in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds that could make our product candidates obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing our product candidates or competitors to our product candidates before we do. Specialized, smaller or early-stage companies may also prove to be significant competitors, particularly those with a focus and expertise in stem cell therapies. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and results of operations will suffer.

Our marketed products may be used by physicians for indications that are not approved by the FDA. If the FDA finds that we marketed our products in a manner that promoted off-label use, we may be subject to civil or criminal penalties.

Under the Federal Food, Drug and Cosmetic Act ("FDCA"), and other laws, if any of our product candidates are approved by the FDA, we would be prohibited from promoting our products for off-label uses. This means, for example, that we would not be able to make claims about the use of our marketed products outside of their approved indications, and we would not be able to proactively discuss or provide information on off-label uses of such products, with very specific and limited exceptions. The FDA does not, however, prohibit physicians from prescribing products for off-label uses in the practice of medicine. Should the FDA determine that our activities constituted the promotion of off-label use, the FDA could issue a warning or untitled letter or, through the Department of Justice, bring an action for seizure or injunction, and could seek to impose fines and penalties on us and our executives. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions, and also may figure into civil litigation against us.

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, was passed. The Affordable Care Act is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and the health insurance industry, impose new taxes and fees on the healthcare industry and impose additional health policy reforms. There have been a number of judicial and congressional challenges to certain aspects of the Affordable Care Act, and we expect that with the current administration efforts will continue to repeal or significantly amend the Affordable Care Act. We can provide no assurance that the Affordable Care Act, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Currently, the outcome of potential reforms and changes to government negotiation/regulation to healthcare costs are unknown. If changes in policy limit reimbursements that we are able to receive through federal programs, it could negatively impact reimbursement levels from those payors and private payors, and our business, revenues or profitability could be adversely affected.

If we or our collaborators fail to obtain and sustain an adequate level of reimbursement for our products by third-party payors, sales and profitability would be adversely affected.

Our and our collaborators' ability to commercialize any products successfully will depend, in part, on the extent to which coverage and reimbursement for our products and related treatments will be available from government healthcare programs, private health insurers, managed care plans, and other organizations. Additionally, even if there is a commercially viable market, if the level of third-party reimbursement is below our expectations, our revenue and profitability could be materially and adversely affected.

Third-party payors, such as government programs, including Medicare or Medicaid in the United States, or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for medical products and services, and many third-party payors limit or delay coverage of or reimbursement for newly approved healthcare products. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A current trend in the U.S. healthcare industry as well as in other countries around the world is toward cost containment. Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for any product, which could result in product revenue and profitability being lower than anticipated.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or other regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our and any collaborator's costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments and treatment codes for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Furthermore, reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Our existing or future collaborators, if any, may elect to reduce the price of our products in order to increase the likelihood of obtaining reimbursement approvals which could adversely affect our revenues and profits. In many countries, including for example in Japan, products cannot be commercially launched until reimbursement is approved. Further, the post-approval price negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may thereby adversely affect our sales and profitability. In the event that countries impose prices which are not sufficient to allow us or our collaborators to generate a profit, our collaborators may refuse to launch the product in such countries or withdraw the product from the market, which would adversely affect sales and profitability.

Due to the novel nature of our stem cell therapy and the potential for our product candidates to offer therapeutic benefit in a single administration, we face uncertainty related to pricing and reimbursement for these product candidates.

Our target patient populations for some of our product candidates may be relatively small, and as a result, the pricing and reimbursement of our product candidates, if approved, must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected. Due to the novel nature of our stem cell technology, the manner and level at which reimbursement is provided for services related to our product candidates (e.g., for administration of our product to patients) is uncertain. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products. Further, if the results of our clinical trials and related cost benefit analyses do not clearly demonstrate the efficacy or overall value of our product candidates in a manner that is meaningful to prescribers and payors, our pricing and reimbursement may be adversely affected.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly EU member states, Japan, Australia and Canada, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, revenues or profitability could be adversely affected.

If the market opportunities for our product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer. Because the target patient populations of certain of our product candidates are small, we must be able to successfully identify physicians with access to appropriate patients and achieve a significant market share to maintain profitability and growth.

Our projections of the number of people with diseases targeted by our product candidates are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. In addition, physicians who we believe have access to patients in need of our products may in fact not often treat the diseases targeted by our product candidates, and may not be amenable to use of our product. Further, the number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

We are exposed to risks related to our licensees and our international operations, and failure to manage these risks may adversely affect our operating results and financial condition.

We and our subsidiaries operate out of Australia, the United States, Singapore, the United Kingdom and Switzerland. We have licensees, with rights to commercialize products based on our MSC technology, including JCR in Japan. Our primary manufacturing collaborator, Lonza, serves us primarily out of their facilities in Singapore, and through contractual relationships with third parties, has access to storage facilities in the U.S., Europe, Australia and Singapore. As a result, a significant portion of our operations are conducted by and/or rely on entities outside the markets in which certain of our trials take place, our suppliers are sourced, our product candidates are developed, and, if any such product candidates obtain regulatory approval, our products may be sold. Accordingly, we import a substantial number of products and/or materials into such markets. We may be denied access to our customers, suppliers or other collaborators or denied the ability to ship products from any of these sites as a result of a closing of the borders of the countries in which we operate, or in which these operations are located, due to economic, legislative, political and military conditions in such countries. For example, on June 23, 2016, the electorate in the United Kingdom, or UK, voted in favor of leaving the European Union (EU) (commonly referred to as "Brexit"). Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom's vote to leave the European Union creates an uncertain political and economic environment in the United Kingdom and potentially across other European Union member states, which may last for a number of months or years. If any of our product candidates are approved for commercialization, we may enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- logistics and regulations associated with shipping cell samples and other perishable items, including infrastructure conditions and transportation delays;
- potential import and export issues and other trade barriers and restrictions with the U.S. Customs and Border Protection and similar bodies in other jurisdictions;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- reduced protection for intellectual property rights in some countries and practical difficulties of enforcing intellectual property and contract rights abroad;
- changes in diplomatic and trade relationships, including new tariffs, trade protection measures, import or export licensing requirements, trade embargoes and other trade barriers;
- tariffs imposed by the U.S. on goods from other countries, including the recently implemented tariffs and additional tariff that have been proposed by the U.S. government on various imports from China and the EU and by the governments of these jurisdictions on certain U.S. goods, and any other possible tariffs that may be imposed on products such as ours, the scope and duration of which, if implemented, remains uncertain;
- deterioration of political relations between the U.K. and the EU, which could have a material adverse effect on our sales and operations in these countries;
- changes in social, political and economic conditions or in laws, regulations and policies governing foreign trade, manufacturing, development and investment both domestically as well as in the other countries and jurisdictions into which we sell our products;
- fluctuations in currency exchange rates and the related effect on our results of operations;
- increased financial accounting and reporting burdens and complexities;
- potential increases on tariffs or restrictions on trade generally;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Use of animal-derived materials could harm our product development and commercialization efforts.

Some of the manufacturing materials and/or components that we use in, and which are critical to, implementation of our technology involve the use of animal-derived products, including FBS. Suppliers or regulatory changes may limit or restrict the availability of such materials for clinical and commercial use. While FBS is commonly used in the production of various marketed biopharmaceuticals, the suppliers of FBS that meet our strict quality standards are limited in number and region. As such, to the extent that any such suppliers or regions face an interruption in supply (for example, if there is a new occurrence of so-called "mad cow disease"), it may lead to a restricted supply of the serum currently required for our product manufacturing processes. Any restrictions on these materials would impose a potential competitive disadvantage for our products or prevent our ability to manufacture our cell products. The FDA has issued regulations for controls over bovine material in animal feed. These regulations do not appear to affect our ability to purchase the manufacturing materials we currently use. However, the FDA may propose new regulations that could affect our operations. Our inability to develop or obtain alternative compounds would harm our product development and commercialization efforts. There are certain limitations in the supply of certain animal-derived materials, which may lead to delays in our ability to complete clinical trials or eventually to meet the anticipated market demand for our cell products.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the human clinical use of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products, even if such products are approved;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigations;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals, or labeling, marketing or promotional restrictions;
- increased cost of liability insurance;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our ordinary share price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Additionally, our insurance policies have various exclusions, and we may be subject to a product liability claim for which we have no coverage or reduced coverage. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Risks Related to Our Intellectual Property

We may not be able to protect our proprietary technology in the marketplace.

Our success will depend, in part, on our ability to obtain patents, protect our trade secrets and operate without infringing on the proprietary rights of others. We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property of our product candidates. Patents might not be issued or granted with respect to our patent applications that are currently pending, and issued or granted patents might later be found to be invalid or unenforceable, be interpreted in a manner

that does not adequately protect our current product or any future products, or fail to otherwise provide us with any competitive advantage. As such, we do not know the degree of future protection that we will have on our proprietary products and technology, if any, and a failure to obtain adequate intellectual property protection with respect to our product candidates and proprietary technology could have a material adverse impact on our business.

Filing, prosecuting and defending patents throughout the world would be prohibitively expensive, so our policy is to patent technology in jurisdictions with significant or otherwise relevant commercial opportunities or activities. However, patent protection may not be available for some of the products or technology we are developing. If we must spend significant time and money protecting or enforcing our patents, designing around patents held by others or licensing, potentially for large fees, patents or other proprietary rights held by others, our business, results of operations and financial condition may be harmed.

The patent positions of biopharmaceutical products are complex and uncertain.

The scope and extent of patent protection for our product candidates are particularly uncertain. To date, our principal product candidates have been based on specific subpopulations of known and naturally occurring adult stem cells. We anticipate that the products we develop in the future will continue to include or be based on the same or other naturally occurring stem cells or derivatives or products thereof. Although we have sought and expect to continue to seek patent protection for our product candidates, their methods of use and methods of manufacture, any or all of them may not be subject to effective patent protection. Publication of information related to our product candidates by us or others may prevent us from obtaining or enforcing patents relating to these products and product candidates. Furthermore, others may independently develop similar products, may duplicate our products, or may design around our patent rights. In addition, any of our issued patents may be declared invalid. If we fail to adequately protect our intellectual property, we may face competition from companies who attempt to create a generic product to compete with our product candidates. We may also face competition from companies who develop a substantially similar product to our other product candidates that may not be covered by any of our patents.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our current or future products, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We maintain certain of our proprietary know-how and technological advances as trade secrets, especially where we do not believe patent protection is appropriate or obtainable, including, but not exclusively, with respect to certain aspects of the manufacturing of our products. However, trade secrets are difficult to protect. We take a number of measures to protect our trade secrets including, limiting disclosure, physical security and confidentiality and non-disclosure agreements. We enter into confidentiality agreements with our employees, consultants, outside scientific collaborators, contract manufacturing partners, sponsored researchers and other advisors and third parties to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection, or failure to adequately protect our intellectual property could enable competitors to develop generic products or use our proprietary information to develop other products that compete with our products or cause additional, material adverse effects upon our business, results of operations and financial condition.

We may be forced to litigate to enforce or defend our intellectual property rights, and/or the intellectual property rights of our licensors.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets against unauthorized use. In so doing, we may place our intellectual property at risk of being invalidated, unenforceable, or limited or narrowed in scope and may no longer be used to prevent the manufacture and sale of competitive product. Further, an adverse result in any litigation or other proceedings before government agencies such as the United States Patent and Trademark Office ("USPTO"), may place pending applications at risk of non-issuance. Further, interference proceedings, derivation proceedings, entitlement proceedings, ex parte reexamination, inter partes reexamination, inter partes review, post-grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge inventorship, ownership, claim scope, or validity of our patent applications. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation.

Intellectual property disputes could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and/or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our ADSs and ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of litigation proceedings more effectively than we can because of their greater financial resources and personnel. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology or enter into strategic collaborations that would help us bring our product candidates to market. As a result, uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

U.S. patent reform legislation and court decisions could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued U.S. patents.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Under the current patent laws, a third party that files a patent application in the USPTO before us for a particular invention could therefore be awarded a patent covering such invention even if we had made that invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application.

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation and proceedings. These include allowing third party submissions of prior art to the USPTO during patent prosecution and additional procedures for attacking the validity of a patent through USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because a lower evidentiary standard applies in USPTO proceedings compared to the evidentiary standards applied in United States federal courts in actions seeking to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if challenged in a district court action. Accordingly, a third party may attempt to use available USPTO procedures to invalidate our patent claims that would not otherwise have been invalidated if first challenged by the third party in a district court action. The new post-grant review (PGR) proceedings added as of September 2012 by the America Invents Act, which are similar to European "opposition" proceedings and provide third-party petitioners with the ability to challenge the validity of a patent on more expansive grounds than those permitted in other USTPO proceedings, allow for validity to be examined by the USPTO based not only on prior art patents and publications, but also on prior invalidating public use and sales, the presence of non-statutory subject matter in the patent claims and inadequate written description or lack of enablement. Discovery for PGR proceedings is accordingly likely to be expansive given that the issues addressed in PGR are more comprehensive than those addressed in other USPTO proceedings. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

As compared to intellectual property-reliant companies generally, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. These rulings have created uncertainty with respect to the validity and enforceability of patents, even once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

If third parties claim that intellectual property used by us infringes upon their intellectual property, commercialization of our product candidates and our operating profits could be adversely affected.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon patents, trademarks, copyrights, or other intellectual property rights owned by third parties, and we cannot provide assurances that other companies will not, in the future, pursue such infringement claims against us or any third-party proprietary technologies we have licensed. Any such claims could also be expensive and time consuming to defend and divert management's attention and resources, and could delay or prevent us from commercializing our product candidates. Our competitive position could suffer as a result. Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our product candidates, we have not conducted a freedom-to-operate search or analysis for our product candidates, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our product candidates. Thus, we cannot guarantee that our product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity of our product candidates, our business may be materially harmed.

Depending on the timing, duration and specifics of FDA marketing approval of our product candidates, if any, one of the U.S. patents covering each of such approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates, including by the EMA in the EU or the PMDA in Japan. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. In addition, if a patent we wish to extend is owned by another party and licensed to us, we may need to obtain approval and cooperation from our licensor to request the extension.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks Related to Our Business and Industry

If we fail to attract and keep senior management and key scientific, commercial, regulatory affairs and other personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.

We are highly dependent on members of our executive management, particularly Dr. Silviu Itescu, our Chief Executive Officer. Dr. Itescu was an early pioneer in the study and clinical development of stem cell therapeutics and is globally recognized in the field of regenerative medicine. The loss of the services of Dr. Itescu or any other member of the executive management team could impede the achievement of our research, development and commercialization objectives. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, regulatory affairs, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

Our employees, principal investigators, consultants and collaboration partners may engage in misconduct or other improper activities, including noncompliance with laws and regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements (including arrangements with healthcare providers, opinion leaders, research institutions, distributors and payors) in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of activity relating to pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, or, given we are a listed company in Australia and the United States, breach of insider trading or other securities laws and regulations. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We may acquire other companies or assets which could divert our management's attention, result in additional dilution to our shareholders and otherwise disrupt our operations and harm our operating results.

We have in the past and may in the future seek to acquire businesses, products or technologies that we believe could complement or expand our product offerings, enhance our technical capabilities or otherwise offer growth opportunities. For example, we acquired MSC assets from Osiris Therapeutics, Inc. in 2013. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- incurrence of acquisition-related costs;
- diversion of management's attention from other business concerns;
- unanticipated costs or liabilities associated with the acquisition;
- harm to our existing business relationships with collaborators as a result of the acquisition;
- harm to our brand and reputation;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results arising from the impairment assessment process. Acquisitions may also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our business, results of operations and financial condition may be adversely affected.

We and our collaborators must comply with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We and our collaborators are subject to various federal, state and local environmental laws, rules and regulations, including those relating to the discharge of materials into the air, water and ground, the manufacture, storage, handling, use, transportation and disposal of hazardous and biological materials, and the health and safety of employees with respect to laboratory activities required for the development of products and technologies. In the event of contamination or injury, or failure to comply with environmental, occupational health and safety and export control laws and regulations, it could cause an interruption of our commercialization efforts, research and development efforts, or business operations, and we could be held liable for any resulting damages and any such liability could exceed our assets and resources.

We work with outside scientists and their institutions in developing product candidates. These scientists may have other commitments or conflicts of interest, which could limit our access to their expertise and harm our ability to leverage our discovery platform.

We work with scientific advisors and collaborators at academic research institutions in connection with our product development. These scientific advisors serve as our link to the specific pools of trial participants we are targeting in that these advisors may:

- identify individuals as potential candidates for study;
- obtain their consent to participate in our research;
- perform medical examinations and gather medical histories;
- conduct the initial analysis of suitability of the individuals to participate in our research based on the foregoing; and
- collect data and biological samples from trial participants periodically in accordance with our study protocols.

These scientists and collaborators are not our employees, rather they serve as either independent contractors or the primary investigators under research collaboration agreements that we have with their sponsoring academic or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to our business.

If our ability to use cumulative carry forward net operating losses is or becomes subject to certain limitations or if certain tax incentive credits from which we benefit expire or no longer apply to us, our business, results of operations and financial condition may be adversely affected.

We are an Australian company subject to taxation in Australia and other jurisdictions. As of June 30, 2019, our cumulative operating losses have a total potential tax benefit of $112.0 million at local tax rates (excluding other temporary differences). These losses may be available for use once we are in a tax profitable position. These losses were incurred in different jurisdictions and can only be offset against profits earned in the relevant jurisdictions. Tax losses are able to be carried forward at their nominal amount indefinitely in Australia and in Singapore, and for up to 20 years in the U.S. as long as certain conditions are met; however, new tax reform legislation in the United States allows for indefinite carryforward of any net operating loss arising in a tax year ending after December 31, 2018, subject to certain conditions. In order to use these tax losses, it is necessary to satisfy certain tests and, as a result, we cannot assure you that the tax losses will be available to offset profits if and when we earn them. Utilization of our net operating loss and research and development credit carryforwards in the U.S. may be subject to substantial annual limitation due to ownership change limitations that could occur in the future generally provided by Section 382 of the Internal Revenue Code of 1986, as amended. In addition, U.S. tax reform introduced a limitation on the amount of net operating losses arising in taxable years beginning after December 31, 2017, that a corporation may deduct in a single tax year equal to the lesser of the available net operating loss carryover or 80 percent of a taxpayer’s pre-net operating loss deduction taxable income. With respect to carryforward net operating losses in the U.S. that are subject to the 20-year carry-forward limit, our carry forward net operating losses first start to expire in 2032. In addition, we are eligible for certain research and development tax incentive refundable credits in Australia that may increase our available cash flow. The Australian federal government's Research and Development Tax Incentive grant is available for eligible research and development purposes based on the filing of an annual application.

There can be no assurances that we will continue to benefit from these incentives or that such tax incentive credit programs will not be revoked or modified in any way in the future. The Australian government may in the future decide to modify the requirements of, reduce the amounts of the research and development tax incentive credits available under, or discontinue its research and development tax incentive program. For instance, the Australian government undertook a review of its Research and Development Tax Incentive program in 2016 and in the May 2018 Federal budget announced its intention to pass certain recommendations of the review panel into law to reduce the research and development tax incentive credits available in certain circumstances. One of the changes announced in May 2018 was to reduce the amount of the research and development tax incentive credits available by capping the annual refundable tax offset amount at A$4.0 million for companies with an annual aggregate turnover of less than A$20.0 million, such as us, however, refundable tax offsets related to spend incurred on clinical trials conducted in Australia would not be capped. If the Research and Development Tax program incentives are revoked or modified, or if we no longer qualify as a small-medium business under the A$20.0 million turnover test or we are no longer eligible for such incentives due to other circumstances, our business, results of operations and financial condition may be adversely affected.

For the year ended June 30, 2019, our combined worldwide turnover is in excess of A$20.0 million making us ineligible for the refundable cash tax offset for the research and development tax incentive. As a result, we recognized income of $Nil and $1.4 million, respectively, from the Research and Development Tax Incentive program for the years ended June 30, 2019 and 2018.

Taxing authorities could reallocate our taxable income within our subsidiaries, which could increase our consolidated tax liability.

We conduct operations in multiple tax jurisdictions and the tax laws of those jurisdictions generally require that the transfer prices between affiliated companies in different jurisdictions be the same as those between unrelated companies dealing at arms' length, and that such prices are supported by contemporaneous documentation. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us, and possibly interest and penalties, and could adversely affect our business, results of operations and financial condition.

The pharmaceutical industry is highly regulated and pharmaceutical companies are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act.

Healthcare fraud and abuse regulations are complex and can be subject to varying interpretations as to whether or not a statute has been violated. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute which prohibits, among other things, the knowing and willful payment of remuneration to induce or reward patient referrals, prescribing or recommendation of products, or the generation of business involving any item or service which may be payable by the federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients);
- the federal False Claims Act which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment for government funds (e.g., payment from Medicare or Medicaid) or knowingly making, using, or causing to be made or used a false record or statement, material to a false or fraudulent claim for government funds;
- the federal *Health Insurance Portability and Accountability Act of 1996* ("HIPAA"), as amended by the *Health Information Technology for Economic and Clinical Health Act*, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HIPAA imposes civil and criminal liability for the wrongful access or disclosure of protected health information;
- the federal *Physician Payments Sunshine Act*, created under Section 6002 of the *Patient Protection and Affordable Care Act* ("ACA"), as amended, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, those physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members;
- the FDCA, which, among other things, regulates the testing, development, approval, manufacture, promotion and distribution of drugs, devices and biologics. The FDCA prohibits manufacturers from selling or distributing "adulterated" or "misbranded" products. A drug product may be deemed misbranded if, among other things, (i) the product labeling is false or misleading, fails to contain requisite information or does not bear adequate directions for use; (ii) the product is manufactured at an unregistered facility; or (iii) the product lacks the requisite FDA clearance or approval;
- the U.S. *Foreign Corrupt Practices Act* ("FCPA"), which prohibits corrupt payments, gifts or transfers of value to non-U.S. officials; and
- non-U.S. and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Any failure to comply with these laws, or the regulations adopted thereunder, could result in administrative, civil, and/or criminal penalties, and could result in a material adverse effect on our reputation, business, results of operations and financial condition.

The federal fraud and abuse laws have been interpreted to apply to arrangements between pharmaceutical manufacturers and a variety of health care professionals and healthcare organizations. Although the federal Anti-Kickback Statute has several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, all elements of the potentially

applicable exemption or safe harbor must be met in order for the arrangement to be protected, and prosecutors have interpreted the federal healthcare fraud statutes to attack a wide range of conduct by pharmaceutical companies. In addition, most states have statutes or regulations similar to the federal anti-kickback and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws. Further, the current administration has indicated an interest in excluding transactions with certain payors or other healthcare providers from safe harbor protection. This may impact the manner in which manufacturers contract with payors, and negatively impact our market opportunities for our products.

Further, the ACA, among other things, amended the intent standard under the Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA makes clear that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the federal False Claims Act. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

A failure to adequately protect private health information could result in severe harm to our reputation and subject us to significant liabilities, each of which could have a material adverse effect on our business.

Throughout the clinical trial process, we may obtain the private health information of our trial subjects. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the *American Recovery and Reinvestment Act 2009* ("ARRA"), Congress amended the privacy and security provisions of HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers conducting certain electronic transactions, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on certain individuals and entities that provide services to or perform certain functions on behalf of healthcare providers and other covered entities involving the use or disclosure of individually identifiable health information, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements to federal regulators, and in some cases local and national media, for individuals whose health information has been inappropriately accessed or disclosed. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with certain encryption or other standards developed by the U.S. Department of Health and Human Services, or HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The EU's General Data Protection Regulation, Canada's *Personal Information Protection and Electronic Documents Act* and other data protection, privacy and similar national, state/provincial and local laws and regulations may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches, and the failure to so comply may lead to fines or penalties.

Our operations are subject to anti-corruption laws, including Australian bribery laws, the United Kingdom Bribery Act, and the FCPA and other anti-corruption laws that apply in countries where we do business.

Anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Although we believe that we have adequate policies and enforcement mechanisms to ensure legal and regulatory compliance with the FCPA, the U.K. Bribery Act 2010 and other similar regulations, we participate in collaborations and relationships with third parties, and it is possible that any of our employees, subcontractors, agents or partners may violate any such legal and regulatory requirements, which may expose us to criminal or civil enforcement actions, including penalties and suspension or disqualification from U.S. federal procurement contracting. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

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

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur additional legal, accounting and other expenses.

In order to maintain our current status as a foreign private issuer, either (1) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (2) (a) a majority of our executive officers or directors must not be U.S. citizens or residents, (b) more than 50 percent of our assets cannot be located in the U.S. and (c) our business must be administered principally outside the U.S. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC rules and Nasdaq listing standards. Further, we would be required to comply with U.S. GAAP, as opposed to IFRS, in the preparation and issuance of our financial statements for historical and current periods. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs.

If we fail to maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Section 404(a) of the *Sarbanes-Oxley Act of 2002* (the "Sarbanes-Oxley Act"), requires that our management assess and report annually on the effectiveness of our internal controls over financial reporting and identify any material weaknesses in our internal controls over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight.

If either we are unable to conclude that we have effective internal controls over financial reporting or our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal controls over financial reporting as required by Section 404(b) of the Sarbanes-Oxley Act, investors may lose confidence in our operating results, the price of the ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, we may not be able to remain listed on Nasdaq Global Select Market ("Nasdaq").

We have incurred and will continue to incur significant increased costs as a result of operating as a company whose ADSs are publicly traded in the United States, and our management will continue to be required to devote substantial time to compliance initiatives.

As a company whose ADSs are publicly traded in the United States, we have incurred and will continue to incur significant legal, accounting, insurance and other expenses. The Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the SEC and Nasdaq, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives, and we will need to add additional personnel and build our internal compliance infrastructure. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our senior management. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially regulatory investigations and enforcement and/or civil litigation.

We have never declared or paid dividends on our ordinary shares, and we do not anticipate paying dividends in the foreseeable future. Therefore, you must rely on price-appreciation of our ordinary shares or ADSs for a return on your investment.

We have never declared or paid cash dividends on our ordinary shares. For the foreseeable future, we currently intend to retain all available funds and any future earnings to support our operations and to finance the growth and development of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to compliance with applicable laws and covenants under the loan facilities with Hercules and NovaQuest or other current or future credit facilities, which may restrict or limit our ability to pay dividends, and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. We do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. As a result, a return on your investment in our ordinary shares or ADSs will likely only occur if our ordinary share or ADS price appreciates. There is no guarantee that our ordinary shares or ADSs will appreciate in value in the future.

Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares or ADSs.

We are incorporated in Australia and are subject to the takeover laws of Australia. Among other things, we are subject to the Australian *Corporations Act 2001* (the "Corporations Act"). Subject to a range of exceptions, the Corporations Act prohibits the acquisition of a direct or indirect interest in our issued voting shares if the acquisition of that interest will lead to a person's voting power in us increasing to more than 20%, or increasing from a starting point that is above 20% and below 90%. Australian takeover laws may discourage takeover offers being made for us or may discourage the acquisition of a significant position in our ordinary shares. This may have the ancillary effect of entrenching our board of directors and may deprive or limit our shareholders' opportunity to sell their ordinary shares or ADSs and may further restrict the ability of our shareholders to obtain a premium from such transactions.

Risks Related to Our Trading Markets

The market price and trading volume of our ordinary shares and ADSs may be volatile and may be affected by economic conditions beyond our control.

The market price of our ordinary shares and ADSs may be highly volatile and subject to wide fluctuations. In addition, the trading volume of our ordinary shares and ADSs may fluctuate and cause significant price variations to occur. We cannot assure you that the market price of our ordinary shares and ADSs will not fluctuate or significantly decline in the future.

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

- 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;
- actual or anticipated fluctuations in our quarterly operating results or those of our competitors;
- 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;
- additions to or departures of our key management personnel;
- issuances by us of debt or equity securities;
- litigation or investigations 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;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- changes in trading volume of ADSs on the Nasdaq and of our ordinary shares on the ASX;
- 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 companies; and
- conditions in the U.S. or Australian financial markets or changes in general economic conditions.

In the past, following periods of volatility in the market price of a company's securities, shareholders often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of senior management, require significant expenditure for defense costs, and, if adversely determined, could have a material adverse effect on our results of operations and financial condition.

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

Our ADSs are listed on the Nasdaq and our ordinary shares are listed on the ASX. We cannot predict the effect of this dual listing 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 development of an active trading market for the ADSs in the United States. The price of the ADSs could also be adversely affected by trading in our ordinary shares on the ASX, and vice versa.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the market price and trading volume of our ordinary shares and/or ADSs could decline.

The trading market for our ordinary shares and ADSs could be influenced by the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may discontinue research on our company, to the extent such coverage currently exists, or in other cases, may never publish research on our company. If too few securities or industry analysts commence coverage of our company, the trading price for our ordinary shares and ADSs would likely be negatively impacted. If one or more of the analysts who cover us downgrade our ordinary shares or ADSs or publish inaccurate or unfavorable research about our business, the market price of our ADSs would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares and/or ADSs could decrease, which might cause our price and trading volume to decline.

Risks Related to Ownership of Our ADSs

An active trading market for the ADSs may not develop in the United States.

Our ADSs are listed in the United States on the Nasdaq under the symbol "MESO." However, we cannot assure you that an active public market in the United States for the ADSs will develop on that exchange, or if developed, that this market will be sustained.

We currently report our financial results under IFRS, which differs in certain significant respect 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 U.S. GAAP, including differences related to revenue recognition, intangible assets, share-based compensation expense, income tax and earnings per share. 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.

As a foreign private issuer, we are permitted and expect to follow certain home country corporate governance practices in lieu of certain Nasdaq requirements applicable to domestic issuers and we are permitted to file less information with the Securities and Exchange Commission than a company that is not a foreign private issuer. This may afford less protection to holders of our ADSs.

As a "foreign private issuer," as defined in Rule 405 under the *Securities Exchange Act of 1933*, as amended (the "Securities Act"), whose ADSs will be listed on the Nasdaq, we will be permitted to, and plan to, follow certain home country corporate governance practices in lieu of certain Nasdaq requirements. For example, we may follow home country practice with regard to certain corporate governance requirements, such as the composition of the board of directors and quorum requirements applicable to shareholders' meetings. This difference may result in a board that is more difficult to remove and less shareholder approvals required generally. In addition, we may follow home country practice instead of the Nasdaq Global Select Market requirement to hold executive sessions and to obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions or private placements of securities. The above differences may result in less shareholder oversight and requisite approvals for certain acquisition or financing related decisions. Further, we may follow home country practice instead of the Nasdaq Global Select Market requirement to obtain shareholder approval prior to the establishment or amendment of certain share option, purchase or other compensation plans. This difference may result in less shareholder oversight and requisite approvals for certain company compensation related decisions. A foreign private issuer must disclose in its annual reports filed with the Securities and Exchange Commission, or SEC, and the Nasdaq Global Select Market, the requirements with which it does not comply followed by a description of its applicable home country practice. The Australian home country practices described above may afford less protection to holders of the ADSs than that provided under the Nasdaq Global Select Market rules.

Further, as a foreign private issuer, we are exempt from certain rules under the "Exchange Act", that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as a company that files as a domestic issuer whose securities are registered under the Exchange Act, nor are we generally required to comply with the SEC's Regulation FD, which restricts the selective disclosure of material non-public information. Accordingly, the information may not be disseminated in as timely a manner, or there may be less information publicly available concerning us generally than there is for a company that files as a domestic issuer.

ADS holders may be subject to additional risks related to holding ADSs rather than ordinary shares.

ADS holders do not hold ordinary shares directly and, as such, are subject to, among others, the following additional risks.

- As an ADS holder, we will not treat you as one of our shareholders and you will not be able to exercise shareholder rights, except through the American depositary receipt, or ADR, depositary as permitted by the deposit agreement.
- Distributions on the ordinary shares represented by your ADSs will be paid to the ADR depositary, and before the ADR depositary makes a distribution to you on behalf of your ADSs, any withholding taxes that must be paid will be deducted. Additionally, if the exchange rate fluctuates during a time when the ADR depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.
- We and the ADR depositary may amend or terminate the deposit agreement without the ADS holders' consent in a manner that could prejudice ADS holders.

ADS holders must act through the ADR depositary to exercise your voting rights and, as a result, you may be unable to exercise your voting rights on a timely basis.

As a holder of ADSs (and not the ordinary shares underlying your ADSs), we will not treat you as one of our shareholders, and you will not be able to exercise shareholder rights. The ADR depositary will be the holder of the ordinary shares underlying your ADSs, and ADS holders will be able to exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the deposit agreement relating to the ADSs. There are practical limitations on the ability of ADS holders to exercise their voting rights due to the additional procedural steps involved in communicating with these holders. For example, holders of our ordinary shares will receive notice of shareholders' meetings by mail or email and will be able to exercise their voting rights by either attending the shareholders meeting in person or voting by proxy. ADS holders, by comparison, will not receive notice directly from us. Instead, in accordance with the deposit agreement, we will provide notice to the ADR depositary of any such shareholders meeting and details concerning the matters to be voted upon. As soon as practicable after receiving notice from us of any such meeting, the ADR depositary will mail to holders of ADSs the notice of the meeting and a statement as to the manner in which voting instructions may be given by ADS holders. To exercise their voting rights, ADS holders must then instruct the ADR depositary as to voting the ordinary shares represented by their ADSs. Due to these procedural steps involving the ADR depositary, the process for exercising voting rights may take longer for ADS holders than for holders of ordinary shares. The ordinary shares represented by ADSs for which the ADR depositary fails to receive timely voting instructions will not be voted. Under Australian law and our Constitution, any resolution to be considered at a meeting of the shareholders shall be decided on a show of hands unless a poll is demanded by the shareholders at or before the declaration of the result of the show of hands. Under voting by a show of hands, multiple "yes" votes by ADS holders will only count as one "yes" vote and will be negated by a single "no" vote, unless a poll is demanded.

If we are or become classified as a passive foreign investment company, our U.S. securityholders may suffer adverse tax consequences.

Based upon an analysis of our income and assets for the taxable year ended June 30, 2019, we do not believe we were a passive foreign investment company (a "PFIC") for our most recent tax year. In general, if at least 75% of our gross income for any taxable year consists of passive income or at least 50% of the average quarterly value of assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, then we will be classified as a PFIC for U.S. federal income tax purposes. Passive income for this purpose generally includes dividends, interest, certain royalties and rents, and gains from commodities and securities transactions. Passive assets for this purpose generally includes assets held for the production of passive income. Accordingly, passive assets generally include any cash, cash equivalents and cash invested in short-term, interest bearing, debt instruments or bank deposits that are readily convertible into cash. Since PFIC status depends upon the composition of our income and assets and the market value of our assets from time to time, and as the determination of PFIC status must be made annually at the end of each taxable year, there can be no assurance that we will not be considered a PFIC for any future taxable year. Investors should be aware that our gross income for purposes of the PFIC income test depends on the receipt of active revenue, and there can be no assurances that such active revenue will continue, or that we will receive other gross income that is not considered passive for purposes of the PFIC income test. If we were a PFIC for any taxable year during a U.S. investor's holding period for the ordinary shares or ADSs, we would ordinarily continue to be treated as a PFIC for each subsequent year during which the U.S. investor owned the ordinary shares or ADSs. If we were treated as a PFIC, U.S. investors would be subject to special punitive tax

rules with respect to any "excess distribution" received from us and any gain realized from a sale or other disposition (including a pledge) of the ordinary shares or ADSs unless a U.S. investor made a timely "qualified electing fund" or "mark-to-market" election. For a more detailed discussion of the U.S. tax consequences to U.S. investors if we were classified as a PFIC, see Item 10.E- "Taxation — Certain Material U.S. Federal Income Tax Considerations to U.S. Holders — Passive Foreign Investment Company".

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, any dividends that we 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 these 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.

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

While we do not anticipate paying any dividends on our ordinary shares in the foreseeable future, if such a dividend is declared, 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. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs.

You may be subject to limitations on transfers of your ADSs.

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 requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

U.S. investors may have difficulty enforcing civil liabilities against our company, our directors or members of our senior management.

Several of our officers and directors are non-residents of the United States, and a substantial portion of the assets of such persons are located outside the U.S. As a result, it may be impossible to serve process on such persons in the United States or to enforce judgments obtained in U.S. courts against them based on civil liability provisions of the securities laws of the U.S. Even if you are successful in bringing such an action, there is doubt as to whether Australian courts would enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the U.S. or elsewhere may be unenforceable in Australia or elsewhere outside the U.S. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Australia will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The U.S. and Australia do not currently have a treaty or statute providing for recognition and enforcement of the judgments of the other country (other than arbitration awards) in civil and commercial matters.

As a result, our public shareholders and holders of the ADSs may have more difficulty in protecting their interests through actions against us, our management, our directors than would shareholders of a corporation incorporated in a jurisdiction in the United States.

Our Constitution and Australian laws and regulations applicable to us 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 United States. Our Constitution, as well as the Corporations Act, sets forth various rights and obligations that apply to us as an Australian company and which may not apply to a U.S. corporation. These requirements may operate differently than those of many U.S. companies.

Item 4. Information on the Company

4.A History and Development of Mesoblast

Mesoblast Limited

Mesoblast Limited was incorporated on June 8, 2004 as a public company in Australia under the *Corporations Act 2001* with an indefinite duration. On December 16, 2004 we became listed on the Australian Securities Exchange (the "ASX"). On November 13, 2015, we became listed on the Nasdaq Global Select Market ("Nasdaq") and from this date we have been dual-listed in Australia and the U.S.. Our registered office is located at the following address:

Mesoblast Ltd
Level 38
55 Collins Street
Melbourne VIC 3000
Australia
Telephone: +61 3 9639 6036
Web: www.mesoblast.com

Our agent for service of process in the United States is Mesoblast Inc., 505 Fifth Avenue, Level 3, New York, NY 10017. All information we file with the SEC is available through the SEC's Electronic Data Gathering, Analysis and Retrieval system, which may be accessed through the SEC's website at www.sec.gov.

For a list of our significant subsidiaries, see Exhibit 8.1 to this Annual Report.

Important Corporate Developments

Fiscal year 2019 to date of annual report

August — The United States Food and Drug Administration ("FDA") provided guidance on the clinical development pathway for marketing authorization of MPC-150-IM ("Revascor") in end-stage heart failure patients implanted with a left ventricular assist device ("LVAD").

July — Mesoblast reported increased revenues of 54% for the quarter and 37% for the year on sales of TEMCELL® Hs. Inj., a registered trademark of JCR ("TEMCELL"), in Japan for the treatment of steroid-refractory acute graft versus host disease ("aGVHD") by licensee JCR Pharmaceuticals Co. Ltd. ("JCR").

The Kentgrove Capital equity facility for up to A$120.0 million (approximately US$82.0 million), was extended for two years.

The American Heart Association journal Circulation Research published a Special Article highlighting the important potential clinical benefits of Revascor as an immunotherapy in patients with advanced chronic heart failure ("CHF"), stating that there is a biologic rationale for the use of Revascor in targeting cardiac inflammation in order to improve heart failure outcomes.

June — The FDA granted Orphan Drug Designation for the use of rexlemestrocel-L (Revascor) for the prevention of post implantation mucosal bleeding in heart failure patients implanted with an LVAD.

Health economics and outcomes research data presented at the 24th European Hematology Association Congress indicated that a steroid-refractory state in aGVHD may result in significant deterioration in quality of life and additional direct healthcare costs of an average of up to US$500,000 per patient.

Mesoblast's partnership with JCR in Japan was expanded to the use of TEMCELL for the treatment of newborns who lack sufficient blood supply and oxygen to the brain, a condition termed hypoxic ischemic encephalopathy ("HIE"). Mesoblast has the right to use all safety and efficacy data generated by JCR in Japan to support its commercialization plans for MSC-100-IV ("remestemcel-L") in the United States and other major healthcare markets. Mesoblast will receive royalties on TEMCELL product sales for HIE.

May — The first component of a rolling submission for a Biologics License Application ("BLA") to the FDA for remestemcel-L in the treatment of children with aGVHD was filed. The FDA has agreed to a rolling review of the BLA which enables individual components to be submitted and reviewed on an ongoing basis rather than waiting for all sections to be completed. The rolling process will provide opportunity for ongoing and frequent communication, and during this process the Company expects it will be able to adequately address any substantial matters raised by the FDA. The FDA previously granted Fast Track designation for remestemcel-L in aGVHD that allows for a rolling BLA review process and eligibility for priority review once the BLA filing is completed and accepted by the FDA.

March — Mesoblast and the International Center for Health Outcomes and Innovation Research ("InCHOIR") entered into a Memorandum of Understanding to conduct a confirmatory clinical trial using Revascor for reduction of gastrointestinal ("GI") bleeding in end-stage heart failure patients implanted with an LVAD. GI bleeding episodes are a major life-threatening complication of LVAD implants that occur in 20-40% of recipients in the first six months, resulting in recurrent hospitalizations and compromising quality of life. Confirmation of previous observations that our cell therapy reduced major bleeding episodes and related hospitalizations could identify a therapeutic approach that could greatly benefit these patients.

JCR filed to extend marketing approval of TEMCELL for use in patients with Epidermolysis Bullosa ("EB"). TEMCELL is already approved for the treatment of aGVHD. The parties have amended their License Agreement in order for JCR to access our mesenchymal stem cell ("MSC") wound healing patents to enable it to develop and commercialize TEMCELL for EB. Mesoblast will receive royalties on TEMCELL product sales for EB. JCR has received Orphan Designation for TEMCELL in the treatment of EB based on promising results from an investigator-initiated trial at Osaka University Hospital where TEMCELL was subcutaneously administered. JCR also intends to seek a label extension for TEMCELL in Japan for intravenous delivery of TEMCELL.

Joseph R. Swedish was appointed as non-executive Chairman of Mesoblast. Mr Swedish is a highly experienced healthcare executive and leader, most recently serving as Chairman, President and CEO of Anthem Inc., a Fortune 29 company and the leading health benefits provider in the U.S. For 12 consecutive years, Modern Healthcare named Mr Swedish as one of the 100 Most Influential People in Healthcare, ranking in the top 20 of the health sector's most senior-level executives, high-level government administrators, elected officials, academics, and thought-leaders for five consecutive years. He has been a Mesoblast board member since June 2018, and also serves on the boards of IBM Corporation, CDW Corporation, Proteus Digital Health, and Centrexion Therapeutics.

February — The last patient was dosed in the Phase 3 events-driven trial of Revascor for advanced CHF. The 566-patient trial will complete when sufficient primary endpoint events have accrued. Results from a prior Phase 2 trial identified the patients most likely to benefit from Revascor as being those at high risk of recurrent hospitalization events and death. These results guided the trial design and selection criteria for enrollment of high-risk patients in the current Phase 3 trial in order to maximize the probability that the Phase 3 results would confirm the Phase 2 results.

January — Mesoblast drew a further US$15.0 million from our US$75.0 million, non-dilutive, four-year credit facility with Hercules Capital, Inc. ("Hercules"). The funds will be used primarily to ramp up our product commercialization programs including building out a targeted sales force for our product candidate for aGVHD. The additional non-dilutive capital was made available after the success of our product candidate Revascor in having significantly reduced hospitalization rates from major GI bleeding in patients with end-stage heart failure and LVAD compared with controls in the 159-patient trial.

December — Eric Strati, PhD, was appointed to the new position of Senior Vice President, Commercial to drive commercial launch activities of remestemcel-L in the U.S. and Europe for the treatment of aGVHD.

Recent meetings were held with the FDA to support our planned regulatory filing for commercialization of remestemcel-L in aGVHD. We gained agreement from the FDA on the proposed chemistry and manufacturing controls for commercialization. The FDA also provided guidance on the presentation of data from the completed 55-patient Phase 3 trial and the 241-patient Expanded Access Program ("EAP") to be included in the filing for the proposed indication.

November — Announced results of a 159-patient randomized placebo-controlled trial evaluating Revascor in the treatment of end-stage heart failure patients implanted with a LVAD which were presented at the 2018 American Heart Association Scientific Sessions.

- The trial succeeded in achieving the clinically meaningful outcome of reduction in GI bleeding and related hospitalizations;
- Results confirm the previous pilot trial, which also demonstrated significant reduction in GI bleeding and related hospitalizations in Revascor treated LVAD patients;
- Pilot trial results formed the basis for the FDA Regenerative Medicine Advanced Therapy ("RMAT") designation granted in December 2017; and

- While the trial did not meet the overall primary endpoint of temporary weaning, Revascor treatment did significantly improve weaning in the 44% of patients with chronic ischemic heart failure.

October — Completion of the transaction with Tasly Pharmaceutical Group ("Tasly") to establish a strategic partnership in China for our allogeneic mesenchymal precursor cell ("MPC") product candidates Revascor for heart failure and MPC-25-IC for heart attacks. Tasly received exclusive rights to, and will fund all development, manufacturing and commercialization activities in China for Revascor and MPC-25-IC.

- We received $40.0 million on closing and will receive $25.0 million on product regulatory approvals in China, double-digit escalating royalties on net product sales as well as six escalating milestone payments upon the product candidates reaching certain sales thresholds in China;
- Tasly and Mesoblast have established a joint steering committee to oversee, review and co-ordinate the development, manufacturing and commercialization activities for these cardiovascular product candidates in China; and
- The companies plan to leverage each other's clinical trial results in China and the United States and other major jurisdictions respectively to support their respective regulatory submissions for Revascor and MPC-25-IC.

September — Our heart failure product candidate Revascor for use in children with hypoplastic left heart syndrome ("HLHS") was featured at the First Cardiac Regenerative Symposium for Congenital Heart Disease in Baltimore, Maryland. The symposium focused on the potential for using cellular therapies in the treatment of complex congenital heart conditions. This trial has the potential to extend the safety profile of Revascor beyond adults, where it is being studied in two complementary late-stage clinical trials in patients with advanced and end-stage CHF, to children with congenital heart disease.

Continued strong survival outcomes through Day 180 in children with steroid refractory aGVHD ("SR-aGVHD") treated with our Phase 3 product candidate remestemcel-L were announced. Our open-label Phase 3 trial enrolled 55 children with steroid-refractory aGVHD (aged between six months and 17 years) at 32 sites across the United States, with the vast majority (89%) suffering from the most severe form of aGVHD (Grade C/D).

These Phase 3 outcomes are consistent with previous results in 241 children with steroid-refractory aGVHD who failed to respond to multiple biologic agents and were treated under an EAP that followed outcomes through 100 days. The multi-infusion regimen in both the EAP and the Phase 3 trial was well tolerated. Existing Fast Track designation from the FDA allows eligibility for priority review and a rolling BLA review process.

July — Shawn Cline Tomasello was appointed as a non-executive director on our board of directors, bringing with her substantial commercial and transactional experience. She was Chief Commercial Officer at Kite Pharma Inc., where she played a pivotal role in the company's acquisition in 2017 by Gilead Sciences, Inc. for $11.9 billion, and was previously Chief Commercial Officer at Pharmacyclics, Inc., which was acquired in 2015 by AbbVie, Inc. for $21.0 billion.

On June 29, 2018, we entered into a $50.0 million financing facility with NovaQuest Capital Management, L.L.C. ("NovaQuest") for the continued development and commercialization of remestemcel-L for children with SR-aGVHD. NovaQuest was formed in 2000 as a strategic investment unit within Quintiles (now IQVIA), the world's largest clinical research organization. On closing, Mesoblast drew $30.0 million and issued $10.0 million in ordinary shares with an additional US$10.0 million to be drawn on marketing approval of remestemcel-L by the FDA. Prior to maturity in July 2026, the loan is only repayable from net sales of remestemcel-L in the treatment of pediatric patients who have failed to respond to steroid treatment for aGVHD, in the United States and other geographies excluding Asia. Interest on the loan will accrue at a rate of 15% per annum with the interest only period lasting 4 years. The financing is subordinated to the senior creditor, Hercules.

Fiscal year 2018

June — Day 100 survival outcomes of remestemcel-L, in children with SR-aGVHD were presented at the 2018 annual meeting of the International Society for Stem Cell Research in Melbourne. Top line Day 100 results demonstrated 87% survival rate for Day 28 responders to remestemcel-L treatment (33/38), and an overall survival rate of 75% (41/55). The multi-infusion regimen of remestemcel-L was well tolerated.

Joseph R. Swedish joined Mesoblast's Board of Directors bringing more than two decades of healthcare leadership experience as the CEO for major U.S. healthcare organizations, including as Executive Chairman, President and CEO of Anthem Inc. He replaced Dr Ben-Zion Weiner.

May — Josh Muntner was appointed Chief Financial Officer, based in New York, bringing substantial U.S. corporate finance, transactional and capital markets experience to Mesoblast.

Mesoblast entered into partnership with Cartherics Pty Ltd (“Cartherics”) to develop allogeneic off-the-shelf CAR-T cells armed with multiple targeting receptors for use in solid cancers. Mesoblast and Cartherics will jointly own the intellectual property produced using their combined technologies.

April — The independent Data Monitoring Committee for the Phase 3 trial evaluating Revascor in moderate to advanced CHF conducted a scheduled review of available data from 465 randomized patients and recommended continuation of the trial without modification.

March — Enrollment completed in the Phase 3 trial evaluating a single intra-discal injection of product candidate MPC-06-ID in patients with chronic low back pain due to degenerative disc disease (“DDD”). The 2:1 randomized, placebo-controlled Phase 3 trial enrolled 404 patients across 48 centers in the United States and Australia.

The Company entered into a $75.0 million non-dilutive, four-year credit facility with Hercules, a leading specialty finance company, drawing the first tranche of $35.0 million on closing.

February — The Phase 3 trial of remestemcel-L in children with SR-aGVHD successfully met the primary endpoint of Day 28 OR rate. In the 55 children enrolled in the open-label trial conducted across 32 sites in the U.S., the Day 28 Overall Response (“OR”) rate was 69%, a statistically significant increase compared to the protocol-defined historical control rate of 45% (p=0.0003). Among patients who received at least one treatment infusion and were followed up for 100 days (n=50), the mortality rate was 22%, in contrast to Day 100 mortality rates as high as 70% in patients who fail to respond to initial steroid therapy. The treatment regimen of remestemcel-L was well tolerated.

These Phase 3 study results of remestemcel-L were presented at the tandem annual scientific meetings of the Center for International Blood & Marrow Transplant Research and the American Society of Blood and Marrow Transplantation held in Salt Lake City from February 21-25, 2018.

December — The FDA granted RMAT designation for Revascor in the treatment of heart failure patients with left ventricular systolic dysfunction and a LVAD. The RMAT designation under the 21st Century Cures Act aims to expedite the development of regenerative medicine therapies intended for the treatment of serious diseases and life-threatening conditions.

Enrollment of the Phase 3 trial of remestemcel-L in children with aGVHD was completed.

TiGenix NV (“TiGenix”), now a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (“Takeda”), was granted exclusive worldwide access to certain of Mesoblast’s patents to support global commercialization of its adipose-derived MSC product Alofisel®, previously known as Cx601, for the local treatment of fistulae. As consideration, Mesoblast will receive up to €20.0 million in payments, as well as single digit royalties on net sales of Alofisel®.

Frost & Sullivan named Mesoblast the 2017 Global Technology Leader in the Cell Therapy Industry.

Results from the randomized, placebo-controlled Phase 2 trial of MPC-300-IV over 52 weeks in patients with biologic refractory rheumatoid arthritis (“RA”) presented at the 2017 American College of Rheumatology Annual Meeting in San Diego

September — A multi-center team of researchers led by Icahn School of Medicine at Mount Sinai Hospital, New York, completed enrollment of a 159-patient Phase 2b trial evaluating Revascor for the treatment of end-stage heart failure in patients with left ventricular systolic dysfunction and a LVAD.

A fully underwritten 1 for 12 pro-rata accelerated non-renounceable entitlement offer raising approximately A$50.7 million was completed with proceeds to fund Phase 3 clinical programs, commercial manufacturing and ongoing operations.

August — Plans to achieve an accelerated market entry of product candidate Revascor in the treatment of patients with the most advanced stages of CHF, defined as New York Heart Association Class III and Class IV, were announced.

Results of the Phase 2a trial of MPC-75-IA for prevention of radiographic and clinical features of knee osteoarthritis after traumatic injury were published in the journal Arthritis Research & Therapy. The results showed a single intra-articular injection of MPC-75-IA reduced cartilage loss and bone changes by six months, and improved pain and function for over two years, when compared to controls.

4.B Business Overview

Mesoblast's leadership in the development and commercialization of allogeneic cellular medicines is based on its innovative technology platform, proprietary manufacturing processes and multiple Phase 3 assets.

Our off-the-shelf product candidates target advanced stages of diseases with high, unmet medical needs.

Three product candidates are being evaluated in Phase 3 clinical trials for approval by the FDA:

- MSC-100-IV (remestemcel-L) for steroid refractory acute graft versus host disease;
- MPC-150-IM (Revascor) for advanced heart failure; and
- MPC-06-ID for chronic low back pain due to degenerative disc disease.

We also have a promising emerging pipeline of products for follow-on indications.

Two allogeneic MSC products developed and commercialized by Mesoblast licensees have been approved in Japan and Europe, with both licensees the first to receive full regulatory approval for an allogeneic cellular medicine in these major markets.

Mesoblast's goal is for remestemcel-L to be the first commercially available allogeneic MSC product in the United States.

Innovative Technology Platform

Mesoblast is developing immuno-selected, culture expanded cellular medicines based on MPCs and their progeny, MSCs. These rare mesenchymal lineage cells (approximately 1:100,000 of bone marrow cells) are found around blood vessels and are central to blood vessel maintenance, repair and regeneration. Preclinical studies have shown that these cells respond to signals associated with tissue damage, secreting mediators that promote tissue repair and modulate immune responses.

Mesoblast's immuno-selection process provides a homogeneous population of MPCs, which are at the apex of the mesenchymal lineage hierarchy, with receptors that appear to respond to activating inflammation and damaged-tissue signals. This enables targeting of multiple pathways that may result in therapeutic benefits in a number of complex and intractable diseases.

A key feature of Mesoblast's mesenchymal lineage cells is that they are allogeneic and immune tolerant. They are intended to be administered without the need for donor–recipient matching or recipient immune suppression. They are often referred to as 'off-the-shelf' cellular medicines.

Mesenchymal Lineage Stem Cells

Mesenchymal lineage cells are present around blood vessels in all tissues where they can respond effectively to various signals associated with tissue damage. This response includes the secretion of a variety of biomolecules, including growth factors, cytokines, chemokines and immunomodulatory biomolecules that affect various reparative mechanisms associated with the maintenance of tissue health. Based on biologic evidence, the potential beneficial effects of these biomolecules on damaged tissues are believed to include:

- Blood vessel function and regeneration: Mesenchymal lineage cells play a central role in the maintenance, repair and regeneration of blood vessels. This is achieved in large part through the secretion of growth factors which act on neighboring endothelial cells to promote blood vessel regeneration and function.
- Tissue repair: Mesenchymal lineage cells represent a key cellular constituent of stem cell niches in multiple adult tissues such as the bone marrow, heart and brain where they facilitate endogenous tissue repair by multiple mechanisms, including promotion of survival and function of mature cells within a given tissue or of the endogenous stem cells with which they are associated in niches within these tissues. This is achieved by secretion of a broad repertoire of bioactive molecules, including chemokines, growth factors and enzymes, which promote survival and proliferation together with remodeling of the extracellular matrix of the tissue.

- Immunomodulation: Located at the interface between the circulation and the tissues, mesenchymal lineage cells play a physiological role in modulating immune responses via their ability to alter the effector functions of extravasated white blood cells by up-regulation of a battery of secreted immunomodulatory proteins.

Our technology platform enables development of a diverse range of products derived from the mesenchymal cell lineage in adult tissues. MPCs constitute the earliest known cell type in the MLC lineage in vivo.

MPCs can be isolated using monoclonal antibodies and culture-expanded using methods that enable efficient expansion without differentiation. MSCs are defined biologically in culture following density gradient separation from other tissue cell types and following culture by plastic adherence. MSCs presumably represent culture-expanded in vitro progeny of the undifferentiated MPCs present in vivo. The functional characteristics of each cell type enable product development for specific indications.

Allogeneic, Off-the-Shelf, Commercially Scalable Products

Our proprietary mesenchymal lineage cell-based products have distinct biological characteristics enabling their use for allogeneic purposes.

Immune Privilege: Mesenchymal lineage cells are immune privileged, in that they do not express specific cell surface co-stimulatory molecules that initiate immune allogeneic responses.

Expansion: We have developed proprietary methods that enable the large scale expansion of our cells while maintaining their ability to produce the key biomolecules associated with tissue health and repair. This allows us to produce a cellular product intended to demonstrate consistent and well-defined characterization and activity.

In contrast, autologous stem cell products, which are produced from the patient's own stem cells, require individual product regulatory testing and do not benefit from manufacturing economies of scale. Moreover, autologous therapies may be vulnerable to significant patient-to-patient variability.

Revenue Generating Products and Late-Stage Assets

Each of Mesoblast's product candidates has distinct technical characteristics, target indications, individual reimbursement strategy, commercialization potential, and unique partnering opportunities.

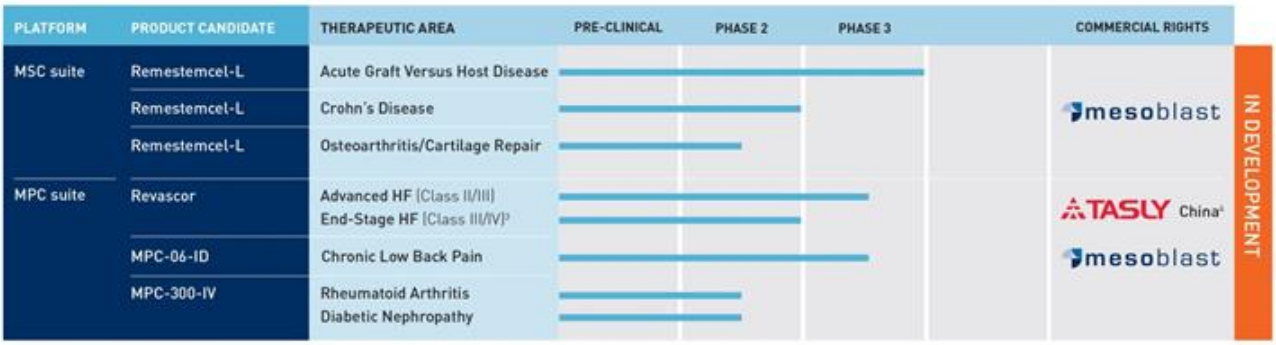
Products Commercialized by Licensees

1 Mesoblast receives royalty income from its licensee JCR Pharmaceuticals Co Ltd on sales of JCR's TEMCELL® Hs. Inj. product in Japan.
2 Mesoblast receives royalty income from its licensee Takeda Pharmaceuticals on Takeda's worldwide sales of its product Alofisel® in the local treatment of perianal fistulae.
This chart is figurative and does not purport to show individual trial progress within a clinical program.

Mesoblast's licensee in Japan, JCR, is marketing its MSC-based product in Japan for the treatment of aGVHD in children and adults. TEMCELL was the first allogeneic cellular medicine to receive full regulatory approval in Japan. Mesoblast receives royalty income on sales of TEMCELL in Japan.

In 2017, Mesoblast granted TiGenix, now a wholly owned subsidiary of Takeda, exclusive access to certain of its patents to support global commercialization of Alofisel®, previously known as Cx601, the first allogeneic MSC therapy to receive central marketing authorization approval from the European Commission. Mesoblast receives royalty income on Takeda's worldwide sales of Alofisel® in the local treatment of perianal fistulae.

Mesoblast Product Candidates



3 Study funded by the United States National Institutes of Health (NIH) and the Canadian Health Research Institute; conducted by the NIH-funded Cardiothoracic Surgical Trials Network.
4 Tasly's rights are limited to China; Tasly also has rights to develop MPC-25-IC for Acute Cardiac Ischemia.

This chart is figurative and does not purport to show individual trial progress within a clinical program.

Our Phase 3 events-driven clinical trial evaluating Revascor for patients with moderate to advanced CHF has completed recruitment, and continues to accumulate primary events, across North America. Our Phase 3 clinical trial evaluating MPC-06-ID for chronic low back pain completed enrollment in March 2018 and is in follow up phase until early 2020. The Phase 3 trial of remestemcel-L for pediatric SR-aGVHD has successfully met its primary endpoint of increased Day 28 Overall Response compared with a protocol-defined historical control rate (69% vs 45%, p=0.0003). Overall Response at Day 28 predicted highest survival at Day 100 and Day 180, 85% and 79%, respectively. The Company is currently in the process of submitting a rolling BLA with the FDA. In addition, we have conducted preclinical and clinical research with our product candidates in acute cardiac ischemia, Crohn's disease, spinal fusion and prevention of knee osteoarthritis after an anterior cruciate ligament repair.

Remestemcel-L for the Treatment of aGVHD

Overview

Remestemcel-L is an intravenously delivered product candidate for the treatment of acute steroid-refractory graft versus host disease, or SR-aGVHD, following allogeneic bone marrow transplant. Available data from clinical dose ranging studies identified an effective dose to be 2 million MSCs/kg, body weight, to be administered repeatedly for at least four weeks after diagnosis of aGVHD. For the U.S. market, the unit packaging is 25 million cells per vial for intravenous infusion.

In a bone marrow transplant, donor cells can attack the recipient, causing aGVHD. The donor T-cell mediated inflammatory response involves secretion of TNF-alpha and IFN-gamma, resulting in activation of pro-inflammatory T-cells and tissue damage in the skin, gut and liver, which can be fatal.

Remestemcel-L was developed to counteract the inflammatory processes by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of endogenous anti-inflammatory cells to involved tissues.

Remestemcel-L has been used for the treatment of SR-aGVHD in children in the U.S., Canada and several European countries under an EAP. This program enrolled 241 patients suffering from SR-aGVHD.

Market Opportunity

According to the Center for International Blood and Marrow Transplant Research, there are approximately 30,000 allogeneic BMTs globally per year for diseases including hematological cancers, with ~20% of all cases in the pediatric population. Nearly 50% of all allogeneic BMT patients develop aGVHD. Liver or gastrointestinal involvement occur in up to 60% of all patients with aGVHD and are associated with the greatest risk of death, with mortality rates of up to 85%.

We believe the U.S. aGVHD market requires a small, targeted commercial footprint. The target market for aGVHD will primarily be board-certified physicians in hematology/oncology who perform hematopoietic stem cell transplants. In the U.S., there are approximately 75 centers that perform pediatric transplants, with 50% of all transplants occurring at approximately 15 centers. Similarly, there are approximately 110 centers that perform adult transplants with half of those transplants occurring at approximately 20 centers.

Current Status and Anticipated Milestones

A single-arm, open-label Phase 3 study of 55 pediatric patients with SR-aGVHD treated with remestemcel-L was completed in 2018. The patients were enrolled in 32 sites across the United States, with 89% of patients suffering from the most severe form, Grade C/D aGVHD.

This trial met its primary endpoint of Day 28 OR rate (69% versus 45% historical control rate, p=0.0003). Subsequent top line Day 100 results demonstrated 87% survival rate for Day 28 responders to remestemcel-L treatment (33/38), and an overall survival rate of 75% (41/55). The strong survival outcomes continued through the final analysis at Day 180. In addition, the multi-infusion regimen of remestemcel-L was well tolerated.

In May this year, Mesoblast filed the first component of a rolling submission for a BLA to the FDA for this indication. The FDA has agreed to a rolling review of the BLA which enables individual components to be submitted and reviewed on an ongoing basis rather than waiting for all sections to be completed.

The rolling process will provide opportunity for ongoing communication, and during this process the Company expects it will be able to adequately address any substantial matters raised by the FDA. Remestemcel-L has received Fast Track designation for aGVHD and under this designation Mesoblast intends to request a priority review once its BLA filing is completed and accepted by the FDA.

Mesoblast anticipates conducting further clinical trials to study remestemcel-L for the treatment of SR-aGVHD in adults. Additionally, Mesoblast intends to provide remestemcel-L for evaluation under an investigator-initiated trial to evaluate it as a potential treatment for SR chronic GVHD.

Revascor for the Treatment of Advanced and End-Stage Chronic Heart Failure (CHF) Due to Left Ventricular Dysfunction

Overview

Revascor is being evaluated for the treatment of advanced CHF. Revascor consists of 150 million MPCs administered by direct cardiac injection in patients suffering from moderate/severe or end-stage CHF and progressive loss of heart function following damage to the heart muscle caused by a heart attack, coronary artery disease, hypertension, genetic factors, or other causes.

MPCs release a range of factors when triggered by specific receptor-ligand interactions within damaged tissue. Based on preclinical data, we believe that the factors released from the MPCs induce functional cardiac recovery by simultaneous activation of multiple pathways, including induction of endogenous vascular network formation, reduction in harmful inflammation, reduction in cardiac fibrosis, and regeneration of heart muscle through activation of intrinsic tissue precursors.

The unit dose of 150 million cells was based on multiple preclinical large animal studies in ischemic and non-ischemic heart failure models which identified an optimal cell dose above 110 million. A completed Phase 2 dose- ranging study in patients with moderate to advanced CHF of either ischemic or non-ischemic etiology identified the dose of 150 million cells as the most effective for both improvement in left ventricular volumes and remodeling and in prevention of heart failure related hospitalizations or cardiac death.

Revascor is also being evaluated in patients with end-stage CHF implanted with an LVAD. This trial was conducted by a multi-center team of researchers within the United States National Institutes of Health (“NIH”)-funded Cardiothoracic Surgical Trials Network (“CTSN”), led by Icahn School of Medicine at Mount Sinai, New York. The National Institute of Neurological Disorders and Stroke, and the Canadian Institutes for Health Research are also supporting this trial. Results of this Phase 2 trial were released in November 2018.

Market Opportunity

CHF is a chronic condition characterized by an enlarged heart and insufficient blood flow to the organs and extremities of the body. The condition progresses over time and can be caused by many factors that put an excess demand on the heart muscle, including high blood pressure, incompetent valves, infections of the heart muscle or valves, or congenital heart problems.

In 2016, more than 15 million patients in the seven major global pharmaceutical markets are estimated to have been diagnosed with CHF. The American Heart Association estimated in 2017 that prevalence is expected to grow 46% by 2030 in the U.S., affecting more than 8 million Americans. CHF causes severe economic, social, and personal costs. In the U.S., it is estimated that CHF results in direct costs of $60.2 billion annually when identified as a primary diagnosis and $115.0 billion as part of a disease milieu.

CHF is classified in relation to the severity of the symptoms experienced by the patient. The most commonly used classification system for functional severity of heart failure, established by the NYHA, is:

- Class I (mild): patients experience none or very mild symptoms with ordinary physical activity
- Class II (mild): patients experience fatigue and shortness of breath during moderate physical activity
- Class III (moderate): patients experience shortness of breath during even light physical activity
- Class IV or end-stage (severe): patients are exhausted even at rest

Risk for recurrent heart failure-related hospitalizations and terminal cardiac events increases progressively with increases in left ventricular volumes, reduction in left ventricular ejection fraction, and progression in NYHA functional class. About 40% of all heart failure patients have a low ejection fraction (<35-40%), NYHA Class II, III or IV CHF, and are at considerable risk of repeated hospitalizations and death despite maximal drug therapy.

Patients with advanced or Class III/IV CHF continue to represent the greatest unmet medical need despite recent advances in new therapeutic agents for heart failure. In contemporary studies, Class III/IV heart failure patients, characterized by heart failure hospitalizations in the previous 12 months, severely impaired baseline cardiac function, increased systolic and diastolic volumes, and elevated B-type natriuretic peptide (BNP) levels, have been reported to have a 50% incidence of terminal cardiac events or cardiovascular hospitalization for decompensated heart failure over a median period of 16.6 months.

The definitive method of treating end-stage disease currently is a heart transplant or implanting a mechanical assist device. Although there are many patients awaiting a heart transplant, due to limited supply there were only 3,191 heart transplants performed in the U.S. in 2016.

Results from our Phase 2 trials in patients with Class II/III CHF and in patients with end-stage CHF requiring mechanical assist devices have shown that our MPCs appear to have the potential to positively impact patients with the advanced forms of CHF due to diminished left ventricular systolic function. We believe that targeting advanced heart failure patients with the most unmet need can provide us with the most effective Phase 3 program, the most efficient path to market, and the opportunity for the most attractive pricing.

Completed Phase 2 Trial in NYHA Class II/III CHF Patients

The primary objective of the Phase 2 study was to evaluate the safety and tolerability of three increasing doses (25, 75, or 150 million cells) of MPCs compared to control in 60 patients with CHF due to left ventricular systolic dysfunction of either ischemic or non-ischemic etiology. The secondary objectives were to look at efficacy via multiple parameters, and to identify an optimal effective dose and the optimal target population for MPC treatment.

Endomyocardial injections of MPCs in patients with CHF were feasible and safe. The incidence of adverse events was similar across all groups, and there was no clinically significant immune response in any patients who received MPCs.

The 150 million cell dose showed the greatest effect on left ventricular remodeling and functional capacity and a threshold benefit for reducing heart failure-related major adverse cardiovascular events (“HF-MACE”) long-term.

Completed Pilot Trial in Patients with End-Stage Heart Failure Requiring Mechanical Support

A multi-center, randomized, double-blind, sham-procedure controlled trial conducted by a team of researchers within the NIH-funded CTSN evaluated 30 patients 2:1 randomized to epicardial injection of 25 million MPCs or medium (control) during LVAD implantation for either bridge-to-transplant or destination therapy.

This trial has demonstrated feasibility and safety, and suggested that a single low-dose MPC injection improved cardiac function and had an early benefit on survival. The results of this trial were presented at the American Heart Association Scientific Sessions 2013 and published in *Circulation* in June 2014.

Completed Phase 2 Trial in Patients with End-Stage Heart Failure Requiring Mechanical Support

A Phase 2 trial of Revascor in 159 patients with end-stage heart failure and an implantable LVAD has completed enrollment, with results for the trial's primary endpoint presented at the American Heart Association Conference held in Chicago in November 2018.

The trial was a prospective, multi-center, double-blind, placebo controlled, 2:1 randomized (MPC to placebo), single-dose cohort trial to evaluate the safety and efficacy of injecting a dose of 150 million MPCs into the native myocardium of LVAD recipients. Patients with advanced CHF, implanted with an FDA-approved LVAD as bridge-to-transplant or destination therapy, were eligible to participate in the trial. All patients were followed until 12 months post randomization.

In this Phase 2 trial, the trial did not show a significant difference in the ability for patients to tolerate a wean for a period of 60 minutes. However in relation to the clinically meaningful endpoint of reduction in major GI bleeding episodes and related hospitalizations, a single injection of Revascor administered directly into the heart resulted in a 76% reduction in major GI bleeding events and in a 65% reduction in associated hospitalizations. This suggests that Revascor reversed endothelial dysfunction which is responsible for the abnormal vasculature in the GI tract and severe bleeding in LVAD patients.

Reduction in GI bleeding and associated hospitalizations in the previous 30-patient pilot trial of Mesoblast's MPCs were the basis of the RMAT designation granted in December 2017 by the FDA for use of Revascor in LVAD patients.

Current Status and Anticipated Milestones

Program for Class II/III CHF patients

A multicenter, double-blinded, 1:1 randomized, sham-procedure-controlled Phase 3 trial of Revascor has completed enrollment of 566 patients across North America with NYHA Class II/III disease at high risk of repeated heart failure hospitalizations or a terminal cardiac event (cardiac death, LVAD placement, heart transplant or insertion of an artificial heart). The events-driven trial continues to collect primary events and is expected to read out top line results in 1H 2020. The enrollment criteria for this trial included a prior decompensated heart failure event (e.g. hospitalization) within the previous nine months and/or very high level of NT-proBNP, a protein used in diagnosis and screening of CHF. These inclusion criteria are expected to result in enrichment for patients with substantial left ventricular contractile abnormality, advanced CHF due to left ventricular systolic dysfunction and higher risk of recurrent decompensated heart failure hospitalizations and TCEs. This target patient population was shown to respond effectively to treatment with Revascor in our previous Phase 2 trial.

The trial's primary efficacy endpoint is a comparison of recurrent non-fatal HF-MACE between either MPC-treated patients or sham-treated controls.

Program in Patients Requiring Mechanical Support

The FDA has recently provided guidance on the clinical development pathway for marketing authorization of Revascor in end-stage heart failure patients implanted with a LVAD.

- FDA reiterated that a reduction in major gastrointestinal bleeding events and/or epistaxis, collectively termed major mucosal bleeding events, is an important clinical outcome in patients implanted with an LVAD;
- Data from the recently completed 159-patient placebo-controlled trial showing that Revascor reduced major mucosal bleeding events can support product marketing authorization through a BLA, with confirmatory clinical data; and
- FDA agreed on a confirmatory Phase 3 trial of Revascor in LVAD patients, with a primary endpoint of reduction in major mucosal bleeding events, and key secondary endpoints demonstrating improvement in various parameters of cardiovascular function.

In March 2019, Mesoblast and the InCHOIR at the Icahn School of Medicine entered into a Memorandum of Understanding to conduct a confirmatory clinical trial for this indication.

GI bleeding episodes are a major life-threatening complication of LVAD implants that occur in 20-40% of recipients in the first six months, resulting in recurrent hospitalizations and compromising quality of life. Confirmation of observations in the Phase 2 trial and a previous pilot study that our cell therapy reduced major bleeding episodes and related hospitalizations could identify a therapeutic approach that could greatly benefit these patients. Mesoblast recently applied for and were granted Orphan designation for Revascor for the treatment of major mucosal bleeding in patients implanted with an LVAD.

Strategic Partnerships

In September 2018, Mesoblast entered into a strategic cardiovascular partnership with Tasly for China. Tasly plans to meet with the National Medical Products Administration of China to discuss the regulatory approval pathway for Revascor in China. Tasly and Mesoblast will leverage each other's clinical trial results in China, the U.S. and other territories to support their respective regulatory submissions.

MPC-06-ID for the Treatment of Chronic Low Back Pain (CLBP)

Overview

MPC-06-ID is our proprietary Phase 3 product candidate being evaluated for the treatment of patients with CLBP caused by degenerative disc disease ("DDD"). MPC-06-ID consists of a unit dose of 6 million MPCs administered by syringe directly into a damaged disc.

In CLBP, damage to the disc is the result of a combination of factors related to aging, genetics, and micro-injuries, which compromises the disc's capacity to act as a fluid-filled cushion between vertebrae and to provide anatomical stability. Damage to the disc also results in an inflammatory response with ingrowth of nerves which results in chronic pain. This combination of anatomic instability and nerve ingrowth results in CLBP and functional disability.

With respect to mechanisms of action in CLBP, extensive pre-clinical studies have established that MLCs have anti-inflammatory effects and secrete multiple paracrine factors that stimulate new proteoglycan and collagen synthesis by chondrocytes in vitro and by resident cells in the nucleus and annulus in vivo.

Market Opportunity

In 2016, over 7 million people in the U.S. alone were estimated to suffer from CLBP caused by DDD, of which 3.2 million patients have moderate disease. After failure of conservative measures (medication, injections, epidural steroid, physical therapy etc.), there is a need for treatments that both reduce pain and improve function over a sustained period of time. When disc degeneration has progressed to a point that pain and loss of function can no longer be managed by conservative means, major invasive surgery such as spinal fusion is the most commonly offered option.

All therapies for progressive, severe and debilitating pain due to degenerating intervertebral discs treat the symptoms of the disease. However, they are not disease modifying and do not address the underlying cause of the disease. Surgical intervention is not always successful in addressing the patient's pain and functional deficit. Surgeons estimate that between 50% to 70% of patients ultimately fail back surgery, with failure defined as either not achieving at least a 50% reduction of symptoms within four months or experiencing new-onset pain and spasm. Total costs of low back pain are estimated to be between $100.0 billion and $200.0 billion annually with two thirds of attributed to patients' decreased wages and productivity.

As a result, we believe that the most significant unmet need and commercial opportunity in the treatment of CLBP is a therapy that has the ability to impact the chronic pain and disability associated with the condition.

Completed Phase 2 Clinical Trial

The primary objective of our Phase 2 study comparing two doses and two controls in 100 patients was to evaluate the safety of MPCs in CLBP. Secondary objectives were to evaluate efficacy parameters such as radiographic, low back pain, function/disability, medication usage, work status and quality of life improvement measures. Patients were evaluated at 1, 3, 6 and 12 months after treatment with longer term follow-up evaluations continuing at 24 and 36 months.

Eligible subjects were at least 18 years of age with chronic lumbar back pain for 6 months or greater duration due to moderate DDD with one painful lumbar vertebral level between L1 and S1. Subjects had to have failed at least 3 months of non-operative management with exposure to physical therapy. The study evaluated intra-discal injection of two separate doses: 6 million MPCs, which is MPC-06-ID, and 18 million MPCs with both MPC doses administered with HA, and compared to saline (placebo control) or HA alone (vehicle control) injection, using a pre-specified Per Protocol population analysis. 100 subjects across 15 sites were randomized with 20 receiving saline, 20 receiving HA, 30 receiving MPC-06-ID with HA, and 30 receiving 18 million MPCs with HA. The mean duration of DDD in these patients was approximately 6 years. Baseline pain, function scores, and radiographic scores were similar among all groups.

In July 2016, 24-month results from the Phase 2 trial were presented at the 24th Annual Scientific Meeting of the Spine Intervention Society and received the 2016 Best Basic Science Abstract award at the meeting.

Data and analyses of the 36-month Phase 2 trial support the Phase 3 trial of MPC-06-ID for CLBP and the rationale for MPC dose selection, use of saline control, and the trial's endpoints.

Current Status and Anticipated Milestones

The Phase 3 clinical trial for CLBP completed enrollment in March 2018 with 404 patients enrolled across 48 centers in the United States and Australia randomized 2:1 to receive either 6 million MPCs or saline control. The trial's primary endpoint of Overall Treatment Success (using a composite of 50% improvement in lower back pain and 15 point improvement in function at both 12 and

24 months with no treatment or surgical interventions at the treated level through 24 months) is an acceptable endpoint, as per guidance from the FDA. Follow-up of patients in the Phase 3 trial of MPC-06-ID is continuing to a 24-month assessment of safety and efficacy.

MPC-300-IV for the treatment of Biologic-Refractory Rheumatoid Arthritis and Diabetic Nephropathy

The diverse and potent anti-inflammatory properties of MPCs are the foundation for their usefulness in immune-mediated diseases such as RA and diabetic kidney disease (or diabetic nephropathy), where monocytes, macrophages and activated pro-inflammatory T cells play a very active and destructive role in disease pathogenesis through activation of multiple pro-inflammatory cytokine pathways. We have conducted studies in patients with biologic-refractory RA and diabetic nephropathy using our other Tier 1 product candidate MPC-300-IV.

In November 2017, we announced 52-week data from a trial in 48 patients who had failed biologics for RA. A single intravenous infusion of MPC-300-IV was well tolerated and demonstrated improvement in clinical symptoms, physical function and reduced disease activity relative to placebo. We believe the safety and efficacy results from the Phase 2 trial support further development of this product candidate as a potential first-line treatment option in RA patients who have previously received a prior anti-TNF or other biologic agent.

In October 2016, we announced that results from our Phase 2 trial of MPC-300-IV, in 24 patients with diabetic kidney disease were published in the peer-reviewed journal *EBioMedicine*. The paper, entitled 'Allogeneic Mesenchymal Precursor Cells in Diabetic Nephropathy: A Randomized, Placebo Controlled, Dose Escalation Study', concluded that a single intravenous infusion of MPC-300-IV was well tolerated and had positive effects on renal function at the 12-week primary endpoint in a Phase 2 trial in adult patients with type 2 diabetic nephropathy. This trial was conducted in Australia.

Complementary Technologies

In addition to having the most mature and diverse allogeneic cell therapy product pipeline and technology platform in the field of cellular medicines, we have strategically targeted the acquisition of rights to technologies that are complementary to and synergistic with our mesenchymal lineage cell technology platform. The aim of this activity is to maintain our technology leadership position in the regenerative medicine space, while simultaneously expanding our targeted disease applications and managing the life-cycle of our current lead programs.

Our complementary technologies and additional product candidates include other types of mesenchymal lineage cells, cell surface modification technologies, pay-loading technology and protein and gene technologies.

Manufacturing and Supply Chain

Our manufacturing strategy for our cellular product candidates focuses on the following important factors: (i) clear product delineation to protect pricing and partner markets by creating distinct products using discrete manufacturing processes, culture conditions, formulations, routes of administration, and/or dose regimens; (ii) establishing proprietary commercial scale-up and supply to meet increasing demand; (iii) implementing efficiencies and yield improvement measures to reduce cost-of-goods; (iv) maintaining regulatory compliance with best practices; and (v) establishing and maintaining multiple manufacturing sites for product supply risk mitigation.

The stem cell manufacturing and distribution process generally involves five major steps.

- Procure bone marrow—acquire bone marrow from healthy adults with specific FDA-defined criteria, which is accompanied by significant laboratory testing to establish the usability of the donated tissues.
- Create master cell banks—isolate MLCs from the donated bone marrow and perform a preliminary expansion to create master cell banks. Each individual master cell bank comes from a single donor.
- Expand to therapeutic quantities—expand master cell banks to produce therapeutic quantities, a process that can yield thousands of doses per master cell bank, with the ultimate number depending on the dose for the respective product candidate being produced.
- Formulate, package and cryopreserve.
- Distribute—with the exception of procurement and creation of master cell banks, our manufacturing is currently conducted in Lonza's Singapore facility, and products will be cryopreserved, then shipped to storage sites in the U.S. and other jurisdictions via cryoshippers. Those distribution centers then send the products on to treatment centers in cryoshippers. Treatment centers will either move the products into their own freezers, or receive the cryoshipper in "real

time" and product stays in the cryoshipper until thawed for patient use within a well-defined window. We intend to continue utilizing this approach in the future, except that we intend to establish distribution relationships in various regions.

To date our product candidates have been manufactured in two-dimensional, or 2D, planar, 10-layer cell factories, using media containing fetal bovine serum, or FBS.

The relatively small patient numbers and orphan drug designation for remestemcel-L lead us to believe that 2D manufacturing will be adequate to meet demand for this product candidate if fully approved. We also believe that 2D manufacturing process and facilities are commercially feasible for Phase 3 trial supply and the initial launch of MPC-06-ID for CLBP.

However, to build up commercial supply for certain of our product candidates long-term, we are developing novel manufacturing processes using three-dimensional, or 3D, bioreactors with greater capacity to improve efficiency and yields, with resulting lower-cost of goods. We intend to evaluate products produced in 3D bioreactors in pre-clinical and potentially clinical studies, which may serve as FDA required comparability studies to 2D if successful.

We are also focusing on the introduction of FBS-free media which has the potential to result in efficiency and yield improvements to the current 2D process which may prove sufficient for commercial production of some of our final products. We intend to conduct comparability studies to illustrate that products produced with this media are equivalent to those produced using FBS based media. While we remain confident in our ability to deliver successful outcomes from each of these activities, any unexpected issues or challenges faced in doing so could delay our programs or prevent us from continuing our programs.

Our manufacturing activities to date have met stringent criteria set by international regulatory agencies, including the FDA. By using well-characterized cell populations, our manufacturing processes promote reproducibility and batch-to-batch consistency for our allogeneic cell product candidates. We have developed robust quality assurance procedures and lot release assays to support this reproducibility and consistency.

Intellectual Property

We have a large patent portfolio of issued and pending claims covering compositions of matter, uses for our mesenchymal lineage cell-based technologies and other proprietary regenerative product candidates and technologies, as well as for elements of our manufacturing processes, with approximately 995 patents and patent applications across 68 patent families as of August 2019.

One of our major objectives is to continue to protect and expand our extensive estate of patent rights and trade secrets, which we believe enables us to deliver commercial advantages and long-term protection for our product candidates based on our proprietary technologies, and support our corporate strategy to target large, mature and emerging healthcare markets for our exploratory therapeutic product candidates.

More specifically, our patent estate includes issued patent and patent applications in major markets, including, but not limited to, the United States, Europe, Japan and China. The patents that we have obtained, and continue to apply for, cover mesenchymal lineage cell technologies and product candidates derived from these technologies, irrespective of the tissue source, including bone marrow, adipose, placenta, umbilical cord and dental pulp.

These patents cover, among other technology areas, a variety of MLCs (including MPCs and MSCs), and the use of MLC for expansion of hematopoietic stem cells, or HSCs. Among the indication-specific issued or pending patents covering product candidates derived from our mesenchymal lineage cells are those which are directed to our lead product candidates: CLBP, CHF, aGVHD and chronic inflammatory conditions such as RA. We also have issued and pending patents covering other pipeline indications, including diabetic kidney disease, inflammatory bowel disease (e.g., Crohn's disease), neurologic diseases, eye diseases and additional orthopedic diseases. In addition, we have in-licensed patents covering complementary technologies, such as other types of mesenchymal lineage cells, cell surface modification technologies, pay-loading technology and protein and gene technologies, as part of our strategy to expand our targeted disease applications and manage the life-cycle of our current lead programs.

Our patent portfolio also includes issued and pending coverage of proprietary manufacturing processes that are being used with our current two-dimensional manufacturing platform as well as the 3D bioreactor manufacturing processes currently under development. These cell manufacturing patents cover isolation, expansion, purification, scale up, culture conditions, aggregates minimization, cryopreservation, release testing and potency assays. In addition, we maintain as a trade secret, among other things, our proprietary FBS-free media used in our 3D bioreactor manufacturing processes.

We maintain trade secrets covering a significant body of know-how and proprietary information relating to our core product candidates and technologies. We protect our confidential know-how and trade secrets in a number of ways, including requiring all

employees and third parties that have access to our confidential information to sign non-disclosure agreements, limiting access to confidential information on a need-to-know basis, maintaining our confidential information on secure computers, and providing our contract manufacturers with certain key ingredients for our manufacturing process.

In addition, in many major jurisdictions there are other means that may be available to us by which we would be able to extend the period during which we have commercial exclusivity for our product candidates, which include, but are not limited to the exclusive right to reference our data, orphan drug exclusivity and patent term extensions.

As part of our strategy, we seek patent protection for our product candidates and technologies in major jurisdictions including the United States, Europe, Japan, China, and Australia and file independent and/or counterpart patents and patent applications in other jurisdictions globally that we deem appropriate under the circumstances, including India, Canada, Hong Kong, Israel, Korea and Singapore. As of August 2019, our patent portfolio includes the following patents and patent applications in the following major jurisdictions: 73 granted U.S. patents and 45 pending U.S. patent applications; 54 granted Japanese patents and 26 pending Japanese patent applications; 26 granted Chinese patents and 22 pending Chinese patent applications; 48 granted European patents and 33 pending European patent applications; and 52 granted Australian patents and 20 pending Australian patent applications.

Our policy is to patent the technology, inventions and improvements that we consider important to the development of our business, only in those cases in which we believe that the costs of obtaining patent protection is justified by the commercial potential of the technology and associated product candidates, and typically only in those jurisdictions that we believe present significant commercial opportunities to us. In those cases where we choose neither to seek patent protection nor protect the inventions as trade secrets, we may publish the inventions so that it defensively becomes prior art in order for us to secure a freedom to operate position and to prevent third parties from patenting the invention.

We also seek to protect as trade secrets our proprietary and confidential know-how and technologies that are either not patentable or where we deem it inadvisable to seek patent protection. To this end, we generally require all third parties with whom we share confidential information and our employees, consultants and advisors to enter into confidentiality agreements prohibiting the disclosure of confidential information. These agreements with our employees and consultants engaged in the development of our technologies require disclosure and assignment to us of the ideas, developments, discoveries and inventions, and associated intellectual property rights, important to our business. Additionally, these confidentiality agreements, among others, require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party's proprietary technology.

License and Collaboration Agreements

All of our revenue relates to up-front, royalty and milestone payments recognized under the license and collaboration agreements below. For further information on the categorical revenue breakdown during the last three fiscal years, see "Item 18. Financial Statements – Note 3".

JCR Pharmaceuticals Co., Ltd.—Hematological Malignancies and Hepatocytes Collaboration in Japan

In October 2013, we acquired all of Osiris Therapeutics, Inc.'s business and assets related to culture expanded MSCs. These assets included assumption of a collaboration agreement with JCR ("JCR Agreement"), which will continue in existence until the later of 15 years from the first commercial sale of any product covered by the agreement and expiration of the last Osiris patent covering any such product. JCR is a research and development oriented pharmaceutical company in Japan. Under the JCR Agreement we assumed from Osiris, JCR has the right to develop our MSCs in two fields for the Japanese market: exclusive in conjunction with the treatment of hematological malignancies by the use of HSCs derived from peripheral blood, cord blood or bone marrow, or the First JCR Field; and non-exclusive for developing assays that use liver cells for non-clinical drug screening and evaluation, or the Second JCR Field. Under the JCR Agreement, JCR obtained rights in Japan to our MSCs, for the treatment of aGVHD. JCR also has a right of first negotiation to obtain rights to commercialize MSC-based products for additional orphan designations in Japan. We retain all rights to those products outside of Japan.

JCR received full approval in September 2015 for its MSC-based product for the treatment of children and adults with aGVHD, TEMCELL. TEMCELL is the first culture-expanded allogeneic stem cell product to be approved in Japan. It was launched in Japan in February 2016.

Under the JCR Agreement, JCR is responsible for all development and manufacturing costs including sales and marketing expenses. With respect to the First JCR Field, we are entitled to future payments of up to $1.0 million in the aggregate when JCR reaches certain commercial milestones and to escalating double-digit royalties in the twenties. These royalties are subject to possible renegotiation downward in the event of competition from non-infringing products in Japan. With respect to the Second JCR Field, we are entitled to a double digit profit share in the fifties.

Intellectual property is licensed both ways under the JCR Agreement, with JCR receiving exclusive and non-exclusive rights as described above from us and granting us non-exclusive, royalty-free rights (excluding in the First JCR Field and Second JCR Field in Japan) under the intellectual property arising out of JCR's development or commercialization of MSC-based products licensed in Japan.

JCR has the right to terminate the JCR Agreement for any reason, and we have a limited right to terminate the JCR Agreement, including a right to terminate in the event of an uncured material breach by JCR. In the event of a termination of the JCR Agreement other than for our breach, JCR must provide us with its owned product registrations and technical data related to MSC-based products licensed in Japan and all licenses of our intellectual property rights will revert to us.

In the past 12 months, we have expanded our partnership with JCR in Japan for two new indications: for wound healing in patients with EB in October 2018, and for neonatal HIE, a condition suffered by newborns who lack sufficient blood supply and oxygen to the brain, in June 2019. We will receive royalties on TEMCELL product sales for EB and HIE, if and when such indications receive marketing approval in Japan. JCR filed to extend marketing approval of TEMCELL in Japan for EB in March 2019.

We have the right to use all safety and efficacy data generated by JCR in Japan to support our development and commercialization plans for our MSC product candidate remestemcel-L in the United States and other major healthcare markets, including for GVHD, EB and HIE.

Lonza—Manufacturing Collaboration

In September 2011, we entered into a manufacturing services agreement, or MSA, with Lonza Walkersville, Inc. and Lonza Bioscience Singapore Pte. Ltd., collectively referred to as Lonza, a global leader in biopharmaceutical manufacturing. Under the MSA, we pay Lonza on a fee for service basis to provide us with manufacturing process development capabilities for our product candidates, including formulation development, establishment and maintenance of master cell banks, records preparation, process validation, manufacturing and other services.

We have agreed to order a certain percentage of our clinical requirements and commercial requirements for MPC products from Lonza. Lonza has agreed not to manufacture or supply commercially biosimilar versions of any of our product candidates to any third party, during the term of the MSA, subject to our meeting certain thresholds for sales of our products.

We can trigger a process requiring Lonza to construct a purpose-built manufacturing facility exclusively for our product candidates. In return if we exercise this option, we will purchase agreed quantities of our product candidates from this facility. We also have a right to buy out this manufacturing facility at a pre-agreed price two years after the facility receives regulatory approval.

The MSA will expire on the later of December 31, 2020 or the three-year anniversary of the date of the first commercial sale of product supplied under the MSA, unless it is sooner terminated. We have the option of extending the MSA for an additional 10 years, followed by the option to extend for successive three-year periods subject to Lonza's reasonable consent. We may terminate the MSA with two years prior written notice, and Lonza may terminate with five years prior written notice. The MSA may also terminate for other reasons, including if the manufacture or development of a product is suspended or abandoned due to the results of clinical trials or guidance from a regulatory authority. In the event we request that Lonza construct the manufacturing facility described above, neither we nor Lonza may terminate before the third anniversary of the date the facility receives regulatory approval to manufacture our product candidates, except in certain limited circumstances. Upon expiration or termination of the MSA, we have the right to require Lonza to transfer certain technologies and lease the Singapore facility or the portion of such facility where our product candidates are manufactured, subject to good faith negotiations.

We currently rely, and expect to continue to rely, on Lonza for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture of our product candidates if marketing approval is obtained.

Singapore Economic Development Board (EDB)—Singapore Operations

In May 2014, the Economic Development Board of Singapore, or EDB, granted us certain financial incentives tied to revenues generated by our Singapore operations, among other things. These incentives include two separate 15-year periods (each broken into five-year increments) of potential incentives, one related primarily to non-manufacturing activities and the other related to manufacturing activities. We will be eligible for these incentives if we meet certain investment or activity thresholds in Singapore, including employment levels, amounts of business or manufacturing related expenses, and the performance of various services including business development, planning, manufacturing, intellectual property management, marketing and distribution.

For example, in order to obtain full financial benefits from the EDB for our manufacturing-related incentives, we must manufacture at least 50% of the global volume of our first three commercial products in Singapore (subject to certain exceptions), and we would be required to construct and operate a manufacturing facility in Singapore, and hire and maintain a specified number of professionals (including supply chain personnel) in connection with the operation of that facility. The activities under our MSA with Lonza could be used to fulfill all or part of the requirements to obtain the EDB financial incentives.

Central Adelaide Local Health Network Incorporated—Mesenchymal Precursor Cell Intellectual Property

In October 2004, we, through our wholly-owned subsidiary, Angioblast Systems Inc., now Mesoblast, Inc., acquired certain intellectual property relating to our MPCs, or Medvet IP, pursuant to an Intellectual Property Assignment Deed, or IP Deed, with Medvet Science Pty Ltd, or Medvet. Medvet's rights under the IP Deed were transferred to Central Adelaide Local Health Network Incorporated, or CALHNI, in November 2011. In connection with our use of the Medvet IP, we are obligated to pay CALHNI, as successor in interest to Medvet, (i) certain aggregated milestone payments of up to $2.2 million and single-digit royalties on net sales of products covered by the Medvet IP, for cardiac muscle and blood vessel applications and bone and cartilage regeneration and repair applications, subject to minimum annual royalties beginning in the first year of commercial sale of those products and (ii) and single-digit royalties on net sales of the specified products for applications outside the specified fields. Additionally, we are obligated to pay CALHNI a double-digit percentage in the teens of any revenue that we receive in exchange for a grant of a sublicense to the Medvet IP in the specified fields. Under the IP Deed, we also granted to Medvet a non-exclusive, royalty-free license to the Medvet IP for non-commercial, internal research and academic research.

Pursuant to the IP Deed, we were assigned the rights in three U.S. patents or patent applications (including all substitutions, continuations, continuations-in-part, divisional, supplementary protection certificates, renewals, all letters patent granted thereon, and all reissues, reexaminations, extensions, confirmations, revalidations, registrations and patents of addition and foreign equivalents thereof) and all future intellectual property rights, including improvements, that might arise from research conducted at CALHNI related to MPCs and methods of isolating, culturing and expanding MPCs and their use in any therapeutic area. We also acquired all related materials, information and know-how.

Osiris Acquisition—Continuing Obligations

In October 2013, we and Osiris entered into a purchase agreement, as amended, or the Osiris Purchase Agreement, under which we acquired all of Osiris' business and assets related to culture expanded MSCs. Pursuant to the Osiris Purchase Agreement, we also agreed to make certain milestone and royalty payments to Osiris pertaining to remestemcel-L for the treatment of aGVHD and Crohn's disease. Each milestone payment is for a fixed dollar amount and may be paid in cash or our ordinary shares or ADSs, at our option. The maximum amount of future milestone payments we may be required to make to Osiris is $40.0 million. Any ordinary shares or ADSs we issue as consideration for a milestone payment will be subject to a contractual one year holding period, which may be waived in our discretion. In the event that the price of our ordinary shares or ADSs decreases between the issue date and the expiration of any applicable holding period, we will be required to make an additional payment to Osiris equal to the reduction in the share price multiplied by the amount of issued shares under that milestone payment. This additional payment can be made either wholly in cash or 50% in cash and 50% in our ordinary shares, in our discretion. We have also agreed to pay varying earnout amounts as a percentage of annual net sales of acquired products, ranging from low single-digit to 10% of annual sales in excess of $750.0 million. These royalty payments will cease after the earlier of a ten year commercial sales period and the first sale of a competing product.

Tasly Pharmaceutical Group — Cardiovascular Alliance for China

In July 2018, we entered into a Development and Commercialization Agreement with Tasly.

The Development and Commercialization Agreement provides Tasly with exclusive rights to develop, manufacture and commercialize in China Revascor for the treatment or prevention of CHF and MPC-25-IC for the treatment or prevention of AMI. Tasly will fund all development, manufacturing and commercialization activities in China for Revascor and MPC-25-IC. On closing, we received a $20.0 million upfront technology access fee. Further, we will receive $25.0 million upon product regulatory approvals in China. Mesoblast will receive double-digit escalating royalties on net product sales. Mesoblast is eligible to receive six escalating milestone payments upon the product candidates reaching certain sales thresholds in China.

Tasly can terminate the Development and Commercialization Agreement with a specified amount of notice, on the later of (a) third anniversary of the agreement coming into effect and (b) receipt of marketing approval in China for each of Revascor or MPC-25-IC. Mesoblast has termination rights with respect to certain patent challenges by Tasly and if certain competing activities are undertaken by Tasly. Either party may terminate the agreement on material breach of the agreement if such breach is not cured within the specified cure period or if certain events related to bankruptcy of the other party occur.

TiGenix NV – patent license for treatment of fistulae

In December 2017, we entered into a Patent License Agreement with TiGenix, now a wholly owned subsidiary of Takeda, which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived MSC product Alofisel®, previously known as Cx601, a product candidate of Takeda, for the local treatment of fistulae. The agreement includes the right for Takeda to grant sub-licenses to affiliates and third parties.

As part of the agreement, we received $5.9 million (€5.0 million) before withholding tax as a non-refundable up-front payment and a further payment of $5.9 million (€5.0 million) before withholding tax 12 months after the patent license agreement date. We are entitled to further payments of up to €10.0 million when Takeda reaches certain product regulatory milestones. Additionally, we receive single digit royalties on net sales of Alofisel®.

The agreement will continue in full force in each country (other than the United States) until the date upon which the last issued claim of any licensed patent covering Alofisel® expires in such country (currently expected to be 2029) or, with respect to the United States, until the later of (i) the date upon which the last issued claim of any licensed patent covering Alofisel® in the United States expires (currently expected to be around 2031) or (ii) the expiration of the regulatory exclusivity period in the United States with an agreed maximum term.

Either we or Takeda may terminate the agreement for any material breach that is not cured within 90 days after notice thereof. We also have the right to terminate the agreement, with a written notice in the event that Takeda file a petition in bankruptcy or insolvency or Takeda makes an assignment of substantially all of its assets for the benefit of its creditors.

Takeda have the right to terminate their obligation to pay royalties for net sales in a specific country if it is of the opinion that there is no issued claim of any licensed patent covering Alofisel® in such country, subject to referral of the matter to the joint oversight/cooperation committee established under the agreement if we disagree.

Competition

The biotechnology and pharmaceutical industries are highly competitive and are characterized by rapidly advancing technologies and a strong emphasis on proprietary products. Any product candidates that we and our collaborators successfully develop and commercialize will compete with existing products and new products that may become available in the future.

A number of our potential competitors, particularly large biopharmaceutical companies, have significantly greater financial resources and general expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Our market has been characterized by significant consolidation by pharmaceutical and biotechnology companies, which is likely to result in even more resources being concentrated among a smaller number of our potential competitors.

Government Regulation

We are developing cellular therapy product candidates. These products are subject to extensive legislation. Governmental authorities around the world, including the FDA, are charged with the administration and enforcement of numerous laws and regulations that impact all aspects of the development, production, importing, testing, approval, labeling, promotion, advertising, and sale of products such as ours. Such governmental authorities are also charged with administering what is often a lengthy and technical review and approval process before candidate therapies such as ours may be marketed for any use. Authorization or approval for marketing must generally be obtained from the local health authorities in each country in which the product is to be sold. Approval and authorization procedures may differ from country to country, as may the requirements for maintaining approvals. It is typical however for these procedures to require evidence of rigorous testing and documentation regarding the candidate therapy, which may include significant non-clinical and clinical evaluations. Extensive controls and requirements apply to the non-clinical and clinical development of our therapeutic candidates. Those requirements and their enforcement and implementation by local regulatory authorities around the world significantly impact whether a product candidate can be developed into a marketable product, and notably impact the cost, resources and timing for any such development. Changes in regulatory requirements and differences in requirements from country to country may also increase the costs of bringing new technologies such as ours to market and maintaining approvals, if obtained.

To obtain marketing approval of a new product, an extensive dossier of evidence establishing the safety, efficacy and quality of the product must be submitted for review by regulatory authorities. Dossier form and substance, while often similar may have notable differences in different countries. Submission of an application to regulators does not guarantee approval to market that product, despite the fact that criteria for approval in many countries may be quite similar. Some regulatory authorities may require additional data and analyses, and may have standards that apply that are more stringent than others for review of the submitted dossier and content. Additionally, the review process, risk tolerance, and openness to new technologies may vary from country to country.

Obtaining marketing approval can take several months to several years, depending on the country, the quality of the data, the efficiencies and procedures of the reviewing regulatory authority and their familiarity with the product technology. Some countries, like the US, may have accelerated approval processes for certain categories of products, for example products which represent a breakthrough in the field, or which meet certain thresholds and have obtained certain designations of particular interest. Nevertheless, ultimate availability to patients may be affected, even post approval, by requirements in some countries to negotiate selling prices and reimbursement terms with government regulators or other payors.

Maintaining marketing approval may require the conduct of additional post-approval studies in some situations, and the continued capture, monitoring and assessment of safety and other information about the product, as well as adherence to requirements to ensure the purity and integrity of manufactured product. The process for obtaining and maintaining regulatory authorizations and approvals to market our products and the subsequent compliance with appropriate federal, state, local and foreign laws and regulations require the expenditure of substantial time and the commitment of significant financial and other resources, and we may not be able to obtain the required regulatory approvals.

Product Development Process

All of our product candidates are regulated as biological products by the Center for Biologics Evaluation and Research in the FDA. In the United States, biological products are subject to federal regulation under the federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service ("PHS") Act, and other federal, state, local and foreign statutes and regulations. Both the FDCA and the PHS Act, as applicable, and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, import, export, reporting, advertising and other promotional practices involving drugs and biological products. Before clinical testing of a new drug or biological product may commence, the sponsor of the clinical study must submit an application for investigational new drug ("IND") application to FDA, which must include, among other information, the proposed clinical study protocol(s). To obtain marketing authorization once clinical testing has concluded, a BLA must be submitted for FDA approval.

The process required by the FDA before a biological product may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory studies, meaning in vivo and in vitro experiments in which an investigational product is studied prospectively in a test system under laboratory conditions to determine its safety, must be conducted according to cGLP (good laboratory practice) regulations, as well as, in the case of nonclinical laboratory studies involving animal test systems, in accordance with applicable requirements for the humane use of laboratory animals and other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical studies may begin;
- performance of adequate and well-controlled human clinical studies according to the FDA's cGCPs (good clinical practices) and all other applicable regulatory requirements for the protection of human research subjects and their health information, to establish the safety, purity and potency of the proposed product for its intended use and to ensure the product has an appropriate risk-benefit profile;
- development and demonstration of a manufacturing process that can produce product of consistent and adequate quality;
- submission to the FDA of a BLA for marketing approval demonstrating the quality, safety, and efficacy of the product which must be supported by substantial evidence from adequate and well-controlled clinical investigations as well as demonstration of mode of action through non-clinical studies, evidence to support appropriate manufacturing capabilities and controls, and evidence of the stability of the product in the form it is intended to be provided;
- negotiation with FDA of proposed product labeling (and determination of appropriate risk mitigation strategies and programs, if any required), as well as participation in any required advisory committee proceedings;
- satisfactory completion of an FDA inspection of all manufacturing, testing and distribution facilities where the product is produced, tested or stored and distributed, to assess compliance with cGMP (good manufacturing practices) to assure that the facilities, methods and controls for production are adequate to preserve the product's identity, strength, purity and potency;
- potential FDA inspection of nonclinical facilities and likely inspection of select clinical study sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA.

Human testing of a biological product candidate is preceded by preclinical testing, including nonclinical laboratory studies in which the product candidate is studied prospectively in a test system under laboratory conditions to determine its safety. A test system

may include any animal, plant, microorganism, or subparts thereof to which the test or control article is administered or added for study.

The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study covered by the IND on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. The FDA may also impose clinical holds on a product candidate at any time during clinical studies due to safety concerns or non-compliance. If the FDA imposes a clinical hold, studies may not recommence unless FDA removes the clinical hold and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate such studies.

Clinical studies involve the administration of the product candidate to subjects under the supervision of qualified independent investigators, generally physicians or other qualified scientists and medical personnel who are not employed by or under the study sponsor's control. Clinical studies are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical study will be stopped if certain adverse events, or AEs, should occur. Each new protocol and certain amendments to the protocol must be submitted to the FDA. Clinical studies must be conducted in accordance with the FDA's cGCP regulations and guidance, and monitored to ensure compliance with applicable regulatory requirements. These include the requirement that written informed consent is obtained from all subjects who participate in the study. Further, each clinical study must be reviewed and approved by an independent Institutional Review Board, or IRB, at or servicing each institution at which the clinical study will be conducted. An IRB is charged with protecting the welfare and rights of study participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent document that must be signed by each clinical study subject or his or her legal representative and must monitor the clinical study until completed. Throughout the study, certain information about certain serious adverse events must be reported to the IRB, in some cases on an expedited basis, and to FDA (as well as to regulators in other countries in which studies of the product are also being conducted).

Human clinical studies are typically conducted in three sequential phases that may in some cases overlap or be combined:

- ***Phase 1***. The product candidate is initially introduced into a small number of human subjects. In the case of cellular therapy products, the initial human testing is conducted in patients with the disease or condition targeted by the biological product candidate. Phase 1 studies are intended to determine the metabolism and pharmacologic actions (including adverse reactions), the side effects associated with increasing doses, immunogenicity, and, if possible, to gain early evidence of effectiveness. The information obtained in Phase 1 should be sufficient to permit the design of well-controlled, scientifically valid Phase 2 studies.
- ***Phase 2***. Controlled clinical studies are conducted in a larger number of human subjects to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study. Phase 2 studies are intended to assess side effects and risks, and to examine exposure–response relationships, and to further explore pharmacologic actions and immunogenicity associated with the drug. These studies also provide helpful information for the design of phase 3 studies.
- ***Phase 3***. Assuming preliminary evidence suggesting effectiveness has been obtained in phase 2 (generally considered to be "proof of concept"), controlled studies are conducted in a larger group of subjects to gather additional information about effectiveness and safety in order to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.

Post-approval clinical studies, sometimes referred to as Phase 4 clinical studies, may be conducted after initial marketing approval. In some cases FDA may require a Phase 4 study to be performed as a condition of product approval. Sponsors also can voluntarily conduct Phase 4 studies to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up or in select populations. FDA regulations extend to all phases of clinical development, and apply to sponsors and investigators of clinical studies. FDA oversight includes inspection of the sites and investigators involved in conducting the studies.

Concurrent with clinical studies, companies usually complete additional animal studies, and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements.

To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things; the sponsor must develop methods for testing the identity, purity and potency of the final biological product. All such testing and controls requires the application of significant human and financial resources.

Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

After the completion of clinical studies of a product candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each BLA must be accompanied by a substantial user fee. PDUFA also imposes an annual product fee for biologics and an annual establishment fee on facilities used to manufacture prescription biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Additionally, an application fee is not assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews the BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any marketing application that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the application to determine, among other things, whether the proposed product is safe and effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, potency and purity. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the application without a REMS, if required.

Before approving a BLA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical studies were conducted in compliance with IND study and cGCP requirements. To assure cGMP and cGCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the marketing application, it will issue a complete response letter describing specific deficiencies in the application identified by the FDA. Additionally, the complete response letter may recommend actions that the applicant might take to place the application in a condition for approval. Such recommended actions could include the conduct of additional studies. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post-approval clinical studies, to further assess a product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

One of the performance goals agreed to by the FDA under the PDUFA is to complete its review of 90% of standard BLAs within 10 months from filing and 90% of priority BLAs within six months from filing, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the application sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and the commitment of substantial human and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation.

Other post-approval requirements applicable to drug and biological products include reporting post marketing surveillance to continuously monitor the safety of the approved product. This is done through the collection of spontaneous reports of adverse events and side effects, the assessment of safety signals, if any, and prescription event monitoring, among other methods. FDA maintains a system of postmarketing surveillance because all possible side effects of a new drug may not be evident in preapproval studies, which involve only several hundred to several thousand patients. Through postmarketing surveillance and risk assessment programs, FDA and sponsors seek to identify adverse events that did not appear during the drug approval process. In addition, FDA monitors adverse events such as adverse reactions and poisonings. FDA may use this information for a variety of purposes to identify safety signals not previously identified with the product, to update drug labeling, and, on rare occasions, to reevaluate the approval or marketing decision with respect to a product.

In addition, post-approval regulatory requirements include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of drug and biological products. The FDA will also conduct routine scheduled and unannounced inspections of drug production and control facilities and processes, using field investigators and analysts, to assure ongoing safety and effectiveness of approved marketed products. Inspections may be made in conjunction with regulators from other jurisdictions and in certain cases, inspection findings and observations may be made public or may impair our ability to use the inspected facility, or to continue to produce and market a product.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct- to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet and notably, social media. In addition, discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. Sanctions authorized under FDA's legal authorities could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Violations of the FDCA may serve as a basis for the refusal of, or exclusion from, government contracts, including federal reimbursement programs, as well as other adverse consequences including lawsuits and actions by state attorneys general. Any agency or judicial enforcement action could have a material adverse effect on us. Drug and biological product manufacturers and other entities involved in the manufacture and distribution of approved drug or biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to a manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a new drug application, or NDA, or BLA plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Under the Hatch-Waxman Amendments, a drug product containing a new chemical entity as its active ingredient is entitled to five years of market exclusivity, and a product for which the sponsor is required to generate new clinical data is entitled to three years of market exclusivity. A drug or biological product can also obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A new biologic is granted 12 years of exclusivity from the time of first licensure during which a biosimilar may not be launched.

Government Regulation Outside of the U.S.

European Union Regulation

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution of our products. In particular, we view the EU and Japan as important jurisdictions for our business.

For purposes of developing our products, we must obtain the requisite approvals from regulatory authorities in each country prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies. In the EU, for example, a clinical trial application ("CTA"), must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical study development may proceed.

The EU has two main procedures for obtaining marketing authorizations in the EU Member States: a centralized procedure or national authorization procedure, under the latter of which one can seek go through the mutual recognition procedure or the decentralized procedure. All biotechnology products are assessed through the centralized procedure.

Under the centralized authorization procedure, sponsors submit a single marketing-authorization application to the EMA. This allows the marketing-authorization holder to market the product and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorization. EMA's Committee for Medicinal products for Human Use ("CHMP") carries out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not. Once granted by the EMA, the centralized marketing authorization is valid in all EU Member States as well as in the European Economic Area countries Iceland, Liechtenstein and Norway. The centralized procedure is mandatory for biotechnology products.

Any product candidates we seek to commercialize in the EU are subject to review and approval by the European Medicines Authority ("EMA"). Submissions for marketing authorization to the EMA must be received and validated by that body which appoints a Rapporteur and Co-Rapporteur to review it. The entire review process must be completed within 210 days, with a "clock-stop" at day 120 to allow the submitting company to respond to questions set forth in the Rapporteur and Co-Rapporteur's assessment report. Once the company responds in full, the clock for review re-starts on day 121. If further clarification is needed, the EMA may request an Oral Explanation on day 180, and the company submitting the application must appear before the CHMP to provide the requested information. On day 210, the CHMP will vote to recommend for or against the approval of the application. The final decision of EMA for marketing authorization following a positive CHMP recommendation is typically made within 60 days, with a draft decision within 15 days of the CHMP recommendation.

After Marketing Authorizations have been granted, the company must submit periodic safety reports to the EMA (if approval was granted under the Centralized Procedure) or to the National Health Authorities (if approval was granted under the DCP or the MRP). In addition, pharmacovigilance measures must be implemented and monitored to ensure appropriate adverse event collection, evaluation and expedited reporting, as well as timely updates to any applicable risk management plans. For some medications, post approval studies may be required to complement available data with additional data to evaluate long term effects or to gather additional efficacy data.

European marketing authorizations have an initial duration of five years. After this time, the marketing authorization may be renewed by the competent authority on the basis of re-evaluation of the risk/benefit balance. Any marketing authorization which is not followed within three years of its granting by the actual placing on the market of the corresponding medicinal product ceases to be valid.

EU Exclusivity Periods

To obtain regulatory approval of an investigational biological product under EU regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the U.S. is similar to that required in the EU, with the exception of, among other things, country-specific document requirements. The EU also provides opportunities for market exclusivity. For example, in the EU, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the EU can receive 10 years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the U.S. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to 10 years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

In addition to law and regulation specific to drug development, we note that new data protection regulations that have gone into effect in Europe are likely to have a significant impact on our activities, personnel, and may have an impact on our ability to timely complete clinical trials and effectively develop and commercialize our product candidates. The General Data Protection Regulation (the "GDPR") was approved and adopted by the EU Parliament in April 2016 and went into effect on May 25, 2018. Unlike a Directive, the GDPR does not require any enabling legislation to be passed by any government. The GDPR not only applies to organizations located within the EU but may also apply to organizations located outside of the EU if they offer goods or services to, or monitor the behavior of, EU data subjects or if they process the personal data of subjects residing in the European Union. The implications of this regulation are therefore far reaching and may impose significant burdens on the Company and its processes and systems. Additionally, the UK government has implemented a Data Protection Bill, which also went into effect on May 25, 2018, that substantially implements the GDPR. For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, coverage, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with cGCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government programs such as Medicare or Medicaid, managed care plans, private health insurers, and other organizations. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Third-party payors may attempt to control costs by limiting coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication, and by limiting the amount of reimbursement for particular procedures or drug treatments. In addition, in the United States, participation in government health programs such as Medicare and Medicaid are subject to complex rules and controls relating to price reporting and calculation of prices to ensure that pricing provided to government entities for periodic reporting purposes is aligned and compliant with numerous complex statutory requirements. The infrastructure and/or external resources necessary to ensure continued compliance with these requirements is extensive and manufacturers are subject to audit both by the Centers for Medicare and Medicaid Services and by State Medicaid authorities.

The cost of pharmaceuticals and devices continues to generate substantial governmental and third party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically

reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that the third-party payors reimbursement policies will not adversely affect our ability to sell our product profitably.

Healthcare Reform

In the U.S. and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs. In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The Medicare Modernization Act expanded Medicare coverage for drug purchases by the elderly by establishing Medicare Part D and introduced a new reimbursement methodology based on average sales prices for physician administered drugs under Medicare Part B. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class under the new Medicare Part D program. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and reimbursement rate that we receive for any of our approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates.

Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. We expect that the rebates, discounts, taxes and other costs resulting from the ACA over time will have a negative effect on our expenses and profitability in the future. Furthermore, expanded government investigative authority and increased disclosure obligations may increase the cost of compliance with new regulations and programs.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. Sequestration cuts went into effect on April 1, 2013, and the Bipartisan Budget Act of 2013 extended sequestration for Medicare for another two years, through 2023. A bill signed by President Obama on February 15, 2014, further extended these cuts for an additional year, through fiscal year 2024. On January 21, 2014, President Obama signed the fiscal year 2014 omnibus appropriations bill, modifying for fiscal year 2014 and fiscal year 2015 the cuts that went into effect under the sequester on March 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

The current presidential administration and Congress are also expected to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modifications or repeal of any of the provisions of the ACA including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the pharmaceutical industry as a whole is currently unknown. But, any changes to the ACA are likely to have an impact on our results of operations and may have a material adverse effect on our results of operations. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

While the status of the ACA under the current administration remains in question, it is possible that healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenue. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, and formulary restrictions among private payors including the largest pharmacy benefit managers have increased over recent months, especially as regards to new and high cost market entrants. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

In addition, different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may be marketed only once a reimbursement price has been agreed upon. Some of these countries may require, as condition of obtaining reimbursement or pricing approval, the completion of clinical trials that compare the cost- effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross- border imports from low-priced markets exert a commercial pressure on pricing within a country.

Other Healthcare Laws and Compliance Requirements

In the U.S., the research, manufacturing, distribution, sale and promotion of drug products, including biologics, and medical devices are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, divisions of the U.S. Department of Health and Human Services, including the Office of Inspector General and the Centers for Medicare and Medicaid Services, the U.S. Department of Justice, state Attorneys General, and other state and local government agencies. For example, sales, marketing and scientific/educational grant programs must comply with fraud and abuse laws such as the federal Anti-Kickback Statute, as amended, the federal False Claims Act, as amended, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The federal Anti-Kickback Statute prohibits any person, including a prescription drug manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. The term “remuneration” has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Even the award of grant moneys, or the provision of in kind support, publicity and even authorship, in certain cases, may be deemed to be “remuneration.” Although there are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exception and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The reach of the Anti-Kickback Statute was broadened by the recently enacted ACA, so that the government need no longer prove, for purposes of establishing intent under the federal Anti-Kickback Statute, that a person or entity had actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below). Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute, and some of these state prohibitions apply to the referral of patients for healthcare items or services reimbursed by any third-party payor, including private payors. In at least some cases, these state laws do not contain safe harbors.

The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government and share in any recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare numbers when detailing the provider of services, improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug’s label), and allegations as to misrepresentations with respect to the services rendered.

Substantial resources have been allocated by both the Department of Justice and the Federal Bureau of Investigation, among other branches of the US government to identify and investigate possible health care fraud activities. Recent investigations include those relating to allegedly egregious price increases by manufacturers and alleged fraud involving co-pay arrangements supported by sponsors. As new theories of liability arise, there is a corresponding cost of doing business in order to maintain compliance.

Our future activities relating to the reporting of discount and rebate information and other information affecting federal, provincial, state and third party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance. Also, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created several new federal crimes including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud provision of HIPAA prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements provision prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. For example, HIPAA and its implementing regulations established uniform federal standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act ("HITECH"), which became effective on February 17, 2010. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

There are also an increasing number of state "sunshine" laws that require manufacturers to make reports to states on pricing and marketing information, as well as regarding payments to healthcare professionals. Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit certain other sales and marketing practices. State laws are not harmonized and contain different reporting requirements and restrictions which must be noted and adhered to. We currently do not report under these state laws, but will be required to do if we are successful in obtaining marketing authorization for our products. We will need to develop the infrastructure or rely on third party contractors to assist us in our compliance with these laws, and failure to comply may result in financial and other penalties and consequences. In addition, beginning in 2013, a similar "sunshine" federal requirement began requiring manufacturers to track and report to the federal government certain payments and other transfers of value made to certain covered recipients, including physicians and other healthcare professionals, and teaching hospitals. In addition to payments, reporting may encompass requirements to report on ownership or investment interests held by physicians and their immediate family members. The efforts and resources needed to track and report payments go well beyond our affiliates operating in the United States, as reporting is required also for payments made by affiliated entities in many cases to US covered recipients. In other jurisdictions (eg, Australia, Japan and Europe) similar "sunshine-like" laws have also been adopted, which may require disclosure of certain payment and other information to covered recipients. Extensive administration and systems, including to aggregate and categorize spend, are necessary in order to enable compliant and timely reporting under these requirements. The US federal government began disclosing the reported information on a publicly available website in 2014. These laws may affect our development, sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. If we fail to track and report as required by these laws or otherwise fail to comply with these laws, we could be subject to the penalty and sanctions of the pertinent state and federal authorities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of premarketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-approval requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Australian Disclosure Requirements

Business Strategies and Prospects for Future Years

We are focused on the following core strategic imperatives:

- continue to innovate and optimize our disruptive technology platform for cell-based therapeutics;
- develop a portfolio of clinically distinct products;
- focus on bringing late-stage products to market and portfolio prioritization;
- enabling manufacturing scale-up to meet demands of the portfolio;
- leverage talent base to continue to establish a culture of shared leadership and accountability;
- focus on strategic partnerships;
- focus on prudent cash management; and
- continue to strengthen our substantial and robust intellectual property estate.

Dividends

No dividends were paid during the course of the fiscal year ended June 30, 2019. There are no dividends or distributions recommended or declared for payment to members, but not yet paid, during the year.

4.C Organizational Structure

See "Item 4. Information on the Company – 4.B Business Overview – Overview", "Item 18. Financial Statements – Note 12" and Exhibit 8.1 to this Annual Report.

4.D Property, Plants and Equipment

We lease approximately 11,150 square feet of office space in Melbourne, Australia, where our headquarters are located. We pay approximately A$846,000 per year for this lease, which expires in April 2026. We also lease approximately 15,600 square feet in New York City, where significant development and commercial activities are conducted. We pay $1,073,000 per year for this lease. We also lease laboratory and office space in Singapore. We pay approximately S$388,000 per year for this lease, which expires in August 2022. We also lease laboratory and office space in Texas and pay approximately $202,000 per year for this lease, which expires in May 2022. All of our manufacturing operations are currently located at Lonza's manufacturing facilities. See "Item 4.B Business Overview – Manufacturing and Supply Chain."

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

5.A Operating Results

This operating and financial review should be read together with our consolidated financial statements in this Annual Report, which have been prepared in accordance with IFRS as published by the IASB.

Financial Overview

We have incurred significant losses since our inception. We have incurred net losses during most of our fiscal periods since our inception. For the year ended June 30, 2019, we had an accumulated deficit of $470.0 million. Our net loss for the year ended June 30, 2019 was $89.8 million.

We anticipate that we may continue to incur significant losses for the foreseeable future. There can be no assurance that we will ever achieve or maintain profitability.

We expect our future capital requirements will continue as we:

- continue the research and clinical development of our product candidates;
- initiate and advance our product candidates into larger clinical studies;
- seek to identify, assess, acquire, and/or develop other product candidates and technologies;
- seek regulatory and marketing approvals in multiple jurisdictions for our product candidates that successfully complete clinical studies;
- establish collaborations with third parties for the development and commercialization of our product candidates, or otherwise build and maintain a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- further develop and implement our proprietary manufacturing processes and expand our manufacturing capabilities and resources for commercial production;
- seek coverage and reimbursement from third-party payors, including government and private payors for future products;
- make interest payments, principal repayments and other charges on our debt financing arrangements;
- make milestone or other payments under our agreements pursuant to which we have licensed or acquired rights to intellectual property and technology;
- seek to maintain, protect, and expand our intellectual property portfolio; and
- seek to attract and retain skilled personnel.

We expect our research and development expenditure to decrease over the next 12 to 24 months as we complete our phase 3 trials or if we are able to successfully partner one or more of our products. We expect management and administration expenses to remain relatively consistent. Subject to us achieving successful regulatory approval, we expect an increase in our total expenses driven by an increase in our selling, general and administrative expenses as we move towards commercialization. Therefore we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not know when, or if, we will generate revenues from our product sales significant enough to generate profits. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one or more of our cell-based product candidates. For further discussion on our ability to continue as a going concern, see Note 1(i) in our accompanying financial statements.

Commercialization and Milestone Revenue. Commercialization and milestone revenue relates to up-front, royalty and milestone payments recognized under development and commercialization agreements; milestone payments, the receipt of which is dependent on certain clinical, regulatory or commercial milestones; as well as royalties on product sales of licensed products, if and when such product sales occur; and revenue from the supply of products. Payment is generally due on standard terms of 30 to 60 days.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue or deferred consideration in our consolidated balance sheets, depending on the nature of arrangement. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified within non-current liabilities.

In the year ended June 30, 2019, we recognized $5.0 million in commercialization revenue relating to royalty income earned on sales of TEMCELL® Hs. Inj., a registered trademark of JCR (“TEMCELL”), in Japan by our licensee, JCR Pharmaceuticals Co. Ltd. (“JCR”), compared with $3.6 million for the year ended June 30, 2018. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

In the year ended June 30, 2019, we recognized $10.0 million in milestone revenue from the $20.0 million up-front payment received in October 2018 in relation to our strategic alliance with Tasly Pharmaceutical Group (“Tasly”) for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC. Tasly has received exclusive rights to, and will fund all development, manufacturing and commercialization activities in China for MPC-150-IM and MPC-25-IC. Upon completion of this strategic alliance on September 14, 2018, we recognized revenue of $10.0 million in the year ended June 30, 2019 for the up-front technology access fee receivable from Tasly as this is the portion of revenue that control has been transferred to Tasly. There was no milestone revenue recognized in relation to this strategic alliance with Tasly in the year ended June 30, 2018.

In the year ended June 30, 2019, we also recognized $1.0 million in milestone revenue upon our licensee JCR achieving a sales milestone on cumulative net sales of TEMCELL in Japan, compared with $1.5 million in the year ended June 30, 2018. These amounts were recorded in revenue as there are no further performance obligations required in regards to these milestones.

In the year ended June 30, 2018, we recognized $11.8 million (€10.0 million) in milestone revenue in relation to our patent license agreement with TiGenix NV ("TiGenix"), now a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda"), which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived mesenchymal stem cell ("MSC") product, Alofisel® a registered trademark of TiGenix, a product candidate of Takeda, for the local treatment of fistulae. The agreement includes the right for Takeda to grant sub-licenses to affiliates and third parties. Within this $11.8 million, $5.9 million (€5.0 million) was recognized in relation to the non-refundable up-front payment received upon execution of our patent license agreement with Takeda in December 2017 and $5.9 million (€5.0 million) in milestone revenue was recognized in December 2017 in relation to a further payment received in December 2018 for product Alofisel® as all performance obligations had been satisfied at that time. There was no milestone revenue recognized in relation to the Takeda agreement in the year ended June 30, 2019.

Interest Revenue. Interest revenue is accrued on a time basis by reference to the principal outstanding and at the effective interest rate applicable.

Research and Development. Research and development expenditure is recognized as an expense as incurred.

Our research and development expenses consist primarily of:

- third party costs comprising all external expenditure on our research and development programs such as fees paid to Contract Research Organizations ("CROs"), and consultants who perform research on our behalf and under our direction, rent and utility costs for our research and development facilities, and database analysis fees;
- third party costs under license and/or sub-license arrangements for the research and development, license, manufacture and/or commercialization of products and/or product candidates, such as payments for options to acquire rights to products and product candidates as well as contingent obligations under the agreements;
- product support costs consisting primarily of salaries and related overhead expenses for personnel in research and development functions (for example wages, salaries and associated on costs such as superannuation, share-based incentives and payroll taxes, plus travel costs and recruitment fees for new hires);
- intellectual property support costs comprising payments to our patent attorneys to progress patent applications and all costs of renewing of our granted patents; and
- amortization of currently marketed products on a straight-line basis over the life of the asset.

Our research and development expenses are not charged to specific products or programs, since the number of clinical and preclinical product candidates or development projects tends to vary from period to period and since internal resources are utilized across multiple products and programs over any given period of time. As a result, our management does not maintain and evaluate research and development costs by product or program. Acquired in-process research and development is capitalized as an asset and is not amortized but is subject to impairment review during the development phase. Upon completion of its development, the acquired in-process research and development amortization will commence.

Manufacturing Commercialization. Manufacturing commercialization expenditure is recognized as an expense as incurred. Our manufacturing commercialization expenses consist primarily of:

- salaries and related overhead expenses including share-based incentives for personnel in manufacturing functions;
- fees paid to our contract manufacturing organizations, which perform process development on our behalf and under our direction; and
- costs related to laboratory supplies used in our manufacturing development efforts.

Management and Administration. Management and administration expenses consist primarily of salaries and related costs including share-based incentives for employees in executive, corporate and administrative functions. Other significant management and administration expenses include legal and professional services, rent and depreciation of leasehold improvements, insurance and information technology services.

Fair Value Remeasurement of Contingent Consideration. Remeasurement of contingent consideration pertains to the acquisition of assets from Osiris Therapeutics, Inc. ("Osiris"). The fair value remeasurement of contingent consideration is recognized as a net result of changes to the key assumptions of the contingent consideration valuation such as probability of success, market penetration, developmental timelines, product pricing, and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration. As the net result of changes to the key assumptions and the time period shortening, we recognized a net remeasurement loss of $6.3 million and a net remeasurement gain of $10.5 million for the years ended June 30, 2019 and 2018, respectively.

Other Operating Income and Expenses. Other operating income and expenses primarily comprise remeasurement of borrowing arrangements, tax incentives and foreign exchange gains and losses.

Remeasurement of borrowing arrangements pertains to our loan and security agreement with NovaQuest Capital Management, L.L.C. ("NovaQuest"). Remeasurement of borrowing arrangements is recognized when changes in our estimated net sales trigger an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument's original effective interest rate. We recognized a remeasurement loss of $0.7 million in the year ended June 30, 2019 as a net result of changes to the key assumptions such as development timelines and market penetration. There was no remeasurement of borrowing arrangements recognized in the year ended June 30, 2018.

Tax incentives comprise payments from the Australian Government's Innovation Australia Research and Development Tax Incentive program for research and development activities conducted in relation to our qualifying research that meets the regulatory criteria. The research and development tax incentive credit is available for our research and development activities in Australia as well as research and development activities outside of Australia to the extent such non-Australian based activities relate to intellectual property owned by our Australian resident entities do not exceed half the expenses for the relevant activities and are approved by the Australian Government. A refundable tax offset is available to eligible companies with an annual aggregate turnover of less than A$20.0 million. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending. For the years ended June 30, 2019 and 2018, the rate of the refundable tax offset is 43.5%. All other eligible entities may obtain a non-refundable tax offset of 38.5% of the eligible research and development expenditure.

The combined worldwide turnover of the Mesoblast Group is in excess of A$20.0 million for the year ended June 30, 2019 making us ineligible for the refundable tax offset for the research and development tax incentive. Consequently, no income was recognized from the Research and Development Tax Incentive program for the year ended June 30, 2019, compared with $1.8 million that was recognized for the year ended June 30, 2018. We recorded a $0.1 million loss in research and development tax incentive income for the year ended June 30, 2019 which relates to a change in the original estimate of the research and development tax incentive income that we would receive from the Australian Government for the year ended June 30, 2018.

Foreign exchange gains and losses relate to unrealized foreign exchange gains and losses on our foreign currency amounts in our Australian based entity, whose functional currency is the A$, and foreign currency amounts in our Switzerland and Singapore based entities, whose functional currencies are the US$, plus realized gains and losses on any foreign currency payments to our suppliers due to movements in exchange rates. We recognized a foreign exchange loss of $0.2 million in the year ended June 30, 2019 and a foreign exchange gain of $0.2 million in the year ended June 30, 2018.

Finance Costs. Finance costs consists of remeasurement of borrowing arrangements, accrued interest expense and interest expense in relation to the amortization of transaction costs and other charges associated with the borrowings as represented in our consolidated balance sheet using the effective interest rate method over the period of initial recognition through maturity.

Remeasurement of borrowing arrangements pertains to our loan and security agreement with Hercules Capital, Inc. ("Hercules"). Remeasurement of borrowing arrangements is recognized when there is a revision in the estimated future cash flows which is recorded as an adjustment of the carrying amount of the financial liability. The carrying amount adjustment is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument's original effective interest rate. We recognized a remeasurement gain of $0.4 million in the year ended June 30, 2019 as a result of drawing a further tranche of $15.0 million from our existing credit facility with Hercules in January 2019. There was no remeasurement of borrowing arrangements recognized in the year ended June 30, 2018.

Income Tax Benefit/Expense. Income tax benefit/expense consists of net changes in deferred tax assets and liabilities recognized on the balance sheet during the period. We recognized a non-cash income tax benefit of $9.0 million in the year ended June 30, 2019 and $30.7 million in the year ended June 30, 2018.

Results of Operations

Comparison of Our Results for the Year ended June 30, 2019 with the Year ended June 30, 2018

The following table summarizes our results of operations for the years ended June 30, 2019 and 2018, together with the changes in those items in dollars and as a percentage.

(in U.S. dollars, in thousands except per share information)	Year ended June 30, 2019	2018	$ Change	% Change
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	$ 5,003	$ 3,641	1,362	37%
Milestone revenue	11,000	13,334	(2,334)	(18%)
Interest revenue	719	366	353	96%
Total revenue	**16,722**	**17,341**	**(619)**	**(4%)**
Research & development	(59,815)	(65,927)	6,112	(9%)
Manufacturing commercialization	(15,358)	(5,508)	(9,850)	179%
Management and administration	(21,625)	(21,907)	282	(1%)
Fair value remeasurement of contingent consideration	(6,264)	10,541	(16,805)	(159%)
Other operating income and expenses	(1,086)	1,312	(2,398)	(183%)
Finance costs	(11,328)	(1,829)	(9,499)	NM
Loss before income tax	**(98,754)**	**(65,977)**	**(32,777)**	**50%**
Income tax benefit	8,955	30,687	(21,732)	(71%)
Loss attributable to the owners of Mesoblast Limited	**$ (89,799)**	**$ (35,290)**	**(54,509)**	**154%**
Losses per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**% Change**
Basic - losses per share	(18.16)	(7.58)	(10.60)	140%
Diluted - losses per share	(18.16)	(7.58)	(10.60)	140%

* NM = not meaningful.

Revenue

Revenues were $16.7 million for the year ended June 30, 2019, compared with $17.3 million for the year ended June 30, 2018, a decrease of $0.6 million. The following table shows the movement within revenue for the years ended June 30, 2019 and 2018, together with the changes in those items.

(in U.S. dollars, in thousands)	Year ended June 30, 2019	2018	$ Change	% Change
Revenue:				
Milestone revenue	$ 11,000	$ 13,334	(2,334)	(18%)
Commercialization revenue	5,003	3,641	1,362	37%
Interest revenue	719	366	353	96%
Revenue	**$ 16,722**	**$ 17,341**	**(619)**	**(4%)**

Milestone revenue was $11.0 million in the year ended June 30, 2019, a decrease of $2.3 million as compared with $13.3 million in the year ended June 30, 2018. This $2.3 million decrease in the year ended June 30, 2019 is due to the recognition of $11.8 million in milestone revenue in the year ended June 30, 2018 in relation to our patent license agreement with Takeda. Within this $11.8 million, $5.9 million was recognized in relation to the non-refundable up-front payment received upon execution of our patent license agreement with Takeda in December 2017 and $5.9 million of milestone revenue was recognized in December 2017 in relation to a further payment received in December 2018 for product Alofisel® as all performance obligations had been satisfied at that time. There was no milestone revenue recognized in relation to the Takeda agreement in the year ended June 30, 2019. This $11.8 million decrease in milestone revenue from Takeda was offset by an increase of $10.0 million in milestone revenue recognized in the year ended June 30, 2019 due to the recognition of $10.0 million in milestone revenue upon completion of the strategic alliance with Tasly for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC in September 2018. There was no milestone revenue recognized in relation to this strategic alliance with Tasly in the year ended June 30, 2018. We also recognized $1.0 million and $1.5 million in milestone revenue during the years ended June 30, 2019 and 2018, respectively, upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan.

Commercialization revenue from royalty income earned on sales of TEMCELL in Japan by our licensee JCR was $5.0 million in the year ended June 30, 2019, an increase of $1.4 million (37%) as compared with $3.6 million in the year ended June 30, 2018.

The $0.3 million increase in interest revenue for the year ended June 30, 2019 compared with the year ended June 30, 2018 was primarily driven by us retaining higher cash reserves in the year ended June 30, 2019, when compared with the year ended June 30, 2018.

Research and development

Research and development expenses were $59.8 million for the year ended June 30, 2019, compared with $65.9 million for the year ended June 30, 2018, a decrease of $6.1 million. The $6.1 million decrease in research and development expenses primarily reflects a decrease in third party costs, intellectual property support costs and amortization of current marketed products.

(in U.S. dollars, in thousands)	Year ended June 30, 2019	2018	$ Change	% Change
Research and development:				
Third party costs	$ 38,365	$ 44,192	(5,827)	(13%)
Product support costs	17,002	16,861	141	1%
Intellectual property support costs	2,993	3,258	(265)	(8%)
Amortization of current marketed products	1,455	1,616	(161)	(10%)
Research and development	**$ 59,815**	**$ 65,927**	**(6,112)**	**(9%)**

Third party costs, which consist of all external expenditure on our research and development programs, decreased by $5.8 million in the year ended June 30, 2019 compared with the year ended June 30, 2018.

This $5.8 million decrease was due to a reduction in our third party costs for our phase 3 clinical trials for MPC-150-IM (CHF), MPC-06-ID (CLBP) and MSC-100-IV (“remestemcel-L”) as activities and costs were higher in the prior year given the trials were enrolling patients, whereas in the year ended June 30, 2019 activities and costs have reduced as enrollment was completed for MPC-150-IM (CHF), MPC-06-ID (CLBP) and remestemcel-L in January 2019, March 2018 and December 2017 respectively. We continued to incur costs for these programs, as well as other pre phase 3 programs, during the year as patients were monitored during follow up visits and other testing was completed.

Product support costs, which consist primarily of salaries and related overhead expenses for personnel in research and development functions, have increased by $0.1 million for the year ended June 30, 2019 compared with the year ended June 30, 2018. This increase is primarily due to an increase of $1.1 million across salaries and associated costs as full time equivalents increased by 3.0 (7%) from 44.1 for the year ended June 30, 2018 to 47.1 for the year ended June 30, 2019. There was also an increase of $0.2 million in travel expenses and $0.1 million in consulting in the year ended June 30, 2019 compared with June 30, 2018. These increases were offset by a decrease of $1.3 million in share-based payment expenses for the year ended June 30, 2019 due to a reduction in the value of options vesting compared with the year ended June 30, 2018.

Also included in research and development expenses are intellectual property support costs, which consist of payments to our patent attorneys to progress patent applications and all costs of renewing our granted patents. These costs have decreased by $0.3 million in the year ended June 30, 2019 compared with the year ended June 30, 2018 primarily due to decreased activities across our MSC-based patent portfolio.

Amortization of current marketed products decreased by $0.1 million from $1.6 million for the year ended June 30, 2018 to $1.5 million for the year ended June 30, 2019.

Manufacturing commercialization

Manufacturing commercialization expenses, which consist of fees paid to our contract manufacturing organizations and laboratory supplies used in manufacturing commercialization of our MPC and MSC based products, increased by $9.8 million from the year ended June 30, 2018 compared with the year ended June 30, 2019. The increase was primarily due to an increase in process validation activities required ahead of the Biologics License Application ("BLA") filing of remestemcel-L in the year ended June 30, 2019 compared with the year ended June 30, 2018.

(in U.S. dollars, in thousands)	Year ended June 30, 2019	2018	$ Change	% Change
Manufacturing commercialization:				
MSC platform technology	$ 12,341	$ 2,317	10,024	NM
MPC platform technology	1,167	745	422	57%
Manufacturing support costs	1,850	2,446	(596)	(24%)
Manufacturing commercialization	**$ 15,358**	**$ 5,508**	**9,850**	**179%**

The MSC-based manufacturing commercialization expenses increased by $10.0 million in the year ended June 30, 2019 compared with the year ended June 30, 2018 primarily due to an increase in process validation activities in preparation for filing the BLA for remestemcel-L.

The MPC-based manufacturing commercialization expenses increased by $0.4 million in the year ended June 30, 2019 compared with the year ended June 30, 2018 primarily due to an increase in purchases of raw materials.

Manufacturing support costs, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, decreased by $0.6 million from $2.4 million for the year ended June 30, 2018 to $1.8 million for the year ended June 30, 2019. There was a decrease of $0.2 million in share-based payment expenses and $0.2 million in consultancy expenses for the year ended June 30, 2019 compared with the year ended June 30, 2018. There was also a decrease of $0.2 million across salaries and associated costs as full time equivalents decreased by 1.1 (16%) from 7.0 for the year ended June 30, 2018 to 5.9 for the year ended June 30, 2019.

Management and administration

Management and administration expenses were $21.6 million for the year ended June 30, 2019, compared with $21.9 million for the year ended June 30, 2018, a decrease of $0.3 million. This decrease was primarily due to a decrease in labor and associated expenses offset by an increase in legal and professional fees associated with establishing the strategic alliance with Tasly for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC announced in July 2018.

(in U.S. dollars, in thousands)	Year ended June 30, 2019	2018	$ Change	% Change
Management and administration:				
Labor and associated expenses	$ 9,953	$ 11,237	(1,284)	(11%)
Corporate overheads	8,107	7,824	283	4%
Legal and professional fees	3,565	2,846	719	25%
Management and administration	**$ 21,625**	**$ 21,907**	**(282)**	**(1%)**

Labor and associated expenses decreased by $1.3 million from $11.2 million for the year ended June 30, 2018 to $9.9 million for the year ended June 30, 2019. The number of full time equivalents increased by 0.2 (1%) from 25.5 for the year ended June 30, 2018 to 25.7 for the year ended June 30, 2019; however overall costs of salaries and associated expenses decreased by $0.4 million in the year ended June 30, 2019 compared with the year ended June 30, 2018. There was also a decrease of $0.2 million in share-based payment expenses and $0.4 million in recruitment expenses in the year ended June 30, 2019, compared with the year ended June 30, 2018. These decreases were offset by an increase of $0.2 million in consultancy expenses in the year ended June 30, 2019, compared with the year ended June 30, 2018. Labor and associated expenses also experienced favorable exchange rate fluctuations of $0.5 million in the year ended June 30, 2019 compared with the year ended June 30, 2018, as the A$ weakened against the US$ given the majority of management and administration expenses are incurred in A$ by our headquarter office located in Australia.

Corporate overhead expenses increased by $0.3 million from $7.8 million for the year ended June 30, 2018 to $8.1 million for the year ended June 30, 2019 primarily due to an increase in insurance and rent in the period.

Legal and professional fees increased by $0.7 million from $2.8 million for the year ended June 30, 2018 to $3.5 million for the year ended June 30, 2019 primarily due to increased legal and professional fees associated with establishing the strategic alliance with Tasly for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC that was announced in July 2018.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration was a $6.3 million loss for the year ended June 30, 2019 compared with a $10.5 million gain for the year ended June 30, 2018, a decrease of $16.8 million. The $6.3 million loss for the year ended June 30, 2019 was due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This loss was a net result of changes to the key assumptions of the contingent consideration valuation such as probability of success, market penetration, development timelines, product pricing, and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

The $10.5 million gain for the year ended June 30, 2018 was due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This gain was a net result of changes to the key assumptions of the contingent consideration valuation such as developmental timelines, product pricing, market penetration, market population and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

With respect to future milestone payments, contingent consideration will be payable in cash or shares at our discretion. With respect to commercialization, product royalties will be payable in cash which will be funded from royalties received from net sales.

Other operating income and expenses

In other operating income and expenses, we recognized an expense of $1.1 million for the year ended June 30, 2019, compared with an income of $1.3 million for the year ended June 30, 2018, a decrease in income of $2.4 million. The following table shows movements within other operating income and expenses for the years ended June 30, 2019 and 2018, together with the changes in those items:

(in U.S. dollars, in thousands)	Year ended June 30, 2019	2018	$ Change	% Change
Other operating income and expenses:				
Remeasurement of borrowing arrangements	$ (752)	$ —	(752)	NM
Foreign withholding tax	(52)	(656)	604	(92%)
Foreign exchange (losses)/gains (net)	(208)	161	(369)	NM
Research and development tax incentive income	(74)	1,807	(1,881)	(104%)
Other operating income and expenses	**$ (1,086)**	**$ 1,312**	**(2,398)**	**(183%)**

In the year ended June 30, 2019, we recognized a $0.7 million loss for remeasurement of borrowing arrangements in relation to the adjustment of the carrying amount of our financial liability to reflect the revised future cash flow as a net result of changes to the key assumption in development timelines and market penetration in relation to our existing credit facility with NovaQuest. There was no remeasurement of borrowing arrangements recognized in the year ended June 30, 2018.

Foreign withholding tax decreased by $0.6 million from $0.7 million for the year ended June 30, 2018 to $0.1 million for the year ended June 30, 2019. In the year ended June 30, 2018, the $0.7 million of foreign withholding tax recognized primarily relates to revenue recognized from our patent license agreement with Takeda entered into in December 2017.

We are subject to foreign exchange gains and losses on foreign currency cash balances, creditors and debtors. In the year ended June 30, 2018, we recognized a foreign exchange gain of $0.2 million. In the year ended June 30, 2019 we recognized a foreign exchange loss of $0.2 million, primarily due to movements in exchange rates on Euro receivable balances in our Singapore based entity as the US$ depreciated against the Euro during the period.

We recorded a $0.1 million loss in research and development tax incentive income for the year ended June 30, 2019, compared with a gain of $1.8 million for the year ended June 30, 2018, a decrease of $1.9 million. This $0.1 million loss relates to a change in the original estimate of the research and development tax incentive income that we would receive from the Australian Government for the year ended June 30, 2018. We have recognized incentive income pertaining to the eligible expenditure undertaken in each of these periods. At each period end, management estimates the refundable tax incentives available to us based on available information at the time. The combined worldwide turnover of the Mesoblast Group is in excess of A$20.0 million for the year ended June 30, 2019 making us ineligible for the refundable tax offset for the research and development tax incentive. Consequently, no income was recognized from the Research and Development Tax Incentive program for the year ended June 30, 2019 compared with $1.8 million that was recognized for the year ended June 30, 2018. We engage tax specialists to review, on an annual basis, the quantum of our previous research and development tax claims and our on-going eligibility to claim the research and development tax incentive in Australia.

Finance costs

(in U.S. dollars, in thousands)	Year ended June 30, 2019	2018	$ Change	% Change
Finance costs:				
Remeasurement of borrowing arrangements	$ (376)	$ —	(376)	NM
Interest expense	11,704	1,829	9,875	NM
Finance costs	**$ 11,328**	**$ 1,829**	**9,499**	**NM**

In the year ended June 30, 2019, we recognized a $0.4 million gain for remeasurement of borrowing arrangements in relation to the adjustment of the carrying amount of our financial liability to reflect the revised estimated future cash flows as a result of drawing a further tranche of $15.0 million from our existing credit facility with Hercules in January 2019. There was no remeasurement of borrowing arrangements recognized in the year ended June 30, 2018.

Interest expenses increased by $9.9 million from $1.8 million for the year ended June 30, 2018 to $11.7 million for the year ended June 30, 2019.

In the year ended June 30, 2019, we recognized $6.4 million of interest expenses in relation to our loan and security agreement entered into with Hercules on March 6, 2018, an increase of $4.6 million as compared with $1.8 million for the year ended June 30, 2018. Within this $6.4 million, $4.4 million was recognized with regard to interest expense payable on the loan balance within the year and a further $2.0 million of interest expense was recognized with regard to the amortization of transaction costs incurred on the outstanding loan principal within the year using the effective interest rate method over the period of initial recognition through maturity.

In the year ended June 30, 2019, we recognized $5.3 million of interest expenses in relation to our loan and security agreement entered into with NovaQuest on June 29, 2018, an increase of $5.3 million as compared with $Nil for the year ended June 30, 2018. This $5.3 million is recognized with regard to interest expense accrued and amortization of transaction costs on the loan principal balance. All interest payments will be deferred until after the first commercial sale of our allogeneic product candidate remestemcel-L in pediatric acute graft versus host disease (“aGVHD”).

Loss after income tax

(in U.S. dollars, in thousands)	Year ended June 30, 2019	2018	$ Change	% Change
Loss before income tax	$ (98,754)	$ (65,977)	(32,777)	50%
Income tax benefit	8,955	30,687	(21,732)	(71%)
Loss after income tax	**$ (89,799)**	**$ (35,290)**	**(54,509)**	**154%**

Loss before income tax was $98.8 million for the year ended June 30, 2019 compared with $66.0 million for the year ended June 30, 2018, an increase in the loss by $32.8 million. This increase is the net effect of the changes in revenues and expenses which have been fully explained above.

A non-cash income tax benefit of $9.0 million was recognized in the year ended June 30, 2019, in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period.

A non-cash income tax benefit of $30.7 million was recognized in the year ended June 30, 2018 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period, primarily due to a revaluation of our deferred tax assets and liabilities recognized as a result of changes in tax rates. Deferred taxes are measured at the rate in which they are expected to settle within the respective jurisdictions, which can change based on factors such as new legislation or timing of utilization and reversal of associated assets and liabilities. On December 22, 2017, the United States signed into law the Tax Cuts and Jobs Act ("the Tax Act"), which changed many aspects of U.S. corporate income taxation, including a reduction in the corporate income tax rate from 35% to 21%. We recognized the tax effects of the Tax Act in the year ended June 30, 2018, the most significant of which was a tax benefit resulting from the remeasurement of deferred tax balances to 21%.

Comparison of Our Results for the Year ended June 30, 2018 with the Year ended June 30, 2017

The following table summarizes our results of operations for the years ended June 30, 2018 and 2017, together with the changes in those items in dollars and as a percentage.

(in U.S. dollars, in thousands except per share information)	Year ended June 30, 2018	2017	$ Change	% Change
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	$ 3,641	1,444	2,197	152%
Milestone revenue	13,334	500	12,834	NM
Interest revenue	366	468	(102)	(22%)
Total revenue	**17,341**	**2,412**	**14,929**	**NM**
Research & development	(65,927)	(58,914)	(7,013)	12%
Manufacturing commercialization	(5,508)	(12,065)	6,557	(54%)
Management and administration	(21,907)	(23,007)	1,100	(5%)
Fair value remeasurement of contingent consideration	10,541	(130)	10,671	NM
Other operating income and expenses	1,312	1,489	(177)	(12%)
Finance costs	(1,829)	—	(1,829)	NM
Loss before income tax	**(65,977)**	**(90,215)**	**24,238**	**(27%)**
Income tax benefit/(expense)	30,687	13,400	17,287	129%
Loss attributable to the owners of Mesoblast Limited	**$ (35,290)**	**$ (76,815)**	**41,525**	**(54%)**
Losses per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**% Change**
Basic - losses per share	(7.58)	(19.25)	11.67	(61%)
Diluted - losses per share	(7.58)	(19.25)	11.67	(61%)

* NM = not meaningful.

Revenue

Revenues were $17.3 million for the year ended June 30, 2018, compared with $2.4 million for the year ended June 30, 2017, an increase of $14.9 million. The following table shows the movement within revenue for the years ended June 30, 2018 and 2017, together with the changes in those items.

(in U.S. dollars, in thousands)	Year ended June 30, 2018	2017	$ Change	% Change
Revenue:				
Milestone revenue	$ 13,334	500	12,834	NM
Commercialization revenue	3,641	1,444	2,197	152%
Interest revenue	366	468	(102)	(22%)
Revenue	**$ 17,341**	**$ 2,412**	**14,929**	**NM**

Milestone revenue was $13.3 million in the year ended June 30, 2018, an increase of $12.8 million as compared with $0.5 million in the year ended June 30, 2017. This $12.8 million increase in the year ended June 30, 2018 is due to increases in milestone revenues for Alofisel®, licensed with Takeda, and TEMCELL, licensed with JCR. There was an $11.8 million increase in milestone revenue recognized in relation to our patent license agreement with Takeda. Within this $11.8 million, $5.9 million was recognized in relation to the non-refundable up-front payment received upon execution of our patent license agreement with Takeda in December 2017 and $5.9 million of milestone revenue was recognized in relation to further payments due within 12 months of the patent license agreement date for product Alofisel®. There was no milestone revenue recognized in relation to the Takeda agreement in the year ended June 30, 2017. We also recognized $1.5 million and $0.5 million in milestone revenue during the years ended June 30, 2018 and 2017, respectively, upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan, an increase of $1.0 million.

Commercialization revenue was $3.6 million in the year ended June 30, 2018, an increase of $2.2 million as compared with $1.4 million in the year ended June 30, 2017. This $2.2 million increase in commercialization revenue is from royalty income earned on sales of TEMCELL in Japan by our licensee JCR, with $3.6 million of royalty revenue recognized in the year ended June 30, 2018 compared with $1.4 million of royalty revenue recognized in the year ended June 30, 2017.

The $0.1 million decrease in interest revenue from the year ended June 30, 2018 compared with the year ended June 30, 2017 was primarily driven by us retaining higher cash reserves in the year ended June 30, 2017, when compared with the year ended June 30, 2018.

Research and development

Research and development expenses were $65.9 million for the year ended June 30, 2018, compared with $58.9 million for the year ended June 30, 2017, an increase of $7.0 million. The $7.0 million increase in research and development expenses primarily reflects an increase in expenditures on our clinical program for MPC-150-IM.

(in U.S. dollars, in thousands)	Year ended June 30, 2018	2017	$ Change	% Change
Research and development:				
Third party costs	$ 44,192	$ 37,249	6,943	19%
Product support costs	16,861	17,122	(261)	(2%)
Intellectual property support costs	3,258	3,208	50	2%
Amortization of current marketed products	1,616	1,335	281	21%
Research and development	**$ 65,927**	**$ 58,914**	**7,013**	**12%**

Third party costs, which consist of all external expenditure on our research and development programs, increased by $6.9 million in the year ended June 30, 2018 compared with the year ended June 30, 2017.

Within this $6.9 million increase, there was a $12.4 million increase in third party costs for the advancement of our Tier 1 products due to clinical advancement during the period for the year ended June 30, 2018 compared with the year ended June 30, 2017. In the year ended June 30, 2018 we incurred costs on our MPC-150-IM (CHF), MPC-06-ID (CLBP), remestemcel-L and MPC-300-IV (inflammatory conditions) Tier 1 products. The increase in Tier 1 third party costs were offset by a $5.5 million decrease in third party costs for our Tier 2 and pipeline products for the year ended June 30, 2018 compared with the year ended June 30, 2017 as we prioritized our funds towards Tier 1 products.

Product support costs, which consist primarily of salaries and related overhead expenses for personnel in research and development functions, have decreased by $0.2 million for the year ended June 30, 2018 compared with the year ended June 30, 2017. In the year ended June 30, 2018, operational streamlining initiatives from the June 2016 strategic review were maintained resulting in full time equivalents reducing by 4.3 (9%) from 48.4 for the year ended June 30, 2017 to 44.1 for the year ended June 30, 2018. This led to cost savings of $0.9 million across salaries and associated costs and $0.1 million in consulting expenses, for the year ended June 30, 2018 compared with the year ended June 30, 2017. The cost savings of $1.0 million in the year ended June 30, 2018 were offset by an increase of $0.8 million in share based payment expenses in the year ended June 30, 2018 compared with the year ended June 30, 2017.

Also included in research and development expenses are intellectual property support costs, which consist of payments to our patent attorneys to progress patent applications and all costs of renewing our granted patents. These costs remained consistent in the year ended June 30, 2018 compared with the year ended June 30, 2017.

Amortization of current marketed products increased by $0.3 million from $1.3 million for the year ended June 30, 2017 to $1.6 million for the year ended June 30, 2018.

Manufacturing commercialization

Manufacturing commercialization expenses, which consist of fees paid to our contract manufacturing organizations and laboratory supplies used in manufacturing commercialization of our MPC and MSC based products, decreased by $6.6 million from the year ended June 30, 2017 compared with the year ended June 30, 2018. The decrease was primarily due to a reduction in the number of production runs completed in the year ended June 30, 2018 compared with the year ended June 30, 2017 due to the clinical supply demands for all ongoing trials being met.

(in U.S. dollars, in thousands)	Year ended June 30, 2018	2017	$ Change	% Change
Manufacturing commercialization:				
MSC platform technology	$ 2,317	$ (285)	2,602	NM
MPC platform technology	745	10,058	(9,313)	(93%)
Manufacturing support costs	2,446	2,292	154	7%
Manufacturing commercialization	**$ 5,508**	**$ 12,065**	**(6,557)**	**(54%)**

The MSC-based manufacturing commercialization expenses increased by $2.6 million in the year ended June 30, 2018 compared with the year ended June 30, 2017 primarily due to a credit of $1.2 million relating to a Goods and Services-Tax (“GST”) received in the year ended June 30, 2017 for MSC-based product expenditure incurred in prior years. There was also an increase of $1.4 million in the year ended June 30, 2018, compared with the year ended June 30, 2017, relating to an increase in process validation activities for MSC-based manufacturing.

The MPC-based manufacturing commercialization expenses decreased by $9.3 million in the year ended June 30, 2018 compared with the year ended June 30, 2017 as there were no production runs required for MPC-based clinical supply in the year ended June 30, 2018, whereas in the year ended June 30, 2017, we incurred costs for materials and completed a number of production runs for our MPC-based products to meet clinical supply.

Manufacturing support costs, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, increased by $0.1 million from $2.3 million for the year ended June 30, 2017 to $2.4 million for the year ended June 30, 2018. In the year ended June 30, 2018, operational streamlining initiatives from the June 2016 strategic review were maintained resulting in full time equivalents decreasing by 0.9 (11%) from 7.9 for the year ended June 30, 2017 to 7.0 for the year ended June 30, 2018 resulting in cost savings of $0.2 million in salaries and associated expenses. The cost savings of $0.2 million in the year ended June 30, 2018 were offset by an increase of $0.1 million in share based payment expenses and an increase of $0.2 million in consultancy fees in the year ended June 30, 2018 compared with the year ended June 30, 2017.

Management and administration

Management and administration expenses were $21.9 million for the year ended June 30, 2018, compared with $23.0 million for the year ended June 30, 2017, a decrease of $1.1 million. This decrease was primarily due to a reduction of corporate overheads and legal and professional fees.

(in U.S. dollars, in thousands)	Year ended June 30, 2018	2017	$ Change	% Change
Management and administration:				
Labor and associated expenses	$ 11,237	$ 10,678	559	5%
Corporate overheads	7,824	8,689	(865)	(10%)
Legal and professional fees	2,846	3,640	(794)	(22%)
Management and administration	**$ 21,907**	**$ 23,007**	**(1,100)**	**(5%)**

Labor and associated expenses increased by $0.6 million from $10.6 million for the year ended June 30, 2017 to $11.2 million for the year ended June 30, 2018. There was an increase in full time equivalents of 0.6 (2%) from 24.9 for the year ended June 30, 2017 to 25.5 for the year ended June 30, 2018, however overall costs of salaries and associated expenses remained consistent in the year ended June 30, 2018 compared with the year ended June 30, 2017. There was an increase of $0.3 million across recruitment and other expenses and an increase of $0.2 million in short term incentives for the year ended June 30, 2018 compared with the year ended June 30, 2017. This increase was offset by a decrease of $0.1 million in consultancy expenses in the year ended June 30, 2018, compared with the year ended June 30, 2017. Labor and associated expenses also experienced unfavorable exchange rate fluctuations of $0.2 million in the year ended June 30, 2018 compared with the year ended June 30, 2017, as the A$ strengthened against the US$ given the majority of management and administration expenses are incurred in A$ by our headquarter office located in Australia.

Corporate overhead expenses decreased by $0.9 million from $8.7 million for the year ended June 30, 2017 to $7.8 million for the year ended June 30, 2018 as operational streamlining from the strategic review in June 2016 enabled us to reduce rent and information technology support services. There was also a reduction in depreciation expenses as a result of certain manufacturing assets being fully depreciated in June 2017.

Legal and professional fees decreased by $0.8 million from $3.6 million for the year ended June 30, 2017 to $2.8 million for the year ended June 30, 2018 as legal activities decreased in the period.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration was a $10.5 million gain for the year ended June 30, 2018 compared with a $0.1 million loss for the year ended June 30, 2017, an increase of $10.6 million. The $10.5 million gain for the year ended June 30, 2018 is due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This gain is a net result of changes to the key assumptions of the contingent consideration valuation such as developmental timelines, product pricing, market penetration, market population and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

The $0.1 million loss for the year ended June 30, 2017 is due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This loss is a net result of changes to the key assumptions of the contingent consideration valuation such as developmental timelines, probability of success, market penetration, market population and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

With respect to future milestone payments, contingent consideration will be payable in cash or shares at our discretion. With respect to commercialization, product royalties will be payable in cash which will be funded from royalties received from net sales.

Other operating income and expenses

Other operating income and expenses were $1.3 million for the year ended June 30, 2018, compared with $1.5 million for the year ended June 30, 2017, a decrease of $0.2 million. The following table shows movements within other operating income and expenses for the years ended June 30, 2018 and 2017, together with the changes in those items:

(in U.S. dollars, in thousands)	Year ended June 30, 2018	2017	$ Change	% Change
Other operating income and expenses:				
Research and development tax incentive income	$ 1,807	$ 1,532	275	18%
Foreign withholding tax	(656)	—	(656)	NM
Foreign exchange gains/(losses) (net)	161	(43)	204	NM
Other operating income and expenses	**$ 1,312**	**$ 1,489**	**(177)**	**(12%)**

Research and development tax incentive income increased by $0.3 million from $1.5 million for the year ended June 30, 2017 to $1.8 million for the year ended June 30, 2018. We have recognized incentive income pertaining to the eligible expenditure undertaken in each of these periods. At each period end, management estimates the refundable tax incentive available to us based on available information at the time. We employ independent tax specialists to review, on an annual basis, the quantum of our previous research and development tax claims and our on-going eligibility to claim the research and development tax incentive in Australia.

Of the $1.8 million research and development tax incentive recorded in other income for the year ended June 30, 2018, $0.1 million of income relates to a change in the original estimate of the research and development tax incentive income that we would receive from the Australian Government for the year ended June 30, 2017.

Within the $1.5 million research and development tax incentive recorded in other income for the year ended June 30, 2017, there is a reversal of $0.1 million of income due to a change in the original estimate of the research and development tax incentive income for the year ended June 30, 2016.

In the year ended June 30, 2018, we recognized $0.7 million of foreign withholding tax expenses primarily related to revenue recognized from our patent license agreement with Takeda entered into in December 2017. There were no foreign withholding tax expenses recognized in the year ended June 30, 2017.

We are subject to foreign exchange gains and losses on foreign currency cash balances, creditors and debtors and for the year ended June 30, 2017 these balances were minimal and therefore only minor foreign exchange losses have been recognized. In the year ended June 30, 2018 we recognized a foreign exchange gain of $0.2 million, primarily due to movements in exchange rates on Euro deposits and receivables held in the Swiss and Singapore entities, respectively, as the US$ appreciated against the Euro.

Finance costs

(in U.S. dollars, in thousands)	Year ended June 30, 2018	2017	$ Change	% Change
Finance costs:				
Interest expense	$ 1,829	—	1,829	NM
Finance costs	**$ 1,829**	**—**	**1,829**	**NM**

In the year ended June 30, 2018, we recognized $1.8 million of interest expenses in relation to our loan and security agreement entered into with Hercules on March 6, 2018. Within this $1.8 million, $1.1 million was recognized in relation to interest expense accrued on the loan balance within the year and a further $0.7 million of interest expense was recognized in relation to the amortization of transaction costs incurred on the outstanding loan principal for the year ended June 30, 2018 using the effective interest rate method over the period of initial recognition through maturity. There was no interest expense recognized in the year ended June 30, 2017.

Loss after income tax

(in U.S. dollars, in thousands)	Year ended June 30, 2018	2017	$ Change	% Change
Loss before income tax	$ (65,977)	$ (90,215)	24,238	(27%)
Income tax benefit/(expense)	30,687	13,400	17,287	129%
Loss after income tax	**$ (35,290)**	**$ (76,815)**	**41,525**	**(54%)**

Loss before income tax was $66.0 million for the year ended June 30, 2018 compared with $90.2 million for the year ended June 30, 2017, a decrease in the loss of $24.2 million. This decrease is the net effect of the changes in revenues and expenses which have been fully discussed above.

A non-cash income tax benefit of $30.7 million was recognized in the year ended June 30, 2018 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period, primarily due to a revaluation of our deferred tax assets and liabilities recognized as a result of changes in tax rates. Deferred taxes are measured at the rate in which they are expected to settle within the respective jurisdictions, which can change based on factors such as new legislation or timing of utilization and reversal of associated assets and liabilities. On December 22, 2017, the United States signed into law the Tax Act, which changed many aspects of U.S. corporate income taxation, including a reduction in the corporate income tax rate from 35% to 21%. We recognized the tax effects of the Tax Act in the year ended June 30, 2018, the most significant of which was a tax benefit resulting from the remeasurement of deferred tax balances to 21%.

A non-cash income tax benefit of $13.4 million was recognized in the year ended June 30, 2017 in relation to the net change in deferred tax assets and liabilities recognized on the balance sheet during the period.

Certain Differences Between IFRS and U.S. GAAP

IFRS differs from U.S. GAAP in certain respects. Management has not assessed the materiality of differences between IFRS and U.S. GAAP. Our significant accounting policies are described in "Item 18 Financial Statements – Note 22".

Quantitative and Qualitative Disclosure about Market Risk

The following sections provide quantitative information on our exposure to interest rate risk, share price risk, and foreign currency exchange risk. We make use of sensitivity analyses which are inherently limited in estimating actual losses in fair value that can occur from changes in market conditions. For further assessment on our market risks, see "Item 18. Financial Statements – Note 10(a)."

Foreign currency exchange risk

We have foreign currency amounts owing primarily in our Australian based entity, whose functional currency is the A$, relating to clinical, regulatory and overhead activities. We also have foreign currency amounts in our Switzerland and Singapore based entities, whose functional currencies are the US$. We also have foreign currency amounts owing in various other non-US$ currencies in A$ and US$ functional currency entities, relating to clinical, regulatory and overhead activities. These foreign currency balances give rise to a currency risk, which is the risk of the exchange rate moving, in either direction, and the impact it may have on our financial performance.

We manage the currency risk by evaluating levels to hold in each currency by assessing our future activities which will likely be incurred in those currencies which enables us to minimize foreign currency deposits held in each entity.

Interest rate risk

Our main interest rate risk arises from the portion of our long-term borrowings with a floating interest rate, which exposes us to cash flow interest rate risk. As interest rates fluctuate, the amount of interest payable on financing where the interest rate is not fixed will also fluctuate. Interest rate risk can be managed by interest rate swaps, which can be entered into to convert the floating interest rate to a fixed interest rate as required. Additionally, we can repay the loan facility at our discretion and we can also refinance if we are able to achieve terms suitable to us in the marketplace or from our existing lenders.

We completed a cost benefit analysis of entering an interest rate swap arrangement in the period. We did not enter into any interest rate swaps during the year ended June 30, 2019.

We are also exposed to interest rate risk that arises through movements in interest income we earn on our deposits. The interest income derived from these balances can fluctuate due to interest rate changes. This interest rate risk is managed by periodically reviewing interest rates available for suitable interest bearing accounts to ensure we earn interest at market rates. We ensure that sufficient funds are available, in at call accounts, to meet our working capital requirements.

Price risk

Price risk is the risk that future cash flows derived from financial instruments will be altered as a result of a market price movement, which is defined as movements other than foreign currency rates and interest rates. We are exposed to price risk which arises from long-term borrowings under our facility with NovaQuest, where the timing and amount of principal and interest payments is dependent on net sales of product candidate remestemcel-L for the treatment of aGVHD in pediatric patients in the United States and other territories excluding Asia. As net sales of remestemcel-L for the treatment of aGVHD in pediatric patients in these territories increase/decrease, the timing and amount of principal and interest payments relating to the financing arrangement will also fluctuate, resulting in an adjustment to the carrying amount of the financial liability. The adjustment is recognized in the Income Statement as remeasurement of borrowing arrangements within other operating income and expenses in the period the revision is made.

We do not consider any exposure to price risk other than those already described above.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with IFRS. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other

factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in our consolidated financial statements included in the annual report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

We adopted IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018, using the modified retrospective approach. Revenue from contracts with customers is measured and recognized in accordance with the five step model prescribed by the standard.

First, contracts with customers within the scope of IFRS 15 are identified. Distinct promises within the contract are identified as performance obligations. The transaction price of the contract is measured based on the amount of consideration we expect to be entitled from the customer in exchange for goods or services. Factors such as requirements around variable consideration, significant financing components, noncash consideration, or amounts payable to customers also determine the transaction price. The transaction is then allocated to separate performance obligations in the contract based on relative standalone selling prices. Revenue is recognized when, or as, performance obligations are satisfied, which is when control of the promised good or service is transferred to the customer.

There was no cumulative impact of the adoption of IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018.

Revenues from contracts with customers comprise commercialization and milestone revenue. We also have revenue from research and development tax incentives and interest revenue.

Commercialization and milestone revenue

Commercialization and milestone revenue generally includes non-refundable up-front license and collaboration fees; milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones; as well as royalties on product sales of licensed products, if and when such product sales occur; and revenue from the supply of products. Payment is generally due on standard terms of 30 to 60 days.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue or deferred consideration in our consolidated balance sheets, depending on the nature of arrangement. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified within non-current liabilities.

Milestone revenue

We apply the five-step method under the standard to measure and recognize milestone revenue.

The receipt of milestone payments is often contingent on meeting certain clinical, regulatory or commercial targets, and is therefore considered variable consideration. We estimate the transaction price of the contingent milestone using the most likely amount method. We include in the transaction price some or all of the amount of the contingent milestone only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the contingent milestone is subsequently resolved. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received. Any changes in the transaction price are allocated to all performance obligations in the contract unless the variable consideration relates only to one or more, but not all, of the performance obligations.

When consideration for milestones is a sale-based or usage-based royalty that arises from licenses of IP (such as cumulative net sales targets), revenue is recognized at the later of when (or as) the subsequent sale or usage occurs, or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Licenses of intellectual property

When licenses of IP are distinct from other goods or services promised in the contract, we recognize the transaction price allocated to the license as revenue upon transfer of control of the license to the customer. We evaluate all other promised goods or services in the license agreement to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct.

The transaction price allocated to the license performance obligation is recognized based on the nature of the license arrangement. The transaction price is recognized over time if the nature of the license is a “right to access” license. This is when we undertake activities that significantly affect the IP to which the customer has rights, the rights granted by the license directly expose the customer to any positive or negative effects of our activities, and those activities do not result in the transfer of a good or service to the customer as those activities occur. When licenses do not meet the criteria to be a right to access license, the license is a “right to use” license, and the transaction price is recognized at the point in time when the customer obtains control over the license.

Sales-based or usage-based royalties

Licenses of IP can include royalties that are based on the customer’s usage of the IP or sale of products that contain the IP. We apply the specific exception to the general requirements of variable consideration and the constraint on variable consideration for sales-based or usage-based royalties promised in a license of IP. The exception requires such revenue to be recognized at the later of when (or as) the subsequent sale or usage occurs and the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

Tasly arrangement

In July 2018, we entered into a strategic alliance with Tasly for the development, manufacture and commercialization in China of our allogeneic MPC products, MPC-150-IM and MPC-25-IC. Tasly received exclusive rights for MPC-150-IM and MPC-25-IC in China and Tasly will fund all development, manufacturing and commercialization activities in China.

We received a $20.0 million up-front technology access fee from Tasly upon closing of this strategic alliance in October 2018. We are also entitled to receive $25.0 million on product regulatory approvals in China, double-digit escalating royalties on net product sales and up to six escalating milestone payments when the product candidates reach certain sales thresholds in China.

Under IFRS 15, upon completion of this strategic alliance on September 14, 2018, we recognized $10.0 million in milestone revenue from the $20.0 million up-front technology access fee received in October 2018 as this is the portion of revenue that control has been transferred to Tasly. We recognized the remaining $10.0 million from the $20.0 million up-front payment as deferred consideration on the consolidated balance sheet. The deferred consideration amount will be recognized in revenue when and if control transfers to Tasly based on our decision regarding the exercise of our rights in the terms and conditions of the agreement.

For the comparative period, being the year ended June 30, 2018, no milestone revenue was recognized in relation to this strategic alliance with Tasly.

TiGenix arrangement

In December 2017, we entered into a patent license agreement with TiGenix, now a wholly owned subsidiary of Takeda, which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived MSC product, Alofisel® a registered trademark of TiGenix, previously known as Cx601, a product candidate of Takeda, for the local treatment of fistulae. The agreement includes the right for Takeda to grant sub-licenses to affiliates and third parties.

As part of the license agreement, we received $5.9 million (€5.0 million) before withholding tax as a non-refundable up-front payment and recognized this amount in revenue in December 2017 upon receipt. In December 2018, we received a milestone payment of $5.9 million (€5.0 million) before withholding tax and recognized this amount in revenue in December 2017 as all performance obligations had been satisfied at that time. We are entitled to further payments up to €10.0 million when Takeda reaches certain product regulatory milestones. Additionally, we receive single digit royalties on net sales of Alofisel®.

No milestone revenue was recognized in relation to the patent license agreement with Takeda in the year ended June 30, 2019.

In the year ended June 30, 2018, we recognized $11.8 million in milestone revenue in relation to our patent license agreement with Takeda. Within this $11.8 million, $5.9 million (€5.0 million) was recognized in relation to the non-refundable up-front payment received upon execution of the Group’s patent license agreement with Takeda in December 2017 and $5.9 million (€5.0 million) was recognized in December 2017 in relation to further payments received in December 2018 for product Alofisel® as all performance obligations had been satisfied at that time. These amounts were recorded in revenue as there were no further performance obligations required in regards to these milestones.

JCR arrangement

In October 2013, we acquired all of Osiris' culture-expanded, MSC-based assets. These assets included assumption of a collaboration agreement with JCR, a research and development oriented pharmaceutical company in Japan. Revenue recognized under this model is limited to the amount of cash received or for which we are entitled, as JCR has the right to terminate the agreement at any time.

Under the JCR Agreement, JCR is responsible for all development and manufacturing costs including sales and marketing expenses. Under the JCR Agreement we assumed from Osiris, JCR has the right to develop our MSCs in two fields for the Japanese market: exclusive in conjunction with the treatment of hematological malignancies by the use of hematopoietic stem cells derived from peripheral blood, cord blood or bone marrow, or the First JCR Field; and non-exclusive for developing assays that use liver cells for non-clinical drug screening and evaluation, or the Second JCR Field. With respect to the First JCR Field, we are entitled to payments when JCR reaches certain commercial milestones and to escalating double-digit royalties. These royalties are subject to possible renegotiation downward in the event of competition from non-infringing products in Japan. With respect to the Second JCR Field, we are entitled to a double digit profit share. In the past 12 months, we have expanded our partnership with JCR in Japan for two new indications: for wound healing in patients with Epidermolysis Bullosa ("EB") in October 2018, and for hypoxic ischemic encephalopathy ("HIE"), a condition suffered by newborns who lack sufficient blood supply and oxygen to the brain, in June 2019. We will receive royalties on TEMCELL product sales for EB and HIE, if and when such indications receive marketing approval in Japan. We apply the sales-based and usage-based royalty exception for licenses of intellectual property and therefore recognize royalty revenue at the later of when the subsequent sale or usage occurs and the associated performance obligation has been satisfied.

In the year ended June 30, 2019, we recognized $5.0 million, in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan by our licensee JCR, compared with $3.6 million for the year ended June 30, 2018. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

In the year ended June 30, 2019, we recognized $1.0 million in milestone revenue upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan, compared with $1.5 million in the year ended June 30, 2018. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

Government grant income

Revenue from government grants is recognized in the consolidated income statement on a systematic basis over the periods in which the entity recognizes as expense the related costs for which the grants are intended to compensate in accordance with IAS 20 *Accounting for Government Grants and Disclosure of Government Assistance.*

The Australian government allows a refundable tax offset to eligible companies with an annual aggregate turnover of less than A$20.0 million. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending at the rate of 43.5% for periods from July 1, 2016. All other eligible entities may obtain a non-refundable tax offset equal to 38.5% of their eligible research and development expenditure. We have assessed our research and development activities and expenditure to determine which of these expenses are likely to be eligible under the incentive scheme. At each period end, we estimate and recognize the refundable tax offset available to us based on available information at the time.

The receivable for reimbursable amounts that have not been collected is reflected in trade and other receivables on our consolidated balance sheets.

The combined worldwide turnover of the Mesoblast Group is in excess of A$20.0 million for the year ended June 30, 2019 making us ineligible for the refundable tax offset for the research and development tax incentive. Consequently, no income was recognized from the Research and Development Tax Incentive program for the year ended June 30, 2019, compared with $1.8 million that was recognized for the year ended June 30, 2018. We recorded a $0.1 million loss in research and development tax incentive income for the year ended June 30, 2019 which relates to a change in the original estimate of the research and development tax incentive income that we would receive from the Australian Government for the year ended June 30, 2018.

Goodwill

We have recognized goodwill as a result of two separate acquisitions. Goodwill of $118.4 million was recognized on acquisition of Angioblast Systems Inc. in 2010, $13.9 million was recognized on the acquisition of the MSC assets from Osiris ("MSC business combination") in 2013 and $2.1 million was recognized on finalization of the MSC business combination of Osiris in 2015. In all cases the goodwill recognized represented excess in the purchase price over the net identifiable assets and in-process research and development acquired in the transaction. We have a single operating unit and all goodwill has been allocated to that unit.

The goodwill resulting from these acquisitions is tested for impairment in accordance with IAS 36 *Impairment of Assets* which requires testing be performed at any time during an annual period, provided the test is performed at the same time every year. During the year ended June 30, 2019, we elected to change the annual impairment testing date from the fourth quarter to the third quarter of each year to align with industry best practice. A full assessment was performed at March 31, 2019 and no impairment of goodwill was identified. Additionally, assets must be tested for impairment if there is an indication that an asset may be impaired. The recoverable amounts of our assets and cash-generating units have been determined based on fair value less costs to sell calculations, which require the use of certain assumptions. See Note 6 of our consolidated financial statements and the related note thereto included in our 20-F for more information regarding the assumptions used in determining the fair value less costs to sell.

In-process research and development

IFRS requires that acquired in-process research and development be measured at fair value and carried as an indefinite life intangible asset subject to impairment reviews. We have recognized in-process research and development as a result of two separate acquisitions. In-process research and development of $387.0 million was recognized on the acquisition of Angioblast Systems Inc. in 2010 and $126.7 million was recognized on the acquisition of assets from Osiris in 2013 and $24.0 million was reclassified to current marketed products upon the TEMCELL asset becoming available for use in Japan. In 2016, we fully impaired $61.9 million of in-process research and development relating to our product candidates, MPC-MICRO-IO for the treatment of age-related macular degeneration and MPC-CBE for the expansion of hematopoietic stem cells within cord blood, as we suspended further patient enrollment of the Phase IIa MPC-MICRO-IO clinical trial and the Phase III MPC-CBE clinical trial as we prioritized the funding of our Tier 1 product candidates. The remaining carrying amount of in-process research and development as at June 30, 2019 and June 30, 2018 was $427.8 million. We still believe these product candidates remain viable upon further funding, or partnership, and accordingly these products should not be regarded as abandoned, where typically, abandoned programs would be closed down and the related research and development efforts are considered impaired and the asset is fully expensed.

All in-process research and development recognized on our balance sheet is a result of a business acquisition and is considered to be an indefinite life intangible asset on the basis that it is incomplete and cannot be used in its current form. Indefinite life intangible assets are not amortized but rather are tested for impairment annually in accordance with IAS 36 *Impairment of Assets* which requires testing annually, or whenever there is an indication that an asset may be impaired. During the year ended June 30, 2019, we elected to change the annual impairment testing date from the fourth quarter to the third quarter of each year to align with industry best practice. A full assessment was performed at March 31, 2019 and no impairment of the in-process research and development was identified. There was no impairment charge recognized during the years ended June 30, 2019 and 2018.

In-process research and development will continue to be tested for impairment until the related research and development efforts are either completed or abandoned. At the time of completion, when the asset becomes available for use, all costs recognized in in-process research and development that related to the completed asset are transferred to the intangible asset category, current marketed products, at the asset's historical cost.

Current marketed products

Current marketed products contain products that are currently being marketed. The assets are recognized on our balance sheet as a result of business acquisitions or reclassifications from in-process research and development upon completion. Upon completion, when assets become available for use, assets are reclassified from in-process research and development to current marketed products at the historical value that they were recognized at within the in-process research and development category.

Upon reclassification to the current marketed products category, management determines the remaining useful life of the intangible assets and amortizes them from the date they become available for use. In order for management to determine the remaining useful life of the asset, management would consider the expected flow of future economic benefits to the entity with reference to the product life cycle, competitive landscape, obsolescence, market demand, any remaining patent useful life and any other relevant factors.

Management has chosen to amortize all intangible assets with a finite useful life on a straight-line basis over the useful life of the asset. Current marketed products are tested for impairment in accordance with IAS 36 *Impairment of Assets* which requires testing whenever there is an indication that an asset may be impaired.

In February 2016, we reclassified $24.0 million from in-process research and development to current marketed products upon the TEMCELL asset becoming available for use in Japan.

Impairment of assets

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

We impair assets in accordance with IAS 36 *Impairment of Assets.* IAS 36 outlines that an impairment loss must be recognized if an asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and its value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). The recoverable amounts of our assets and cash-generating units have been determined based on fair value less costs to sell calculations, which require the use of certain assumptions. See Note 6(b)(v) of our consolidated financial statements and the related note thereto included in our annual report for more information regarding the assumptions used in determining the fair value less costs to sell.

Management maintains internal valuations of each asset annually (or more frequently should indicators of impairment be identified) and valuations from independent experts are requested periodically, within every three year period. The internal valuations are continually reviewed by management and consideration is given as to whether there are indicators of impairment which would warrant impairment testing. An external valuation of our assets was carried out by an independent expert as at June 30, 2017 with the recoverable amount of each asset exceeding its carrying amount.

The recoverable amount of our cash generating unit, including goodwill and in-process research and development, exceeded the carrying amounts in the annual impairment testing completed in March 31, 2019 and, therefore, no impairment charges were recorded.

Investments and other financial assets

We invest our cash in term deposits and other similar low risk products. We classify investments as either a cash equivalent or a short-term investment in accordance with IAS 7 *Statement of Cash Flows*. For a deposit to be classified as a cash equivalent it should be held for the purpose of meeting short-term cash commitments rather than for investment or other purposes and IAS 7 outlines that:

- it must be readily convertible to a known amount of cash (qualifies when it has a short maturity, of say, 3 months or less from the date of acquisition); and
- it must be subject to insignificant risk of change of value.

We review the terms and conditions of each deposit to determine if it is a cash equivalent in accordance with IAS 7.

Deposits with maturity dates between 3 months and 12 months are classified as short term investments. The carrying amount of short-term investments approximates fair value due to the short maturities of these instruments, and there are no unrealized gains or losses associated with these instruments. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset and liability.

As at June 30, 2019 and June 30, 2018, we did not hold any deposits with maturity dates between 3 months and 12 months and therefore we did not hold any deposits classified as short term investments.

Fair Value Measurements

For financial instruments that are measured on the balance sheet at fair value, IFRS 7 *Financial Instruments: Disclosures* requires disclosure of the fair value measurements by level of the following fair value measurement hierarchy:

- Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, trading and financial assets at fair value through other comprehensive income securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by us is the current bid price. These instruments are included in level 1.
- Level 2: The fair value of financial instruments that are not traded in an active market (for example, foreign exchange contracts) is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.
- Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for provisions (contingent consideration) and equity securities (unlisted).

Our level 3 asset consists of an investment in unlisted equity securities in the biotechnology sector. Level 3 assets were 100% of total assets measured at fair value as at June 30, 2019 and June 30, 2018.

Our level 3 liabilities consist of a contingent consideration provision related to the acquisition of Osiris' MSC business. Level 3 liabilities were 100% of total liabilities measured at fair value as at June 30, 2019 and June 30, 2018. There were no transfers between any of the levels for recurring fair value measurements during the year.

The following table summarizes the assumptions, techniques, and significant unobservable inputs used in level 3 fair value measurements:

(in U.S. dollars, in thousands, except percent data)	Fair value as of June 30,				Range of inputs (weighted average) Year Ended June 30,		
Description	2019	2018	Valuation technique	Unobservable inputs[1]	2019	2018	Relationship of unobservable inputs to fair value
Contingent consideration provision	47,534	42,070	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Year ended June 30, 2019: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%. Year ended June 30, 2018: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%.
				Expected unit revenues	n/a	n/a	Year ended June 30, 2019: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%. Year ended June 30, 2018: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%.
				Expected sales volumes	n/a	n/a	Year ended June 30, 2019: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%. Year ended June 30, 2018: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%.

(1) There were no significant inter-relationships between unobservable inputs that materially affect fair values.

Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Fees paid on the establishment of loan facilities are recognized as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. In this case, the fee is deferred until the draw down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalized as a prepayment for liquidity services and amortized over the period of the facility to which it relates.

Borrowings are removed from the balance sheet when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred of liabilities assumed, is recognized as remeasurement of borrowing arrangements within other operating income and expenses.

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

Net deferred tax assets

We record deferred tax assets if, based upon the available evidence, it is more likely than not that we will recognize some or all of the deferred tax assets. Deferred tax assets were recognized for unused tax losses based on the scheduling of reversals of deferred tax liabilities and to the extent that it is probable that future taxable profit will be available against which the unused tax losses can be utilized. We have recorded deferred tax assets that relate to operating tax losses and deductible temporary differences to offset taxable temporary differences (deferred tax liabilities) following our conclusion in the year ended June 30, 2016 to retain existing intellectual property assets in their relative jurisdictions as we are no longer planning to consolidate intellectual property assets. There have been no significant developments on this conclusion during the year ended June 30, 2019.

Accrued research and development and manufacturing commercialization expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

Examples of estimated accrued expenses include fees paid to:

- CROs in connection with clinical studies;
- investigative sites in connection with clinical studies;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, process development and distribution of clinical supplies.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones.

In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. To date, there have been no material differences from our estimates to the amount actually incurred.

Australian Disclosure Requirements

Significant Changes in the State of Affairs

There have been no significant changes within the state of our affairs during the year ended June 30, 2019 except as noted in the “Important Corporate Developments” section included in Item 4.A.

Likely Developments and Expected Results of Operations

Our continued progress in clinical development brings our leading products closer to approval and commercial reality. In May 2019, we filed the first component of a rolling submission for a BLA to the U.S. Food and Drug Administration (“FDA”) for remestemcel-L in the treatment of children with aGVHD, a life-threatening complication of an allogeneic bone marrow transplant.

The FDA has agreed to a rolling review of the BLA which enables individual components to be submitted and reviewed on an ongoing basis rather than waiting for all sections to be completed. The rolling process will provide opportunity for ongoing communication, and during this process we expect to be able to adequately address any substantial matters raised by the FDA.

Other significant milestones are expected in the upcoming financial year in relation to our other Tier 1 product candidates, as detailed elsewhere in this report.

Environmental Regulations

Our operations are not subject to any significant environmental regulations under either Commonwealth of Australia or State/Territory legislation. We consider that adequate systems are in place to manage our obligations and are not aware of any breach of environmental requirements pertaining to us.

5.B Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses from operations since our inception in 2004 and as of June 30, 2019, we had an accumulated deficit of $470.0 million. We had cash and cash equivalents of $50.4 million as of June 30, 2019 and incurred net cash outflows from operations of $57.8 million for the year ended June 30, 2019.

We have an overarching strategy to fund operations predominately through non-dilutive strategic and commercial transactions. In line with this strategy in 2018, we entered into a strategic partnership with Tasly and into loan and security agreements with Hercules and NovaQuest. Under the agreements with Hercules and NovaQuest, we have up to an additional US$35.0 million available subject to achievement of certain milestones.

We will also consider equity-based financing to fund operational requirements. Mesoblast have entered into a Subscription Commitment Letter with its largest institutional shareholder, M&G Investment Management, for US$15.0 million in Mesoblast ordinary shares, exercisable by the Company on or before 31 December 2019, subject to customary diligence and with pricing to be agreed at the time Mesoblast gives notice. In addition, in July 2019 we extended the fully discretionary equity facility with Kentgrove Capital from which we can raise capital of up to A$120.0 million (approximately US$82.0 million) over the next 24 months, the quantum and timing of capital raised will be subject to the market price and trading volumes of our ordinary shares during the period and our obligations under ASX Listing Rule 7.1.

There is uncertainty related to our ability to to raise funds through entering strategic and commercial transactions, equity-based or debt-based financings to meet our requirements. The continuing viability of us and our ability to continue as a going concern and meet our debts and commitments as they fall due are dependent upon non-dilutive funding in the form of strategic and commercial transactions, equity-based or debt-based financing to fund future operations.

Management and the directors believe that we will be successful in the above matters and, accordingly, have prepared the financial report on a going concern basis, notwithstanding that there is a material uncertainty that may cast significant doubt on our ability to continue as a going concern and that we may be unable to realize our assets and liabilities in the normal course of business.

References to matters that may cast significant doubt about our ability to continue as a going concern also raise substantial doubt as contemplated by the Public Company Accounting Oversight Board standards. For our audited financial statements, see “Item 18 Financial Statements” included in our Form 20-F.

Audit Report

Our auditor has included an “emphasis of matter” paragraph in the audit report relating to our ability to continue as a going concern (refer Note 1(i)).

Cash flows

(in thousands)	Year ended June 30, 2019	2018	2017
Cash Flow Data:			
Net cash (outflows) in operating activities	(57,790)	(75,012)	(95,471)
Net cash (outflows)/ inflows in investing activities	(1,000)	(1,153)	142
Net cash inflows in financing activities	71,608	68,613	60,005
Net increase/(decrease) in cash and cash equivalents	**12,818**	**(7,552)**	**(35,324)**

Comparison of cash flows for the Year ended June 30, 2019 with the Year ended June 30, 2018

Net cash outflows in operating activities

Net cash outflows for operating activities were $57.8 million for the year ended June 30, 2019, compared with $75.0 million for the year ended June 30, 2018, a decrease of $17.2 million. The decrease of $17.2 million is due to an increase in cash inflows of $22.6 million offset by an increase in cash outflows of $5.4 million in the year ended June 30, 2019 compared with the year ended June 30, 2018.

The $22.6 million increase in inflows comprised: inflows from milestone payments received increased by $20.0 million in relation to the up-front technology access fee received upon closing of the strategic alliance with Tasly in October 2018; inflows from royalty income earned on sales of TEMCELL in Japan increased by $1.3 million during the year ended June 30, 2019 compared with the year ended June 30, 2018; receipts for the research and development tax incentive increased by $1.7 million in the year ended June 30, 2019 compared with the year ended June 30, 2018; inflows from interest receipts increased by $0.3 million as our cash reserves have increased in year ended June 30, 2019 when compared with the year ended June 30, 2018; these increases in inflows were offset by a $0.5 million decrease from cumulative net sales milestone payments received on TEMCELL in Japan during the year ended June 30, 2019, compared with the year ended June 30, 2018; and reduced receipts by $0.2 million in relation to payments received on our patent license agreement with Takeda in the year ended June 30, 2019 when compared with June 30, 2018.

Outflows for payments to suppliers and employees and interest and other costs of finance paid increased by $5.4 million from $85.5 million for the year ended June 30, 2018 to $90.9 million for the year ended June 30, 2019 primarily due to an increase in payments in relation to manufacturing commercialization costs as we complete process validation activities required for the BLA filing of remestemcel-L and an increase in interest expenses in the year ended June 30, 2019, compared with the year ended June 30, 2018.

Net cash inflows in investing activities

Net cash outflows for investing activities decreased by $0.2 million from $1.2 million for the year ended June 30, 2018 to $1.0 million for the year ended June 30, 2019 primarily due to a $0.2 million decrease in outflows for payments for contingent consideration in the year ended June 30, 2019 compared with the year ended June 30, 2018.

Net cash inflows in financing activities

Net cash inflows for financing activities were $71.6 million for the year ended June 30, 2019, compared with $68.6 million for the year ended June 30, 2018, an increase of $3.0 million. The net cash inflows in the year ended June 30, 2019 include a $28.9 million receipt of net proceeds drawn pursuant to a non-dilutive, eight-year credit facility with NovaQuest, a $14.6 million receipt of net proceeds from drawing a further tranche of funding from our existing credit facility with Hercules, a $10.0 million receipt of gross proceeds from a share placement with NovaQuest in July 2018 and a $20.0 million receipt of gross proceeds from a share placement with Tasly in October 2018. In the year ended June 30, 2018, we received a $40.4 million receipt of gross proceeds from an institutional and retail entitlement offer to eligible existing shareholders in September 2017 and a $31.7 million receipt of net proceeds drawn at closing in March 2018 from a non-dilutive, four-year credit facility with Hercules. We also received $0.3 million in receipts from employee share option exercises during the year ended June 30, 2019, compared to $0.1 million for the year ended June 30, 2018. Additionally, there was $0.6 million of payments for associated capital raising costs and $1.6 million of payments for other associated borrowings cost in the year ended June 30, 2019, compared with $3.2 million of share issue costs and $0.4 million on payments for borrowings costs in the year ended June 30, 2018, a net decrease in outflows for capital raising and borrowing costs of $1.4 million.

Comparison of cash flows for the Year ended June 30, 2018 with the Year ended June 30, 2017

Net cash outflows in operating activities

Net cash outflows for operating activities were $75.0 million for the year ended June 30, 2018, compared with $95.5 million for the year ended June 30, 2017, a decrease of $20.5 million. The decrease of $20.5 million is due to a decrease in cash outflows of $15.1 million and an increase in cash inflows of $5.4 million in the year ended June 30, 2018 compared with the year ended June 30, 2017.

Outflows decreased by $15.1 million due to a reduction in payments to suppliers and employees primarily in relation to a decrease in manufacturing commercialization costs in the year ended June 30, 2018, compared with the year ended June 30, 2017, as the clinical supply demands for all ongoing trials have been met and a reduction in payments in relation to research and development primarily on MPC-150-IM (CHF) and Tier 2 products in the year ended June 30, 2018, compared with the year ended June 30, 2017.

The $5.4 million increase of inflows comprised: inflows from milestone revenue increased by $5.6 million in relation to the non-refundable up-front payment received upon execution of our patent license agreement with Takeda in December 2017; inflows from milestone payments received on achievement of cumulative net sales milestones for TEMCELL in Japan increased by $1.0 million during the year ended June 30, 2018, compared with the year ended June 30, 2017; inflows from royalty income earned on sales of TEMCELL in Japan increased by $1.7 million during the year ended June 30, 2018, compared with the year ended June 30, 2017; these increases in inflows were offset by a $2.8 million decrease in receipts for the research and development tax incentive during the year ended June 30, 2018, compared with the year ended June 30, 2017 due to a $1.6 million receipt being delayed until July 2018 that would have otherwise been receipted in the year ended June 30, 2018; and reduced interest receipts by $0.1 million as our cash reserves have decreased in year ended June 30, 2018 when compared with the year ended June 30, 2017.

Net cash inflows in investing activities

Net cash outflows for investing activities were $1.2 million for the year ended June 30, 2018, compared with net cash inflows for investing activities of $0.1 million for the year ended June 30, 2017, an increase of $1.3 million. The increase of $1.3 million is due to an increase in cash outflows of $0.9 million and a decrease in cash inflows of $0.4 million.

The $0.9 million increase in outflows comprised: a $1.0 million increase in outflows for payments for contingent consideration in the year ended June 30, 2018, compared with $Nil for the year ended June 30, 2017; this increase in outflows was offset by a reduction of $0.1 million in payments for fixed assets, such as plant and equipment, in the year ended June 30, 2018 when compared with the year ended June 30, 2017.

The inflows decreased by $0.4 million due to proceeds from rental deposits of $0.4 million which were returned to us in the year ended June 30, 2017 on completion of part of the sublease agreement of our New York office space.

Net cash inflows in financing activities

Net cash inflows for financing activities were $68.6 million for the year ended June 30, 2018, compared with $60.0 million for the year ended June 30, 2017, an increase of $8.6 million. The net cash inflows in the year ended June 30, 2018 include a $40.4 million receipt of gross proceeds from an institutional and retail entitlement offer to eligible existing shareholders in September 2017 and a $31.7 million receipt of net proceeds drawn at closing in March 2018 from a non-dilutive, four-year credit facility with Hercules. In the year ended June 30, 2017, we received gross proceeds of $21.7 million from Mallinckrodt Pharmaceuticals on January 6, 2017, in a private placement, and a $40.1 million receipt of gross proceeds from an institutional private placement on March 31, 2017. We also received $0.1 million in receipts from employee share option exercises during the years ended June 30, 2018 and 2017. Additionally, there was $3.2 million of payments for associated capital raising costs in the year ended June 30, 2018, compared with $1.9 million of share issue costs in the year ended June 30, 2017 and $0.4 million of payments for other associated borrowings costs in the year ended June 30, 2018, an increase in outflows of $1.7 million.

Operating Capital Requirements

To date, revenues have not been significant. We do not know when, or if, we will generate revenues from our product sales significant enough to generate profits. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize more of our cell-based product candidates. We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our cell-based product candidates, and begin to commercialize any approved products either directly ourselves or through a collaborator or partner. We are subject to all of the risks inherent in the development of new cell-based products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect to incur additional costs associated with operating as a U.S. public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We expect that our research and development expenses will decrease in the short term (12 to 24 months) as we complete our phase 3 trials or if we are able to successfully partner one or more of our product candidates. We expect management and administration expenses to remain relatively consistent. Subject to us achieving successful regulatory approval we expect an increase in our total expenses driven by an increase in our product manufacturing and selling, general and administrative expenses as we move towards commercialization. Therefore, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our ordinary shares. If we incur further indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Borrowings

Hercules

On March 6, 2018, we entered into a loan and security agreement with Hercules, for a $75.0 million non-dilutive, four-year credit facility. We drew the first tranche of $35.0 million on closing and a further tranche of $15.0 million was drawn in January 2019, which resulted in an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument's original effective interest rate. In the year ended June 30, 2019, we recognized a $0.4 million gain in the Income Statement as remeasurement of borrowing arrangements within finance costs.

An additional $25.0 million may be drawn as certain conditions and milestones are met. The loan matures in March 2022 with principal repayments commencing in October 2019 with the ability to defer the commencement of principal repayments to October 2020 if certain milestones are met. Interest on the loan is payable monthly in arrears on the 1st day of the month. At closing date, the interest rate was 9.45% per annum. On March 22, 2018, June 14, 2018, September 27, 2018 and December 20, 2018, in line with the increases in the U.S. prime rate, the interest rate on the loan increased to 9.70%, 9.95%, 10.20% and 10.45%, respectively.

NovaQuest

On June 29, 2018, we drew the first tranche of $30.0 million of the principal amount from the $40.0 million loan and security agreement with NovaQuest. There is a four-year interest only period, until July 2022, with the principal repayable in equal quarterly instalments over the remaining period of the loan. A $0.4 million loan administration fee is payable annually in June and is recognized as a current liability. The loan matures in July 2026. Interest on the loan will accrue at a fixed rate of 15% per annum.

All interest and principal payments will be deferred until after the first commercial sale of our allogeneic product candidate remestemcel-L in pediatric aGVHD. We can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of pediatric aGVHD are significantly higher than current forecasts.

If there are no net sales of pediatric aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of pediatric aGVHD exceed the amount of accrued interest owing and, from 2022, principal and accrued interest owing ("the payment cap"), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of pediatric aGVHD is less than the payment cap, then the payment is limited to 25% of net sales of pediatric aGVHD. Any unpaid interest will be added to the principal amounts owing and shall accrue further interest. At maturity date, any unpaid loan balances are repaid.

Because of this relationship of net sales and repayments, changes in our estimated net sales may trigger an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument's original effective interest rate. The adjustment is recognized in the Income Statement as remeasurement of borrowing arrangements within other operating income and expenses in the period the revision is made.

In the year ended June 30, 2019, $0.7 million have been recognized as adjustment to the carrying amount of the financial liability compared with $Nil in the year ended June 30, 2018.

Compliance with loan covenants

Our loan facilities with Hercules and NovaQuest contain a number of covenants that impose operating restrictions on us, which may restrict our ability to respond to changes in our business or take specified actions. In addition, under our loan and security agreement with Hercules, we are obliged to maintain certain levels of cash in the United States and a minimum unrestricted cash balance across the Group.

The Group has complied with the financial and other restrictive covenants of its borrowing facilities during the year ended June 30, 2019.

5.C Research and Development, Patents and Licenses

For a description of the amount spent during each of the last three fiscal years on company-sponsored research and development activities, as well as the components of research and development expenses, see "Item 5.A Operating Results – Results of Operations."

For a description of our research and development process, see "Item 4.B Business Overview."

5.D Trend Information

As a biotechnology company which primarily is still in the development stage, we are subject to costs of our clinical trials and other work necessary to support applications for regulatory approval of our product candidates. Health regulators have increased their focus on product safety. In addition, regulators have also increased their attention on whether or not a new product offers evidence of substantial treatment effect. These developments have led to requests for more clinical trial data, for the inclusion of a higher number of patients in clinical trials, and for more detailed analyses of the trials. In light of these developments, we expect these aspects of our research and development expenses may need to increase as we continue to fund our programs to the market. Notwithstanding this upward trend, our research and development expenses may still fluctuate from period to period due to varied rates of patient enrollment and the timing of our clinical trials as our existing trials are completed and new trials commence. We cannot predict with any degree of accuracy the outcome of our research or commercialization efforts.

5.E Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, other than operating leases as mentioned below, as defined under SEC rules.

5.F Contractual Obligations and Commitments

Borrowing commitments:

As of June 30, 2019, the maturity profile of the anticipated future contractual cash flows including interest in relation to our borrowings, on an undiscounted basis and which, therefore differs from the carrying value, is as follows:

(in U.S. dollars, in thousands)	Within 1 year	Between 1-2 years	Between 2-5 years	Over 5 years	Total contractual cash flows	Carrying amount
Borrowings[1][2]	(18,845)	(29,790)	(57,634)	(34,728)	(140,997)	(81,286)
	(18,845)	**(29,790)**	**(57,634)**	**(34,728)**	**(140,997)**	**(81,286)**

(1) Contractual cash flows include payments of principal, interest and other charges. Interest is calculated based on debt held at June 30, 2019 without taking into account drawdowns of further tranches.

(2) In relation to the contractual maturities of the NovaQuest borrowings, there is variability in the maturity profile of the anticipated future contractual cash flows given the timing and amount of payments are calculated based on our estimated net sales of pediatric aGVHD**.**

Lease commitment – as lessee:

We lease various offices under non-cancellable operating leases. The leases have varying terms, escalation clauses and renewal rights. On renewal, the terms of the leases are renegotiated. As of June 30, 2019, our lease commitments are as follows:

(in thousands)	Total	Within one year	Later than one year but no later than three years	Later than three years but no later than five years	Later than five years
Operating leases	7,460	2,100	2,763	1,341	1,256
Total commitments	7,460	2,100	2,763	1,341	1,256

Lease commitments include amounts in A$ and Singapore dollars which have been translated to US$ as of June 30, 2019 using foreign exchange rates published by the Reserve Bank of Australia.

In addition to the obligations in the table above, as of June 30, 2019 we also had the following significant contractual obligations described below.

Contingent liabilities

We acquired certain intellectual property relating to our MPCs, or Medvet IP, pursuant to an Intellectual Property Assignment Deed, or IP Deed, with Medvet Science Pty Ltd, or Medvet. Medvet's rights under the IP Deed were transferred to Central Adelaide Local Health Network Incorporated, or CALHNI, in November 2011. In connection with our use of the Medvet IP, on completion of certain milestones we will be obligated to pay CALHNI, as successor in interest to Medvet, (i) certain aggregated milestone payments of up to $2.2 million and single-digit royalties on net sales of products covered by the Medvet IP, for cardiac muscle and blood vessel applications and bone and cartilage regeneration and repair applications, subject to minimum annual royalties beginning in the first year of commercial sale of those products and (ii) single-digit royalties on net sales of the specified products for applications outside the specified fields.

We have entered into a number of agreements with other third parties pertaining to intellectual property. Contingent liabilities may arise in the future if certain events or developments occur in relation to these agreements and as of June 30, 2019 we have assessed these contingent liabilities to be remote.

Capital commitments

We did not have any commitments for future capital expenditure outstanding as of June 30, 2019.

Item 6. Directors, Senior Management and Employees

(Start of the Remuneration Report for **Australian Disclosure Requirements**)

Our board of directors ("the Board") presents the 2018/2019 Remuneration Report, which has been prepared in accordance with the relevant *Corporations Act 2001* ("Corporations Act") and accounting standard requirements. The remuneration report has been audited as required by s308 (3C) of the Corporations Act. The remuneration report sets out remuneration information for our company's key management personnel ("KMP") for the financial year ended June 30, 2019.

6.A Key Management Personnel

Key management personnel, as defined in the International Accounting Standards 24 'Related Party Disclosures' and the Australian *Corporations Act 2001*, have authority and responsibility for planning, directing and controlling the activities of our company, directly or indirectly, and include any director (whether executive or otherwise). With this definition in mind, the Board has determined that in addition to themselves and Silviu Itescu (CEO), Josh Muntner (CFO) is to be designated as key management personnel from July 1, 2018 onwards.

Our key management personnel are listed in table below:

Name	Position	Change from last year
Non-executive directors		
Joseph Swedish	Chair, Board of Directors Member, Audit and Risk Committee	Promoted to Chair – April 1, 2019 Appointed – January 19, 2019
William Burns	Vice Chair, Board of Directors Member, Nomination and Remuneration Committee	No change Appointed – January 19, 2019
Donal O'Dwyer	Non-executive Director Chair, Nomination and Remuneration Committee Member, Audit and Risk Committee	No change No change No change
Michael Spooner	Non-executive Director Chair, Audit and Risk Committee Member, Nomination and Remuneration Committee	No change No change No change
Eric Rose	Non-executive Director	No change
Shawn Cline Tomasello(1)	Non-executive Director	Appointed – July 11, 2018
Brian Jamieson	Chair, Board of Directors	Resigned – March 31, 2019
Executive director		
Silviu Itescu	Chief Executive Officer Executive Director	No change No change
Other executive KMP		
Josh Muntner(2)	Chief Financial Officer	Appointed – May 28, 2018

Notes

1. Shawn Cline Tomasello was appointed to the board as a Non-executive Director on July 11, 2018 and is considered key management personnel from the appointment date.
2. Josh Muntner was appointed as Chief Financial Officer with an effective date of May 28, 2018 and is considered key management personnel from July 1, 2018 onwards.

Details of Directors and Senior Management

Board of Directors

Joseph Swedish, MHA

Appointed as Chairman of the Board of Directors on April 1, 2019.

Experience and expertise

Joseph. R. Swedish has more than two decades of healthcare leadership experience as the CEO for major United States healthcare enterprises. He has served as Executive Chairman, President and CEO of Anthem, Inc. from 2013 to 2018, and he is currently a Senior Adviser to Anthem, Inc., America's leading health benefits provider. Prior to joining Anthem, Inc., Mr Swedish was CEO for several major integrated healthcare delivery systems, including Trinity Health and Centura Health. Currently, he sits on the Board of Directors of IBM Corporation, CDW Corporation, Proteus Digital Health and Centrexion Therapeutics. Mr Swedish is past Chairman of Duke University's Fuqua School of Business Board of Visitors and is a current member. Previously, he was Chairman of the Catholic Health Association and America's Health Insurance Plans (AHIP). Mr Swedish received a bachelor's degree from the University of North Carolina at Charlotte and his master's degree in health administration from Duke University. His extensive experience as a leader in the US healthcare sector, particularly in resource allocation and reimbursement metrics, provides industry, leadership and management experience as Mesoblast transitions to a commercial stage company.

Other current directorships of listed public companies
Non-Executive Director, IBM Corporation (since 2017)
Non-Executive Director, CDW Corporation (since 2015)

Former directorships of listed public companies within the last 3 years
Executive Chairman, Anthem, Inc. (2013 - 2018)

William Burns, BA

Non-Executive Member of the Board of Directors

Experience and expertise

Mr. Burns has served on our board of directors since 2014 and was appointed Vice Chairman in 2016. He spent his entire management career at the Beecham Group and F. Hoffmann-La Roche Ltd. He was Chief Executive Officer of Roche Pharmaceuticals from 2001 to 2009, when he joined the board of directors of F. Hoffmann-La Roche Ltd. until he retired in 2014. He is the Chair of Molecular Partners, and has been a Non-Executive Director of Shire PLC, Chugai Pharmaceutical Co., Genentech, Crucell, and Chairman of Biotie Therapies Corp. from 2014 until its sale to Acorda Therapeutics Inc. in 2016. Mr Burns is also a member of the Oncology Advisory Board of the Universities of Cologne/Bonn in Germany. In 2014, he was appointed a trustee of the Institute of Cancer Research, London, and in 2016 a Governor of The Wellcome Trust in London, UK. His extensive experience in the pharmaceutical industry, specifically as a member of the board of directors of other pharmaceutical companies, provides pharmaceutical, healthcare, industry, leadership and management expertise.

Other current directorships of listed public companies
Chair of Molecular Partners (since 2018)

Former directorships of listed public companies within the last 3 years
Chairman, Biotie Therapies Corp. (2014 – 2016)
Non-executive Director, Shire (UK) (2010 – 2018)

Donal O'Dwyer, BE, MBA

Non-Executive Member of the Board of Directors

Experience and expertise

Mr. O'Dwyer has served on our board of directors since 2004. He has over 25 years of experience as a senior executive in the global cardiovascular and medical devices industries. From 1996 to 2003, Mr. O'Dwyer worked for Cordis Cardiology, the cardiology division of Johnson & Johnson's Cordis Corporation, initially as its president (Europe) and from 2000 as its worldwide president. Prior to joining Cordis, Mr. O'Dwyer worked with Baxter Healthcare, rising from plant manager in Ireland to president of the Cardiovascular Group, Europe, now Edwards Lifesciences. Mr. O'Dwyer is a qualified civil engineer with an MBA. He is on the

board of directors of a number of life sciences companies including Cochlear Limited, Fisher & Paykel Healthcare Ltd and NIB Holdings Ltd. He was on the board of directors of CardieX Ltd (formerly called Atcor Medical Holdings Ltd) for over 14 years resigning in February 2019. With his experience as a senior executive and a director, as well as his extensive experience in the cardiovascular and medical devices industries, Mr. O'Dwyer provides business, science, engineering and management expertise.

Other current directorships of listed public companies
Non-executive Director, Cochlear Ltd (since 2005)
Non-executive Director, Fisher & Paykel Healthcare (since 2013)
Non-executive Director, NIB Holdings Ltd (since 2016)

Former directorships of listed public companies within the last 3 years
Non-executive Director, CardieX Ltd (formerly called Atcor Medical Holdings Ltd) (since 2004 – 2019)

Michael Spooner, BCom, ACA, MAICD

Non-Executive Member of the Board of Directors

Experience and expertise

Mr. Spooner has served on our board of directors since 2004. During this period he has filled various roles including as Executive Chairman from the date of our Australian IPO in 2004 until 2007. Over the past several years, Mr. Spooner has served on the board of directors in various capacities at several Australian and international biotechnology companies, including BiVacor Pty Ltd (2009-2013), Advanced Surgical Design & Manufacture Limited (2010-2011), Peplin, Inc. (2004-2009), Hawaii Biotech, Inc. (2010-2012), Hunter Immunology Limited (2007-2008), and Ventracor Limited (2001-2003). He is the chairman of Simavita Limited since May 2016 and Chairman of MicrofuidX since February 2018. Prior to returning to Australia in 2001, Mr. Spooner spent much of his career internationally where he served in various roles including as a partner to PA Consulting Group, a UK-based management consultancy and a Principal Partner and Director of Consulting Services with PricewaterhouseCoopers (Coopers & Lybrand) in Hong Kong. In addition Mr. Spooner has owned and operated several international companies providing services and has consulted to a number of U.S. and Asian public companies. Mr. Spooner provides executive management, commercial, business strategy and accounting expertise as well as established relationships with investment firms and business communities worldwide.

Other current directorships of listed public companies
Chairman, Simavita Ltd (since 2016)

Former directorships of listed public companies within the last 3 years
None

Eric Rose, MD

Non-Executive Member of the Board of Directors

Experience and expertise

Dr. Rose has served on our board of directors since 2013. He is currently Executive Chairman of SIGA Technologies. From 2008 through 2012, Dr. Rose served as the Edmond A. Guggenheim Professor and Chairman of the Department of Health Evidence and Policy at the Mount Sinai School of Medicine. From 1994 through 2007, Dr. Rose served as Chairman of the Department of Surgery and Surgeon-in-Chief of the Columbia Presbyterian Center of New York Presbyterian Hospital. From 1982 through 1992, he led the Columbia Presbyterian heart transplantation program in the United States. Dr. Rose currently sits on the board of directors of ABIOMED. His experience as a surgeon, researcher and businessman provides medical, pharmaceutical, scientific and industry expertise.

Other current directorships of listed public companies
Executive Chairman, SIGA Technologies, Inc. (since 2007)
Non-executive Director, ABIOMED, Inc. (2007 – 2012, 2014 – present)

Former directorships of listed public companies within the last 3 years
None

Shawn Cline Tomasello, BS, MBA

Appointed to the Board as a Non-Executive Director on July 11, 2018.

Experience and expertise

With more than 30 years' experience in the pharmaceutical and biotech industries, Shawn Cline Tomasello has substantial commercial and transactional experience. Since 2015, Ms Tomasello has been Chief Commercial Officer at leading immuno-oncology cell therapy company Kite Pharma, where she played a pivotal role in the company's acquisition in 2017 by Gilead Sciences for $11.9 billion. Prior to this she served as Chief Commercial Officer at Pharmacyclics, Inc., which was acquired in 2015 by AbbVie, Inc. for $21 billion. Ms Tomasello previously was President of the Americas, Hematology and Oncology at Celgene Corporation where she managed over $4 billion in product revenues, and was instrumental in various global expansion and acquisition strategies. She has also held senior positions at Genentech, Pfizer Laboratories, Miles Pharmaceuticals and Procter & Gamble. Ms Tomasello currently serves on the Board of Directors of Centrexion Therapeutics, Corp., Oxford Bio Therapeutics, Ltd., Diplomat Pharmacy, Inc., Gamida Cell, Ltd. and UroGen Pharma, Ltd. She previously served on the Board of Clementia Pharmaceuticals, Inc. which was acquired by Ipsen, SA. as well as Geneos Therapeutics, Inc. She received a MBA from Murray State University and a B.S. in Marketing from the University of Cincinnati. Her extensive experience in the pharmaceutical and biotech industries, particularly in the commercial and transactional fields, provides industry, leadership and management expertise.

Other current directorships of listed public companies
Non-Executive Director, Diplomat Pharmacy, Inc. (since 2015)
Director, Gamida Cell, Ltd. (since 2019)
Director, UroGen Pharma, Ltd. (since 2019)

Former directorships of listed public companies within the last 3 years
Director, Clementia Pharmaceuticals, Inc. which was acquired by Ipsen, SA. (2018 – 2019)

Brian Jamieson, FCA

Non-executive Chairman of the Board of Directors - Resigned March 31, 2019

Experience and expertise

Mr. Jamieson has served on our board of directors as Chairman since 2007 after retiring as Chief Executive of Minter Ellison Melbourne. Previously he was Chief Executive Officer at KPMG Australia, a KPMG Board Member in Australia, and a member of the USA Management Committee. Mr. Jamieson is Chairman of Sigma Healthcare Limited and a Non-Executive Director of Highfield Resources Ltd, and Director and Treasurer of the Bionics Institute. He is a Fellow of the Institute of Chartered Accountants in Australia and a Fellow of the Australian Institute of Company Directors.

Other current directorships of listed public companies
Chairman, Sigma Healthcare Ltd (since 2005)
Non-executive Director, Highfield Resources Ltd (since 2018)

Former directorships of listed public companies within the last 3 years
Non-executive Director, Tatts Group Ltd (2005 – 2017)

Charlie Harrison, BA, LLB (Hons)

Company Secretary

Experience and expertise

Mr Harrison joined Mesoblast as a legal counsel in 2013. He was previously a senior associate at the international law firm Allens, working in their Hong Kong and Melbourne offices for nine years as a corporate lawyer. Mr Harrison has an Arts/Law degree from the University of Melbourne. He was appointed Company Secretary in 2014.

Other current directorships of listed public companies
None

Former directorships of listed public companies within the last 3 years
None

Senior Management

Silviu Itescu, MBBS (Hons), FRACP, FACP, FACRA

Chief Executive Officer

Executive Member of the Board of Directors

Experience and expertise

Dr. Itescu is our Chief Executive Officer ("CEO"). He has served our board of directors since our founding in 2004, was Executive Director from 2007 to 2011, and became CEO and Managing Director in 2011. Prior to founding Mesoblast in 2004, Dr. Itescu established an international reputation as a physician scientist in the fields of stem cell biology, autoimmune diseases, organ transplantation, and heart failure. He has been a faculty member of Columbia University in New York, and of Melbourne and Monash universities in Australia. In 2011, Dr. Itescu was named BioSpectrum Asia Person of the Year. In 2013, he received the inaugural Key Innovator Award from the Vatican's Pontifical Council for Culture for his leadership in translational science and clinical medicine in relation to adult stem cell therapy. Dr. Itescu has consulted for various international pharmaceutical companies, has been an adviser to biotechnology and health care investor groups, and has served on the board of directors of several publicly listed life sciences companies.

Other current directorships of listed public companies
None

Former directorships of listed public companies within the last 3 years
None

Josh Muntner, BFA, MBA

Chief Financial Officer

Mr Muntner has accrued 20 years' experience in healthcare investment banking and corporate finance, and has been involved in a wide range of healthcare-related transactions with approximately $11.0 billion in value. Most recently, he led corporate development and financial transactions at Nasdaq-listed biotechnology company, ContraFect Corporation. Previously, Mr Muntner served as Managing Director and Co-Head of Healthcare Investment Banking at Janney Montgomery Scott, and spent nine years at Oppenheimer & Co. and its U.S. predecessor, CIBC World Markets. He also served as an investment banker at Prudential Securities. Mr Muntner has a BFA from Carnegie Mellon and a MBA from the Anderson School at UCLA.

Peter Howard, BSc, LLB (Hons)

General Counsel

Mr. Howard has served as our General Counsel and Corporate Executive since July 2011. As external counsel and partner at Australian law firm, Middletons (now, K&L Gates), Mr. Howard has been integrally involved with Mesoblast since its inception and public listing on the ASX in 2004. More generally, Mr. Howard has extensive experience with many biopharmaceutical firms and major research institutions, covering public listings, private financings, strategic, licensing, intellectual property and mergers and acquisition activities. He has done so in several roles, including as a partner at a major law firm, entrepreneur, director and senior executive.

Paul Simmons, PhD

Head of Research and New Product Development

Dr. Simmons has served as our Head of Research and New Product Development since 2011. He has nearly 30 years of experience in stem cell research, especially research in basic hematopoiesis and in precursor cells for the stromal system of the bone marrow, and served as President of the International Society of Stem Cell Research, or ISSCR, from 2006 to 2007. Prior to joining Mesoblast, Dr. Simmons held the C. Harold and Lorine G. Wallace Distinguished University Chair at the University of Texas Health from 2008 to 2011 and served as the inaugural Professor and Director of the Centre for Stem Cell Research at the Brown Foundation Institute of Molecular Medicine from 2006 to 2011. Dr. Simmons is, or has served as, an associate editor, a member of the editorial board, or a reviewer on multiple scientific and medical journals including Experimental Hematology, Cytotherapy and Stem Cell Research, Cell Stem Cell, Stem Reports, Science and Nature.

John McMannis, PhD

Head of Manufacturing

Dr. McMannis has served as our Head of Manufacturing since 2011. He has 27 years of experience in clinical cellular therapy trials in both academic and commercial environments. Before joining Mesoblast, Dr. McMannis served at the University of Texas MD Anderson Cancer Center as a Professor of Medicine from 1999 to 2011, and as the Director of the Cell Therapy Laboratory from 1999 to 2011, and as the Technical Director of the Cord Blood Bank from 2008 to 2011. Before his tenure at the University of Texas MD Anderson Cancer Center, Dr. McMannis was a Senior Director Technical Affairs at the Immunotherapy Division of Baxter and Therapy Scientist at COBE BCT (now Terumo BCT). Dr. McMannis has served on the scientific advisory boards at BioSafe SA, Biolife Solutions, Inc., and General Electric and on the board of directors for the American Association of Blood Banks, or AABB, and the National Marrow Donor Program, or NMDP, which operates the “Be the Match” donor program.

Geraldine Storton, BSc, MMS, MBA

Head of Regulatory Affairs and Quality Management

Ms. Storton is a seasoned pharmaceutical executive with more than 24 years’ experience across the full value chain of Pharmaceutical and Medical Device Research and Development, production and commercialization worldwide. She has an extensive background in regulatory affairs and quality, most recently as a consultant to cell therapy companies. Prior to this, Ms. Storton held executive roles at Hospira, and its predecessor companies in both regulatory affairs and quality, with a focus on major program management. As Vice President, Program Management, Quality, at Hospira headquarters in Chicago, she led a company-wide quality remediation program to improve compliance in manufacturing across 15 facilities worldwide. As Regional Director, Commercial Quality ANZ, Asia and Japan, Ms. Storton was responsible for quality oversight and management of all products sold in Asia Pacific countries. Her responsibilities included regulatory compliance, batch release, field actions, complaints management, change control, due diligence and new product launch. As director of global regulatory operations, Ms. Storton managed development and registration of new products and on-market management of the existing product portfolio for all Hospira’s products developed or manufactured within Asia Pacific for global distribution. She joined Mesoblast in December 2015.

Michael Schuster, MBA

Pharma Partnering

Mr. Schuster, who joined Mesoblast in 2004, leads the Group's partnering discussions. Previously he was the head of the Group's investor relations outreach program and was part of the founding executive team at both Mesoblast Limited and Angioblast Systems, Inc. Mr. Schuster was Executive Vice President of Global Therapeutic Programs from 2010 to 2013 and was the Director of Business Development and Vice President of Operations from 2004 to 2010. He holds an undergraduate degree in science from Tufts University, a Master’s degree in Immunology & Microbiology from New York Medical College, and an MBA from Fordham University in New York.

Eric Strati Pharm.D., MBA

Pharma Partnering

Eric Strati has over 17 years of experience across a broad range of industries within the healthcare sector including pharmaceutical, biotechnology, investment banking, and pharmacy benefit management. Prior to joining Mesoblast in 2015, Dr Strati held various commercial leadership roles including new product planning, lifecycle management, sales, marketing, and payer strategy. Previous positions include most recently as Executive Director, Managed Markets at Novartis, medical affairs positions at Genzyme and Bristol-Myers Squibb, and Vice President of Global Pharmaceutical Equity Research at HSBC. He earned his Bachelors of Science in Pharmacy and MBA in Health Systems Management from Union University, and Doctor of Pharmacy from University of Kansas.

Fred Grossman D.O. FAPA

Chief Medical Officer – Appointed August 19, 2019

Dr. Grossman joined Mesoblast in August 2019 and leads the Medical Affairs, Drug Safety Clinical Operations and Biostatistics teams. Dr Grossmann is a Board-Certified psychiatrist and Fellow of the American Psychiatric Association with over 30 years of experience in research, academia, and practice. He has held executive positions leading and building clinical development, medical affairs, and pharmacovigilance in large and small pharmaceutical companies including Eli Lilly, Johnson & Johnson, Bristol Myers Squibb, Sunovion, Glenmark, and NeuroRx. Dr. Grossman has developed and supported the launch of numerous blockbuster

medications addressing significant unmet medical needs across multiple therapeutic areas including CNS, immunology, immuno-oncolology, respiratory, cardiovascular/metabolics, and virology. He has close relationships with thought leaders worldwide and has negotiated directly with the FDA and Global Health Authorities for approval of many drugs across therapeutic areas. He has numerous publications and presentations and has held several academic appointments.

Donna Skerrett, MD

Chief Medical Officer – Resigned effective date August 19, 2019, at which point she was appointed as an adviser for our Graft Versus Host Disease program.

Dr Skerrett has more than 20 years of combined experience in transfusion medicine, cellular therapy, and transplantation. She was Director of Transfusion Medicine and Cellular Therapy at Weill Cornell Medical Center in New York from 2004 to 2011, and previously served as Associate Director of Transfusion Medicine and Director of Stem Cell Facilities at Columbia University's New York-Presbyterian Hospital. From 2004, she held various roles at Mesoblast in clinical and regulatory affairs and was Chief Medical Officer from 2011 to 2019.

There are no family relationships among any of our directors and senior management. The business address of each of our directors and senior management is Mesoblast Limited, Level 38, 55 Collins Street, Melbourne, VIC 3000, Australia.

Directors' Interests

The relevant interest of each director, as defined by section 608 of the Corporations Act, in the share capital of Mesoblast, as notified by the directors to the ASX in accordance with section 205G(1) of the Corporations Act, at the date of this report is as follows:

Director	Mesoblast Limited ordinary shares	Options over Mesoblast Limited Ordinary Shares
Silviu Itescu	68,958,928	—
Josh Muntner	—	300,000
William Burns	30,330	200,000
Donal O'Dwyer	1,149,142	100,000
Eric Rose	—	200,000
Michael Spooner	1,069,000	100,000
Joseph Swedish(1)	—	500,000
Shawn Cline Tomasello	—	200,000

(1) 300,000 of the options granted in connection with Mr Swedish's appointment as Chairman of Mesoblast and are subject to shareholder approval which will be sought at the upcoming AGM.

Meeting of Directors

The number of meetings our board of directors (including committee meetings of directors) held during the year ended June 30, 2019 and the number of meetings attended by each director were:

	Board of Directors		Audit and Risk Committee		Nomination and Remuneration Committee	
Director	A	B	A	B	A	B
Joseph Swedish	10	9	2	1	—	—
William Burns	10	10	—	—	2	1
Silviu Itescu	10	10	—	—	—	—
Brian Jamieson	8	8	3	3	5	4
Donal O'Dwyer	10	10	4	4	5	5
Eric Rose	10	10	—	—	—	—
Shawn Tomasello	10	9	—	—	—	—
Michael Spooner	10	10	4	4	5	5

A = Number of meetings held during the time the director held office or was a member of the committee.

B = Number of meetings attended by board/committee members

— = Not a member of the relevant committee

NB: Certain directors attended various committee meetings by invitation in addition to those shown above.

6.B Compensation

Executive summary

Mesoblast is a multinational company operating at the forefront of a highly specialized industry in which our people are key to developing our proprietary adult stem cell technologies. The Company's remuneration strategy is designed to ensure that we can attract experienced leaders and emerging experts in an innovative field and on a global basis, including within the United States where 61% of our employees are based, including many of our technical experts. Given the Company's relatively small employee base of 83 employees and the lengthy and technical process involved in developing and commercializing biopharmaceutical products, it is also important that our remuneration framework is successful in retaining and appropriately incentivizing our executive and employee base. At the same time, the Company's remuneration framework is aimed to meet the expectations of our global shareholder base and align their interests with those of our Company and our people.

As detailed in this report, our remuneration structure is driven by the setting and achievement of key, well-defined milestones that are critical to progressing our technology, with the ultimate goal being to bring our product candidates to market in order to improve patient outcomes and enhance value for our global shareholder base.

The structure and quantum of remuneration remains largely consistent with the previous period, comprising fixed remuneration (TFR), short-term incentives (STI) and equity-based long-term incentives (LTI), with a few notable exceptions discussed below. The Nomination & Remuneration Committee and Board continue to review the remuneration framework on an annual basis to ensure it continues to support Mesoblast's strategy and the delivery of long-term value creation for our shareholders.

For the STI component of the CEO's remuneration earned in 2018/2019, the Board intends to pay 50% of this amount in time based options – subject to the shareholders approving the option grant at our next AGM. STI awards were paid entirely in cash in prior years.

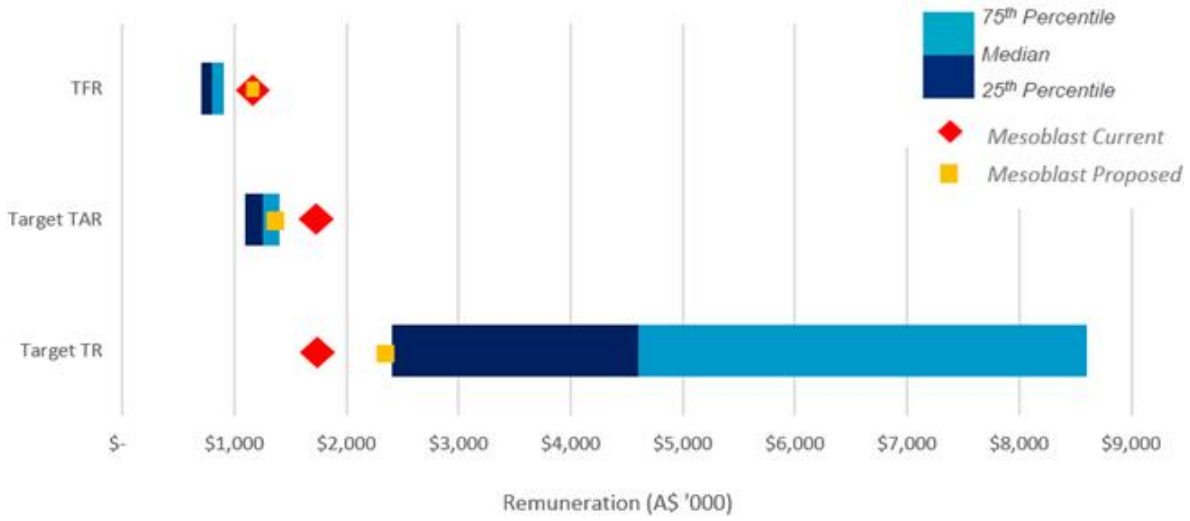
Remuneration changes for FY20

For the 2019/20 financial year, the CEO's total remuneration will change from 50% fixed and 50% STI with no LTI, to 40% fixed, 20% STI and 40% LTI. The LTI component will be in the form of options over ordinary shares in our Company. It is planned that the options be divided into three equal tranches and vest on the achievement of pre-specified milestones, as well as minimum holding periods from grant.

This approach has been determined as a part of a broader review of our CEO's remuneration framework which was completed during the reporting year by a leading international consulting firm Mercer that specializes in remuneration matters. Their benchmarking analysis compared our CEO's remuneration package to his peer group in our industry. The peer group was selected after considering many factors including market capitalization, quantum of revenue and business characteristics such as "pre-revenue" status, R&D expense, maturity of the company, the lifecycle of the company's primary drug and the geographic operations. The comparator peer group primarily comprised of CEOs of other biotechnology companies which had a comparable market capitalization and were based in the US, given this is where the majority of Mesoblast's employees and operations are based, and given that these are the types of companies with which Mesoblast primarily competes with for talent.

As illustrated on the chart reporting the results of the benchmarking analysis below, our CEO's Target Total Remuneration (Target TR) is low compared to his peer group. More specifically, while TFR and STI were positioned above the 75th percentile, due to the lack of LTIs offered to our CEO, our CEO's total remuneration (TR) was positioned below the 25th percentile of the peer group.

The Board recognises that some stakeholders would prefer that executive remuneration be compared exclusively to that of other ASX-listed companies, however the reality for our business is that the success of our Company is predicated on the ability for us to attract, motivate, and retain the calibre of people that can achieve the research and development, and commercialization goals that will drive successful outcomes for shareholders. The Board therefore chooses to benchmark its executive remuneration against the peers with which it directly competes for talent, in line with the benchmarking approach taken for all other roles in the organisation.



- *Total Fixed Remuneration (TFR): Base salary + guaranteed cash allowances + superannuation + other monetary benefits for Mesoblast and base salary for peer companies (as is common in US companies)*
- *Target Total Annual Remuneration (Target TAR): TFR + actual short-term incentives*
- *Target Total Remuneration (Target TR): Equal to Target TAR for Mesoblast (given no LTI) and Target TAR + long-term incentives for peer companies*
- *Based on the benchmarking analysis the board made the decision to change the remuneration package of our CEO the resulting remuneration package is illustrated on the chart above as 'Mesoblast Proposed'.*

Upon reviewing the benchmarking analysis the board made the decision to change the remuneration package of our CEO to better align his remuneration package with his peers. These changes result in the CEO's new remuneration package moving below the 75th percentile of the peer group on a cash basis and remaining below the 25th percentile of the peer group on a total remuneration basis.

This approach also aligns the CEO's remuneration structure with those of other key executives of the Company. As previously reported, we have introduced milestone-based vesting of certain option grants for executives, as a further tool to align the executives' priorities to those of the Company. As a further refinement to this scheme any future milestone based options that are issued will have the additional minimum holding periods.

The Board believes the changes set out above will assist to further incentivize in the medium-term while continuing to facilitate long-term retention for key management. In addition, the Company has provided greater transparency in relation to the specific KPIs, which form the basis of the Company's STI and LTI payouts (see "Overview of performance and remuneration outcomes for the year ended June 30, 2019" below). We believe our remuneration framework remains fair and balanced, provides the appropriate incentives for the executives to deliver on achieving the key milestones that will ultimately drive long-term shareholder returns and meet the needs and expectations of our shareholders, employees and other stakeholders.

Responses to feedback received in relation to FY18 remuneration report

The Board received varied feedback across our stakeholder group in connection with the FY18 remuneration. While our responses to this feedback are reflected throughout this report, we have also summarized some of the key items within the below table. The Board welcomes feedback, and continually reviews its approach to remuneration.

The ‘feedback received’ column by no means represents the views of our entire shareholder group.

Feedback received – FY18 AGM	Mesoblast response
The CEO’s fixed remuneration is higher than that of ASX-listed companies with similar market capitalizations to Mesoblast	This is recognized, however, as described above, the Board benchmarks remuneration at Mesoblast relative to similar sized companies with which Mesoblast competes for talent. This group is comprised predominately of US-based companies, and it is noted that the CEO’s total target remuneration is below the 25th percentile of this group. No increases to the CEO’s fixed remuneration have been made since July 2015.
A portion of the CEO’s STI should be deferred	For the STI component of the CEO’s remuneration earned in 2018/2019, the Board intends to pay 50% of this amount in time based options – subject to the shareholders approving the option grant at our next AGM. Following the benchmarking exercise described above, the CEO’s STI opportunity will be reduced by 50% in FY20.
The CEO does not participate in the LTI	From FY20, the CEO’s remuneration mix will change substantially. STI opportunity will be reduced by 50%, and LTI participation will commence. The CEO’s total target remuneration remains below the 25th percentile of our peer group.
There is minimal disclosure regarding LTI performance measures	While zero options vested to the CEO or CFO during FY19, in order to provide greater transparency to shareholders, we have reported milestone achievements which have triggered either partial or full vesting of LTI performance objectives for options held by non-KMPs (see “LTI Remuneration outcomes during the year ended June 30, 2019” below).
NEDs should not receive option grants	The Board considers that the grant of options to non-executive directors can be an important component of providing competitive benefits, in particular for the non-executive directors in the international biotechnology sector. For that reason, the Company's non-executive directors were issued options in the 2018/19 financial year, as part of the Board renewal process which saw Mr Swedish and Ms Tomasello appointed to the Board and the retirement of Mr Jamieson. That said, there is no intention to make options an annual or regular part of NED remuneration.

	Fixed remuneration	
Name	FY19 %	FY20 %
Fixed remuneration	50%	40%
STI opportunity	50%	20%
LTI opportunity	0%	40%

Overview of performance and remuneration outcomes for the year ended June 30, 2019

Remuneration outcomes for the year ended June 30, 2019

When assessing company performance in light of remuneration, traditional financial metrics, such as profitability, total shareholder return (TSR), short-term share price movements, and earnings per share (EPS) are not meaningful, nor can they be effectively used to accurately reflect the performance of our company. Our long term value creation occurs through progressive achievement of well-defined milestones that are critical for achieving product approval and commercialization, in a timely fashion and within budget (see Remuneration Strategy and Framework for further detail on our framework). Annually the Board prioritizes the key Company milestones for the coming year. These milestones form the CEO’s KPIs, the overall priorities for the Company and establish the basis for all STI payments. At the end of the financial year, the Board assesses the overall Company performance, and the CEO’s individual performance against these KPIs. The achievement of these KPIs is assessed in the context of total corporate performance against budget which ensures cost control is always a key part of the performance framework and is regularly measured and reported.

STI Remuneration outcomes for the year ended June 30, 2019

The Board assesses overall company performance when determining the STI payout. For the year ended June 30, 2019 the Board, utilizing all information available to it on specific achievements, has assessed the overall company's performance at 80% of target for the year ended June 30, 2019 as outlined in the table below:

Assessment of Performance for year ended 2019

Key Objective Category	Key Achievement	Weighting	Rating	Assessed Performance
Execute on Major Clinical Programs				
Graft vs Host Disease (GvHD)	•Phase 3 trial – reported successful day 180 survival outcomes	30%	90%	27%
Chronic Heart Failure (CHF)	•Phase 2 trial in LVAD patients – reported clinically meaningful results •Phase 3 trial in CHF – completed enrolment and final patient dosed •Memorandum of understanding signed with inCHOIR to conduct a confirmatory trial in GI bleeding in LVAD patients •FDA granted Revascor Orphan Drug status for end stage CHF for LVAD patients			
Chronic Lower Back Pain (CLBP)	•Phase 3 trial – 12 month follow up visits completed			
Execute on Financing and Partnering Strategy				
Financing	•Additional US$15 million in non-dilutive capital from Hercules credit facility after successful readout of Phase 2 trial in LVAD patients	25%	65%	16%
Partnering	•Expansion of partnership with JCR for both skin disease and brain disease in newborns in Japan •Cardiovascular partnership established with Tasly Pharmaceutical Group for China in July 2018 as reported in the assessment of company performance last year. In the current year the partnership was further developed including through the establishment of a joint steering committee.			
Manufacturing				
	•Significant advances achieved in process validation activities required ahead of the BLA filing for MSC-100-IV for the treatment of aGVHD	20%	95%	19%
Commercialization				
	•FDA agreed to a rolling review of BLA submission •Initiated rolling submission of BLA •Key appointments made within the commercial team	15%	60%	9%
Organization Structure and Development				
	•Key appointments made to provide the required capabilities to deliver on financing and commercialization plans as the organization readies for the potential commercial launch of our first product: – Appointment of Joseph R. Swedish as Chairman – Appointment of Josh Muntner (CFO) as KMP – Appointment of Eric Strati, PhD as Senior Vice President, Commercial – Appointment of Fred Grossman, D.O. FAPA as Chief Medical Officer	10%	90%	9%
		100%	NA	80%

LTI Remuneration outcomes during the year ended June 30, 2019

Neither the CEO or CFO had any LTI awards vest during FY19.

Whilst no milestone options vested to KMP in FY19, the following table reports LTI outcomes for milestone options held by senior management (non-KMP employees). The milestone targets are determined in a manner relevant to each individual's role, and refer to specific outcomes and time targets within the categories and strategic objectives set out below. It should be noted that the achievement of a milestone may not necessarily result in the full vesting of an option tranche, with the Board holding ultimate discretion in determining the final remuneration outcome, based on the nature of the achievement (including whether the milestone was achieved in line with time and cost targets).

Assessment of LTI performance

Category	Strategic Objectives	Weighting	Outcome
Corporate strategy	Execute on partnering and licensing strategy based on completion of corporate deals across major clinical programs	38%	Partially Met
Clinical & regulatory	Execute on specified milestones within major clinical programs including completion of recruitment within trials and regulatory progress.	29%	Partially Met
Manufacturing	Completion of specified manufacturing activities and process development outcomes	22%	Partially Met
Finance	Execution of funding activities and implementation of financial reporting and compliance requirements (including Sarbanes-Oxley Act requirements)	6%	Met
Other product development	Development of second generation technologies	5%	Partially Met

In assessing these performance objectives, the Remuneration and Nomination Committee and the Board considered the following achievements over the performance period (other confidential, commercially sensitive matters were taken into account):

Corporate strategy

- Execution of an agreement with Tasly for cardiovascular rights for China, with entitlement to US$40 million on closing, US$25 million on product regulatory approvals, double digit escalating royalties and six escalating milestone payments on achievement of sales thresholds.
- Execution of a global license with TiGenix for the local treatment of fistulae, with entitlement to receive up to €20 million in upfront and milestones payments and single digit royalties on net sales.
- Execution of license extensions with JCR for use of TEMCELL in the treatment of brain disease in newborns and in the treatment of skin disease.

Clinical & regulatory

- Completion of recruitment in Phase 3 CHF trial.
- Completion of recruitment in Phase 3 GVHD trial.
- Successfully achieved the primary endpoint, and day 100 and day 180 survival outcomes, in the Phase 3 GVHD trial.
- Completion of recruitment in Phase 3 CLBP trial.
- Initiated a rolling submission of BLA with the FDA for GvHD.
- Receipt of RMAT designation for product candidate for the treatment of LVAD heart failure patients.

Manufacturing and Other product development

- All achievements pertained to commercially sensitive milestones.

Finance

- Completion of successful funding activities within the performance period.
- Successfully implemented and maintained compliance with the Sarbanes-Oxley Act for control over financial reporting.

Executive KMP remuneration received in FY19

The table below represents remuneration paid to each executive KMP during the year.

Fixed remuneration and cash bonus (STI) relates to amounts received during the year and share based option payments and vested LTI represent equity from prior years.

2019		Short-term benefits					Post-employment benefits	Long-term benefits			
Name	Currency	Salary & fees $	Cash Bonus (1) $	Annual Leave/ Holiday Pay $	Non-monetary benefits $	Health and Other Benefits (3) $	Super-annuation $	Long service leave $	Share-based payments Options $	Other Termi-nation benefits $	Total $
Silviu Itescu (CEO)	A$	1,010,000	808,000	71,867	—	—	20,531	16,880	—	—	1,927,278
Josh Muntner (CFO)	A$	534,042	213,617	23,952	—	39,726	—	—	81,076	—	892,413
Total executive KMP	**A$**	**1,544,042**	**1,021,617**	**95,819**	**—**	**39,726**	**20,531**	**16,880**	**81,076**	**—**	**2,819,691**
Total executive KMP(2)	**US$**	**1,104,453**	**730,762**	**68,539**	**—**	**28,416**	**14,686**	**12,074**	**57,994**	**—**	**2,016,924**

(1) STI bonus payable for performance in the year ended June 30, 2019, not paid as at June 30, 2019. For our CEO the Board intends to pay 50% of this amount in time based options – subject to the shareholders approving the option grant at our next AGM.

(2) The US$ results has been determined by calculating the average rate of the exchange rates on the last trading day of each month during the period, at a rate of 0.7153 for the year ended June 30, 2019.

(3) Health and other benefits for Josh Muntner includes health, dental, vision, life, long and short term disability insurances.

2018		Short-term benefits					Post-employment benefits	Long-term benefits			
Name	Currency	Salary & fees $	Cash Bonus(1) $	Annual Leave(3) $	Non-monetary benefits $	Other $	Super-annuation $	Long service leave(3) $	Share-based payments Options(4) $	Other Termi-nation benefits $	Total $
Silviu Itescu (CEO)	A$	1,010,000	909,000	77,694	—	—	20,049	16,880	—	—	2,033,623
Paul Hodgkinson (CFO)	A$	389,583	—	(17,399)	—	—	20,049	(9,605)	(92,281)	—	290,347
Total executive KMP	**A$**	**1,399,583**	**909,000**	**60,295**	—	—	**40,098**	**7,275**	**(92,281)**	—	**2,323,970**
Total executive KMP(2)	**US$**	**1,086,637**	**705,748**	**46,813**	**—**	**—**	**31,132**	**5,648**	**(71,647)**	**—**	**1,804,330**

(1) STI bonus payable for performance in the year ended June 30, 2018, not paid as at June 30, 2018.

(2) The US$ results has been translated at the average weighted exchange rate of 0.7764 for the year ended June 30, 2018.

(3) Annual leave compensation for Paul Hodgkinson presents as negative compensation because on his resignation on May 31, 2018, annual leave provision balance as at June 30, 2017 were reversed and recognized in annual leave compensation. On Paul Hodgkinson's resignation on May 31, 2018, long service leave provision balances as at this date were reversed and recognized in long service leave compensation.

(4) On Paul Hodgkinson's resignation, in accordance with the plan rules, non-vested options were forfeited which has reversed previously recognized share based payment compensation.

Remuneration Strategy and Framework

Executive Remuneration – Framework

Mesoblast's executive remuneration framework is designed to attract, reward and retain a highly specialized group of individuals working at the top of their respective fields in varied geographic locations. Key elements of the Mesoblast remuneration framework are as follows:

Remuneration Framework Summary

		Performance-based Remuneration	
	Fixed Pay	**Short-term Incentives**	**Long-term Incentives**
Strategic Rationale	Assessed on market relativities based on roles and accountabilities.	The performance conditions which attach to the STI are based on key corporate / budgetary milestones and the achievement of strategic goals which are designed to generate long-term value creation in the interests of shareholders. Refer to '*Short-Term Incentives (STIs) Program'* within the 'Remuneration Strategy and Framework' section.	This incentive drives the achievement of objectives relevant to each executive's role, strengthening the link between the incentive rewards and the generation of shareholder returns. Refer to '*Long-Term Incentives (LTIs) Program'* within the 'Remuneration Strategy and Framework' section.
Description	Set according to each role's accountabilities, the incumbent's experience and qualifications, their performance in the role and regional market relativities.	Set at a target relative to fixed pay and paid for performance against annual corporate and individual key performance indicators (KPIs). Executive KPIs are typically milestone related as befitting a pre-revenue company.	Set at a target relative to fixed pay based on value at the time of grant with consideration to internal relativities. Delivers value to the participant through share price growth. Under the Employee Share Option Plan, LTI grants are either time based or milestone based depending on the employee's role.
Considerations	Supplemented by statutory and customary benefits relevant to each region (e.g., superannuation in Australia; medical insurance in the US.)	STIs are typically set at a smaller proportion of our total target remuneration than LTIs to conserve cash outflow.	The Board exercises discretion to adjust LTI grants from the target remuneration mix as needed. For instance, if a decline in share price would produce an incongruous LTI quantum (i.e., number of options).
Review	Reviewed annually for changes in market relativities and the individual's performance and growth in the role.	Annual outcomes are assessed by the CEO (for his direct reports) and the Board (for the CEO) based on performance against KPIs.	Grants are reviewed annually based on the nature of the role, its contribution to long term objectives and individual performance.
Oversight	Individual outcomes are reviewed and approved first by the Nomination & Remuneration Committee and then the Board.		
Delivered as	Cash.	Cash and options (CEO only).	Options.

A pay mix for performance

The executive KMP's target remuneration mix is as follows:

	Fixed Remuneration %		At-Risk STI %		At-Risk LTI %	
Name	**2019**	**2018**	**2019**	**2018**	**2019**	**2018**
Silviu Itescu	50	50	50	50	—	—
Josh Muntner	50	—	25	—	25	—
Paul Hodgkinson	—	40	—	20	—	40

The Board has customized the CEO's remuneration mix in comparison with that of other Company executive KMP in recognition that he continues to be a substantial shareholder of Mesoblast. As explained in the executive summary above, a recent benchmarking analysis has been completed and the CEO's remuneration mix will change from July 1, 2019 onwards.

Short-Term Incentives (STIs) Program

The following table outlines a summary of the 2019 Short-Term Incentive Plan:

What is the 2019 STI?	An incentive plan under which eligible employees are (subject to satisfaction of specified performance measures) granted a cash amount, which is based on a percentage range of each participant's fixed remuneration (determined according to role and ability to influence our performance). Performance is assessed against a combination of company and individual measures.
When is the 2019 STI grant paid to eligible employees?	The STI amount will be paid, between September 30, 2019 and October 2019, to each participant who satisfies applicable performance measures, following assessment of performance against the applicable measures for the financial year ended June 30, 2019.
Who participates in the 2019 STI?	All employees hired on or before March 31, 2019 are eligible for consideration. Employees hired during the year are recognized on a pro-rata basis.
Why does our board of directors consider the 2019 STI an appropriate incentive?	The STI is a globally recognized form of reward for management, aimed at ensuring focus and alignment our goals and strategy. Based on both company and individual measures, and in conjunction with other factors, our board of directors believes that it helps encourage and reward high performance.
What are the performance conditions under the 2019 STI?	Individual performance is measured against the achievement of individual KPIs, key corporate and budgetary milestones and achievement of strategic goals all of which lead to long-term shareholder value creation.
What is the relationship between our performance and allocation of STIs?	At the end of the financial year our board of directors assesses our overall company performance based on the achievement of Company and CEO's KPIs. This assessment will adjust how much of our bonus pool is eligible for allocation. For the financial year ended June 30, 2019, the Board assessed our overall Company performance as meeting 80% of objectives. People Leaders evaluate employees and make recommendations of the bonus amount each employee should receive based on the bonus pool they have available for allocation and with reference to individual target bonus opportunities and individual performance against objectives.
What is the period over which our performance is assessed?	The assessment period is the financial year preceding the payment date of the STI (July 1 through June 30).

Long-Term Incentives (LTIs) Program

In designing a LTI mechanism that is appropriate to our global team where 61% of our employees are based in the United States, we seek to balance:

- Australian practice and governance expectations, where LTI are expected to have performance hurdles other than price and employment milestones alone;
- United States practices, where options are a widely distributed remuneration component, typically issued without a price premium, performance hurdles or milestones, and which vest on a more regular basis (e.g. rolling monthly basis);
- a strong preference for a single reward mechanism to maintain executive cohesion and teamwork; and
- alignment with driving shareholder value.

Since July 1, 2015 Mesoblast has used a single LTI plan, our Employee Share Option Plan ("ESOP"). The ESOP was approved by shareholders at the AGM held in November 2016. LTIs consist of options over ordinary shares of our company under the rules of the ESOP. Recognizing that option grants in the US where the majority of our LTI participants reside typically have a ten year term, grants made since July 10, 2015 have had a seven year term. The Board considers the appropriate term at the time each grant is approved.

The current framework for executive LTI grants allows the Board flexibility to ensure the LTI program works efficiently. Options vest upon either the achievement of pre-specified milestones or based on time.

- Milestone based vesting aligns each executive's key objectives with milestones that are expected to generate shareholder returns.
- Time based options vest in three equal tranches, one year, two years and three years after the date of grant provided performance conditions are met.
- Time based vesting options are effective in retaining executives which is also important for generating shareholder returns.

This framework gives the Board the flexibility it needs to ensure maximum effectiveness from LTI grants and allows it the flexibility to offer packages that are sufficiently competitive to attract, motivate and retain key talent, particularly in the US. The ability for the Board to choose the type of grant is important. For example, in our industry milestone events can have a time horizon that is longer than 12 months. The Board generally grants options annually, and therefore an executive could still be working towards the milestones from the prior year grant and it would be duplicative and inefficient to grant options with similar milestones and more appropriate to grant time based vesting options. In an effort to maintain an efficient LTI program with limited duplication of milestones, in the year ended June 30, 2019 the board granted time based vesting options to all eligible employees including executives.

LTI allocations are determined with consideration to the nature of the role within our organization, market value of LTI locations for comparable roles, previous grants made and the remuneration mix described above where a modified Black-Scholes calculation is used to determine the value of the option. If LTI valuations decline due to a decline in our share price the Board has taken a view that this should not automatically drive an increase in LTI grants to maintain the desired remuneration mix. In recent years LTI grants have remained stable in terms of number of options granted reflecting the Board's assessment that this grant size will deliver the desired value to the participants over time.

Outside this executive milestone framework we issue time based options under the LTI, to other participants at an exercise price per share that is typically 10% higher than the five day volume weighted average share price calculated at grant date. The options generally vest in three equal tranches over three years. This is an important remuneration component in the biotechnology sector which allows us to be competitive in the market place. We believe this approach is appropriate at this stage and that applying additional performance hurdles to our time LTI grants would make it problematic for us to attract and retain the people we need, particularly in the US, and would ultimately be negative for our company. This is an area we continue to review and assess.

The following is a summary of the key features of the LTI instrument, our ESOP:

What is the ESOP?	An incentive plan under which eligible participants are granted options over our ordinary shares.
Why does our board of directors consider the ESOP an appropriate long-term incentive?	The ESOP is designed to reward participants for out-performance and to align long-term interests of shareholders and participants, by linking a significant proportion of at-risk remuneration to our future performance.
Who participates in the ESOP?	All eligible participants, who are in positions to influence achievement of our long- term outcomes and where warranted by market practice for attraction and retention. In FY19 ,the CEO did not participate in the LTI due to his substantial shareholding in Mesoblast. As mentioned in the Executive Summary, the CEO will participate in the ESOP from FY20.
What are the key features of the ESOP?	Pricing and vesting conditions are determined by a participant's designation as either an: • executive participant • other participant
In what circumstances are ESOP entitlements forfeited?	The ESOP will be forfeited upon cessation of employment prior to the conclusion of the performance period in circumstances where a participant is a "bad leaver". Bad leaver is defined as part of the ESOP rules and includes serious misconduct. If the Board designate a former employee as a bad leaver they forfeit all rights, entitlements and interests in any unexercised options, both vested and unvested. Otherwise a leaver may retain vested options subject to exercising the option within 60 days of cessation of employment or within a longer period if so determined by the Board. Unvested options lapse immediately upon cessation of employment.
What are the performance conditions under the ESOP?	Executive LTI grants which vest based on milestones are issued with an exercise price per share that is equal to the fair market value at grant date and vest with the achievement of objectives relevant to each executive's role. Typically each executive has two or three objectives, each of which is assigned to a tranche of options. Milestones from our initial grant under this framework relate to achievements such as: progress with patient enrollment for a specific program, signing a partnering agreement, and submitting a regulatory filing. Time based options are issued with an exercise price per share that is typically 10% higher than the five day volume weighted average share price calculated at grant date and vest over three years. In addition participants have to remain in employment with the Company for the LTIs to vest.
Why did our board of directors choose the above performance conditions/hurdles?	A participant's designation as an executive participant or other participant is determined according to their seniority and the nature of their responsibilities. The objectives selected as vesting milestones for our executives are expected to generate positive shareholder returns, thereby creating direct alignment between executive and shareholder rewards.
What is the relationship between our performance and allocation of options?	Equity-based remuneration is an integral part of remuneration in the biotechnology industry as they reward share price growth and seek to conserve cash. With the executive milestone vesting framework, executives must achieve their objectives, to the satisfaction of the Board, for the options to vest. Once vested, the value of the remuneration fluctuates with our share price with an exercise price of when the option was issued. The Board believes that share price growth is an appropriate measure of success as it is the prime driver of investment in the biotechnology sector, and is simply and clearly rewarded using equity-based remuneration.
What is the maximum number of options that may be granted to a participant in the ESOP?	The maximum number of options that may be granted to each participant is determined by the Board, subject to applicable legal thresholds.

When do the options vest?	For executive participants with milestone vesting grants, the Board designs the relevant performance criteria with reference to objectives which can be reasonably forecast and set given the dynamic nature of Mesoblast's business and which will result in shareholder value creation. The Board has authority to designate that options have vested when the related milestone has been met. For time based grants, options typically vest in three equal tranches, one year, two years and three years after the date of grant, provided performance conditions are met.
How are the shares provided to participants under the ESOP?	Shares are issued to the participant upon the holder exercising their option and paying the exercise price to us (once all vesting conditions are satisfied).
Is the benefit of participation in the ESOP affected by changes in the share prices?	Yes, the value participants receive through participation in the ESOP will be reduced if the share price falls during the performance period and will increase if the share price rises over the performance period.

Non-Executive Director ("NED") Remuneration

Our aim is to establish a board of directors comprised of global experts in the biopharmaceutical industry and capital markets. As at June 30, 2019 the Board comprised of six NEDs; two based in Australia, three in the United States and one in Switzerland.

Our NED fees are based on the responsibilities and work involved with directing a company of Mesoblast's technological and geographical complexity, our financial position, regulatory and compliance context, and market practice.

NED Fees and Other Benefits

NEDs receive fixed fees for their services, as approved by shareholders at the 2018 Annual General Meeting, not to exceed a maximum fee pool of A$1,500,000.

In order to attract and retain directors with the appropriate experience for our global business, in FY19 the board reinstated fees of A$10,000 per annum for members of the Audit and Risk Committee and the Nomination and Remuneration Committee and fees of A$20,000 per annum for the chair of the Audit and Risk Committee and the Nomination and Remuneration Committee on January 17, 2019.

On March 31, 2019 Brian Jamieson resigned as chairman of the board, and Joseph Swedish was appointed chairman of the board as his successor. As part of Joseph's appointment as chairman, it was agreed the Board Chair fee would be US$250,000 per annum.

	As at June 30, 2019		
Position	Board of Directors	Audit and Risk Committee	Nomination and Remuneration Committee
Chair (1)	US$250,000	A$20,000	A$20,000
Vice Chair	A$175,000	—	—
Member	A$128,250	A$10,000	A$10,000

(1) Brian Jamieson resigned on March 31, 2019. His fee was A$250,000 per annum. From this point on, Joseph Swedish was appointed as Chair.

NEDs do not receive performance-related remuneration and are not provided with retirement benefits other than statutory superannuation. NEDs are reimbursed for costs directly related to conducting Mesoblast business. The key terms of NED service are documented in a letter of appointment to the Board.

As previously approved by shareholders at the 2018 AGM, to ensure that the Company remains globally competitive in attracting and retaining directors of high caliber and experience, an option grant was provided to NEDs in FY19. This option grant was largely driven by the board renewal process which occurred during the year, including the appointment to the board of Mr Joseph Swedish and Ms Shawn Tomasello. These options are subject to time based vesting and not subject to performance conditions. It should be noted that Mesoblast does not intend to provide option grants to its directors on an annual or regular basis. Further detail on the number of options and exercise price can be found in section "Terms and conditions of share-based payment arrangements".

Remuneration Details - NEDs

Details of the remuneration of our NEDs for the year ended June 30, 2019 are set out below:

2019		Short-term benefits					Post-employment benefits	Long-term benefits	Share-based payments	Other	
Name	Currency	Salary & fees $	Cash Bonus $	Annual Leave $	Non-monetary benefits $	Other $	Super-annuation $	Long service leave $	Options $	Termination benefits $	Total $
William Burns	A$	179,516	—	—	—	—	—	—	21,748	—	201,264
Brian Jamieson	A$	187,500	—	—	—	—	15,399	—	27,185	—	230,084
Donal O'Dwyer	A$	148,465	—	—	—	—	14,104	—	18,124	—	180,693
Eric Rose	A$	128,250	—	—	—	—	—	—	21,748	—	149,998
Michael Spooner	A$	148,465	—	—	—	—	14,104	—	18,124	—	180,693
Joseph Swedish	A$	189,855	—	—	—	—	—	—	134,263	—	324,118
Shawn Tomasello	A$	124,802	—	—	—	—	—	—	93,533	—	218,335
Total non-executive directors	**A$**	**1,106,854**	—	—	—	—	**43,607**	—	**334,725**	—	**1,485,185**
Total non-executive directors (1)	**US$**	**791,732**	**—**	**—**	**—**	**—**	**31,192**	**—**	**239,429**	**—**	**1,062,353**

(1) The US$ results has been determined by calculating the average rate of the exchange rates on the last trading day of each month during the period, at a rate of 0.7153 for the year ended June 30, 2019.

Details of the remuneration of our NEDs for the year ended June 30, 2018 are set out below:

2018		Short-term benefits					Post-employment benefits	Long-term benefits	Share-based payments	Other	
Name	Currency	Salary & fees $	Cash Bonus $	Annual Leave $	Non-monetary benefits $	Other $	Super-annuation $	Long service leave $	Options $	Termination benefits $	Total $
William Burns	A$	175,000	—	—	—	—	—	—	4,632	—	179,632
Brian Jamieson	A$	250,000	—	—	—	—	20,049	—	—	—	270,049
Donal O'Dwyer	A$	134,500	—	—	—	—	12,777	—	—	—	147,277
Michael Spooner	A$	134,500	—	—	—	—	12,777	—	—	—	147,277
Ben-Zion Weiner	A$	128,250	—	—	—	—	—	—	4,632	—	132,882
Eric Rose	A$	128,250	—	—	—	—	—	—	4,632	—	132,882
Joseph Swedish(1)	A$	—	—	—	—	—	—	—	—	—	—
Total non-executive directors	**A$**	**950,500**	—	—	—	—	**45,603**	—	**13,896**	—	**1,009,999**
Total non-executive directors(2)	**US$**	**737,968**	**—**	**—**	**—**	**—**	**35,406**	**—**	**10,789**	**—**	**784,163**

(1) Joseph Swedish was appointed on June 18, 2018. Mr Swedish did not incur any compensation expenses for the year ended June 30, 2018.
(2) The US$ results has been determined by calculating the average rate of the exchange rates on the last trading day of each month during the period, at a rate of 0.7736 for the year ended June 30, 2018.

Remuneration Governance

Role of the Board of Directors and the Nomination and Remuneration Committee

The Board is responsible for Mesoblast's remuneration strategy and approach. The Board established the Nomination and Remuneration Committee as a committee of the Board. It is primarily responsible for making recommendations to the Board on:

- Board appointments
- Non-executive director fees
- Executive remuneration framework
- Remuneration for executive directors, namely the CEO, and other key executives
- Short-term and long-term incentive awards
- Share ownership plans

The Nomination and Remuneration Committee's objective is to ensure remuneration policies are fair and competitive and have regard for industry benchmarks whilst being aligned with the objectives of our company. The Nomination and Remuneration Committee seeks independent advice from remuneration consultants as and when it deems necessary.

Performance Review

The Board conducts periodic performance reviews of the Board and its operations as a whole. A review was last conducted during the financial year ended June 30, 2018. This review encompassed feedback on the Chairman and individual NEDs as well as consideration of Board succession planning, diversity and the breadth and sufficiency of skills represented on the Board.

Use of Remuneration Consultants

During the financial year ended June 30, 2019, the Nomination and Remuneration Committee engaged Mercer, a consulting firm to conduct an analysis of CEO remuneration and benchmarking with comparable companies to assist the Board in making specific changes to the CEO remuneration.

The advice provided by the Consulting Firm does not constitute a 'remuneration recommendation' as a defined in section 9B of the Corporations Act.

Employment Agreements

The employment of our CEO and CFO are formalized in employment agreements, the key terms of which are as follows:

Name	Term	Notice period	Termination benefit
CEO (Silviu Itescu)	Initial term of 3 years commencing April 1, 2014, and continuing subject to a 12 months' notice period.	12 months	12 months base salary
CFO (Josh Muntner)	An ongoing employment agreement until notice is given by either party.	1 month	12 months base salary

On termination of employment our CEO, who is based in Australia, is entitled to receive his statutory entitlements of accrued annual and long service leave, together with any superannuation benefits.

On termination of employment our CFO, who is based in the United States, is entitled to participate in the Company's healthcare plan during the severance period.

There is no entitlement to a termination payment in the event of resignation (except, in the case of the CFO, if the Company has materially reduced his role or benefits or materially moved office location) or removal for misconduct.

The employment of the executive team is also formalized in employment contracts. Three members of the executive team have employment contracts with initial terms ranging from 15 to 25 months, all of which have been fulfilled, and with notice periods

ranging from six to twelve months. The remaining members have continuous employment contracts with no fixed term and notice periods ranging from one to six months.

Additional remuneration disclosures

The table and chart below detail Company performance on a market capitalization basis, against executive key management personnel short-term at-risk compensation:

	2019	2018	2017	2016	2015
Share price (ASX:MSB)					
– closing at June 30	A$1.48	A$1.48	A$2.08	A$1.08	A$3.76
– high for the year	A$2.34	A$2.36	A$3.44	A$4.06	A$5.88
– low for the year	A$1.04	A$1.19	A$1.03	A$1.01	A$3.17
– share price volatility (annual)	62%	53%	52%	60%	46%
Market capitalization at June 30 (in millions)	A$738	A$714	A$891	A$412	A$1,267
– increase/(decrease) – in $ millions	A$24	(A$177)	A$479	(A$855)	(A$170)
– increase/(decrease) – as %	3%	20%	116%	(67%)	(12%)
Short-term incentives – % of target paid to CEO	80%	90%	75%	—	90%
Short-term incentives – as % of base salary paid to CEO	80%	90%	75%	—	90%
Short-term incentives – % of target paid to CFO	80%	—	70%	—	100%
Short-term incentives – as % of base salary paid to CFO	40%	—	35%	—	50%

Relative proportions of fixed versus variable remuneration expenses

For the years ended June 30, 2019 and 2018, the following table shows the relative proportions of remuneration for our executive KMPs that are linked to performance and those that are fixed based on the amounts disclosed as statutory expense above:

	Fixed remuneration		At risk - STI		At risk - LTI	
Name	2019 %	2018 %	2019 %	2018 %	2019 %	2018 %
Silviu Itescu (CEO)	58	55	42	45	—	—
Josh Muntner (CFO)	67	—	24	—	9	—
Paul Hodgkinson (CFO)[1]	—	59	—	—	—	41

(1) Paul Hodgkinson's LTI was adjusted for the impact of the reversal of previously recognized share based payment compensation of non-vested options forfeited upon his resignation in FY18.

Performance-Based Remuneration

The proportion of at-risk performance remuneration for our executive KMPs that was awarded and forfeited during the periods presented was as follows:

		At-Risk STI %	
Name	Total Opportunity A$	Awarded %	Forfeited %
For the year ended June 30, 2019			
Silviu Itescu	1,010,000	80	20
Josh Muntner	267,021	80	20
For the year ended June 30, 2018			
Silviu Itescu	1,010,000	90	10
Paul Hodgkinson	212,500	—	100

Share Based Compensation

Details of options over our ordinary shares provided as remuneration to each director and member of key management personnel for the years ended June 30, 2019 and June 30, 2018 are set out in the tables below:

Remuneration Values

The following table provides the remuneration values:

	Number of options granted	Remuneration consisting of options (1)	Values of options granted (2)	Value of options exercised (3)	Value of options lapsed (4)
For the year ended June 30, 2019					
William Burns	120,000	10.8%	A$64,584	—	—
Brian Jamieson	150,000	11.8%	A$80,730	—	—
Donal O'Dwyer	100,000	10.0%	A$53,820	—	—
Eric Rose	120,000	14.5%	A$64,584	—	—
Michael Spooner	100,000	10.0%	A$53,820	—	—
Joseph Swedish(5)	500,000	41.4%	A$404,790	—	—
Shawn Tomasello	200,000	42.8%	A$155,080	—	—
Josh Muntner	300,000	9.1%	A$173,010	—	—
For the year ended June 30, 2018					
William Burns	—	2.6%	—	—	—
Eric Rose	—	3.5%	—	—	—
Ben-Zion Weiner	—	3.5%	—	—	—
Donal O'Dwyer	—	—	—	A$255,861	—
Paul Hodgkinson	200,000	41.3%	A$117,520	—	—

(1) The percentage of the value of remuneration consisting of options, based on the value of options expensed during the year presented in accordance with IFRS 2 *Share-based Payment*.

(2) The accounting value at acceptance date of options that were granted during the year presented as part of remuneration, determined using Black-Scholes valuation model and in accordance with IFRS 2 *Share-based Payment*. The acceptance date is the date at which the entity and the employee agree to a share-based payment arrangement, being when the entity and the employee have a shared understanding of the terms and conditions of the arrangement.

(3) The intrinsic value at exercise date of options that were exercised during the year presented, having been granted as part of remuneration previously.

(4) The intrinsic value at lapse date of options that lapsed during the year presented because a performance condition was not met, however valued as if the performance condition had been met.

(5) 300,000 of the options granted in connection with Mr Swedish's appointment as Chairman of Mesoblast and are subject to shareholder approval which will be sought at the upcoming AGM.

During the year ended June 30, 2018, as a result of a fully underwritten institutional and retail entitlement offer to existing eligible shareholders (on a 1 for 12 basis) in September 2017, the exercise price of all outstanding options at the time was reduced by A$0.02 per option subject to the ESOP plan under clause 7.3. At the date of alteration, September 13, 2017, the market price of the shares was A$1.38. The difference between the total fair value of the options affected by the alteration immediately before and after the modification was a reduction of A$138,975. There have been no other modifications to any terms and conditions of share-based payment transactions during the year ended June 30, 2019.

Reconciliation of Options held by KMP

The following table shows a reconciliation of options held by each KMP from July 1, 2018 to June 30, 2019:

Name	Year granted	Balance at the start of the year	Granted during the year	Vested		Exercised	Forfeited		Balance at the end of the year		
		Number	Number	Number	%	Number	Number	%	Vested and exercisable	Vested and unexercisable	Unvested
Silviu Itescu	—	—	—	—	—	—	—	—	—	—	—
Josh Muntner	2019	—	300,000	—	—	—	—	—	—	—	300,000
William Burns	2015	80,000	—	80,000	100	—	—	—	80,000	—	—
William Burns	2019	—	120,000	—	—	—	—	—	—	—	120,000
Brian Jamieson	2019	—	150,000	—	—	—	—	—	—	—	150,000
Donal O'Dwyer	2019	—	100,000	—	—	—	—	—	—	—	100,000
Eric Rose	2015	80,000	—	80,000	100	—	—	—	80,000	—	—
Eric Rose	2019	—	120,000	—	—	—	—	—	—	—	120,000
Michael Spooner	2019	—	100,000	—	—	—	—	—	—	—	100,000
Joseph Swedish	2019	—	200,000	66,667	33	—	—	—	66,667	—	133,333
Joseph Swedish(1)	2019	—	300,000	—	—	—	—	—	—	—	300,000
Shawn Tomasello	2019	—	200,000	—	—	—	—	—	—	—	200,000

(1) 300,000 of the options granted in connection with Mr Swedish's appointment as Chairman of Mesoblast and are subject to shareholder approval which will be sought at the upcoming AGM.

Terms and conditions of share-based payment arrangements

The terms and conditions of each grant of options affecting remuneration in the current or a future reporting period are as follows:

Grant date	Vesting date	Expiry date	Exercise price	Value per option at acceptance date	Vested %
4/4/2019	one third - 04/04/2020 one third - 04/04/2021 one third - 04/04/2022	03/04/2026	A$1.49	A$0.78	—
30/11/2018	one third - 30/11/2019 one third - 30/11/2020 one third - 30/11/2021	29/11/2025	A$1.33	A$0.54	—
15/07/2018	one third - 15/07/2019 one third - 15/07/2020 one third - 15/07/2021	14/07/2025	A$1.72	A$0.58	—
11/07/2018	one third - 11/07/2019 one third - 11/07/2020 one third - 11/07/2021	10/07/2025	A$1.56	A$0.78	—
18/06/2018	one third - 18/06/2019 one third - 18/06/2020 one third - 18/06/2021	17/06/2025	A$1.52	A$0.85	33

Shares provided on exercise of remuneration options:

	No. of options exercised during the period	No. of ordinary shares in Mesoblast Limited issued	Exercise Date	Value per share at exercise date (closing price)	Exercise price per option
For the year ended June 30, 2019					
Nil	—	—	—	—	—
For the year ended June 30, 2018					
Donal O'Dwyer	255,912	255,912	December 15, 2017	A$1.42	US$0.323

Options Granted as Remuneration

The following table presents options that have been granted over unissued shares during or since the end of the year ended June 30, 2019, to our Directors and our next 5 most highly remunerated officers.

Name	Issue Date	Exercise Price	Number of shares, under option
Directors			
Silviu Itescu	—	—	—
Non-Directors			
Peter Howard	July 18, 2018	A$1.87	350,000
John McMannis	July 18, 2018	A$1.87	250,000
Michael Schuster	July 18, 2018	A$1.87	350,000
Paul Simmons	July 18, 2018	A$1.87	350,000
Donna Skerrett	July 18, 2018	A$1.87	300,000

Shareholdings

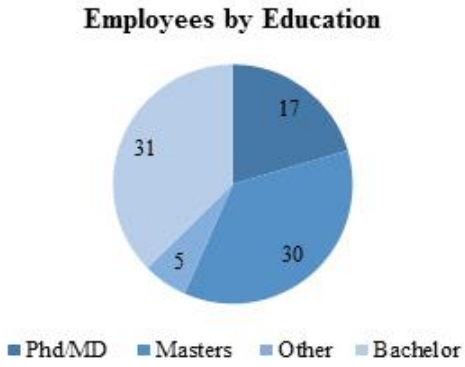
The table below shows a reconciliation of ordinary shares held by each KMP from the beginning to the end of the 2019 financial year in accordance with the Corporations Regulations (section 18).

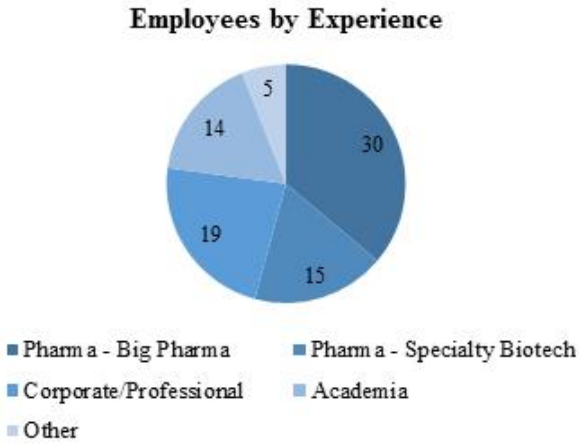
Name	Balance at the start of the year	Received during the year upon exercise of options	Other changes during the year	Balance at the end of the year
Silviu Itescu	68,958,928	—	—	68,958,928
Josh Muntner	—	—	—	—
William Burns	30,330	—	—	30,330
Brian Jamieson	645,000	—	—	645,000
Donal O'Dwyer	1,149,142	—	—	1,149,142
Eric Rose	—	—	—	—
Michael Spooner(1)	1,091,335	—	—	1,091,335
Joseph Swedish	—	—	—	—
Shawn Tomasello	—	—	—	—

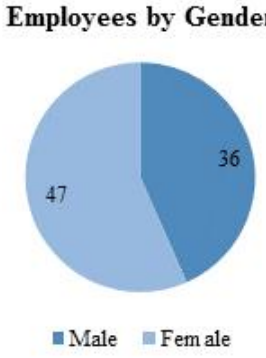
(1) Of this balance, Mr. Spooner has a relevant interest of 1,069,000 ordinary shares.

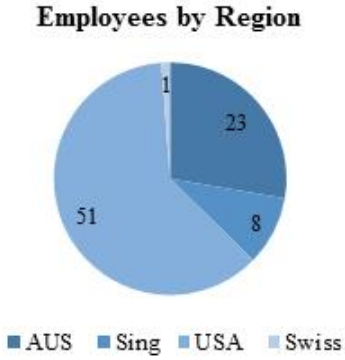
Employee Profile

As of June 30, 2019, we had 83 (2018: 81) employees globally:





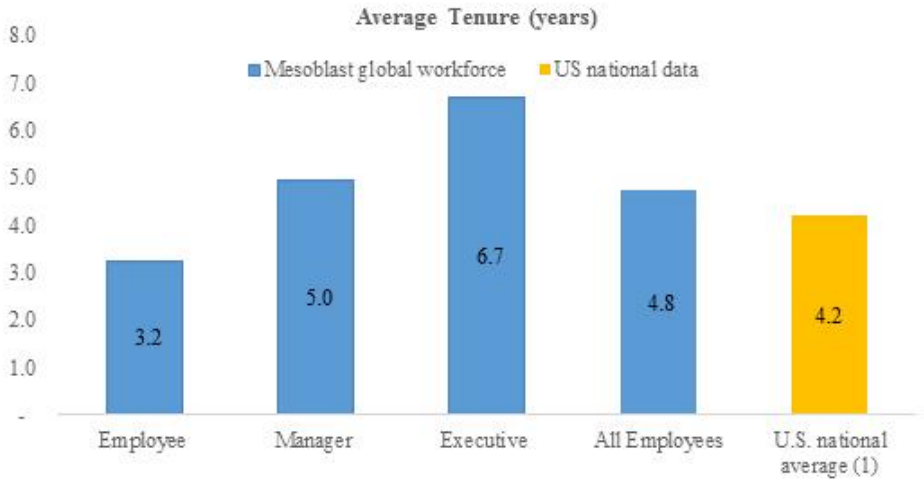




61% of our employees and a majority of our executives are based in the United States where Mesoblast operational activities are concentrated.

Australia is corporate headquarters where 28% of the employees work. This includes the CEO and a portion of the executive team. The remaining 11% of employees are located in Singapore (10%) and 1% in Switzerland where research and development activities are primarily conducted.

As at June 30, 2019, globally the average tenure of our employees is 3.2 years, 5.0 years and 6.7 years for our employees, managers and executives respectively.



(1) The U.S. Bureau of Labor Statistics reported that the median number of years that wage and salary workers had been with their current employer was 4.2 years as of January 2018.

The average tenure of all Mesoblast employees is 4.8 years, which exceeds the U.S. national average of 4.2 years. These results indicate that Mesoblast has been successful in retaining talented employees, which resulted in a higher average workforce tenure compared the US national average, especially with respect to the executive level.

Non-Executive Director Profile

As at June 30, 2019, we have six non-executive Directors ("NED") with diverse industry and regional experience, as the charts below illustrate:

(End of Remuneration Report)

Australian Disclosure Requirements

Shares under option

Unissued ordinary shares of Mesoblast Limited under option at the date of this Directors' report are as follows:

Grant date	Exercise price of options	Expiry date of options	Number of shares under option
9/10/2014	A$4.52	8/10/2019	75,000
25/11/2014	A$4.00	24/11/2019	240,000
12/12/2014	A$4.49	31/10/2019	50,000
6/01/2015	A$4.66	16/12/2019	150,000
12/05/2015	A$4.28	16/02/2020	200,000
10/07/2015	A$4.20	30/06/2022	2,308,334
26/08/2015	A$4.05	16/08/2022	75,000
27/04/2016	A$2.80	6/03/2023	3,193,334
27/04/2016	A$2.74	17/04/2023	200,000
30/06/2016	A$2.20	18/01/2021	1,500,000
31/10/2016	A$2.80	6/03/2023	200,000
06/12/2016	A$1.31	5/12/2023	1,670,000
06/12/2016	A$1.19	5/12/2023	4,154,666
13/01/2017	A$1.65	12/01/2024	300,000
28/06/2017	A$2.23	27/06/2024	150,000
16/09/2017	A$1.54	15/09/2024	100,000
16/09/2017	A$1.40	15/09/2024	150,000
13/10/2017	A$1.94	12/10/2024	1,978,333
13/10/2017	A$1.76	12/10/2024	1,900,000
24/11/2017	A$1.41	23/11/2024	750,000
24/11/2017	A$1.28	23/11/2024	750,000
18/6/2018	A$1.52	17/06/2025	200,000
11/07/2018	A$1.56	10/07/2025	200,000
18/07/2018	A$1.87	17/07/2025	5,845,000
15/07/2018	A$1.72	14/07/2025	300,000
30/11/2018	A$1.33	29/11/2025	590,000
19/01/2019	A$1.45	18/01/2026	5,000
19/01/2019	A$1.45	18/01/2026	150,000
4/04/2019	A$1.48	3/04/2026	300,000 (1)
Sub-total			**27,684,667**
07/07/2010	US$0.340	26/10/2019	319,892
Sub-total			**319,892**
Grand Total			**28,004,559**

(1) 300,000 of the options granted in connection with Mr Swedish's appointment as Chairman of Mesoblast and are subject to shareholder approval which will be sought at the upcoming AGM.

No option holder has any right under the options plan to participate in any other of our share issues.

Shares issued on exercise of options during the year

Detail of shares or interests issued as a result of the exercise of options during or since the end of the financial year are:

Grant date	Number of shares issued	Issue Price	Amount unpaid per share
6/12/2016	50,000	A$1.31	—
6/12/2016	212,000	A$1.19	—
7/7/2010	26,108	US$0.310	—
6/12/2016	25,000	A$1.31	—
6/12/2016	33,334	A$1.31	
Total	**346,442**		—

Indemnification of Officers

During the financial year, we paid premiums in respect of a contract insuring our directors and company secretary, and all of our executive officers. The liabilities insured are to the extent permitted by the *Corporations Act 2001*. Further disclosure required under section 300(9) of the *Corporations Act 2001* is prohibited under the terms of the insurance contract.

Proceedings on Our Behalf

The *Corporations Act 2001* allows specified persons to bring, or intervene in, proceedings on our behalf. No proceedings have been brought or intervened in on our behalf with leave of the Court under section 237 of the *Corporations Act 2001*.

Non-Audit Services

We may decide to employ the auditor on assignments additional to their statutory audit duties where the auditor's expertise and experience are relevant and considered to be important.

The board of directors has considered the position and in accordance with advice received from the audit committee, is satisfied that the provision of the non-audit services is compatible with the general standard of independence for auditors imposed by the *Corporations Act 2001*. The directors are satisfied that the provision of the non-audit services as set out below, did not compromise the auditor independence requirements of the *Corporations Act 2001* because the services are not deemed to undermine the general principles relating to auditor independence as set out in APES 110 Code of Ethics for Professional Accountants.

During both the current and prior financial years, no fees were paid or payable for non-audit services provided by the auditor of the parent entity, its related practices and non-related audit firms.

Auditor's Independence Declaration

A copy of the auditor's independence declaration under Section 307C of the Corporations Act in relation to the audit for the year ended June 30, 2019 is included in Exhibit 99.2 of this annual report on Form 20-F.

Rounding of Amounts

Our company is of a kind referred to in *ASIC Corporations (Rounding in Financial/Directors' Reports) Instrument 2016/191*, issued by the Australian Securities and Investments Commission, relating to the 'rounding off' of amounts in the directors' report. Unless mentioned otherwise, amounts within this report have been rounded off in accordance with that Legislative Instrument to the nearest thousand dollars, or in certain cases, to the nearest dollar.

The components of our directors' report are incorporated in various places within this annual report on the Form 20-F. A table charting these components is included within 'Exhibit 99.1 Appendix 4E'.

Directors' Resolution

This report is made in accordance with a resolution of the directors.

/s/ Joseph R Swedish	/s/ Silviu Itescu
Joseph R Swedish	Silviu Itescu
Chairman	Chief Executive Officer

Dated: August 30, 2019

6.C Board Practices

Our board of directors currently consists of seven members, including six non-executive directors and one executive director, our Chief Executive Officer.

Our directors are generally elected to serve three-year terms in a manner similar to a "staggered" board of directors under Delaware law. No director, except the Managing Director (currently designated as our Chief Executive Officer, Silviu Itescu), may hold office for a period in excess of three years, or beyond the third annual general meeting following the director's last election, whichever is the longer, without submitting himself or herself for re-election. As a result of the staggered terms, not all of our directors will be elected in any given year. The current terms of Messrs. Burns and Rose will expire at the annual shareholders' meeting in 2019.

Name	First election at AGM	Last election at AGM	End of current term
William Burns	2014	2016	2019
Donal O'Dwyer	2004	2017	2020
Eric Rose	2013	2016	2019
Michael Spooner	2004	2018	2021
Joseph Swedish	2018	2018	2021
Shawn Cline Tomasello	2018	2018	2021

We believe that each of our directors has relevant industry experience. The membership of our board of directors is directed by the following requirements:

- our Constitution specifies that there must be a minimum of 3 directors and a maximum of 10, and our board of directors may determine the number of directors within those limits;
- we may appoint or remove any director by resolution passed in the general meeting of shareholders;
- our directors may appoint any person to be a director, and that person only holds office until the next general meeting at which time the director may stand for election by shareholders at that meeting;
- it is the intention of our board of directors that its membership consists of a majority of independent directors who satisfy the criteria for independence recommended by the ASX's Corporate Governance Principles and Recommendations;
- the chairperson of our board of directors should be an independent director who satisfies the criteria for independence recommended by the ASX's Corporate Governance Principles and Recommendations;
- Australia's Corporations Act requires that at least two of our directors must be resident Australians; and
- our board of directors should, collectively, have the appropriate level of personal qualities, skills, experience, and time commitment to properly fulfill its responsibilities or have ready access to such skills where they are not available.

Our board of directors is responsible for, and has the authority to determine, all matters relating to our corporate governance, including the policies, practices, management and operation. The principal roles and responsibilities of our board of directors are to:

- facilitate board of directors and management accountability to our company and its shareholders;
- ensure timely reporting to shareholders;
- provide strategic guidance to us, including contributing to the development of, and approving, the corporate strategy;
- oversee management and ensure there are effective management processes in place;
- monitor:
  - organizational performance and the achievement of our strategic goals and objectives;
  - financial performance including approval of the annual and half-year financial reports and liaison with our auditors;
  - progress of major capital expenditures and other significant corporate projects including any acquisitions or divestments;
  - compliance with our code of conduct;
  - progress in relation to our diversity objectives and compliance with its diversity policy;

- review and approve business plans, the annual budget and financial plans including available resources and major capital expenditure initiatives;
- approve major corporate initiatives;
- enhance and protect the reputation of the organization;
- oversee the operation of our system for compliance and risk management reporting to shareholders; and
- ensure appropriate resources are available to senior management.

Our non-executive directors do not have any service contracts with Mesoblast that provide for benefits upon termination of employment.

Committees

To assist our board of directors with the effective discharge of its duties, it has established a Nomination and Remuneration Committee and an Audit and Risk Management Committee. Each committee operates under a specific charter approved by our board of directors.

Nomination and Remuneration Committee. The members of our Nomination and Remuneration Committee are Messrs. Burns, O'Dwyer (Chairman) and Spooner, all of whom are independent, non-executive directors. The remuneration committee is a committee of our board of directors, and is primarily responsible for making recommendations to our board of directors on:

- board appointments;
- non-executive director fees;
- the executive remuneration framework;
- remuneration of executive directors, including the CEO and other key executives;
- short-term and long-term incentive awards; and
- share ownership plans.

The committee's objective is to ensure remuneration policies are fair and competitive and in line with similar industry benchmarks while aligned with our objectives. The remuneration committee seeks independent advice from remuneration consultants as and when it deems necessary. See "Management—Remuneration."

Audit and Risk Management Committee. The members of our Audit and Risk Management Committee are Messrs. O'Dwyer, Spooner (Chairman) and Swedish, all of whom are independent, non-executive directors. This committee oversees, reviews, acts on and reports on various auditing and accounting matters to our board of directors, including the selection of our independent accountants, the scope of our annual audits, fees to be paid to the independent accountants, the performance of our independent accountants and our accounting practices. In addition, the committee oversees, reviews, acts on and reports on various risk management matters to our board of directors.

The effective management of risk is central to our ongoing success. We have adopted a risk management policy to ensure that:

- appropriate systems are in place to identify, to the extent that is reasonably practical, all material risks that we face in conducting our business;
- the financial impact of those risks is understood and appropriate controls are in place to limit exposures to them;
- appropriate responsibilities are delegated to control the risks; and
- any material changes to our risk profile are disclosed in accordance with our continuous disclosure reporting requirements in Australia.

It is our objective to appropriately balance, protect and enhance the interests of all of our shareholders. Proper behavior by our directors, officers, employees and those organizations that we contract to carry out work is essential in achieving this objective.

We have established a code of conduct, which sets out the standards of behavior that apply to every aspect of our dealings and relationships, both within and outside Mesoblast. The following standards of behavior apply:

- patient well-being;
- comply with all laws that govern us and our operations;
- act honestly and with integrity and fairness in all dealings with others and each other;
- avoid or manage conflicts of interest;
- use our assets properly and efficiently for the benefit of all of our shareholders; and
- seek to be an exemplary corporate citizen.

6.D Employees

As of June 30, 2019, we had 83 employees, 51 of whom are based in the United States, 23 of whom are based in Australia, including our CEO and certain executive team members, 8 of whom are based in Singapore, and 1 of whom is based in Switzerland. We had 81 and 75 employees as of June 30, 2018 and 2017, respectively.

The table below sets forth the breakdown of the total year-end number of our employees by main category of activity and geographic area for the past three years:

As of June 30, 2019	Research & Development	Commercial	Manufacturing	Corporate	Total
USA	37	1	3	10	51
Australia	7	—	—	16	23
Singapore	5	—	2	1	8
Switzerland	—	—	—	1	1
Total	**49**	**1**	**5**	**28**	**83**

As of June 30, 2018	Research & Development	Commercial	Manufacturing	Corporate	Total
USA	31	1	4	12	48
Australia	8	—	—	16	24
Singapore	5	—	2	1	8
Switzerland	—	—	—	1	1
Total	**44**	**1**	**6**	**30**	**81**

As of June 30, 2017	Research & Development	Commercial	Manufacturing	Corporate	Total
USA	29	1	5	9	44
Australia	8	—	—	14	22
Singapore	5	—	2	1	8
Switzerland	—	—	—	1	1
Total	**42**	**1**	**7**	**25**	**75**

We have no collective bargaining agreement with our employees. We have not experienced any work stoppages to date and consider our relations with our employees to be good.

See “Item 6.A Directors and Senior Management – Employee Profile”.

6.E Share Ownership

The table below sets forth information regarding the beneficial ownership of our ordinary shares based on 498,626,208 ordinary shares outstanding at June 30, 2019 by each of our directors and key management personnel.

We have determined beneficial ownership in accordance with the rules of the SEC - it generally means that a person has a beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including options that are exercisable within 60 days of June 30, 2019. Ordinary shares subject to options currently exercisable or exercisable within 60 days of June 30, 2019 are deemed to be outstanding for computing the percentage ownership of the person holding these options and the percentage ownership of any group of which the holder is a member, however are not deemed outstanding for computing the percentage of any other person.

Unless otherwise indicated, to our knowledge each shareholder possesses sole voting and investment power over the ordinary shares listed. None of our shareholders has different voting rights from other shareholders. Unless otherwise indicated, the principal address of each of the shareholders below is c/o Mesoblast Limited, Level 38, 55 Collins Street, Melbourne 3000, Australia.

	Ordinary Shares beneficially owned	
Name	**Number**	**%**
Directors and key management personnel:		
Silviu Itescu(1)	68,958,928	14.3%
Josh Muntner (2)	100,000	*
William Burns(3)	110,330	*
Brian Jamieson(4)	645,000	*
Donal O'Dwyer(5)	1,149,142	*
Eric Rose(6)	80,000	*
Michael Spooner	1,060,000	*
Joseph Swedish(7)	66,667	*
Shawn Tomasello(8)	66,667	*
All directors and key management personnel as a group (9 persons)	**72,236,734**	**14.5%**

* Less than 1% of the outstanding ordinary shares.

(1) Includes (a) 67,756,838 ordinary shares owned by Dr. Itescu, (b) 487,804 ordinary shares owned by Josaka Investments Pty Ltd, the trustee of Dr. Itescu's self-managed superannuation fund and (c) 714,286 ordinary shares owned by Tamit Nominees Pty Ltd, an Australian corporation owned by Dr. Itescu.

(2) Includes 100,000 ordinary shares subject to options exercisable at a price of A$1.72 per share until July 14, 2025.

(3) Includes (a) 30,330 ordinary shares owned by Mr. Burns and (b) 80,000 ordinary shares subject to options exercisable at a price of A$4.00 per share until November 24, 2019.

(4) Includes (a) 150,000 ordinary shares owned by Mr. Jamieson and (b) 495,000 ordinary shares owned by Mr. Jamieson through Timaru Close Pty Ltd.

(5) Includes (a) 1,149,142 ordinary shares owned by Dundrum Investments Ltd. as trustee for The O'Dwyer Family Trust. Mr. O'Dwyer and his spouse are the sole shareholders of Dundrum Investments Ltd.

(6) Includes 80,000 ordinary shares subject to options exercisable at a price of A$4.00 per share until November 24, 2019.

(7) Includes 66,667 ordinary shares subject to options exercisable at a price of A$1.52 per share until June 17, 2025.

(8) Includes 66,667 ordinary shares subject to options exercisable at a price of A$1.56 per share until July 10, 2025.

Item 7. Major Shareholders and Related Party Transactions

7.A Major Shareholders

The following table and accompanying footnotes present certain information regarding the beneficial ownership of our ordinary shares based on 498,626,208 ordinary shares outstanding at June 30, 2019 by each person known by us to be the beneficial owner of more than 5% of our ordinary shares. Based upon information known to us, as of June 30, 2019 we had 32 shareholders in the United States. These shareholders held an aggregate of 95,585,303 of our ordinary shares, or approximately 19% of our outstanding ordinary shares. None of our shareholders has different voting rights from other shareholders.

	Ordinary Shares beneficially owned	
Name	**Number**	**%**
5% or Greater Shareholders:		
Silviu Itescu(1)	68,958,928	13.8%
M&G Investment Group(2)	65,636,115	13.2%
Capital Research Global Investors(3)	30,755,583	6.2%
Thorney Holdings(4)	24,696,000	5.0%

(1) Includes (a) 67,756,838 ordinary shares owned by Dr. Itescu, (b) 487,804 ordinary shares owned by Josaka Investments Pty Ltd, the trustee of Dr. Itescu's self-managed superannuation fund and (c) 714,286 ordinary shares owned by Tamit Nominees Pty Ltd, an Australian corporation owned by Dr. Itescu.

(2) Includes ordinary shares owned indirectly through custodial accounts, over which shares M&G Investment Group retains voting and dispositive power. The address for M&G Investment Group is 5 Laurence Pountney Hill, London EC4R 0HH, United Kingdom.

(3) Includes ordinary shares owned indirectly through custodial accounts, over which shares Capital Research Global Investors retains voting and dispositive power. The address for Capital Research Global Investors is 333 South Hope Street, 55th Floor, Los Angeles, CA 90071, USA.

(4) Includes ordinary shares owned indirectly through custodial accounts, over which shares Thorney Holdings retains voting and dispositive power. The address for Thorney Holdings is 55 Collins Street, Level 39, Melbourne, Victoria 3000, Australia.

To our knowledge, there have not been any significant changes in the ownership of our ordinary shares by major shareholders over the past three years, except as follows (which is based on substantial shareholder notices filed with the ASX and SEC).

- M&G Investment Group reported on March 30, 2017 that, after acquiring 7,196,982 ordinary shares between November 26, 2015 and March 30, 2017, in total it held 54,026,630 ordinary shares (including 1,543,700 ADSs, each representing 5 ordinary shares), or 13.4% of the total voting power as of that date. It reported on July 13, 2017 that it disposed of 368,590 ordinary shares between March 31, 2017 and July 13, 2017, and that in total it held 53,658,040 ordinary shares (including 1,539,053 ADSs, each representing 5 ordinary shares), or 12.35% of the total voting power as of that date. It reported on September 6, 2017 that it acquired 11,794,313 ordinary shares between July 12, 2017 and September 6, 2017, and that in total it held 65,452,353 ordinary shares (including 1,537,794 ADSs each representing 5 ordinary shares), or 14.19% of the total voting power as of that date. It reported on December 31, 2017 that it acquired 3,845,543 ordinary shares between September 7, 2017 and December 31, 2017, and that in total it held 69,297,896 ordinary shares (including 1,532,843 ADSs, each representing 5 ordinary shares), or 14.73% of the total voting power as of that date. It reported on October 16, 2018 that it disposed of 1,348,839 ordinary shares (including 42,631 ADSs, each representing 5 ordinary shares) between December 13, 2017 and September 11, 2018, and that in total it held 68,041,831 ordinary shares (including 1,490,212 ADSs, each representing 5 ordinary shares), or 13.67% of the total voting power as of that date. It reported on January 30, 2019 that in total it held 67,993,821 ordinary shares or 13.67% of the total voting power as of December 31, 2018. It reported on July 12, 2019 that in total it held 65,636,115 ordinary shares (including 1,491,414 ADSs, each representing 5 ordinary shares), or 13.15% of the total voting power as of that date.
- The Capital Group Companies, Inc. reported on February 16, 2016 that since March 24, 2015 it had acquired 3,461,051 ordinary shares. It reported on February 13, 2017 that since February 16, 2016 it had acquired 1,414,762 ordinary shares, and it held 30,364,000 ordinary shares (including 452,000 ADSs, each representing 5 ordinary shares), or 7.9% of the total voting power as of that date. It reported on December 29, 2017 that since February 14, 2017 it had acquired 7,271,080 ordinary shares, and it held 37,365,080 ordinary shares (including 452,000 ADSs, each representing 5 ordinary shares), or 7.9% of the total voting power as of that date. It reported on March 8, 2018 that since December 30, 2017 it had acquired 5,226,000 ordinary shares, and it held 42,591,080 ordinary shares (including 452,800 ADSs, each representing 5 ordinary shares), or 9.0% of the total voting power as of that date. It reported on February 11, 2019 that since March 7, 2018 it had

disposed of 2,963,630 ordinary shares (including 48,450 ADSs, each representing 5 ordinary shares) and it held 39,627,450 ordinary shares (including 404,350 ADSs, each representing 5 ordinary shares), or 7.95% of the total voting power as of that date. It reported on March 18, 2019 that since February 7, 2019 it had disposed of 8,871,867 ordinary shares (including 31,550 ADSs, each representing 5 ordinary shares), and it held 30,755,583 ordinary shares (including 372,800 ADSs, each representing 5 ordinary shares), or 6.17% of the total voting power as of that date.

- Thorney Opportunities Ltd reported on March 31, 2017 that, between April 17, 2015 to March 31, 2017, it acquired 5,845,000 ordinary shares, and in total it held 24,696,000 ordinary shares, or 5.8% of the total voting power as of that date.

7.B Related Party Transactions

The Company has not entered into any related party transactions during the years ended June 30, 2019, 2018 and 2017 other than compensation made to Directors and other members of key management personnel, see “Item 6.B Compensation”.

7.C Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

8.A Consolidated Statements and Other Financial Information

See “Item 18. Financial Statements.”

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently party to any legal proceedings that, in the opinion of our management, would reasonably be expected to have a material adverse effect on our business, financial condition, operating results or cash flows if determined adversely to us. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Dividend policy

Since our inception, we have not declared or paid any dividends on our shares. We intend to retain any earnings for use in our business and do not currently intend to pay cash dividends on our ordinary shares. Dividends, if any, on our outstanding ordinary shares will be declared by and subject to the discretion of our board of directors, and subject to Australian law.

Any dividend we declare will be paid to the holders of ADSs, subject to the terms of the deposit agreement, to the same extent as holders of our ordinary shares, to the extent permitted by applicable law and regulations, less the fees and expenses payable under the deposit agreement. Any dividend we declare will be distributed by the depositary bank to the holders of our ADSs, subject to the terms of the deposit agreement. See “Item 12.D. Description of American Depositary Shares.”

8.B Significant Changes

There were no events that have arisen subsequent to June 30, 2019 and prior to the signing of this report that would likely have a material impact on the financial results presented.

Item 9. The Offer and Listing

9.A Offer and Listing Details

Our ordinary shares have been listed in Australia on the Australian Securities Exchange (ASX) since December 2004. Our ordinary shares have been trading under the symbol “MSB”.

American Depositary Shares (“ADSs”), each representing five ordinary shares, are available in the US through an American Depositary Receipts (“ADR”) program. This program was established under the deposit agreement which we entered into with JP Morgan Chase Bank N.A. as depositary and our ADR holders. Our ADRs have been listed on the Nasdaq Global Select Market since August 2015 and are traded under the symbol “MESO”.

9.B Plan of Distribution

Not applicable.

9.C Markets

See “Item 9.A Offer and Listing Details.”

9.D Selling Shareholders

Not applicable.

9.E Dilution

Not applicable.

9.F Expenses of the Issue

Not applicable.

Item 10. Additional Information

10.A Share Capital

Not applicable.

10.B Memorandum and Articles of Association

Our Constitution is similar in nature to the bylaws of a U.S. corporation. It does not provide for or prescribe any specific objectives or purposes of Mesoblast. Our Constitution is subject to the terms of the ASX Listing Rules and the Australian Corporations Act. It may be modified or repealed and replaced by special resolution passed at a meeting of shareholders, which a resolution is passed by at least 75% of the votes cast by shareholders (including proxies and representatives of shareholders) entitled to vote on the resolution.

Under Australian law, a company has the legal capacity and powers of an individual both within and outside Australia. The material provisions of our Constitution are summarized below. This summary is not intended to be complete nor to constitute a definitive statement of the rights and liabilities of our shareholders, and is qualified in its entirety by reference to the complete text of our Constitution, a copy of which is on file with the SEC.

Directors

Interested Directors

Except as permitted by the Corporations Act and the ASX Listing Rules, a director must not vote in respect of a matter that is being considered at a directors' meeting in which the director has a material personal interest according to our Constitution. Such director must not be counted in a quorum, must not vote on the matter and must not be present at the meeting while the matter is being considered.

Pursuant to our Constitution, the fact that a director holds office as a director, and has fiduciary obligations arising out of that office will not require the director to account to us for any profit realized by or under any contract or arrangement entered into by or on behalf of Mesoblast and in which the director may have an interest.

Unless a relevant exception applies, the Corporations Act requires our directors to provide disclosure of certain interests and prohibits directors of companies listed on the ASX from voting on matters in which they have a material personal interest and from being present at the meeting while the matter is being considered. In addition, unless a relevant exception applies, the Corporations Act and the ASX Listing Rules require shareholder approval of any provision of financial benefits (including the issue by us of ordinary shares and other securities) to our directors, including entities controlled by them and certain members of their families.

Borrowing Powers Exercisable by Directors

Pursuant to our Constitution, our business is managed by our board of directors. Our board of directors has the power to raise or borrow money, and charge any of our property or business or all or any of our uncalled capital, and may issue debentures or give any other security for any of our debts, liabilities or obligations or of any other person, and may guarantee or become liable for the payment of money or the performance of any obligation by or of any other person.

Election, Removal and Retirement of Directors

We may appoint or remove any director by resolution passed in a general meeting of shareholders. Additionally, our directors are elected to serve three-year terms in a manner similar to a "staggered" board of directors under Delaware law. No director except the Managing Director (currently designated as our chief executive officer, Silviu Itescu) may hold office for a period in excess of three years, or beyond the third annual general meeting following the director's last election, whichever is the longer, without submitting himself or herself for re-election.

A director who is appointed during the year by the other directors only holds office until the next general meeting at which time the director may stand for election by shareholders at that meeting.

In addition, provisions of the Corporations Act apply where at least 25% of the votes cast on a resolution to adopt our remuneration report (which resolution must be proposed each year at our annual general meeting) are against the adoption of the report at two successive annual general meetings. Where these provisions apply, a resolution must be put to a vote at the second annual general meeting to the effect that a further meeting, or a spill meeting, take place within 90 days. At the spill meeting, the directors in office when the remuneration report was considered at the second annual general meeting (other than the Managing Director) cease to hold office and resolutions to appoint directors (which may involve re-appointing the former directors) are put to a vote.

Voting restrictions apply in relation to the resolutions to adopt our remuneration report and to propose a spill meeting. These restrictions apply to our key management personnel and their closely related parties. See "Rights and Restrictions on Classes of Shares—Voting Rights" below.

Pursuant to our Constitution, a person is eligible to be elected as a director at a general meeting only if:

- the person is in office as a director immediately before the meeting, in respect of an election of directors at a general meeting that is a spill meeting as defined in section 250V(1) of the Corporations Act;
- the person has been nominated by the directors before the meeting;
- where the person is a shareholder, the person has, at least 35 business days but no more than 90 business days before the meeting, given to us a notice signed by the person stating the person's desire to be a candidate for election at the meeting; or
- where the person is not a shareholder, a shareholder intending to nominate the person for election at that meeting has, at least 35 business days but no more than 90 business days before the meeting, given to us a notice signed by the shareholder stating the shareholder's intention to nominate the person for election, and a notice signed by the person stating the person's consent to the nomination.

Share Qualifications

There are currently no requirements for directors to own our ordinary shares in order to qualify as directors.

Rights and Restrictions on Classes of Shares

Subject to the Corporations Act and the ASX Listing Rules, the rights attaching to our ordinary shares are detailed in our Constitution. Our Constitution provides that any of our ordinary shares may be issued with preferential, deferred or special rights, privileges or conditions, with any restrictions in regard to dividends, voting, return of share capital or otherwise as our board of directors may determine from time to time. Subject to the Corporations Act, the ASX Listing Rules and any rights and restrictions attached to a class of shares, we may issue further ordinary shares on such terms and conditions as our board of directors resolve. Currently, our outstanding ordinary share capital consists of only one class of ordinary shares.

Dividend Rights

Our board of directors may from time to time determine to pay dividends to shareholders; however, no dividend is payable except in accordance with the thresholds set out in the Corporations Act.

Voting Rights

Under our Constitution, the general conduct and procedures of each general meeting of shareholders will be determined by the chairperson, including any procedures for casting or recording votes at the meeting whether on a show of hands or on a poll. A poll may be demanded by the chairman of the meeting; by at least five shareholders present and having the right to vote on at the meeting; or any shareholder or shareholders representing at least 5% of the votes that may be cast on the resolution on a poll. On a show of hands, each shareholder entitled to vote at the meeting has one vote regardless of the number of ordinary shares held by such shareholder. If voting takes place on a poll, rather than a show of hands, each shareholder entitled to vote has one vote for each ordinary share held and a fractional vote for each ordinary share that is not fully paid, such fraction being equivalent to the proportion of the amount that has been paid (not credited) of the total amounts paid and payable, whether or not called (excluding amounts credited), to such date on that ordinary share.

Under Australian law, an ordinary resolution is passed on a show of hands if it is approved by a simple majority (more than 50%) of the votes cast by shareholders present (in person or by proxy) and entitled to vote. If a poll is demanded, an ordinary resolution is passed if it is approved by holders representing a simple majority of the total voting rights of shareholders present (in person or by proxy) who (being entitled to vote) vote on the resolution. Special resolutions require the affirmative vote of not less than 75% of the votes cast by shareholders present (in person or by proxy) and entitled to vote at the meeting.

Pursuant to our Constitution, each shareholder entitled to attend and vote at a meeting may attend and vote:

- in person physically or by electronic means;
- by proxy, attorney or by representative; or
- other than in relation to any clause which specifies a quorum, a member who has duly lodged a valid vote delivered to us by post, fax or other electronic means approved by the directors in accordance with the Constitution.

Under Australian law, shareholders of a public listed company are generally not permitted to approve corporate matters by written consent. Our Constitution does not specifically provide for cumulative voting.

Note that ADS holders may not directly vote at a meeting of the shareholders but may instruct the depositary to vote the number of deposited ordinary shares their ADSs represent. Under voting by a show of hands, multiple “yes” votes by ADS holders will only count as one “yes” vote and will be negated by a single “no” vote, unless a poll is demanded.

There are a number of circumstances where the Corporations Act or the ASX Listing Rules prohibit or restrict certain shareholders or certain classes of shareholders from voting. For example, key management personnel whose remuneration details are included elsewhere in this prospectus are prohibited from voting on the resolution that must be proposed at each annual general meeting to adopt our remuneration report, as well as any resolution to propose a spill meeting. An exception applies to exercising a directed proxy which indicates how the proxy is to vote on the proposed resolution on behalf of someone other than the key management personnel or their closely related parties; or that person is chair of the meeting and votes an undirected proxy where the shareholder expressly authorizes the chair to exercise that power. Key management personnel and their closely related parties are also prohibited from voting undirected proxies on remuneration related resolutions. A similar exception to that described above applies if the proxy is the chair of the meeting.

Right to Share in Our Profits

Subject to the Corporations Act and pursuant to our Constitution, our shareholders are entitled to participate in our profits by payment of dividends. The directors may by resolution declare a dividend or determine a dividend is payable, and may fix the amount, the time for and method of payment.

Rights to Share in the Surplus in the Event of Winding Up

Our Constitution provides for the right of shareholders to participate in a surplus in the event of our winding up.

Redemption Provisions

Under our Constitution and subject to the Corporations Act, the directors have power to issue and allot shares with any preferential, deferred or special rights, privileges or conditions; with any restrictions in regard to the dividend, voting, return of capital or otherwise; and preference shares which are liable to be redeemed or converted.

Sinking Fund Provisions

Our Constitution allows our directors to set aside any amount available for distribution as a dividend such amounts by way of reserves as they think appropriate before declaring or determining to pay a dividend, and may apply the reserves for any purpose for which an amount available for distribution as a dividend may be properly applied. Pending application or appropriation of the reserves, the directors may invest or use the reserves in our business or in other investments as they think fit.

Liability for Further Capital Calls

According to our Constitution, our board of directors may make any calls from time to time upon shareholders in respect of all monies unpaid on partly paid shares respectively held by them, subject to the terms upon which any of the partly paid shares have been issued. Each shareholder is liable to pay the amount of each call in the manner, at the time and at the place specified by our board of directors. Calls may be made payable by instalment.

Provisions Discriminating Against Holders of a Substantial Number of Shares

There are no provisions under our Constitution discriminating against any existing or prospective holders of a substantial number of our ordinary shares.

Variation or Cancellation of Share Rights

The rights attached to shares in a class of shares may only be varied or cancelled by a special resolution of shareholders, together with either:

- a special resolution passed at a separate meeting of members holding shares in the class; or
- the written consent of members with at least 75% of the votes in the class.

General Meetings of Shareholders

General meetings of shareholders may be called by our board of directors or, under the Corporations Act, by a single director. Except as permitted under the Corporations Act, shareholders may not convene a meeting. Under the Corporations Act, shareholders with at least 5% of the votes that may be cast at a general meeting may call and arrange to hold a general meeting. The Corporations Act requires the directors to call and arrange to hold a general meeting on the request of shareholders with at least 5% of the votes that may be cast at a general meeting. Notice of the proposed meeting of our shareholders is required at least 28 days prior to such meeting under the Corporations Act.

No business shall be transacted at any general meeting unless a quorum is present at the time when the meeting proceeds to business. Under our Constitution, the presence, in person or by proxy, attorney or representative, of two shareholders constitutes a quorum, or if we have less than two shareholders, then those shareholders constitute a quorum. If a quorum is not present within 30 minutes after the time appointed for the meeting, the meeting must be either dissolved if it was requested or called by shareholders or adjourned in any other case. A meeting adjourned for lack of a quorum is adjourned to the same day in the following week at the same time and place, unless otherwise decided by our directors. The reconvened meeting is dissolved if a quorum is not present within 30 minutes after the time appointed for the meeting.

Change of Control

Takeovers of listed Australian public companies, such as Mesoblast, are regulated by the Corporations Act, which prohibits the acquisition of a “relevant interest” in issued voting shares in a listed company if the acquisition will lead to that person’s or someone else’s voting power in Mesoblast increasing from 20% or below to more than 20% or increasing from a starting point that is above 20% and below 90% (“Takeovers Prohibition”), subject to a range of exceptions.

Generally, a person will have a relevant interest in securities if the person:

- is the holder of the securities or the holder of an ADS over the shares;
- has power to exercise, or control the exercise of, a right to vote attached to the securities; or
- has the power to dispose of, or control the exercise of a power to dispose of, the securities (including any indirect or direct power or control)

If, at a particular time:-

- a person has a relevant interest in issued securities; and
- the person has:
  - entered or enters into an agreement with another person with respect to the securities;
  - given or gives another person an enforceable right, or has been or is given an enforceable right by another person, in relation to the securities; or
  - granted or grants an option to, or has been or is granted an option by, another person with respect to the securities; and
- the other person would have a relevant interest in the securities if the agreement were performed, the right enforced or the option exercised,

then, the other person is taken to already have a relevant interest in the securities.

There are a number of exceptions to the above Takeovers Prohibition on acquiring a relevant interest in issued voting shares above 20%. In general terms, some of the more significant exceptions include:

- when the acquisition results from the acceptance of an offer under a formal takeover bid;
- when the acquisition is conducted on market by or on behalf of the bidder during the bid period for a full takeover bid that is unconditional or only conditional on certain 'prescribed' matters set out in the Corporations Act;
- when the acquisition has been previously approved by resolution passed at general meeting by shareholders of Mesoblast;
- an acquisition by a person if, throughout the six months before the acquisition, that person or any other person has had voting power in Mesoblast of at least 19% and, as a result of the acquisition, none of the relevant persons would have voting power in Mesoblast more than three percentage points higher than they had six months before the acquisition;
- when the acquisition results from the issue of securities under a pro rata rights issue;
- when the acquisition results from the issue of securities under a dividend reinvestment plan or bonus share plan;
- when the acquisition results from the issue of securities under certain underwriting arrangements;
- when the acquisition results from the issue of securities through a will or through operation of law;
- an acquisition that arises through the acquisition of a relevant interest in another company listed on the ASX or other Australian financial market or a foreign stock exchange approved in writing by ASIC;
- an acquisition arising from an auction of forfeited shares; or
- an acquisition arising through a compromise, arrangement, liquidation or buy-back.

A formal takeover bid may either be a bid for all securities in the bid class or a fixed proportion of such securities, with each holder of bid class securities receiving a bid for that proportion of their holding. Under our Constitution, a proportionate takeover bid must first be approved by resolution of our shareholders in a general meeting before it may proceed.

Breaches of the takeovers provisions of the Corporations Act are criminal offenses. In addition, ASIC and, on application by ASIC or an interested party, such as a shareholder, the Australian Takeovers Panel have a wide range of powers relating to breaches of takeover provisions, including the ability to make orders cancelling contracts, freezing transfers of, and rights (including voting rights) attached to, securities, and forcing a party to dispose of securities including by vesting the securities in ASIC for sale. There are certain defenses to breaches of the takeover provisions provided in the Corporations Act.

Ownership Threshold

There are no provisions in our Constitution that require a shareholder to disclose ownership above a certain threshold. The Corporations Act, however, requires a substantial shareholder to notify us and the ASX once a 5% interest in our ordinary shares is obtained. Further, once a shareholder has (alone or together with associates) a 5% or greater interest in us, such shareholder must notify us and the ASX of any increase or decrease of 1% or more in its interest in our ordinary shares. In addition, the Constitution requires a shareholder to provide information to the Company in relation to its entry into any arrangement restricting the transfer or other disposal of shares, which are of the nature of arrangements that Mesoblast is required to disclose under the ASX Listing Rules. Following our initial public offering in the United States, our shareholders are also subject to disclosure requirements under U.S. securities laws.

Issues of Shares and Change in Capital

Subject to our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, we may at any time grant options over unissued shares and issue shares on any terms, with any preferential, deferred or special rights, privileges or conditions; with any restrictions in regard to dividend, voting, return of capital or otherwise, and for the consideration and other terms that the directors determine. Our power to issue shares includes the power to issue bonus shares (for which no consideration is payable to Mesoblast), preference shares and partly paid shares.

Subject to the requirements of our Constitution, the Corporations Act, the ASX Listing Rules and any other applicable law, including relevant shareholder approvals, we may reduce our share capital (provided that the reduction is fair and reasonable to our shareholders as a whole, does not materially prejudice our ability to pay creditors and obtains the necessary shareholder approval) or buy back our ordinary shares including under an equal access buy-back or on a selective basis. Under the Constitution, the directors may do anything required to give effect to any resolution altering or approving the reduction of our share capital.

Access to and Inspection of Documents

Inspection of our records is governed by the Corporations Act. Any member of the public has the right to inspect or obtain copies of our share registers on the payment of a prescribed fee. Shareholders are not required to pay a fee for inspection of our share registers or minute books of the meetings of shareholders. Other corporate records, including minutes of directors' meetings, financial records and other documents, are not open for inspection by shareholders. Where a shareholder is acting in good faith and an inspection is deemed to be made for a proper purpose, a shareholder may apply to the court to make an order for inspection of our books.

10.C Material Contracts

Loan Agreement with Hercules

In March 2018, we entered into a loan and security agreement with Hercules for a $75.0 million non-dilutive, secured four-year credit facility with an initial interest rate of 9.45%. We drew the first tranche of $35.0 million on closing and a further tranche of $15.0 million was drawn in January 2019. An additional $25.0 million may be drawn as certain milestones are met. The loan matures in March 2022 with principal repayments commencing in October 2019 with the ability to defer the commencement of principal repayments to October 2020 if certain milestones are met. Interest on the loan is payable monthly in arrears on the 1st day of the month. The interest rate is floating. It is computed daily based on the actual number of days elapsed and it is the greater of either 9.45% or the prime rate as reported in the Wall Street Journal plus a certain margin. On March 22, 2018, June 14, 2018, September 27, 2018 and December 20, 2018, in line with the increases in the U.S. prime rate, the interest rate on the loan increased to 9.70%, 9.95%, 10.20% and 10.45%, respectively. The loan agreement contains certain covenants, see "Item 5.B Liquidity and Capital Resource – Borrowings."

Loan Agreement with NovaQuest

In June 2018, we entered into a non-dilutive secured loan with NovaQuest for $40.0 million. There is a four-year interest only period, until July 2022, with the principal repayable in equal quarterly instalments over the remaining period of the loan. The loan matures in July 2026. Interest on the loan will accrue at a fixed rate of 15% per annum. The loan agreement contains certain covenants, see "Item 5.B Liquidity and Capital Resource – Borrowings."

All interest and principal payments will be deferred until after the first commercial sale of our allogeneic product candidate MSC-100-IV in pediatric patients with steroid refractory aGVHD, in the United States and other geographies excluding Asia

("pediatric aGVHD"). We can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of pediatric aGVHD are significantly higher than current forecasts.

If there are no net sales of pediatric aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of pediatric aGVHD exceed the amount of accrued interest owing and from 2022, principal and accrued interest owing ("the payment cap"), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of pediatric aGVHD is less than the payment cap, then the payment is limited to 25% of net sales of pediatric aGVHD. Any unpaid interest will be added to the principal amounts owing and will accrue further interest. At maturity date, any unpaid loan balances are repaid.

Agreements with Tasly Pharmaceutical Group

In July 2018, we entered into a Development and Commercialization Agreement with Tasly.

The Development and Commercialization Agreement provides Tasly with exclusive rights to develop, manufacture and commercialize in China MPC-150-IM for the treatment or prevention of chronic heart failure and MPC-25-IC for the treatment or prevention of acute myocardial infarction. Tasly will fund all development, manufacturing and commercialization activities in China for MPC-150-IM and MPC-25-IC. On closing, we received a $20.0 million upfront technology access fee. Further, we will receive $25.0 million on product regulatory approvals in China. Mesoblast will receive double-digit escalating royalties on net product sales. Mesoblast is eligible to receive six escalating milestone payments upon the product candidates reaching certain sales thresholds in China.

The Development and Commercialization Agreement provides that Tasly can terminate this agreement with a specified amount of notice, on the later of (a) third anniversary of the agreement coming into effect and (b) receipt of marketing approval in China for each of MPC-150-IM or MPC-25-IC. Mesoblast has termination rights with respect to certain patent challenges by Tasly and if certain competing activities are undertaken by Tasly. Either party may terminate the agreement on material breach of the agreement if such breach in not cured within the specified cure period or if certain events related to bankruptcy of the other party occurs.

TiGenix NV – patent license for treatment of fistulae

In December 2017, we entered into a Patent License Agreement with TiGenix NV, now a wholly owned subsidiary of Takeda, which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived mesenchymal stem cell product Alofisel®, previously known as Cx601, a product candidate of Takeda, for the local treatment of fistulae. The agreement includes the right for Takeda to grant sub-licenses to affiliates and third parties.

As part of the agreement, we received $5.9 million (€5.0 million) before withholding tax as a non-refundable up-front payment and a further payment of $5.9 million (€5.0 million) before withholding tax 12 months after the patent license agreement date. We are entitled to further payments up to €10.0 million when Takeda reaches certain product regulatory milestones. Additionally, we receive single digit royalties on net sales of Alofisel®.

The agreement will continue in full force in each country (other than the United States) until the date upon which the last issued claim of any licensed patent covering Alofisel® expires in such country (currently expected to be 2029) or, with respect to the United States, until the later of (i) the date upon which the last issued claim of any licensed patent covering Alofisel® in the United States expires (currently expected to be around 2031) or (ii) the expiration of the regulatory exclusivity period in the United States with an agreed maximum term.

Either we or Takeda may terminate the agreement for any material breach that is not cured within 90 days after notice. We also have the right to terminate the agreement with a written notice in the event that Takeda file a petition in bankruptcy or insolvency or Takeda makes an assignment of substantially all of its assets for the benefit of its creditors.

Takeda has the right to terminate its obligation to pay royalties for net sales in a specific country if it is of the opinion that there is no issued claim of any licensed patent covering Alofisel® in such country, subject to referral of the matter to the joint oversight/cooperation committee established under the agreement if we disagree.

10.D Exchange Controls

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 non-residents must be reported to the Australian Transaction Reports and Analysis Centre ("AUSTRAC"), which monitors such transaction, and amounts on account of potential Australian tax liabilities may be required to be withheld unless a relevant taxation treaty can be shown to apply.

Regulation of acquisition by foreign entities

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 1975. These limitations are in addition to the more general overarching Takeovers Prohibition of an acquisition of more than a 20% interest in a public company (in the absence of an applicable exception) under the takeovers provisions of Australia's Corporations Act by any person whether foreign or otherwise.

Under the Foreign Acquisitions and Takeovers Act, as currently in effect, any foreign person, together with associates, or parties acting in concert, is prohibited from acquiring 20% or more of the shares in any company having consolidated total assets of or that is valued at A$266 million or more (or A$1,154 million or more in case of U.S. investors or investors from certain other countries). No asset threshold applies in the case of foreign government investors. Different rules apply to sensitive industries (such as media, telecommunications, and encryption and security technologies), companies owning land or that are agribusinesses. "Associates" is a broadly defined term under the Foreign Acquisitions and Takeovers Act and includes in relation to any person:

- any relative of the person;
- any person with whom the person is acting or proposes to act in concert;
- any person with whom the person carries on a business in partnership;
- any entity of which the person is a 'senior officer' (such as a director or executive);
- if the person is an entity, any holding entity or any senior officer of the entity;
- any entity whose senior officers are accustomed or obliged to act in accordance with the directions, instructions or wishes of the person or if the person is an entity, its senior officers or vice versa;
- any corporation in which the person holds a 'substantial interest' (i.e., 20%) or any person holding a substantial interest in the person if a corporation;
- a trustee of a trust in which the person holds a substantial interest or if the person is the trustee of a trust, a person who holds a substantial interest in the trust;
- if the person is a foreign government, a separate government entity or a foreign government investor in relation to a foreign country, any other person that is a foreign government, a separate government entity or foreign government investor, in relation to that country.

The Australian Treasurer also has power in certain circumstances to make an order specifying that two or more persons are associates.

In addition, a foreign person may not acquire shares in a company having consolidated total assets of or that is valued at A$266 million or more (or A$1,154 million or more in case of U.S. investors or investors from certain other countries) 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. The same rule applies if the total holdings of all foreign persons and their associates already exceeds 40% and a foreign person (or its associate) acquires any further shares, including in the course of trading in the secondary market of the ADSs. Different rules apply to government investors, and acquisitions of interests in sensitive business acquisitions, agribusiness and land owning entities.

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 and pay the relevant application fees. 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 Foreign

Investment Review Board, an Australian advisory board to the Australian Treasurer has provided 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, among other things, that the Treasurer will reject an application if it is contrary to the national interest.

If the level of foreign ownership in Mesoblast exceeds 40% at any time, we would be considered a foreign person under the Foreign Acquisitions and 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 having total assets of, or that is valued at, A$266 million or more; or (ii) any direct or indirect ownership in Australian land; or (iii) any 'direct interest' in any agribusiness.

The percentage of foreign ownership in our company may 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 acquisition and do not own any property, 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 property in Australia.

Our Constitution does not contain any additional limitations on the right to hold or vote our securities by reason of being a non-resident.

Australian law requires the transfer of shares in our company to be made in writing or electronically through the Clearing House Electronic Sub-register System.

10.E Taxation

The following summary of the material Australian and U.S. federal income tax consequences of an investment in our ADSs or ordinary shares is based upon laws and relevant interpretations thereof in effect as of the date of this Form 20-F, all of which are subject to change, possibly with retroactive effect. This summary does not deal with all possible tax consequences relating to an investment in our ADSs or ordinary shares, such as the tax consequences under U.S. state, local and other tax laws other than Australian and U.S. federal income tax laws.

Certain Material U.S. Federal Income Tax Considerations to U.S. Holders

The following summary describes certain material U.S. federal income tax consequences to U.S. holders (as defined below) of the ownership and disposition of our ordinary shares and ADSs as of the date hereof. Except where noted, this summary deals only with our ordinary shares or ADSs acquired and held as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code. This section does not discuss the tax consequences to any particular holder, nor any tax considerations that may apply to holders subject to special tax rules, such as:

- banks, insurance companies, regulated investment companies and real estate investment trusts;
- financial institutions;
- individual retirement and other tax-deferred accounts;
- certain former U.S. citizens or long-term residents;
- brokers or dealers in securities or currencies;
- traders that elect to use a mark-to-market method of accounting;
- partnerships and other entities treated as partnership or pass through entities for U.S. federal income tax purposes, and partners or investors in such entities;
- tax-exempt organizations (including private foundations);
- persons that may have been subject to the alternative minimum tax;
- persons that hold or dispose of ordinary shares or ADSs as a position in a straddle or as part of a hedging, constructive sale, conversion or other integrated transaction;
- persons that have a functional currency other than the U.S. dollar;
- persons that own (directly, indirectly or constructively) 10% or more of the vote or value of our equity;

- persons subject to special tax accounting rules as a result of any item of gross income with respect to ordinary shares or ADSs being taken into account in an applicable financial statement;
- persons who acquire ordinary shares or ADSs pursuant to the exercise of any employee share option or otherwise as compensation; or
- persons that are not U.S. holders (as defined below).

In this section, a "U.S. holder" means a beneficial owner of ordinary shares or ADSs, other than a partnership or other entity treated as a partnership for U.S. federal income tax purposes, that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States (for U.S. federal income tax purposes);
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any state thereof or the District of Columbia;
- an estate the income of which is includable in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust (i) the administration of which is subject to the primary supervision of a court in the United States and for which one or more U.S. persons have the authority to control all substantial decisions or (ii) that has an election in effect under applicable U.S. income tax regulations to be treated as a U.S. person.

The discussion below is based upon the provisions of the Code, and the U.S. Treasury regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be replaced, revoked or modified, possibly with retroactive effect, so as to result in U.S. federal income tax consequences different from those discussed below. In addition, this summary is based, in part, upon the terms of the deposit agreement and assumes that the deposit agreement, and all other related agreements, will be performed in accordance with their terms.

If a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes acquires, owns or disposes of ordinary shares or ADSs, the U.S. federal income tax treatment of a partner generally will depend on the status of the partner and the activities of the partnership. Partners of partnerships that acquire, own or dispose of ordinary shares or ADSs should consult their tax advisors.

You are urged to consult your own tax advisor with respect to the U.S. federal, as well as state, local and non-U.S., tax consequences to you of acquiring, owning and disposing of ordinary shares or ADSs in light of your particular circumstances, including the possible effects of changes in U.S. federal income and other tax laws and the effects of any tax treaties.

ADSs

Assuming the deposit agreement and all other related agreements will be performed in accordance with their terms, a U.S. holder of ADSs will be treated as the beneficial owner for U.S. federal income tax purposes of the underlying shares represented by the ADSs. The U.S. Treasury has expressed concerns that parties to whom American depositary shares are released before shares are delivered to the depositary, or intermediaries in the chain of ownership between holders of American depositary shares and the issuer of the security underlying the American depositary shares, may be taking actions that are inconsistent with claiming foreign tax credits by holders of American depositary shares. These actions would also be inconsistent with claiming the reduced rate of tax, described below, applicable to dividends received by certain non-corporate holders. Accordingly, the creditability of any foreign taxes and the availability of the reduced tax rate for dividends received by certain non-corporate U.S. holders, each described below, could be affected by actions taken by such parties or intermediaries.

Distributions

Subject to the passive foreign investment company, or PFIC, rules discussed below, U.S. holders generally will include as dividend income the U.S. dollar value of the gross amount of any distributions of cash or property (without deduction for any withholding tax), other than certain pro rata distributions of ordinary shares, with respect to ordinary shares or ADSs to the extent the distributions are made from our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. A U.S. holder will include the dividend income on the day actually or constructively received: (i) by the holder, in the case of ordinary shares, or (ii) by the depositary, in the case of ADSs. To the extent, if any, that the amount of any distribution by us exceeds our current and accumulated earnings and profits, as so determined, the excess will be treated first as a tax-free return of the U.S. holder's tax basis in the ordinary shares or ADSs and thereafter as capital gain. Notwithstanding the foregoing, we do not intend to determine our earnings and profits on the basis of U.S. federal income tax principles. Consequently, any distributions generally will be reported as dividend income for U.S. information reporting purposes. See "— Backup Withholding Tax and Information Reporting

Requirements" below. Dividends paid by us will not be eligible for the dividends-received deduction generally allowed to U.S. corporate shareholders.

The U.S. dollar amount of dividends received by an individual, trust or estate with respect to the ordinary shares or ADSs will be subject to taxation at preferential rates if the dividends are "qualified dividends." Dividends paid on ordinary shares or ADSs will be treated as qualified dividends if (i)(a) we are eligible for the benefits of a comprehensive income tax treaty with the United States that the Secretary of the Treasury of the United States determines is satisfactory for this purpose and includes an exchange of information program or (b) the dividends are with respect to ordinary shares (or ADSs in respect of such shares) which are readily tradable on a U.S. securities market; (ii) certain holding period requirements are met; and (iii) we are not classified as a PFIC for the taxable year in which the dividend is paid or for the preceding taxable year. The Agreement between the Government of the United States of America and the Government of Australia for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, or the Treaty, has been approved for the purposes of the qualified dividend rules, and we expect to qualify for benefits under the Treaty. In addition, our ADSs are listed on the Nasdaq Global Select Market, and as such U.S. Treasury Department guidance indicates that our ADSs will be readily tradable on an established U.S. securities market. Thus, we believe that as long as we are not a PFIC, dividends we pay generally should be eligible for the preferential tax rates on qualified dividends. However, the determination of whether a dividend qualifies for the preferential tax rates must be made at the time the dividend is paid. U.S. holders should consult their own tax advisors regarding the availability of the preferential tax rates on dividends.

Includible distributions paid in Australian dollars, including any Australian withholding taxes, will be included in the gross income of a U.S. holder in a U.S. dollar amount calculated by reference to the spot exchange rate in effect on the date of actual or constructive receipt, regardless of whether the Australian dollars are converted into U.S. dollars at that time. If Australian dollars are converted into U.S. dollars on the date of actual or constructive receipt, the tax basis of the U.S. holder in those Australian dollars will be equal to their U.S. dollar value on that date and, as a result, a U.S. holder generally should not be required to recognize any foreign currency exchange gain or loss. If Australian dollars so received are not converted into U.S. dollars on the date of receipt, the U.S. holder will have a basis in the Australian dollars equal to their U.S. dollar value on the date of receipt. Any foreign currency exchange gain or loss on a subsequent conversion or other disposition of the Australian dollars generally will be treated as ordinary income or loss to such U.S. holder and generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

Dividends received by a U.S. holder with respect to ordinary shares (or ADSs in respect of such shares) will be treated as foreign source income, which may be relevant in calculating the holder's foreign tax credit limitation. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to ADSs or ordinary shares will generally constitute "passive category income" but could, in the case of certain U.S. holders, constitute "general category income."

Subject to certain complex limitations, including the PFIC rules discussed below, a U.S. holder generally will be entitled, at such holder's option, to claim either a credit against such holder's U.S. federal income tax liability or a deduction in computing such holder's U.S. federal taxable income in respect of any Australian taxes withheld. If a U.S. holder elects to claim a deduction, rather than a foreign tax credit, for Australian taxes withheld for a particular taxable year, the election will apply to all foreign taxes paid or accrued by or on behalf of the U.S. holder in the particular taxable year.

The availability of the foreign tax credit and the application of the limitations on its availability are fact specific and are subject to complex rules. You are urged to consult your own tax advisor as to the consequences of Australian withholding taxes and the availability of a foreign tax credit or deduction. See "—Australian Tax Considerations Australian—Income Tax—Taxation of Dividends" below.

Sale, Exchange or Other Disposition of Ordinary Shares or ADSs

Subject to the PFIC rules discussed below, a U.S. holder generally will, for U.S. federal income tax purposes, recognize capital gain or loss, if any, on a sale, exchange or other disposition of ordinary shares or ADSs equal to the difference between the amount realized on the disposition and the U.S. holder's tax basis (in U.S. dollars) in the ordinary shares or ADSs. This recognized gain or loss will generally be long-term capital gain or loss if the U.S. holder has held the ordinary shares or ADSs for more than one year. Generally, for U.S. holders who are individuals (as well as certain trusts and estates), long-term capital gains are subject to U.S. federal income tax at preferential rates. For foreign tax credit limitation purposes, gain or loss recognized upon a disposition generally will be treated as from sources within the United States. The deductibility of capital losses is subject to limitations for U.S. federal income tax purposes.

You should consult your own tax advisor regarding the tax consequences if a foreign tax is imposed on a disposition of ADSs or ordinary shares, including availability of a foreign tax credit or deduction in respect of any Australian tax imposed on a sale or other

disposition of ordinary shares or ADSs. See "—Australian Tax Considerations—Australian Income Tax—Tax on Sales or Other Dispositions of Shares—Capital Gains Tax."

Passive Foreign Investment Company

As a non-U.S. corporation, we will be a PFIC for any taxable year if either: (i) 75% or more of our gross income for the taxable year is passive income (such as certain dividends, interest, rents or royalties and certain gains from the sale of shares and securities or commodities transactions, including amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares or ADSs); or (ii) the average quarterly value of our gross assets during the taxable year that produce passive income or are held for the production of passive income is at least 50% of the value of our total assets. For purposes of the PFIC asset test, passive assets generally include any cash, cash equivalents and cash invested in short-term, interest bearing debt instruments or bank deposits that are readily convertible into cash. If we own at least 25% (by value) of the stock of another corporation, we will be treated, for purposes of the PFIC income and asset tests, as owning our proportionate share of the other corporation's assets and receiving our proportionate share of the other corporation's income.

We do not believe that we were a PFIC for the taxable year ending June 30, 2019. However, if there is a change in the type or composition of our gross income, or our actual business results do not match our projections, it is possible that we may become a PFIC in future taxable years. Investors should be aware that our gross income for purposes of the PFIC income test depends on the receipt of Australian research and development tax incentive credits and other revenue, and there can be no assurances that such tax incentive credit programs will not be revoked or modified, that we will continue to conduct our operations in the manner necessary to be eligible for such incentives or that we will receive other gross income that is not considered passive for purposes of the PFIC income test. The value of our assets for purposes of the PFIC asset test will generally be determined by reference to our market capitalization, which may fluctuate. The composition of our income and assets will also be affected by how, and how quickly, we spend the cash raised in offerings of our ordinary shares or ADSs. Under circumstances where our gross income from activities that produce passive income significantly increases relative to our gross income from activities that produce non-passive income or where we decide not to deploy significant amounts of cash for active purposes, our risk of becoming classified as a PFIC may substantially increase. Since a separate factual determination as to whether we are or have become a PFIC must be made each year (after the close of such year), we cannot assure you that we will not be or become a PFIC in the current year or any future taxable year. There can be no assurance that we will not be a PFIC for any taxable year, as PFIC status is determined each year and depends on the composition of our income and assets and the value of our assets in such year. If we are a PFIC for any taxable year, upon request, we intend to provide U.S. holders with the information necessary to make and maintain a "Qualified Electing Fund" election, as described below.

Default PFIC Rules

If we are a PFIC for any taxable year during which you own our ordinary shares or ADSs, unless you make the mark-to-market election or the Qualified Electing Fund election described below, you will generally be (and remain) subject to additional taxes and interest charges, regardless of whether we remain a PFIC in any subsequent taxable year, (i) on certain "excess distributions" we may make; and (ii) on any gain realized on the disposition or deemed disposition of your ordinary shares or ADSs. Distributions in respect of your ordinary shares (or ADSs in respect of such shares) during the taxable year will generally constitute "excess" distributions if, in the aggregate, they exceed 125% of the average amount of distributions in respect of your ordinary shares (or ADSs) over the three preceding taxable years or, if shorter, the portion of your holding period before such taxable year.

To compute the tax on "excess" distributions or any gain: (i) the "excess" distribution or the gain will be allocated ratably to each day in your holding period for the ADSs or the ordinary shares; (ii) the amount allocated to the current taxable year and any taxable year before we became a PFIC will be taxed as ordinary income in the current year; (iii) the amount allocated to other taxable years will be taxable at the highest applicable marginal rate in effect for that year; and (iv) an interest charge at the rate for underpayment of taxes will be imposed with respect to any portion of the "excess" distribution or gain described under (iii) above that is allocated to such other taxable years. In addition, if we are a PFIC or, with respect to a particular U.S. holder, we are treated as a PFIC for the taxable year in which the distribution was paid or the prior taxable year, no distribution that you receive from us will qualify for taxation at the preferential rate for non-corporate holders discussed in "—Distributions" above. You should consult with your own tax advisor regarding the application of the default PFIC rules based on your particular circumstances.

If we are a PFIC for any taxable year during which a U.S. holder holds our ADSs or ordinary shares and any of our non-U.S. subsidiaries is also a PFIC (i.e., a lower-tier PFIC), such U.S. holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be subject to the rules described above on certain distributions by the lower-tier PFIC and our disposition of shares of the lower-tier PFIC, even though such U.S. holder would not receive the proceeds of those distributions or dispositions. You should consult with your own tax advisor regarding the application to you of the PFIC rules to any of our subsidiaries if we are a PFIC.

Mark-to-Market Election

If we are a PFIC for any taxable year during which you own our ADSs or ordinary shares, you will be able to avoid the rules applicable to "excess" distributions or gains described above if the ordinary shares or ADSs are "marketable" and you make a timely "mark-to-market" election with respect to your ordinary shares or ADSs. The ordinary shares or ADSs will be "marketable" stock as long as they remain regularly traded on a national securities exchange, such as the Nasdaq Global Select Market, or a foreign securities exchange regulated by a governmental authority of the country in which the market is located and which meets certain requirements, including that the rules of the exchange effectively promote active trading of listed stocks. If such stock is traded on such a qualified exchange or other market, such stock generally will be "regularly traded" for any calendar year during which such stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter, but no assurances can be given in this regard. Our ordinary shares are traded on the ASX, which may qualify as an eligible foreign securities exchange for this purpose.

If you are eligible to make a "mark-to-market" election with respect to our ordinary shares or ADSs and you make this election in a timely fashion, you will generally recognize as ordinary income or ordinary loss the difference between the fair market value of your ordinary shares or ADSs on the last day of any taxable year and your adjusted tax basis in the ordinary shares or ADSs. Any ordinary income resulting from this election will generally be taxed at ordinary income rates. Any ordinary losses will be deductible only to the extent of the net amount of previously included income as a result of the mark-to-market election, if any. Your adjusted tax basis in the ordinary shares or ADSs will be adjusted to reflect any such income or loss. Any gain recognized on the sale or other disposition of your ordinary shares or ADSs in a year when we are a PFIC will be treated as ordinary income, and any loss will be treated as an ordinary loss (but only to the extent of the net amount previously included as ordinary income as a result of the mark-to-market election).

Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. holder may continue to be subject to the PFIC rules with respect to such holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes, including shares in any of our subsidiaries that are treated as PFICs.

You should consult with your own tax advisor regarding the applicability and potential advantages and disadvantages to you of making a "mark-to-market" election with respect to your ordinary shares or ADSs if we are or become a PFIC, including the tax issues raised by lower-tier PFICs that we may own and the procedures for making such an election.

QEF Election

Alternative rules to those set forth under "Default PFIC Rules" above apply if an election is made to treat us as a "Qualified Electing Fund," or QEF, under Section 1295 of the Code. A QEF election is available only if a U.S. holder receives an annual information statement from us setting forth such holder's pro rata share of our ordinary earnings and net capital gains, as calculated for U.S. federal income tax purposes.

Upon request from a U.S. holder, we will endeavor to provide to the U.S. holder within 90 days after the request an annual information statement, in order to enable the U.S. holder to make and maintain a QEF election for us or for any of our subsidiaries that is or becomes a PFIC. However, there is no assurance that we will have timely knowledge of our or our subsidiaries' status as a PFIC in the future or of the required information to be provided. You should consult your own tax advisor regarding the availability and tax consequences of a QEF election with respect to the ordinary shares or ADSs or with respect to any lower-tier PFIC that we may own under your particular circumstances.

Reporting

If we are a PFIC for any taxable year during which you own our ordinary shares or ADSs, as a U.S. holder, you will generally be required to file IRS Form 8621 on an annual basis, and other reporting requirements may apply. The PFIC rules are complex and you should consult with your own tax advisor regarding whether we or any of our subsidiaries are a PFIC, the tax consequences of any elections that may be available to you, and how the PFIC rules may affect the U.S. federal income tax consequences of the receipt, ownership, and disposition of our ordinary shares or ADSs.

Tax on Net Investment Income

Certain non-corporate U.S. holders will be subject to a 3.8% tax on the lesser of (i) the U.S. holder's "net investment income" for the relevant taxable year; and (ii) the excess of the U.S. holder's modified adjusted gross income for the taxable year over a certain threshold. A U.S. holder's net investment income will generally include dividends received on the ordinary shares or ADSs and net gains from the disposition of ordinary shares or ADSs, unless such dividend income or net gains are derived in the ordinary course of

the conduct of a trade or business (other than a trade or business that consists of certain passive or trading activities). A U.S. holder that is an individual, estate or trust should consult the holder's tax advisor regarding the applicability of the tax on net investment income to the holder's dividend income and gains in respect of the holder's investment in the ordinary shares or ADSs.

Backup Withholding Tax and Information Reporting Requirements

U.S. backup withholding tax and information reporting requirements generally apply to payments to non-corporate holders of ordinary shares or ADSs. Information reporting will apply to payments of dividends on, and to proceeds from the disposition of, ordinary shares or ADSs by a paying agent within the United States to a U.S. holder, other than U.S. holders that are exempt from information reporting and properly certify their exemption. A paying agent within the United States will be required to withhold at the applicable statutory rate, currently 24%, in respect of any payments of dividends on, and the proceeds from the disposition of, ordinary shares or ADSs within the United States to a U.S. holder (other than U.S. holders that are exempt from backup withholding and properly certify their exemption) if the holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with applicable backup withholding requirements. U.S. holders who are required to establish their exempt status generally must provide a properly completed IRS Form W-9.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. holder's U.S. federal income tax liability. A U.S. holder generally may obtain a refund of any amounts withheld under the backup withholding rules in excess of such holder's U.S. federal income tax liability by filing the appropriate claim for refund with the IRS in a timely manner and furnishing any required information.

Certain U.S. holders may be required to report (on IRS Form 8938) information with respect to such holder's interest in "specified foreign financial assets" (as defined in Section 6038D of the Code), including stock of a non-U.S. corporation that is not held in an account maintained by a U.S. "financial institution". Persons who are required to report specified foreign financial assets and fail to do so may be subject to substantial penalties. U.S. holders are urged to consult their own tax advisors regarding foreign financial asset reporting obligations and their possible application to the holding of ordinary shares or ADSs.

The discussion above is a general summary only. It is not intended to constitute a complete analysis of all tax considerations applicable to an investment in our ADSs or ordinary shares. You should consult with your own tax advisor concerning the tax consequences to you of an investment in our ADSs or ordinary shares in light of your particular circumstances.

Australian Tax Considerations

In this section, we discuss the material Australian income tax, stamp duty and goods and services tax considerations related to the acquisition, ownership and disposal by the absolute beneficial owners of the ordinary shares or ADSs. It is based upon existing Australian tax law as of the date of this annual report, which is subject to change, possibly retrospectively. This discussion does not address all aspects of Australian tax law which may be important to particular investors in light of their individual investment circumstances, such as shares held by investors subject to special tax rules (for example, financial institutions, insurance companies or tax exempt organizations). In addition, this summary does not discuss any foreign or state tax considerations, other than stamp duty and goods and services tax. Prospective investors are urged to consult their tax advisors regarding the Australian and foreign income and other tax considerations of the acquisition, ownership and disposition of the shares. This summary is based upon the premise that the holder is not an Australian tax resident and is not carrying on business in Australia through a permanent establishment (referred to as a "Foreign Shareholder" in this summary).

Australian Income Tax

Nature of ADSs for Australian Taxation Purposes

Ordinary shares represented by ADSs held by a U.S. holder will be treated for Australian taxation purposes as held under a "bare trust" for such holder. Consequently, the underlying ordinary shares will be regarded as owned by the ADS holder for Australian income tax and capital gains tax purposes. Dividends paid on the underlying ordinary shares will also be treated as dividends paid to the ADS holder, as the person beneficially entitled to those dividends. Therefore, in the following analysis we discuss the tax consequences to non-Australian resident holders of ordinary shares which, for Australian taxation purposes, will be the same as to U.S. holders of ADSs.

Taxation of Dividends

Australia operates a dividend imputation system under which dividends may be declared to be "franked" to the extent of tax paid on company profits. Fully franked dividends are not subject to dividend withholding tax. Dividends payable to non-Australian resident shareholders that are not operating from an Australian permanent establishment, or Foreign Shareholders, will be subject to dividend withholding tax, to the extent the dividends are not foreign (i.e., non-Australian) sourced and declared to be conduit foreign income, or CFI, and are unfranked. Dividend withholding tax will be imposed at 30%, unless a shareholder is a resident of a country with which Australia has a double taxation agreement and qualifies for the benefits of the treaty. Under the provisions of the current Double Taxation Convention between Australia and the United States, the Australian tax withheld on unfranked dividends that are not CFI paid by us to which a resident of the United States is beneficially entitled is limited to 15%.

If a company that is a non-Australian resident shareholder directly owns a 10% or more interest, the Australian tax withheld on unfranked dividends (that are not CFI) paid by us to which a resident of the United States is beneficially entitled is limited to 5%. In limited circumstances the rate of withholding can be reduced to zero.

Tax on Sales or Other Dispositions of Shares—Capital Gains Tax

Foreign Shareholders will not be subject to Australian capital gains tax on the gain made on a sale or other disposal of our ordinary shares, unless they, together with associates, hold 10% or more of our issued capital, at the time of disposal or for 12 months of the last 2 years prior to disposal.

Foreign Shareholders who own a 10% or more interest would be subject to Australian capital gains tax if more than 50% of our assets held directly or indirectly, determined by reference to market value, consists of Australian real property (which includes land and leasehold interests) or Australian mining, quarrying or prospecting rights. The Double Taxation Convention between the United States and Australia is unlikely to limit the amount of this taxable gain. Australian capital gains tax applies to net capital gains of Foreign Shareholders at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5%. Net capital gains are calculated after reduction for capital losses, which may only be offset against capital gains.

The 50% capital gains tax discount is not available to non-Australian residents on gains accrued after May 8, 2012. Companies are not entitled to a capital gains tax discount.

Broadly, where there is a disposal of certain taxable Australian property, the purchaser will be required to withhold and remit to the Australian Taxation Office ("ATO") 12.50% of the proceeds from the sale. A transaction is excluded from the withholding requirements in certain circumstances, including where the value of the taxable Australian property is less than A$750,000, the transaction is an on-market transaction conducted on an approved stock exchange, a securities lending, or the transaction is conducted using a broker operated crossing system. There is also an exception to the requirement to withhold where the Commissioner issues a clearance certificate which broadly certifies that the vendor is not a foreign person. The Foreign Shareholder may be entitled to receive a tax credit for the tax withheld by the purchaser which they may claim in their Australian income tax return.

Tax on Sales or Other Dispositions of Shares—Shareholders Holding Shares on Revenue Account

Some Foreign Shareholders may hold ordinary shares on revenue rather than on capital account for example, share traders. These shareholders may have the gains made on the sale or other disposal of the ordinary shares included in their assessable income under the ordinary income provisions of the income tax law, if the gains are sourced in Australia.

Foreign Shareholders assessable under these ordinary income provisions in respect of gains made on ordinary shares held on revenue account would be assessed for such gains at the Australian tax rates for non-Australian residents, which start at a marginal rate of 32.5%. Some relief from Australian income tax may be available to such non-Australian resident shareholders under the Double Taxation Convention between the United States and Australia.

To the extent an amount would be included in a Foreign Shareholder's assessable income under both the capital gains tax provisions and the ordinary income provisions, the capital gain amount would generally be reduced, so that the shareholder would not be subject to double tax on any part of the income gain or capital gain.

The comments above in "Tax on Sales or Other Dispositions of Shares—Capital Gains Tax" regarding a purchaser being required to withhold 12.5% tax on the acquisition of certain taxable Australian property equally applies where the disposal of the Australian real property asset by a foreign resident is likely to generate gains on revenue account, rather than a capital gain.

Dual Residency

If a shareholder were a resident of both Australia and the United States under those countries' domestic taxation laws, that shareholder may be subject to tax as an Australian resident. If, however, the shareholder is determined to be a U.S. resident for the purposes of the Double Taxation Convention between the United States and Australia, the Australian tax may be subject to limitation by the Double Taxation Convention. Shareholders should obtain specialist taxation advice in these circumstances.

Australian Death Duty

Australia does not have estate or death duties. As a general rule, no capital gains tax liability is realized upon the inheritance of a deceased person's ordinary shares. The disposal of inherited ordinary shares by beneficiaries may, however, give rise to a capital gains tax liability if the gain falls within the scope of Australia's jurisdiction to tax (as discussed above).

Stamp Duty

No Australian stamp duty is payable by Australian residents or non-Australian residents on the issue, transfer and/or surrender of the ADSs or the ordinary shares in Mesoblast, provided that all of the ADSs and ordinary shares in Mesoblast are listed on Nasdaq and ASX and the shares issued, transferred and/or surrendered do not represent 90% or more of the issued shares in Mesoblast.

Goods and Services Tax

The supply of ADSs and/or ordinary shares in Mesoblast will not be subject to Australian goods and services tax.

10.F Dividends and Paying Agents

Not applicable.

10.G Statement by Experts

Not applicable.

10.H Documents on Display

Any statement in this Form 20-F about any of our contracts or other documents is not necessarily complete. If the contract or document is filed as an exhibit to the Form 20-F the contract or document is deemed to modify the description contained in this Form 20-F. You must review the exhibits themselves for a complete description of the contract or document.

You may review a copy of our filings with the SEC, as well as other information furnished to the SEC, including exhibits and schedules filed with it, at the SEC's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. In addition, the SEC maintains a website at http://www.sec.gov that contains reports and other information regarding issuers that file electronically with the SEC. These SEC filings are also available to the public from commercial document retrieval services.

We are required to file or furnish reports and other information with the SEC under the Securities Exchange Act of 1934 and regulations under that act. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the form and content of proxy statements and our officers, directors and principal shareholders are exempt from the reporting and short swing profit recovery provisions contained in Section 16 of the Exchange Act.

10.I Subsidiary Information

For information about our subsidiaries, see "Item 18. Financial Statements – Note 12."

Item 11. Quantitative and Qualitative Disclosures about Market Risk

For information about our exposure to market risk and how we manage this risk, see "Item 18. Financial Statements – Note 10."

Item 12. Description of Securities Other than Equity Securities

12.A Debt Securities

Not applicable.

12.B Warrants and Rights

Not applicable.

12.C Other Securities

Not applicable.

12.D American Depositary Shares

Fees Payable by ADR Holders

Holders of our ADRs may have to pay our ADS depositary, JPMorgan Chase Bank N.A. (JPMorgan), fees or charges up to the amounts described in the following table:

Persons depositing or withdrawing ordinary shares or ADS holders must pay:	Description of service
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issuance of ADSs, including issuances pursuant to a deposits of shares, share or rights distributions, stock dividend, stock split, merger or any other transactions affecting the issuance of ADSs • Cancellation of ADSs for the purpose of withdrawal of deposited securities
$0.05 (or less) per ADS	• Cash distribution to ADS holders
$1.50 per ADR	• Transfers of ADRs
$0.05 (or less) per ADS per calendar year	• Administrative services performed by the depositary

Fees Payable by the Depositary to the Issuer

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

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2019. “Disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms and (ii) accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2019.

Management’s Report on Internal Controls over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of June 30, 2019 based on the criteria set forth in *Internal Control-Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the assessment, our management has concluded that its internal control over financial reporting was effective as of June 30, 2019. Our auditor, PricewaterhouseCoopers, an independent registered public accounting firm, have provided an attestation report on our internal control over financial reporting, which is included herein.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Item 16A. Audit Committee Financial Expert

The Board of Directors of Mesoblast Ltd has determined that Michael Spooner possesses specific accounting and financial management expertise and is an Audit Committee Financial Expert as defined by the SEC. The Board of Directors has also determined that Donal O’Dwyer and Joseph Swedish, members of the Audit and Risk Management Committee, have sufficient experience and ability in finance and compliance matters to enable them to adequately discharge their responsibilities. All members of the Audit and Risk Management Committee are “independent” according to the listing standards of the Nasdaq Global Select Market.

Item 16B. Code of Ethics

Our Code of Conduct covers conflicts of interest, confidentiality, fair dealing, protection of assets, compliance with laws and regulations, whistle blowing, security trading and commitments to stakeholders. In summary, the code requires that at all times all Company personnel act with the utmost integrity, objectivity and in compliance with the letter and the spirit of the law and Company policies. This document is accessible on our internet website at: http://www.mesoblast.com/company/corporate-governance/code-of-conduct.

Item 16C. Principal Accountant Fees and Services

Pre-Approval of Audit and Non-Audit Services

The Audit and Risk Management Committee's pre-approval is required for all services provided by PwC. These services may include audit services, audit-related services, tax services and permissible non-audit services, and are subject to a specific budget. The Audit and Risk Management Committee uses a combination of two approaches – general pre-approval and specific pre-approval – in considering whether particular services or categories of services are consistent with the SEC's rules on auditor independence. Under general pre-approval proposed services may be pre-approved without consideration of specific case-by-case services.

Audit and Non-Audit Services Fees

See "Item 18. Financial Statements – Note 18". For the purpose of SEC classification, there were no audit-related, tax or other fees that were paid or payable to PwC that were not pre-approved by the Audit and Risk Management Committee during the years ended June 30, 2019 and 2018.

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

Under Nasdaq Stock Market Rule 5615(a)(3), foreign private issuers, such as our company, are permitted to follow certain home country corporate governance practices instead of certain provisions of the Nasdaq Stock Market Rules. For example, we may follow home country practice with regard to certain corporate governance requirements, such as the composition of the board of directors and quorum requirements applicable to shareholders' meetings. In addition, we may follow home country practice instead of the Nasdaq Stock Market Rules requirement to hold executive sessions and to obtain shareholder approval prior to the issuance of securities in connection with certain acquisitions or private placements of securities. Further, we may follow home country practice instead of the Nasdaq Stock Market Rules requirement to obtain shareholder approval prior to the establishment or amendment of certain share option, purchase or other compensation plans. A foreign private issuer that elects to follow a home country practice instead of any Nasdaq rule must submit to Nasdaq, in advance, a written statement from an independent counsel in such issuer's home country certifying that the issuer's practices are not prohibited by the home country's laws. We submitted such a written statement to Nasdaq.

Other than as set forth below, we currently intend to comply with the corporate governance listing standards in the Nasdaq Stock Market Rules to the extent possible under Australian law. However, we may choose to change such practices to follow home country practice in the future.

The Nasdaq Stock Market Rules require that a listed company specify that the quorum for any meeting of the holders of share capital be at least 33 1/3% of the outstanding shares of the company's common voting stock. We follow our home country practice, rather than complying with this rule. Consistent with Australian law, our bylaws do not require a quorum of at least 33 1/3% of the issued voting shares of Mesoblast for any general meeting of its shareholders. Our constitution provides that a quorum for a general meeting of our shareholders constitutes five shareholders present in person, by proxy, by attorney, or, where the shareholders is a body corporate, by representative. This provision and our practice of holding meetings with this quorum are not prohibited by the ASX Listing Rules or any other Australian law.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

See “Item 18. Financial Statements”.

Item 18. Financial Statements

The following financial statements are filed as part of this annual report on Form 20-F.

Australian Disclosure Requirements

The financial statements cover Mesoblast Limited and its subsidiaries. The financial statements were authorized for issue by the board of directors on August 30, 2019. The directors have the power to amend and reissue the financial statements.

All press releases, financial reports and other information are available on our website: www.mesoblast.com

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Mesoblast Limited

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Mesoblast Limited and its subsidiaries (the "Company") as of June 30, 2019 and 2018, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended June 30, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of June 30, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above 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 and Australian equivalent International Financial Reporting Standards as issued by the Australian Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1(i) to the consolidated financial statements, the Company has suffered recurring losses and net cash outflows from operations and other matters that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1(i). The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Controls over Financial Reporting appearing under Item 15 of the Form 20-F. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated 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 consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers
Melbourne, Australia
August 30, 2019

We have served as the Company's auditor since 2008.

Index to Financial Statements

Mesoblast Limited
Consolidated Income Statement

(in U.S. dollars, in thousands, except per share amount)	Note	Year Ended June 30, 2019	2018	2017
Revenue	3	16,722	17,341	2,412
Research & development		(59,815)	(65,927)	(58,914)
Manufacturing commercialization		(15,358)	(5,508)	(12,065)
Management and administration		(21,625)	(21,907)	(23,007)
Fair value remeasurement of contingent consideration	3	(6,264)	10,541	(130)
Other operating income and expenses	3	(1,086)	1,312	1,489
Finance costs	3	(11,328)	(1,829)	—
Loss before income tax	3	**(98,754)**	**(65,977)**	**(90,215)**
Income tax benefit	4	8,955	30,687	13,400
Loss attributable to the owners of Mesoblast Limited		**(89,799)**	**(35,290)**	**(76,815)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:		**Cents**	**Cents**	**Cents**
Basic - losses per share		(18.16)	(7.58)	(19.25)
Diluted - losses per share		(18.16)	(7.58)	(19.25)

The above consolidated income statement should be read in conjunction with the accompanying Notes.

Mesoblast Limited
Consolidated Statement of Comprehensive Income

(in U.S. dollars, in thousands)	Note	Year Ended June 30, 2019	2018	2017
Loss for the period		**(89,799)**	**(35,290)**	**(76,815)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Changes in the fair value of financial assets	7(b)	(4)	324	31
Exchange differences on translation of foreign operations	7(b)	(137)	(903)	316
Other comprehensive (loss)/income for the period, net of tax		**(141)**	**(579)**	**347**
Total comprehensive losses attributable to the owners of Mesoblast Limited		**(89,940)**	**(35,869)**	**(76,468)**

The above consolidated statement of comprehensive income should be read in conjunction with the accompanying Notes.

Mesoblast Limited
Consolidated Statement of Changes in Equity

(in U.S. dollars, in thousands)	Note	Issued Capital	Share Option Reserve	Investment Revaluation Reserve	Foreign Currency Translation Reserve	Retained Earnings/ (accumulated losses)	Total
Balance as of July 1, 2016		**770,272**	**64,999**	**(334)**	**(38,689)**	**(268,087)**	**528,161**
Loss for the period		—	—	—	—	(76,815)	(76,815)
Other comprehensive income/(loss)		—	—	31	316	—	347
Total comprehensive profit/(loss) for the period		**—**	**—**	**31**	**316**	**(76,815)**	**(76,468)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		60,140	—	—	—	—	60,140
		60,140	—	—	—	—	**60,140**
Transfer exercised options		13	(13)	—	—	—	—
Fair value of share-based payments	17	—	5,036	—	—	—	5,036
Reclassification of modified options to liability		—	(103)	—	—	—	(103)
		13	**4,920**	**—**	**—**	**—**	**4,933**
Balance as of June 30, 2017	7(a)	**830,425**	**69,919**	**(303)**	**(38,373)**	**(344,902)**	**516,766**
Balance as of 1 July 2017		**830,425**	**69,919**	**(303)**	**(38,373)**	**(344,902)**	**516,766**
Loss for the period		—	—	—	—	(35,290)	(35,290)
Other comprehensive income/(loss)		—	—	324	(903)	—	(579)
Total comprehensive profit/(loss) for the period		**—**	**—**	**324**	**(903)**	**(35,290)**	**(35,869)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		49,358	—	—	—	—	49,358
Contributions of equity for unissued ordinary shares, net of transaction costs		9,660	—	—	—	—	9,660
		59,018	**—**	**—**	**—**	**—**	**59,018**
Transfer exercised options		38	(38)	—	—	—	—
Fair value of share-based payments	17	—	5,959	—	—	—	5,959
Reclassification of modified options from liability		—	134	—	—	—	134
		38	**6,055**	**—**	**—**	**—**	**6,093**
Balance as of June 30, 2018	7(a)	**889,481**	**75,974**	**21**	**(39,276)**	**(380,192)**	**546,008**
Balance as of July 1, 2018		**889,481**	**75,974**	**21**	**(39,276)**	**(380,192)**	**546,008**
Loss for the period		—	—	—	—	(89,799)	(89,799)
Other comprehensive income/(loss)		—	—	(4)	(137)	—	(141)
Total comprehensive profit/(loss) for the period		**—**	**—**	**(4)**	**(137)**	**(89,799)**	**(89,940)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		19,441	—	—	—	—	19,441
		19,441	**—**	**—**	**—**	**—**	**19,441**
Transfer of services rendered in shares		1,170	(1,170)	—	—	—	—
Transfer of exercised options		313	(313)	—	—	—	—
Fair value of share-based payments	17	—	5,533	—	—	—	5,533
Reclassification of modified options to liability		—	10	—	—	—	10
		1,483	**4,060**	**—**	**—**	**—**	**5,543**
Balance as of June 30, 2019	7(a)	**910,405**	**80,034**	**17**	**(39,413)**	**(469,991)**	**481,052**

The above consolidated statement of changes in equity should be read in conjunction with the accompanying Notes.

Mesoblast Limited
Consolidated Balance Sheet

(in U.S. dollars, in thousands)	Note	As of June 30, 2019	2018
Assets			
Current Assets			
Cash & cash equivalents	5(a)	50,426	37,763
Trade & other receivables	5(b)	4,060	50,366
Prepayments	5(b)	8,036	12,942
Total Current Assets		**62,522**	**101,071**
Non-Current Assets			
Property, plant and equipment	6(a)	826	1,084
Financial assets at fair value through other comprehensive income	5(c)	2,317	2,321
Other non-current assets	5(d)	3,324	3,361
Intangible assets	6(b)	583,126	584,606
Total Non-Current Assets		**589,593**	**591,372**
Total Assets		**652,115**	**692,443**
Liabilities			
Current Liabilities			
Trade and other payables	5(e)	13,060	18,921
Provisions	6(c)	7,264	5,082
Borrowings	5(f)	14,007	—
Deferred consideration	6(e)	10,000	—
Total Current Liabilities		**44,331**	**24,003**
Non-Current Liabilities			
Deferred tax liability	6(d)	11,124	20,079
Provisions	6(c)	48,329	42,956
Borrowings	5(f)	67,279	59,397
Total Non-Current Liabilities		**126,732**	**122,432**
Total Liabilities		**171,063**	**146,435**
Net Assets		**481,052**	**546,008**
Equity			
Issued Capital	7(a)	910,405	889,481
Reserves	7(b)	40,638	36,719
(Accumulated losses)/retained earnings		(469,991)	(380,192)
Total Equity		**481,052**	**546,008**

The above consolidated balance sheet should be read in conjunction with the accompanying Notes.

Mesoblast Limited
Consolidated Statement of Cash Flows

(in U.S. dollars, in thousands)	Note	Year ended June 30, 2019	2018	2017
Cash flows from operating activities				
Commercialization revenue received		4,359	3,019	1,332
Milestone payment received		26,409	7,125	500
Research and development tax incentive received		1,654	—	2,813
Payments to suppliers and employees (inclusive of goods and services tax)		(86,294)	(84,682)	(100,598)
Interest received		726	367	483
Interest and other costs of finance paid		(4,641)	(816)	—
Income taxes (paid)		(3)	(25)	(1)
Net cash (outflows) in operating activities	8(b)	**(57,790)**	**(75,012)**	**(95,471)**
Cash flows from investing activities				
Investment in fixed assets		(279)	(201)	(311)
Payments for contingent consideration		(721)	(952)	—
Rental deposits received		—	—	453
Net cash inflows/(outflows) in investing activities		**(1,000)**	**(1,153)**	**142**
Cash flows from financing activities				
Proceeds from borrowings		43,572	31,704	—
Payments of transaction costs from borrowings		(1,614)	(392)	—
Proceeds from issue of shares		30,258	40,566	61,932
Payments for share issue costs		(608)	(3,265)	(1,927)
Net cash inflows by financing activities		**71,608**	**68,613**	**60,005**
Net increase/(decrease) in cash and cash equivalents		12,818	(7,552)	(35,324)
Cash and cash equivalents at beginning of period		37,763	45,761	80,937
FX gain/(losses) on the translation of foreign bank accounts		(155)	(446)	148
Cash and cash equivalents at end of period	8(a)	**50,426**	**37,763**	**45,761**

The above consolidated statement of cash flows should be read in conjunction with the accompanying Notes.

Mesoblast Limited ("the Company") and its subsidiaries ("the Group") are primarily engaged in the development of regenerative medicine products. The Group's primary proprietary regenerative medicine technology platform is based on specialized cells known as mesenchymal lineage adult stem cells. The Company was formed in 2004 as an Australian company and has been listed on the Australian Securities Exchange (the "ASX") since 2004. In November 2015, the Company listed in the United States of America ("U.S.") on the Nasdaq Global Select Market ("Nasdaq") and from this date has been dual-listed in Australia and the U.S.

These financial statements and notes are presented in U.S. dollars ("$" or "USD" or "US$"), unless otherwise noted, including certain amounts that are presented in Australian dollars ("AUD" or "A$").

1. Basis of preparation

The general purpose financial statements of Mesoblast Limited and its subsidiaries have been prepared in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board and Australian equivalent International Financial Reporting Standards, as issued by the Australian Accounting Standards Board. Mesoblast Limited is a for-profit entity for the purpose of preparing the financial statements.

(i) Going concern

For the fiscal years ended June 30, 2019, 2018 and 2017, the Group incurred a total comprehensive loss after income tax of $89.9 million, $35.9 million and $76.5 million, respectively, and had net cash outflows from operations of $57.8 million, $75.0 million and $95.5 million, respectively. As of June 30, 2019, the Group held total cash and cash equivalents of $50.4 million.

The Group has an overarching strategy to fund operations predominately through non-dilutive strategic and commercial transactions. In line with this strategy in 2018 the Group entered into a strategic partnership with Tasly and into loan and security agreements with Hercules and NovaQuest. Under the agreements with Hercules and NovaQuest, the Group has up to an additional US$35.0 million available subject to achievement of certain milestones.

The Group will also consider equity-based financing to fund operational requirements. Mesoblast has entered into a Subscription Commitment Letter with its largest institutional shareholder, M&G Investment Management, for US$15.0 million in Mesoblast ordinary shares, exercisable by the Company on or before 31 December 2019, subject to customary diligence and with pricing to be agreed at the time Mesoblast gives notice. In addition, in July 2019 the Group extended its fully discretionary equity facility with Kentgrove Capital from which it can raise capital of up to A$120 million (approximately US$ 82 million) over the next 24 months, the quantum and timing of capital raised will be subject to the market price and trading volumes of Mesoblast's ordinary shares during the period and the Group's obligations under ASX Listing Rule 7.1.

There is uncertainty related to the Group's ability to raise funds through entering strategic and commercial transactions, equity-based or debt-based financings to meet the Group's requirements. The continuing viability of the Group and its ability to continue as a going concern and meet its debts and commitments as they fall due are dependent upon non-dilutive funding in the form of strategic and commercial transactions, equity-based or debt-based financing to fund future operations.

Management and the directors believe that the Group will be successful in the above matters and, accordingly, have prepared the financial report on a going concern basis, notwithstanding that there is a material uncertainty that may cast significant doubt on the Group's ability to continue as a going concern and that it may be unable to realize its assets and liabilities in the normal course of business.

References to matters that may cast significant doubt about the Group's ability to continue as a going concern also raise substantial doubt as contemplated by the Public Company Accounting Oversight Board ("PCAOB") standards.

(ii) Historical cost convention

These financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets at fair value through other comprehensive income, financial assets and liabilities (including derivative instruments) at fair value through profit or loss, certain classes of property, plant and equipment and investment property.

(iii) New and amended standards adopted by the Group

Revenue recognition

The Group adopted IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018, using the modified retrospective approach. Revenue from contracts with customers is measured and recognized in accordance with the five step model prescribed by the standard.

First, contracts with customers within the scope of IFRS 15 are identified. Distinct promises within the contract are identified as performance obligations. The transaction price of the contract is measured based on the amount of consideration the Group expects to be entitled from the customer in exchange for goods or services. Factors such as requirements around variable consideration, significant financing components, noncash consideration, or amounts payable to customers also determine the transaction price. The transaction is then allocated to separate performance obligations in the contract based on relative standalone selling prices. Revenue is recognized when, or as, performance obligations are satisfied, which is when control of the promised good or service is transferred to the customer. Revenues comprise commercialization and milestone revenue, research and development tax incentives and interest revenue.

There was no cumulative impact of the adoption of IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018.

Revenues from contracts with customers comprise commercialization and milestone revenue. The Group also has revenue from research and development tax incentives and interest revenue.

Commercialization and milestone revenue

Commercialization and milestone revenue generally includes non-refundable up-front license and collaboration fees; milestone payments, the receipt of which is dependent on certain clinical, regulatory or commercial milestones; as well as royalties on product sales of licensed products, if and when such product sales occur; and revenue from the supply of products. Payment is generally due on standard terms of 30 to 60 days.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue or deferred consideration in our consolidated balance sheet, depending on the nature of the arrangement. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified within current liabilities. Amounts not expected to be recognized as revenue within 12 months following the balance sheet date are classified within non-current liabilities.

Milestone revenue

The Group applies the five-step method under the standard to measure and recognize milestone revenue.

The receipt of milestone payments is often contingent on meeting certain clinical, regulatory or commercial targets, and is therefore considered variable consideration. The Group estimate the transaction price of the contingent milestone using the most likely amount method. The Group includes in the transaction price some or all of the amount of the contingent milestone only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the contingent milestone is subsequently resolved. Milestone payments that are not within the control of the Group, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received. Any changes in the transaction price are allocated to all performance obligations in the contract unless the variable consideration relates only to one or more, but not all, of the performance obligations.

When consideration for milestones is a sale-based or usage-based royalty that arises from licenses of IP (such as cumulative net sales targets), revenue is recognized at the later of when (or as) the subsequent sale or usage occurs, or when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Licenses of intellectual property

When licenses of IP are distinct from other goods or services promised in the contract, the Group recognizes the transaction price allocated to the license as revenue upon transfer of control of the license to the customer. The Group evaluates all other promised goods or services in the license agreement to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct.

The transaction price allocated to the license performance obligation is recognized based on the nature of the license arrangement. The transaction price is recognized over time if the nature of the license is a “right to access” license. This is when the Group undertakes activities that significantly affect the IP to which the customer has rights, the rights granted by the license directly expose the customer to any positive or negative effects of the Group’s activities, and those activities do not result in the transfer of a good or service to the customer as those activities occur. When licenses do not meet the criteria to be a right to access license, the license is a “right to use” license, and the transaction price is recognized at the point in time when the customer obtains control over the license.

Sales-based or usage-based royalties

Licenses of IP can include royalties that are based on the customer’s usage of the IP or sale of products that contain the IP. The Group applies the specific exception to the general requirements of variable consideration and the constraint on variable consideration for sales-based or usage-based royalties promised in a license of IP. The exception requires such revenue to be recognized at the later of when (or as) the subsequent sale or usage occurs and the performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

Tasly arrangement

In July 2018, the Group entered into a strategic alliance with Tasly Pharmaceutical Group (“Tasly”) for the development, manufacture and commercialization in China of the Group’s allogeneic mesenchymal precursor cell (“MPC”) products, MPC-150-IM and MPC-25-IC. Tasly received all exclusive rights for MPC-150-IM and MPC-25-IC in China and Tasly will fund all development, manufacturing and commercialization activities in China.

The Group received a $20.0 million up-front technology access fee from Tasly upon closing of this strategic alliance in October 2018. The Group is also entitled to receive $25.0 million on product regulatory approvals in China, double-digit escalating royalties on net product sales and up to six escalating milestone payments when the product candidates reach certain sales thresholds in China.

Under IFRS 15, upon completion of this strategic alliance on September 14, 2018, the Group recognized $10.0 million in milestone revenue from the $20.0 million up-front technology access fee received from Tasly in October 2018 as this is the portion of revenue that control has been transferred to Tasly. The Group recognized the remaining $10.0 million from the $20.0 million up-front payment as deferred consideration on the consolidated balance sheet. The deferred consideration amount will be recognized in revenue when and if control transfers to Tasly based on the Group’s decision regarding the exercise of the Group’s rights in the terms and conditions of the agreement.

For the comparative period, being the year ended June 30, 2018 no milestone revenue was recognized in relation to this strategic alliance with Tasly.

TiGenix arrangement

In December 2017, the Group entered into a patent license agreement with TiGenix NV (“TiGenix”), now a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (“Takeda”), which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived mesenchymal stem cell (“MSC") product, Alofisel® a registered trademark of TiGenix, previously known as Cx601, a product candidate of Takeda, for the local treatment of fistulae. The agreement includes the right for Takeda to grant sub-licenses to affiliates and third parties.

As part of the license agreement, the Group received €5.0 million ($5.9 million) as a non-refundable up-front payment and recognized this amount in revenue in December 2017 upon receipt. In December 2018, the Group received a milestone payment of €5.0 million, the Group recognized revenue of €5.0 million ($5.9 million) pertaining to this milestone in December 2017 as all performance obligations had been satisfied at that time. The Group is entitled to further payments up to €10.0 million when Takeda reaches certain product regulatory milestones. Additionally, the Group receives single digit royalties on net sales of Alofisel®.

No milestone revenue was recognized in relation to the patent license agreement with Takeda in the year ended June 30, 2019.

In the year ended June 30, 2018, we recognized $11.8 million in milestone revenue in relation to our patent license agreement with Takeda. Within this $11.8 million, €5.0 million ($5.9 million) was recognized in relation to the non-refundable up-front payment received upon execution of the Group’s patent license agreement with Takeda in December 2017 and €5.0 million ($5.9 million) was recognized in December 2017 in relation to further payments received in December 2018 for product Alofisel®, as all performance obligations had been satisfied at that time. These amounts were recorded in revenue as there were no further performance obligations required in regards to these milestones.

JCR arrangement

In October 2013, the Group acquired all of the culture-expanded, MSC-based assets, from Osiris Therapeutics, Inc. (“Osiris”). These assets included assumption of a collaboration agreement (the “JCR Agreement”) with JCR Pharmaceuticals Co., Ltd. (“JCR”), a pharmaceutical company in Japan. Revenue recognized under this model is limited to the amount of cash received or for which the Group are entitled, as JCR has the right to terminate the agreement at any time.

Under the JCR Agreement, JCR is responsible for all development and manufacturing costs including sales and marketing expenses. Under the JCR Agreement, JCR has the right to develop our MSCs in two fields for the Japanese market: exclusive in conjunction with the treatment of hematological malignancies by the use of hematopoietic stem cells derived from peripheral blood, cord blood or bone marrow, or the First JCR Field; and non-exclusive for developing assays that use liver cells for non-clinical drug screening and evaluation, or the Second JCR Field. With respect to the First JCR Field, the Group are entitled to payments when JCR reaches certain commercial milestones and to escalating double-digit royalties. These royalties are subject to possible renegotiation downward in the event of competition from non-infringing products in Japan. With respect to the Second JCR Field, the Group are entitled to a double digit profit share. In October 2018, the Group expanded its partnership with JCR in Japan for wound healing in patients with Epidermolysis Bullosa (“EB”). The Group will receive royalties on TEMCELL® Hs. Inj. (“TEMCELL”), a registered trademark of JCR product sales for EB. The Group applies the sales-based and usage-based royalty exception for licenses of intellectual property and therefore recognizes royalty revenue at the later of when the subsequent sale or usage occurs and the associated performance obligation has been satisfied.

In the year ended June 30, 2019, the Group recognized $5.0 million in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan by our licensee JCR, compared with $2.5 million for the year ended June 30, 2018. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

In the year ended June 30, 2019, the Group recognized $1.0 million in milestone revenue upon our licensee, JCR, reaching cumulative net sales milestones for sales of TEMCELL in Japan, compared with $1.5 million for the year ended June 30, 2018. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

Financial Instruments

The Group adopted IFRS 9 *Financial Instruments* on July 1, 2018. IFRS 9 introduced revisions in the classification and measurement of financial instruments with a principle-based approach which is driven by cash flow characteristics and business model.

The Group has had following impacts on its financial assets and liabilities from the adoption of the new standard on July 1, 2018:

- Accounting for non-trading equity investments – IFRS 9 requires investments in equity instruments to be recorded at fair value with changes recognized through profit or loss (FVTPL). There is an allowance for management to make an irrevocable election on initial recognition for fair value changes in non-trading equity investments to be recorded in other comprehensive income (FVOCI). On transition to IFRS 9, the Group has made an election to record its financial assets measured at FVOCI in an equity instrument at FVOCI. Therefore, there has been no impact on the measurement of the financial asset on transition.
- Accounting for financial liabilities – Under IFRS 9 there is an allowance for management to make an irrevocable election on initial recognition for financial liabilities that are measured at amortized cost to be measured at FVTPL. The Group has not designated any of its financial liabilities carried at amortized cost as FVTPL using the fair value option upon adoption of IFRS 9 on July 1, 2018. Therefore, there has been no impact on the transition to IFRS 9 from July 1, 2018.

In the opinion of management, the final financial data includes all adjustments, consisting only of normal recurring adjustments, necessary to a fair statement of the results for the interim periods. Other than the new and amended standards adopted by the Group above these final financial statements follow the same accounting policies as compared to the June 30, 2018 consolidated financial statements and related notes as filed with the Australian Securities Exchange and the Securities and Exchange Commission.

(i*v*) *New accounting standards and interpretations not yet adopted*

Certain new accounting standards and interpretations have been published that are not mandatory for the June 30, 2019 reporting period. The Group has not elected to apply any pronouncements before their operative date in the annual reporting period beginning July 1, 2018.

Initial application of the following Standards is not expected to materially impact the amounts recognized or disclosures made in the current financial report and management do not consider these new accounting standards to have a material impact on future transactions made in relation to the Group. The Group is in the process of assessing the impact of these new standards on its accounting policy.

Title of standard	**IFRS 16 *Leases***
Key requirements	IFRS 16 eliminates the classification of leases as either operating leases or finance leases for a lessee; they are recognized on the balance sheet as they are treated in a similar way to finance leases applying IAS 17. Leases are 'capitalized' by recognizing the present value of the lease payments and showing them either as lease assets (right-of-use assets) or together with property, plant and equipment. If lease payments are made over time, a financial liability is required to be recognized to represent the obligation to make future lease payments. There is little change for the accounting for a lessor.
Impact	Alternative methods of calculating the ROU asset are permitted under IFRS 16 which impacts the size of the transition adjustment. The Group will apply the modified retrospective approach as permitted by IFRS 16. Under the modified retrospective transition approach, prior period comparative financial statements are not restated and the Group can choose between two alternate methods of measuring the lease assets on a lease by lease basis. The Group will measure the ROU for operating leases of office space from which it conducts its business as if IFRS 16 had always been applied. The resulting transition adjustment will be recognized as an adjustment to the Group's retained earnings as at 1 July 2019. Based on the elected transition method, the Group will recognize lease liabilities of approximately $5.6 million and ROU assets of approximately $4.7 million. After adjusting for amounts currently recorded on the balance sheet (representing the difference between the cumulative lease expense recognized and cash paid on these leases), this results in a reduction to retained earnings of approximately $0.9 million. The transition adjustment has, as permitted by IFRS 16, been determined by the Group by electing practical expedients to not recognize short-term or low value leases on its statement of financial position at the transition date. Judgement has been applied by the Group in determining the transition adjustment which includes the determination of which contractual arrangements represent a lease, the period over which the lease exists, the incremental borrowing rate of the Group, and the variability of future cash flows. Refer to Note 14(b) for the lease commitments the Group holds as a lessee.
Effective Date	IFRS 16 must be applied for annual reporting periods beginning on or after January 1, 2019. The Group does not intend to adopt IFRS 16 before its mandatory date.

The following standards applicable to the Group but are not yet adopted are summarized below:

2. Significant changes in the current reporting period

(i) Significant events

The financial position and performance of the Group was affected by the following events during the year ended June 30, 2019:

- On July 17, 2018, the Group announced that it had entered into a strategic alliance with Tasly for the development, manufacture and commercialization in China of the Group's allogeneic MPC products, MPC-150-IM and MPC-25-IC, subject to governmental approvals from the PRC.
- In September 2018, the Group announced that Tasly had received all necessary approvals for the transaction. On September 14, 2018, the Group recognized revenue of $10.0 million from the $20.0 million up-front payment received in October 2018 as this is the portion of revenue that control has been transferred to Tasly. The Group recognized the remaining $10.0 million from the $20.0 million up-front payment receivable from Tasly as deferred consideration on the consolidated balance sheet. The deferred consideration amount will be recognized in revenue when and if control transfers to Tasly based on the Group's decision regarding the exercise of the Group's rights in the terms and conditions of the agreement.

3. Loss before income tax

(in U.S. dollars, in thousands)	Note	Year Ended June 30, 2019	2018	2017
Revenue				
Commercialization revenue		5,003	3,641	1,444
Milestone revenue		11,000	13,334	500
Interest revenue		719	366	468
Total Revenue		**16,722**	**17,341**	**2,412**
Clinical trial and research & development		**(37,927)**	**(42,863)**	**(38,141)**
Manufacturing production & development		**(10,912)**	**(3,640)**	**(8,313)**
Employee benefits				
Salaries and employee benefits		(19,504)	(19,343)	(20,039)
Defined contribution superannuation expenses		(339)	(374)	(362)
Equity settled share-based payment transactions(1)		(4,368)	(6,199)	(5,276)
Total Employee benefits		**(24,211)**	**(25,916)**	**(25,677)**
Depreciation and amortization of non-current assets				
Plant and equipment depreciation		(562)	(909)	(1,578)
Intellectual property amortization		(1,577)	(1,741)	(1,479)
Total Depreciation and amortization of non-current assets		**(2,139)**	**(2,650)**	**(3,057)**
Other Management & administration expenses				
Overheads & administration		(11,356)	(8,477)	(8,128)
Consultancy		(3,360)	(3,295)	(3,329)
Legal, patent and other professional fees		(4,098)	(3,436)	(4,452)
Intellectual property expenses (excluding the amount amortized above)		(2,795)	(3,065)	(2,889)
Total Other Management & administration expenses		**(21,609)**	**(18,273)**	**(18,798)**
Fair value remeasurement of contingent consideration				
Remeasurement of contingent consideration	5(g)(iii)	(6,264)	10,541	(130)
Total Fair value remeasurement of contingent consideration		**(6,264)**	**10,541**	**(130)**
Other operating income and expenses				
Remeasurement of borrowing arrangements		(752)	—	—
Research & development tax incentive(2)		(74)	1,807	1,532
Foreign exchange gains/(losses)		(208)	161	(43)
Foreign withholding tax paid		(52)	(656)	—
Total Other operating income and expenses		**(1,086)**	**1,312**	**1,489**
Finance (costs)/gains				
Remeasurement of borrowing arrangements		376	—	—
Interest expense		(11,704)	(1,829)	—
Total Finance costs		**(11,328)**	**(1,829)**	**—**
Total loss before income tax		**(98,754)**	**(65,977)**	**(90,215)**

(1) Share-based payment transactions

For the years ended June 30, 2019, 2018 and 2017, share-based payment transactions have been reflected in the Consolidated Statement of Comprehensive Income functional expense categories as follows:

	Year Ended June 30,		
(in U.S. dollars)	**2019**	**2018**	**2017**
Research and development	2,283,646	3,638,310	2,837,231
Manufacturing and commercialization	329,718	558,928	420,762
Management and administration	1,755,027	2,001,349	2,017,172
Equity settled share-based payment transactions	**4,368,391**	**6,198,588**	**5,275,165**
Legal, patent and other professional fees	620,000	—	—
Total equity settled share-based payment transactions in the profit and loss	**4,988,391**	**6,198,588**	**5,275,165**

(2) Research and development tax incentive

The Group's research and development activities are not eligible from July 1, 2018 to June 30, 2019 for the refundable tax offset, under an Australian Government tax incentive as a result of the Group earning taxable revenues in excess of A$20.0 million for the year ended June 30, 2019. At each period end management estimates the refundable tax offset available to the Group based on available information at the time. The Group engages tax specialists to review, on an annual basis, the quantum of our previous research and development tax claim and our on-going eligibility to claim this tax incentive in Australia. For the year ended June 30, 2019, the Group has recognized loss of $0.1 million due to an adjustment of management's estimate of revenue for the year ended June 30, 2018. For years ended June 30, 2018 and 2017, the Group recognized income of $1.8 million and $1.5 million, respectively.

Of the $0.1 million loss from research and development tax incentive recorded in other income for the year ended June 30, 2019, $0.1 million relates to a change in the original estimate of the research and development tax incentive income the Group estimated it would receive from the Australian Government for the year ended June 30, 2018.

Of the $1.8 million research and development tax incentive recorded in other income for the year ended June 30, 2018, $0.1 million relates to a change in the original estimate of the research and development tax incentive income the Group estimated it would receive from the Australian Government for the year ended June 30, 2017.

Of the $1.5 million research and development tax incentive recorded in other income for the year ended June 30, 2017, $0.1 million relates to a change in the original estimate of the research and development tax incentive income the Group estimated it would receive from the Australian Government for the year ended June 30, 2016.

4. Income tax benefit/(expense)

(in U.S. dollars, in thousands)	Year Ended June 30, 2019	2018	2017
(a) Reconciliation of income tax to prima facie tax payable			
Loss from continuing operations before income tax	(98,754)	(65,977)	(90,215)
Tax benefit at the Australian tax rate of 30% (2018: 30%)	(29,626)	(19,793)	(27,065)
Tax effect of amounts which are not deductible/(exempt) in calculating taxable income:			
Share-based payments expense	1,221	1,544	1,488
Research and development tax concessions	(1,486)	537	2,442
Foreign exchange translation gains/(losses)	(15)	(242)	—
Contingent consideration	1,880	(3,162)	39
Other sundry items	91	1,011	497
Current year tax expense/(benefit)	**(27,935)**	**(20,105)**	**(22,599)**
Adjustments for current tax of prior periods	(18,412)	(3,616)	(5,870)
Differences in overseas tax rates	24,458	5,259	7,797
Tax benefit not recognized	12,934	11,065	7,272
Change in tax rate on Deferred tax assets	—	27,471	—
Change in tax rate on Deferred tax liability	—	(50,761)	—
Previously unrecognized tax losses now recouped to reduce deferred tax expense/(benefit)	—	—	—
Income tax expense/(benefit) attributable to loss before income tax	**(8,955)**	**(30,687)**	**(13,400)**

(in U.S. dollars, in thousands)	Year Ended June 30, 2019	2018	2017
(b) Income tax expense			
Current tax			
Current tax	—	—	—
Total current tax expense	**—**	**—**	**—**
Deferred tax			
(Increase)/decrease in deferred tax assets	(8,856)	20,183	(13,204)
(Decrease)/increase in deferred tax liabilities	(99)	(50,870)	(196)
Total deferred tax (benefit)	**(8,955)**	**(30,687)**	**(13,400)**
Income tax (benefit)	**(8,955)**	**(30,687)**	**(13,400)**

Deferred tax assets have been brought to account only to the extent that it is foreseeable that they are recoverable against future tax liabilities.

Deferred tax assets are recognized for unused tax losses to the extent that it is probable that future taxable profit will be available against which the unused tax losses can be utilized. Deferred tax assets are offset against taxable temporary differences (deferred tax liabilities) when the deferred tax balances relate to the same tax jurisdiction in accordance with our accounting policy.

In the year ended June 30, 2019, the adjustments for current tax of prior periods includes a benefit of $18.2 million relating to a change in estimate in our current tax provision arising from a tax ruling obtained from Inland Revenue Authority of Singapore on November 15, 2018. This ruling allows the Group to claim additional deductions in relation to earn-out payments arising from the acquired MSC assets from Osiris. The Group expects to settle the related tax losses within the tax jurisdiction of Singapore at a future date. The difference in the Australian tax rate of 30% and the tax rate we expect to settle these deferred tax assets at in Singapore, under the tax incentives granted to the Group by the Singapore Economic Development Board, resulted in $14.0 million being recorded in differences in overseas tax rates for the year.

Deferred taxes are measured at the rate in which they are expected to settle within the respective jurisdictions, which can change based on factors such as new legislation or timing of utilization and reversal of associated assets and liabilities. On December 22, 2017, the United States signed into law the Tax Act, which changed many aspects of U.S. corporate income taxation, including a reduction in the corporate income tax rate from 35% to 21%. The Group recognized the tax effects of the Tax Act in the year ended June 30, 2018, the most significant of which was a tax benefit resulting from the remeasurement of deferred tax balances to 21%.

(in U.S. dollars, in thousands)	Year Ended June 30, 2019	2018	2017
(c) Amounts that would be recognized directly in equity if brought to account			
Aggregate current and deferred tax arising in the reporting period and not recognized in net loss or other comprehensive income but which would have been directly applied to equity had it been brought to account:			
Current tax recorded in equity (if brought to account)	(390)	(1,059)	(764)
Deferred tax recorded in equity (if brought to account)	879	877	960
	489	**(182)**	**196**

(in U.S. dollars, in thousands)	Year Ended June 30, 2019	2018	2017
(d) Amounts recognized directly in equity			
Aggregate current and deferred tax arising in the reporting period and not recognized in net loss or other comprehensive income but debited/credited to equity			
Current tax recorded in equity	—	—	—
Deferred tax recorded in equity	—	—	—

(in U.S. dollars, in thousands)	As of June 30, 2019	2018	2017
(e) Deferred tax assets not brought to account			
Unused tax losses			
Potential tax benefit at local tax rates	51,807	41,501	34,896
Other temporary differences			
Potential tax benefit at local tax rates	3,130	3,704	3,908
Other tax credits			
Potential tax benefit at local tax rates	3,220	3,220	—
	58,157	**48,425**	**38,804**

As of June 30, 2019, 2018 and 2017, the Group has deferred tax assets not brought to account of $58.2 million, $48.4 million and $38.8 million, respectively. Deferred tax assets have been brought to account only to the extent that it is foreseeable that they are recoverable against future tax liabilities.

5. Financial assets and liabilities

This note provides information about the Group's financial instruments, including:

- an overview of all financial instruments held by the Group;
- specific information about each type of financial instrument;
- accounting policies; and
- information used to determine the fair value of the instruments, including judgments and estimation uncertainty involved.

The Group holds the following financial instruments:

Financial assets (in U.S. dollars, in thousands)	Notes	Assets at FVOCI(1)	Assets at FVTPL(2)	Assets at amortized cost	Total
As of June 30, 2019					
Cash & cash equivalents	5(a)	—	—	50,426	50,426
Trade & other receivables	5(b)	—	—	4,060	4,060
Financial assets at fair value through other comprehensive income	5(c)	2,317	—	—	2,317
Other non-current assets	5(d)	—	—	3,324	3,324
		2,317	**—**	**57,810**	**60,127**
As of June 30, 2018					
Cash & cash equivalents	5(a)	—	—	37,763	37,763
Trade & other receivables	5(b)	—	—	50,366	50,366
Financial assets at fair value through other comprehensive income	5(c)	2,321	—	—	2,321
Other non-current assets	5(d)	—	—	3,361	3,361
		2,321	**—**	**91,490**	**93,811**

(1) Fair value through other comprehensive income

(2) Fair value through profit or loss

Financial liabilities (in U.S. dollars, in thousands)	Notes	Liabilities at FVOCI(1)	Liabilities at FVTPL(2)	Liabilities at amortized cost	Total
As of June 30, 2019					
Trade and other payables	5(e)	—	—	13,060	13,060
Borrowings	5(f)	—	—	81,286	81,286
Contingent consideration	5(g)(iii)	—	47,534	—	47,534
		—	**47,534**	**94,346**	**141,880**
As of June 30, 2018					
Trade and other payables	5(e)	—	—	18,921	18,921
Borrowings	5(f)	—	—	59,397	59,397
Contingent consideration	5(g)(iii)	**—**	42,070	—	42,070
		—	**42,070**	**78,318**	**120,388**

(1) Fair value through other comprehensive income

(2) Fair value through profit or loss

The Group's exposure to various risks associated with the financial instruments is discussed in Note 10. The maximum exposure to credit risk at the end of the reporting period is the carrying amount of each class of financial assets mentioned above.

a. Cash and cash equivalents

(in U.S. dollars, in thousands)	2019	2018
Cash at bank	50,005	37,221
Deposits at call(1)	421	542
	50,426	**37,763**

(1) As of June 30, 2019 and June 30, 2018, interest-bearing deposits at call include amounts of $0.4 million and $0.4 million, respectively, held as security and are restricted for use.

(i) Classification as cash equivalents

Term deposits are presented as cash equivalents if they have a maturity of three months or less from the date of acquisition.

b. Trade and other receivables and prepayments

(i) Trade receivables

(in U.S. dollars, in thousands)	2019	2018
Trade debtors	1,739	6,630
Funds receivable from debt financing and unissued capital(1)	—	38,950
Income tax and tax incentives recoverable	1,511	3,305
Other receivables	—	615
Foreign withholding tax recoverable	471	471
Security deposit	250	250
Sundry debtors	2	81
Other recoverable taxes (Goods and services tax and value-added tax)	86	53
Interest receivables	1	11
Trade and other receivables	**4,060**	**50,366**

(1) On July 2, 2018, the Group announced it had entered into a financing agreement with NovaQuest on June 29, 2018 to develop and commercialize its allogeneic product candidate MSC-100-IV for pediatric patients with acute Graft versus Host Disease ("aGVHD"). The contractual terms of the agreement pertaining to the receipt of funds were binding and therefore the Group recognized a receivable of $39.0 million at June 30, 2018. On July 10, 2018 the net proceeds from the financing facility of $39.0 million were received and recognized in cash and cash equivalents.

(ii) Prepayments

(in U.S. dollars, in thousands)	2019	2018
Clinical trial research and development expenditure	6,042	12,042
Prepaid insurance and subscriptions	1,095	141
Other	899	759
Prepayments	**8,036**	**12,942**

(iii) Classification as trade and other receivables

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 to 60 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 group 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. Interest receivables are amounts due at maturity of term deposits. Income tax and tax incentives recoverable relates to the Group's claim for the Australian Government tax incentive.

(iv) Other receivables

These amounts generally arise from transactions outside the usual operating activities of the Group.

(v) Fair values of trade and other receivables

Due to the short-term nature of the current receivables, their carrying amount is assumed to be the same as their fair value.

(vi) Impairment and risk exposure

Information about the impairment of trade and other receivables, their credit quality and the Group's exposure to credit risk, foreign currency risk and interest rate risk can be found in Note 10(a) and (b).

c. Financial assets at fair value through other comprehensive income

Financial assets at fair value through other comprehensive income include the following classes of financial assets:

(in U.S. dollars, in thousands)	As of June 30, 2019	2018
Unlisted securities:		
Equity securities	2,317	2,321
	2,317	**2,321**

(i) Classification of financial assets at fair value through other comprehensive income

Financial assets at fair value through other comprehensive income comprises equity securities which are not held for trading, and which the Group has irrevocably elected at initial recognition to recognize in this category. These are strategic investments and the Group considers this classification to be more relevant.

The financial assets are presented as non-current assets unless they mature, or management intends to dispose of them within 12 months of the end of the reporting period.

(ii) Impairment indicators for financial assets at fair value through other comprehensive income

Impairment losses (and reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value. See Note 22(l)(v) for further details about the Group's impairment policies for financial assets.

(iii) Amounts recognized in other comprehensive income

For the years ended June 30, 2019, 2018 and 2017, the Group recognized in statement of comprehensive income a loss of $4 thousand, a gain of $0.3 million and a gain of $31 thousand respectively, for change in fair value of the financial assets through other comprehensive income.

(iv) Fair value, impairment and risk exposure

Information about the methods and assumptions used in determining fair value is provided in Note 5(g). None of the financial assets through other comprehensive income are either past due or impaired.

All financial assets at fair value through other comprehensive income are denominated in USD.

d. Other non-current assets

(in U.S. dollars, in thousands)	As of June 30, 2019	2018
Bank Guarantee	673	710
Letter of Credit	1,178	1,178
U.S. Tax credits	1,473	1,473
	3,324	**3,361**

(i) Classification of financial assets as other non-current assets

Bank guarantee

These funds are held in an account named Mesoblast Limited at National Australia Bank according to the terms of a Bank Guarantee which is security for the sublease agreement for our occupancy of Level 38, 55 Collins Street, Melbourne, Victoria, Australia. The Bank Guarantee is security for the full and faithful performance and observance by the subtenant of the terms, covenants and conditions of the sublease. The Bank Guarantee continues in force until it is released by the lessor.

Letter of credit

These funds held in an account named Mesoblast, Inc. at the Bank of America according to the terms of an irrevocable standby letter of credit which is security for the sublease agreement for our occupancy of 505 Fifth Avenue, New York, New York, United States of America. The letter of credit is security for the full and faithful performance and observance by the subtenant of the terms, covenants and conditions of the sublease. The letter of credit is deemed to automatically extend without amendment for a period of one year at each anniversary but will not automatically extend beyond the final expiration of July 31, 2021.

U.S. Tax credits

These funds are receivable from the Internal Revenue Service ("IRS") as a result of the changes in the U.S. corporate income tax legislation with the Tax Act. Tax credits arising from the Alternative Minimum Tax ("AMT") regime become refundable in 2021.

(ii) Impairment and risk exposure

No other non-current assets are either past due or impaired.

e. Trade and other payables

(in U.S. dollars, in thousands)	2019	2018
Trade payables and other payables	13,060	18,921
Trade and other payables	**13,060**	**18,921**

The carrying amounts of trade and other payables are assumed to be the same as their fair values, due to their short-term nature.

f. Borrowings

(in U.S. dollars, in thousands)	2019	2018
Current		
Secured liabilities:		
Borrowing arrangements	14,007	—
	14,007	**—**
Non-current		
Secured liabilities:		
Borrowing arrangements	65,601	65,000
Less: transaction costs	(6,738)	(6,328)
Amortization of carrying amount, net of payments made	8,416	725
	67,279	**59,397**

(i) Borrowing arrangements

Hercules Capital, Inc.

On March 6, 2018, the Group drew the first tranche of $35.0 million of the principal amount from the $75.0 million floating rate loan with Hercules. An additional tranche of $15.0 million was drawn by the Group on January 14, 2019, which resulted in an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument's original effective interest rate. For the year ended June 30, 2019, a $0.4 million gain has been recognized by the Group in the Income Statement as remeasurement of borrowing arrangements within finance costs.

An additional $25.0 million may be drawn by the Group as certain conditions and milestones are met. The loan matures in March 2022 with principal repayments commencing in October 2019, as a result we have recognized $13.6 million of the borrowings as a current liability. If certain milestones are met before September 30, 2019 the requirement to commence principal repayments will be deferred, potentially until October 2020. Interest on the loan is payable monthly in arrears on the 1st day of the month. At closing date, the interest rate was 9.45%. On March 22, 2018, June 14, 2018, September 27, 2018 and December 20, 2018, in line with the increases in the U.S. prime rate, the interest rate on the loan increased to 9.70%, 9.95%, 10.20% and 10.45%, respectively.

The carrying amount of the loan is secured by a first charge over the assets of the Group, excluding $0.7 million of bank guarantees and $1.2 million of letters of credit included in other non-current assets (refer to Note 5(d)), $0.4 million of interest-bearing deposits at call included in cash and cash equivalents (refer to Note 5(a)) and $0.3 million of cash held as security included in trade and other receivables (refer to Note 5(b)). These items have been used to secure liabilities other than the non-current loan.

NovaQuest Capital Management, L.L.C.

On June 29, 2018, we drew the first tranche of $30.0 million of the principal amount from the $40.0 million secured loan with NovaQuest. There is a four-year interest only period, until July 2022, with the principal repayable in equal quarterly instalments over the remaining period of the loan. A $0.4 million loan administration fee is payable annually in June and is recognized as a current liability. The loan matures in July 2026. Interest on the loan accrues at a fixed rate of 15% per annum.

All interest and principal payments will be deferred until after the first commercial sale of our allogeneic product candidate MSC-100-IV in pediatric patients with steroid refractory aGVHD, in the United States and other geographies excluding Asia (“pediatric aGVHD”). We can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of pediatric aGVHD are significantly higher than current forecasts.

If there are no net sales of pediatric aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of pediatric aGVHD exceed the amount of accrued interest owing and, from 2022, principal and accrued interest owing (“the payment cap”), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of pediatric aGVHD is less than the payment cap, then the payment is limited to 25% of net sales of pediatric aGVHD. Any unpaid interest will be added to the principal amounts owing and shall accrue further interest. At maturity date, any unpaid loan balances are repaid.

Because of this relationship of net sales and repayments, changes in our estimated net sales may trigger an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument’s original effective interest rate. For the year ended June 30, 2019, a $0.7 million loss has been recognized by the Group in the Income Statement as remeasurement of borrowing arrangements within other operating income and expenses.

The carrying amount of the loan and security agreement with NovaQuest is subordinated to the Group’s floating rate loan with the senior creditor, Hercules.

(ii) Compliance with loan covenants

Our loan facilities with Hercules and NovaQuest contain a number of covenants that impose operating restrictions on us, which may restrict our ability to respond to changes in our business or take specified actions. In addition, under our loan and security agreement with Hercules we are obliged to maintain certain levels of cash in the United States, and a minimum unrestricted cash balance across the Group.

The Group has complied with the financial and other restrictive covenants of its borrowing facilities during the year ended June 30, 2019.

(iii) Net debt reconciliation

(in U.S. dollars, in thousands)	Current borrowings	Non-current borrowings	Total
Carrying value - as of June 30, 2018	**3,095**	**28,217**	**31,312**
Changes from financing cash flows			
Proceeds from debt	10,912	32,660	43,572
Payment of transaction costs	—	(2,015)	(2,015)
Repayment of loans	—	—	—
Movement in short-term borrowings	—	—	—
Total changes in liabilities arising on financing cash flows	**10,912**	**30,645**	**41,557**
Other changes			
Accrued transaction costs	—	—	—
Amortization of carrying amount, net of payments made	—	8,417	8,417
Carrying value - as of June 30, 2019	**14,007**	**67,279**	**81,286**

(iv) Fair values of borrowing arrangements

The carrying amount of the borrowings at amortized cost in accordance with our accounting policy is a reasonable approximation of fair value.

g. Recognized fair value measurements

(i) Fair value hierarchy

The following table presents the Group's financial assets and financial liabilities measured and recognized at fair value as of June 30, 2019 and June 30, 2018 on a recurring basis, categorized by level according to the significance of the inputs used in making the measurements:

As of June 30, 2019 (in U.S. dollars, in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Financial assets at fair value through other comprehensive income:					
Equity securities - biotech sector	5(c)	—	—	2,317	2,317
Total Financial Assets		**—**	**—**	**2,317**	**2,317**
Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	5(g)(iii)	—	—	47,534	47,534
Total Financial Liabilities		**—**	**—**	**47,534**	**47,534**

As of June 30, 2018 (in U.S. dollars, in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Financial assets at fair value through other comprehensive income:					
Equity securities - biotech sector	5(c)	—	—	2,321	2,321
Total Financial Assets		**—**	**—**	**2,321**	**2,321**
Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	5(g)(iii)	—	—	42,070	42,070
Total Financial Liabilities		**—**	**—**	**42,070**	**42,070**

There were no transfers between any of the levels for recurring fair value measurements during the period.

The Group's policy is to recognize transfers into and transfers out of fair value hierarchy levels as at the end of the reporting period.

Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, and trading and financial assets at fair value through other comprehensive income) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by the Group is the current bid price. These instruments are included in level 1.

Level 2: The fair value of financial instruments that are not traded in an active market (for example, foreign exchange contracts) is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for provisions (contingent consideration) and equity securities (unlisted).

(ii) Valuation techniques used.

The Group used the discounted cash flow analysis to determine the fair value measurements of level 3 instruments.

(iii) Fair value measurements using significant unobservable inputs (level 3)

The following table presents the changes in level 3 instruments for the years ended June 30, 2019 and June 30, 2018:

(in U.S. dollars, in thousands)	**Contingent consideration provision**
Opening balance - July 1, 2017	63,595
Amount used during the year	(10,984)
Charged/(credited) to consolidated income statement:	
Remeasurement(1)	(10,541)
Closing balance - June 30, 2018	**42,070**
Opening balance - July 1, 2018	42,070
Amount used during the period	(800)
Charged/(credited) to consolidated income statement:	
Remeasurement(2)	6,264
Closing balance - June 30, 2019	**47,534**

(1) In the year ended June 30, 2018 a gain of $10.5 million was recognized on the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This gain is a net result of changes to the key assumptions of the contingent consideration valuation such as developmental timelines, product pricing, market population, market penetration and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

(2) In the year ended June 30, 2019 a loss of $6.3 million was recognized on the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This loss is a net result of changes to the key assumptions of the contingent consideration valuation such as probability of success, market penetration, developmental timelines, product pricing and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

(iv) Valuation inputs and relationship to fair value

The following table summarizes the quantitative information about the significant unobservable inputs used in level 3 fair value measurements:

(in U.S. dollars, in thousands, except percent data)	Fair value as of June 30,		Valuation	Unobservable	Range of inputs (weighted average) Year Ended June 30,		Relationship of unobservable inputs to
Description	2019	2018	technique	inputs[1]	2019	2018	fair value
Contingent consideration provision	47,534	42,070	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Year ended June 30, 2019: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%. Year ended June 30, 2018: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%.
				Expected unit revenues	n/a	n/a	Year ended June 30, 2019: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%. Year ended June 30, 2018: A 10% increase/decrease in the price assumptions adopted would increase/decrease the fair value by 4%.
				Expected sales volumes	n/a	n/a	Year ended June 30, 2019: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%. Year ended June 30, 2018: A 10% increase/decrease in sales volume assumptions adopted would increase/decrease the fair value by 4%.

(1) There were no significant inter-relationships between unobservable inputs that materially affect fair values.

(v) Valuation processes

In connection with the Osiris acquisition, on October 11, 2013 (the “acquisition date”), an independent valuation of the contingent consideration was carried out by an independent valuer.

For the years ended June 30, 2019 and 2018, the Group has adopted a process to value contingent consideration internally. This valuation has been completed by the Group’s internal valuation team and reviewed by the Chief Financial Officer (the "CFO"). The valuation team is responsible for the valuation model. The valuation team also manages a process to continually refine the key assumptions within the model. This is done with input from the relevant business units. The key assumptions in the model have been clearly defined and the responsibility for refining those assumptions has been assigned to the most relevant business units. The remeasurement charged to the consolidated income statement was a net result of changes to key assumptions such as developmental timelines, product pricing, market population, market penetration, probability of success and the increase in valuation as the time period shortens between the valuation date and the potential settlement dates of contingent consideration.

The fair value of contingent consideration (in U.S. dollars, in thousands)	As of June 30, 2019	2018
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets	28,005	23,674
Fair value of royalty payments from commercialization of the intellectual property acquired	19,529	18,396
	47,534	**42,070**

The main level 3 inputs used by the Group are evaluated as follows:

Risk adjusted discount rate: The discount rate used in the valuation has been determined based on required rates of returns of listed companies in the biotechnology industry (having regards to their stage of development, their size and number of projects) and the indicative rates of return required by suppliers of venture capital for investments with similar technical and commercial risks. This assumption is reviewed as part of the valuation process outlined above.

Expected unit revenues: Expected market sale price of the most comparable products currently available in the market place. This assumption is reviewed as part of the valuation process outlined above.

Expected sales volumes: Expected sales volumes of the most comparable products currently available in the market place. This assumption is reviewed as part of the valuation process outlined above.

6. Non-financial assets and liabilities

a. Property, plant and equipment

(in U.S. dollars, in thousands)	Plant and Equipment	Office Furniture and Equipment	Computer Hardware and Software	Total
Year Ended June 30, 2018				
Opening net book amount	751	547	516	1,814
Additions	16	2	176	194
Exchange differences	(1)	(1)	(12)	(14)
Disposals	—	—	(1)	(1)
Depreciation charge	(460)	(134)	(315)	(909)
Closing net book value	**306**	**414**	**364**	**1,084**
As of June 30, 2018				
Cost	4,152	1,249	3,199	8,600
Accumulated depreciation	(3,846)	(835)	(2,835)	(7,516)
Net book value	**306**	**414**	**364**	**1,084**
Year Ended June 30, 2019				
Opening net book amount	306	414	364	1,084
Additions	114	102	107	323
Exchange differences	1	(5)	(13)	(17)
Disposals	—	(2)	—	(2)
Depreciation charge	(217)	(133)	(212)	(562)
Closing net book value	**204**	**376**	**246**	**826**
As of June 30, 2019				
Cost	4,207	1,304	3,023	8,534
Accumulated depreciation	(4,003)	(928)	(2,777)	(7,708)
Net book value	**204**	**376**	**246**	**826**

(i) Depreciation methods and useful lives

Depreciation is calculated using the straight-line method to allocate their cost or revalued amounts, net of their residual values, over the estimated useful lives. The estimated useful lives are:

- Plant and equipment 3 – 15 years
- Office furniture and equipment 3 – 10 years
- Computer hardware and software 3 – 4 years

See Note 22(n) for other accounting policies relevant to property, plant and equipment.

b. Intangible assets

(in U.S. dollars, in thousands)	Goodwill	Acquired licenses to patents	In-process research and development acquired	Current marketed products	Total
Year Ended June 30, 2018					
Opening net book amount	134,453	1,898	427,779	22,220	586,350
Exchange differences	—	(3)	—	—	(3)
Amortization charge	—	(125)	—	(1,616)	(1,741)
Closing net book amount	**134,453**	**1,770**	**427,779**	**20,604**	**584,606**
As of June 30, 2018					
Cost	134,453	2,749	489,698	23,999	650,899
Accumulated amortization	—	(979)	—	(3,395)	(4,374)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**1,770**	**427,779**	**20,604**	**584,606**
Year Ended June 30, 2019					
Opening net book amount	134,453	1,770	427,779	20,604	584,606
Additions	—	100	—	—	100
Exchange differences	—	(4)	—	1	(3)
Amortization charge	—	(122)	—	(1,455)	(1,577)
Closing net book amount	**134,453**	**1,744**	**427,779**	**19,150**	**583,126**
As of June 30, 2019					
Cost	134,453	2,822	489,698	23,999	650,972
Accumulated amortization	—	(1,078)	—	(4,849)	(5,927)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**1,744**	**427,779**	**19,150**	**583,126**

(i) Carrying value of in-process research and development acquired by product

	As of June 30,	
(in U.S. dollars, in thousands)	2019	2018
Cardiovascular products	254,351	254,351
Intravenous products for metabolic diseases and inflammatory/immunologic conditions	70,730	70,730
Osiris MSC products	102,698	102,698
	427,779	**427,779**

For all products included within the above balances, the underlying currency of each item recorded is USD.

(ii) Amortization methods and useful lives

The Group amortizes intangible assets with a finite useful life using the straight-line method over the following periods:

- Acquired licenses to patents 7 – 16 years
- Current marketed products 15 – 20 years

See Note 22(o) for the other accounting policies relevant to intangible assets and Note 22(i) for the Group's policy regarding impairments.

(iii) Significant estimate: Impairment of goodwill and assets with an indefinite useful life

The Group tests annually whether goodwill and its assets with indefinite useful lives have suffered any impairment in accordance with its accounting policy stated in Note 22(i). The recoverable amounts of these assets and cash-generating units have been determined based on fair value less costs to dispose calculations, which require the use of certain assumptions. During the year ended June 30, 2019, we elected to change the annual impairment testing date from the fourth quarter to the third quarter of each year to align with industry best practice. A full assessment was performed at March 31, 2019 and no impairment of the in-process research and development and goodwill was identified.

(iv) Impairment tests for goodwill and intangible assets with and indefinite useful life

In-process research and development acquired is considered to be an indefinite life intangible asset on the basis that it is incomplete and cannot be used in its current form (see Note 22(o)(iii)). The intangible asset's life will remain indefinite until such time it is completed and commercialized or impaired. The carrying value of in-process research and development is a separate asset which has been subject to impairment testing at the cash generating unit level, which has been determined to be at the product level.

On acquisition, goodwill was not able to be allocated to the cash generating unit ("CGU") level or to a group of CGU given the synergies of the underlying research and development. For the purpose of impairment testing, goodwill is monitored by management at the operating segment level. The Group is managed as one operating segment, being the development of adult stem cell technology platform for commercialization. The carrying value of goodwill has been allocated to the appropriate operating segment for the purpose of impairment testing.

The recoverable amount of both goodwill and in-process research and development was assessed as of June 30, 2019 based on the fair value less costs to dispose.

(v) Key assumptions used for fair value less costs to dispose calculations

In determining the fair value less costs to dispose we have given consideration to the following internal and external indicators:

- discounted expected future cash flows of programs valued by the Group's internal valuation team and reviewed by the CFO. The valuation team is responsible for the valuation model. The valuation team also manages a process to continually refine the key assumptions within the model. This is done with input from the relevant business units. The key assumptions in the model have been clearly defined and the responsibility for refining those assumptions has been assigned to the most relevant business units. When determining key assumptions, the business units refer to both external sources and past experience as appropriate. The valuation is considered to be level 3 in the fair value hierarchy due to unobservable inputs used in the valuation;
- the scientific results and progress of the trials since acquisition;
- the valuation of the Group that was applicable to the July 10, 2018 equity placement undertaken with NovaQuest through issuing of the Group's securities on the ASX;
- the market capitalization of the Group on the ASX (ASX:MSB) on the impairment testing date of March 31, 2019; and
- the valuation of the Group's assets from an independent valuation as of June 30, 2017.

Costs of disposal were assumed to be immaterial at June 30, 2019.

Discounted cash-flows used a real post-tax discount rate range of 13.8% to 15.5%, and include estimated real cash inflows and outflows for each program through to patent expiry.

In relation to cash outflows consideration has been given to cost of goods sold, selling costs and clinical trial schedules including estimates of numbers of patients and per patient costs. Associated expenses such as regulatory fees and patent maintenance have been included as well as any further preclinical development if applicable.

The assessment of goodwill showed the recoverable amount of the Group's operating segment, including goodwill and remaining in-process research and development, exceeds the carrying amounts, and therefore there is no impairment. Additionally, the recoverable amount of remaining in-process research and development also exceeds the carrying amounts, and therefore there is no impairment.

There are no standard growth rates applied, other than our estimates of market penetration which increase initially, plateau and then decline.

The assessment of the recoverable amount of each product has been made in accordance with the discounted cash-flow assumptions outlined above. The assessment showed that the recoverable amount of each product exceeds the carrying amount and therefore there is no impairment.

(vi) Impact of possible changes in key assumptions

The Group has considered and assessed reasonably possible changes in the key assumptions and has not identified any instances that could cause the carrying amount of our intangible assets at June 30, 2019 to exceed its recoverable amount.

Whilst there is no impairment, the key sensitivities in the valuation remain the continued successful development of our technology platform.

c. Provisions

	As of June 30, 2019			As of June 30, 2018		
(in U.S. dollars, in thousands)	**Current**	**Non-current**	**Total**	**Current**	**Non-current**	**Total**
Contingent consideration	1,033	46,501	47,534	724	41,346	42,070
Employee benefits	4,231	86	4,317	4,358	101	4,459
Provision for license agreements	2,000	1,742	3,742	—	1,509	1,509
	7,264	**48,329**	**55,593**	**5,082**	**42,956**	**48,038**

(i) Information about individual provisions and significant estimates

Contingent consideration

The contingent consideration provision relates to the Group's liability for certain milestones and royalty achievements pertaining to the acquired MSC assets from Osiris. Further disclosures can be found in Note 5(g)(iii).

Employee benefits

The provision for employee benefits relates to the Group's liability for annual leave, short term incentives and long service leave.

Employee benefits include accrued annual leave. As of June 30, 2019 and 2018, the entire amount of the accrual was $0.7 million and $0.7 million respectively, and is presented as current, since the Group does not have an unconditional right to defer settlement for any of these obligations.

(ii) Movements

The contingent consideration provision relates to the Group's liability for certain milestones and royalty achievements. Refer to Note 5(g)(iii) for movements in contingent consideration for the years ended June 30, 2019 and 2018.

d. Deferred tax balances

(i) Deferred tax balances

(in U.S. dollars, in thousands)	2019	2018
Deferred tax assets		
The balance comprises temporary differences attributable to:		
Tax losses	61,742	55,904
Other temporary differences	3,687	669
Total deferred tax assets	**65,429**	**56,573**
Deferred tax liabilities		
The balance comprises temporary differences attributable to:		
Intangible assets	76,553	76,652
Total deferred tax liabilities	**76,553**	**76,652**
Net deferred tax liabilities	**11,124**	**20,079**
Deferred tax assets expected to be settled within 12 months	—	—
Deferred tax assets expected to be settled after 12 months	65,429	56,573
Deferred tax liabilities expected to be settled within 12 months	99	147
Deferred tax liabilities expected to be settled after 12 months	76,454	76,505

(ii) Movements

(in U.S. dollars, in thousands)	Tax losses(1) (DTA)	Other temporary differences(1) (DTA)	Intangible assets (DTL)	Total (DTL)
As of June 30, 2017	**(74,660)**	**(3,566)**	**127,519**	**49,293**
Reclassifications	1,473	—	—	1,473
Charged/(credited) to:				
- profit or loss	17,283	2,897	(50,867)	(30,687)
As of June 30, 2018	**(55,904)**	**(669)**	**76,652**	**20,079**
Charged/(credited) to:				
- profit or loss	(5,838)	(3,018)	(99)	(8,955)
As of June 30, 2019	**(61,742)**	**(3,687)**	**76,553**	**11,124**

(1) Deferred tax assets are netted against deferred tax liabilities.

e. Deferred consideration

(in U.S. dollars, in thousands)	2019	2018
Opening balance	—	—
Up-front milestone receivable recognized during the period	20,000	—
Amount recognized as revenue in the period	(10,000)	—
Balance as of the end of the period	**10,000**	**—**

Deferred consideration represents the portion of the up-front technology access fee receivable from Tasly that has not been recognized as revenue. In accordance with the Group's accounting policy, revenue related to the licensing of intellectual property is only recognized to the extent that control has been transferred to the customer. The deferred consideration amount will be recognized in revenue when and if control transfers to Tasly based on the Group's decision regarding the exercise of the Group's rights in the terms and conditions of the agreement.

7. Equity

a. Contributed equity

(i) Share capital

	As of June 30,					
	2019	2018	2017	2019	2018	2017
	Shares No.			(U.S. dollars, in thousands)		
Contributed equity						
(i) Share capital						
Ordinary shares	498,626,208	482,639,654	428,221,398	910,405	889,481	830,425
Less: Treasury Shares	(3,500,000)	(3,500,000)	(3,500,000)	—	—	—
Total Contributed Equity	**495,126,208**	**479,139,654**	**424,721,398**	**910,405**	**889,481**	**830,425**

(ii) Movements in ordinary share capital

	As of June 30,			As of June 30,		
	2019	2018	2017	2019	2018	2017
	Shares No.			(U.S. dollars, in thousands)		
Opening balance	482,639,654	428,221,398	381,373,137	889,481	830,425	770,272
Issues of ordinary shares during the period						
Exercise of share options(1)	313,108	289,245	272,579	258	116	149
Share based compensation for services rendered	1,209,187	540,051	280,911	1,170	662	240
Payment for contingent consideration	—	6,029,545	—	—	10,000	—
Entitlement offer to existing eligible shareholders	—	36,191,982	—	—	40,449	—
Placement of shares under an equity facility agreement	—	2,000,000	—	—	—	—
Placement of shares under a share placement agreement(2)	14,464,259	—	46,294,771	20,000	—	61,710
Placement of shares under a license agreement	—	892,857	—	—	1,000	—
Transaction costs arising on share issue	—	—	—	(817)	(2,869)	(1,959)
	15,986,554	45,943,680	46,848,261	20,611	49,358	60,140
Unissued ordinary shares during the period						
Placement of shares under a share placement agreement	—	8,474,576	—	—	10,000	—
Transaction costs arising on share issue	—	—	—	—	(340)	—
	—	8,474,576	—	—	9,660	—
Total contributions of equity during the period	15,986,554	54,418,256	46,848,261	20,611	59,018	60,140
Share options reserve transferred to equity on exercise of options	—	—	—	313	38	13
Ending balance	**498,626,208**	**482,639,654**	**428,221,398**	**910,405**	**889,481**	**830,425**

(1) Options are issued to employees, directors and consultants in accordance with the Mesoblast Employee Share Options Plan (“ESOP”). The shares issued and share capital received upon the exercise of options are recorded above.

(2) During the year ended June 30, 2019, a $20.0 million equity purchase of Mesoblast Limited at A$1.86 per share, representing a 20% premium to a blended volume weighted average price calculated over three months, one month and one day.

(iii) Ordinary shares

Ordinary shares participate in dividends and the proceeds on winding up of the Group in equal proportion to the number of shares held. At shareholders meetings each ordinary share is entitled to one vote when a poll is called, otherwise each shareholder has one vote on a show of hands. Ordinary shares have no par value and the Company does not have a limited amount of authorized capital.

(iv) Employee share options

Information relating to the Group's employee share option plan, including details of shares issued under the scheme, is set out in Note 17.

b. Reserves

(i) Reserves

(in U.S. dollars, in thousands)	As at June 30, 2019	2018
Share-based payments reserve	80,034	75,974
Investment revaluation reserve	17	21
Foreign currency translation reserve	(39,413)	(39,276)
	40,638	**36,719**

(ii) Reconciliation of reserves

(in U.S. dollars, in thousands)	As at June 30,
Share-based payments reserve	**2019**	**2018**
Opening balance	75,974	69,919
Transfer to ordinary shares on exercise of options	(313)	(38)
Share option expense for the year	4,363	5,959
Reclassification of modified options to/(from) liability	10	134
Closing Balance	**80,034**	**75,974**
Investment revaluation reserve		
Opening balance	21	(303)
Changes in the fair value of financial assets through other comprehensive income	(4)	324
Closing Balance	**17**	**21**
Foreign currency translation reserve		
Opening balance	(39,276)	(38,373)
Currency (loss)/gain on translation of foreign operations net assets	(137)	(903)
Closing Balance	**(39,413)**	**(39,276)**

(iii) Nature and purpose of reserves

Share-based payment reserve

The share-based payments reserve is used to recognize:

- the fair value(1) of options issued but not exercised; and
- the fair value(1) of deferred shares granted but not yet vested.

(1) The fair value recognized is determined at the acceptance date, which is the date at which the entity and the employee agree to a share-based payment arrangement, being when the entity and the employee have a shared understanding of the terms and conditions of the arrangement.

Foreign currency translation reserve

Exchange differences arising on translation of a foreign controlled entity are recognized in other comprehensive income and accumulated in a separate reserve within equity. The cumulative amount is reclassified to profit or loss when the net investment is disposed of.

8. Cash flow information

(in U.S. dollars, in thousands) (a) Reconciliation of cash and cash equivalents	As of June 30, 2019	2018	2017
Cash at bank	50,005	37,221	7,722
Deposits at call	421	542	38,039
	50,426	**37,763**	**45,761**

(in U.S. dollars, in thousands) (b) Reconciliation of net cash flows used in operations with loss after income tax	Year Ended June 30, 2019	2018	2017
Loss for the period	(89,799)	(35,290)	(76,815)
Add/(deduct) net loss for non-cash items as follows:			
Depreciation and amortization	2,139	2,650	3,057
Foreign exchange (gains)/losses	(154)	(160)	38
Finance costs	6,914	725	—
Remeasurement of borrowing arrangements	376	—	—
Remeasurement of contingent consideration	6,264	(10,541)	130
Payment under a license agreement paid in shares	—	1,000	—
Payment for services rendered in shares	620	—	—
Equity settled share-based payment	4,368	6,199	5,276
Deferred tax benefit	(8,955)	(30,664)	(13,400)
Change in operating assets and liabilities:			
(Increase)/decrease in trade and other receivables	4,974	(6,093)	(859)
(Increase)/decrease in prepayments	5,237	1,503	(10,201)
Decrease/(increase) in tax assets	1,729	(1,807)	1,282
Increase/(decrease) in trade creditors and accruals	(3,972)	(4,464)	(5,740)
Increase/(decrease) in provisions	2,469	1,930	1,761
Increase/(decrease) in deferred consideration	10,000	—	—
Net cash outflows used in operations	**(57,790)**	**(75,012)**	**(95,471)**

9. Significant estimates, judgments and errors

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgment in applying the Group's accounting policies.

This note provides an overview of the areas that involved a higher degree of judgment or complexity, and of items which are more likely to be materially adjusted due to estimates and assumptions turning out to be wrong. Detailed information about each of these estimates and judgments is included in Notes 1 to 8 together with information about the basis of calculation for each affected line item in the financial statements. In addition, this note also explains where there have been actual adjustments this year as a result of an error and of changes to previous estimates.

Significant estimates and judgments

The areas involving significant estimates or judgments are:

- recognition of revenue (Note 3);
- fair value of contingent liabilities and contingent purchase consideration in a business combination (Note 5(g) and 12);
- fair value of goodwill and other intangible assets including in-process research and development (Note 6(b));

- useful life of intangible assets (Note 6(b));
- recognition of deferred tax assets and deferred tax liabilities (Note 4(b));
- accrued research and development and manufacturing commercialization expenses (Note 5(e)); and
- fair value of share-based payments (Note 17);
- fair value of borrowings (Note 5(f)).

Estimates and judgments are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

10. Financial risk management

This note explains the Group's exposure to financial risks and how these risks could affect the Group's future financial performance. Current year profit and loss information has been included where relevant to add further context.

Risk	Exposure arising from	Measurement	Management
Market risk – currency risk	Future commercial transactions Recognized financial assets and liabilities not denominated in the functional currency of each entity within the Group	Cash flow forecasting Sensitivity analysis	The future cash flows of each currency are forecast and the quantum of cash reserves held for each currency are managed in line with future forecasted requirements. Cross currency swaps are undertaken as required.
Market risk – interest rate risk	Long-term borrowings at floating rates	Sensitivity analysis	The facility can be refinanced and/or repaid. Interest rate swaps can be entered into to convert the floating interest rate to a fixed interest rate as required.
	Term deposits at fixed rates	Sensitivity analysis	Vary length of term deposits, utilize interest bearing accounts and periodically review interest rates available to ensure we earn interest at market rates.
Market risk – price risk	Long-term borrowings	Sensitivity analysis	Forecasts of net sales of the product underlying the NovaQuest borrowing arrangement are updated on a quarterly basis to evaluate the impact on the carrying amount of the financial liability.
Credit risk	Cash and cash equivalents, and trade and other receivables	Aging analysis Credit ratings	Only transact with the best risk rated banks available in each region giving consideration to the products required.
Liquidity risk	Cash and cash equivalents Borrowings	Rolling cash flow forecasts	Future cash flows requirements are forecasted and capital raising strategies are planned to ensure sufficient cash balances are maintained to meet the Group's future commitments.

a. Market risk

(i) Currency risk

The Group has foreign currency amounts owing primarily in the Group's Australian based entity, whose functional currency is the A$ relating to clinical, regulatory and overhead activities. The Group also has foreign currency amounts owing in the Group's Swiss and Singapore based entities, whose functional currencies are the US$. The Group also has foreign currency amounts owing in various other non-US$ currencies in A$ and US$ functional currency entities in the Group relating to clinical, regulatory and overhead activities. These foreign currency balances give rise to a currency risk, which is the risk of the exchange rate moving, in either direction, and the impact it may have on the Group's financial performance.

Currency risk is minimized by ensuring the proportion of cash reserves held in each currency matches the expected rate of spend of each currency.

As of June 30, 2019, the Group held 97% of its cash in USD, and 3% in AUD. As of June 30, 2018 the Group held 92% of its cash in USD, and 8% in AUD.

The balances held at the end of the year that give rise to currency risk exposure are presented in USD in the following table, together with a sensitivity analysis which assesses the impact that a change of +/-20% in the exchange rate as of June 30, 2019 and June 30, 2018 would have had on the Group's reported net profits/(losses) and/or equity balance.

(in U.S. dollars, in thousands) As of June 30, 2019	Foreign currency balance held	+20% Profit/(Loss) USD	-20% Profit/(Loss) USD
Bank accounts - USD	USD 383	$ 77	$ (77)
Bank accounts - CHF	CHF 49	$ 10	$ (10)
Bank accounts - SGD	SGD 83	$ 12	$ (12)
Bank accounts - EUR	EUR 4	$ 1	$ (1)
Trade and other receivables - SGD	SGD 30	$ 4	$ (4)
Trade and other receivables - CHF	CHF 2	$ 0	$ (0)
Trade and other receivables - EUR	EUR 8	$ 2	$ (2)
Trade payables and accruals - USD	(USD 490)	$ (98)	$ 98
Trade payables and accruals - AUD	(AUD 280)	$ (39)	$ 39
Trade payables and accruals - SGD	(SGD 193)	$ (28)	$ 28
Trade payables and accruals - GBP	(GBP 30)	$ (8)	$ 8
Trade payables and accruals - EUR	(EUR 86)	$ (19)	$ 19
Trade payables and accruals - CHF	(CHF 55)	$ (11)	$ 11
Provisions - SGD	(SGD 70)	$ (10)	$ 10
		$ (107)	**$ 107**

(in U.S. dollars, in thousands) As of June 30, 2018	Foreign currency balance held	+20% Profit/(Loss) USD	-20% Profit/(Loss) USD
Bank accounts - USD	USD 81	$ (14)	$ 20
Bank accounts - CHF	CHF 157	$ 31	$ (31)
Bank accounts - SGD	SGD 178	$ 49	$ (49)
Bank accounts - EUR	EUR 2	$ 0	$ (0)
Trade and other receivables - SGD	SGD 29	$ 8	$ (8)
Trade and other receivables - USD	USD 10,000	$ (1,667)	$ 2,500
Trade and other receivables - CHF	CHF 6	$ 1	$ (1)
Trade and other receivables - EUR	EUR 4,750	$ 815	$ (815)
Trade payables and accruals - USD	(USD 1,797)	$ 300	$ (449)
Trade payables and accruals - AUD	(AUD 446)	$ (121)	$ 121
Trade payables and accruals - SGD	(SGD 176)	$ (48)	$ 48
Trade payables and accruals - GBP	(GBP 52)	$ (0)	$ (2)
Trade payables and accruals - EUR	(EUR 1)	$ (0)	$ 0
Trade payables and accruals - CHF	(CHF 50)	$ (10)	$ 10
Trade payables and accruals - SEK	(SEK 118)	$ 2	$ (3)
Provisions - SGD	(SGD 74)	$ (20)	$ 20
Provisions - CHF	(CHF 2)	$ (0)	$ 0
		$ (674)	**$ 1,361**

(ii) Cash flow and fair value interest rate risk

The Group's main interest rate risk arises from long-term borrowings with a floating interest rate, which exposes the Group to cash flow interest rate risk. As interest rates fluctuate, the amount of interest payable on financing where the interest rate is not fixed will also fluctuate. This interest rate risk can be managed by interest rate swaps which can be entered into to convert the floating interest rate to a fixed interest rate as required. Additionally, the Group can repay its loan facility at its discretion and can also refinance if the terms are suitable in the marketplace or from the existing lender.

We completed a cost benefit analysis of entering an interest rate swap arrangement in the period. The Group did not enter into any interest rate swaps during the year ended June 30, 2019.

The exposure of the Group's borrowing to interest rate changes are as follows:

	As of June 30, 2019		As of June 30, 2018	
(in U.S. dollars, in thousands, except percent data)	**Total**	**% of total loans**	**Total**	**% of total loans**
Financial liabilities				
Current borrowings				
Variable rate borrowings - Hercules	13,607	17%	—	0%
Non-current borrowings				
Variable rate borrowings - Hercules	34,619	43%	31,966	54%
	48,226	**60%**	**31,966**	**54%**

An analysis by maturities is provided in Note 10(c) below. The percentage of total loans shows the proportion of loans that are currently at variable rates in relation to the total amount of borrowings.

The borrowings which expose the Group to interest rate risk are described in the table below, together with the maximum and minimum interest rates being earned as of June 30, 2019 and June 30, 2018. The effect on profit is shown if interest rates change by 5%, in either direction, is as follows:

	As of June 30, 2019			As of June 30, 2018		
(in U.S. dollars, in thousands, except percent data)	**Low**	**High**	**USD**	**Low**	**High**	**USD**
Borrowings - USD	10.45%	10.45%	48,226(1)	9.95%	9.95%	31,966(1)
Rate increase by 5%	10.97%	10.97%	261	10.45%	10.45%	159
Rate decrease by 5%	9.93%	9.93%	(261)	9.45%	9.45%	(159)

(1) Effect on profit/loss of interest rate changes is based on the loan principal amount of $50.0 million as of June 30, 2019, and loan principal amount of $35.0 million as of June 30, 2018, with principal payments commencing in October 2019.

The Group is also exposed to interest rate movements which impacts interest income earned on its deposits and at call accounts. The interest income derived from these balances can fluctuate due to interest rate changes. This interest rate risk is managed by periodically reviewing interest rates available for suitable interest bearing accounts to ensure we earn interest at market rates. The Group ensures that sufficient funds are available, in at call accounts, to meet the working capital requirements of the Group.

The deposits held which derive interest revenue are described in the table below, together with the maximum and minimum interest rates being earned as of June 30, 2019 and June 30, 2018. The effect on profit is shown if interest rates change by 10%, in either direction, is as follows:

	As of June 30, 2019			As of June 30, 2018		
(in U.S. dollars, in thousands, except percent data)	**Low**	**High**	**USD**	**Low**	**High**	**USD**
Funds invested - USD	1.76%	1.76%	46,051	0.80%	0.80%	99
Rate increase by 10%	1.94%	1.94%	81	0.88%	0.88%	0
Rate decrease by 10%	1.58%	1.58%	(81)	0.72%	0.72%	0
AUD	**Low**	**High**	**AUD**	**Low**	**High**	**AUD**
Funds invested - AUD	2.23%	2.23%	600	2.72%	2.72%	600
Rate increase by 10%	2.45%	2.45%	1	2.99%	2.99%	2
Rate decrease by 10%	2.01%	2.01%	(1)	2.45%	2.45%	(2)

(iii) Price risk

Price risk is the risk that future cash flows derived from financial instruments will be altered as a result of a market price movement, which is defined as movements other than foreign currency rates and interest rates. The Group is exposed to price risk which arises from long-term borrowings under its facility with NovaQuest, where the timing and amounts of principal and interest payments is dependent on net sales of product candidate MSC-100-IV for the treatment of aGVHD in pediatric patients in the United States and other territories excluding Asia. As net sales of MSC-100-IV for the treatment of aGVHD in pediatric patients in these territories increase/decrease, the timing and amount of principal and interest payments relating to the financing arrangement will also fluctuate, resulting in an adjustment to the carrying amount of financial liability. The adjustment is recognized in the Income Statement as remeasurement of borrowing arrangements within other operating income and expenses in the period the revision is made.

The exposure of the Group's borrowing to price rate changes are as follows:

	As of June 30, 2019		As of June 30, 2018	
(in U.S. dollars, in thousands, except percent data)	**Total**	**% of total loans**	**Total**	**% of total loans**
Financial liabilities				
Current borrowings				
Borrowings - NovaQuest	400	0%	—	0%
Non-current borrowings				
Borrowings - NovaQuest	32,660	40%	27,431	46%
	33,060	**40%**	**27,431**	**46%**

As at June 30, 2019, all other factors held constant, a 20% increase in the forecast net sales of MSC-100-IV for the treatment of aGVHD in pediatric patients in the United States and other territories excluding Asia would increase non-current borrowing and decrease profit by $3.5 million, whereas a 20% decrease in the net sales of MSC-100-IV for the treatment of aGVHD in pediatric patients in the United States and other territories excluding Asia would decrease non-current borrowings and increase profit by $1.6 million.

The Group does not consider it has any exposure to price risk other than those already described above.

b. Credit risk

Credit risk is the risk that one party to a financial instrument will fail to discharge its obligation and cause financial loss to the other party. The Group does not generally have trade receivables. The Group's receivables are tabled below.

	As of June 30,	
(in U.S. dollars, in thousands)	**2019**	**2018**
Cash and cash equivalents		
Deposits at call (Note 5(a)) - minimum A rated	421	542
Cash at bank (Note 5(a)) - minimum A rated	50,005	37,221
Trade and other receivables		
Receivable from other parties (non-rated)	1,740	45,745
Receivable from the Australian Government (Income Tax)	1,511	3,305
Receivable from the Australian Government (Foreign Withholding Tax)	400	400
Receivable from minimum A rated bank deposits (interest)	252	262
Receivable from the Australian Government (Goods and Services Tax)	84	48
Receivable from the United States Government (Income Tax)	71	24
Receivable from the Swiss Government (Value-Added Tax)	2	6
Other non-current assets		
Receivable from the United States Government (U.S. tax credits)	1,467	1,473

c. Liquidity risk

Liquidity risk is the risk that the Group will not be able to pay its debts as and when they fall due. Liquidity risk has been assessed in Note 1(*i*).

All financial liabilities, excluding contingent consideration, held by the Group as of June 30, 2019 and June 30, 2018 are non-interest bearing and mature within 6 months. The total contractual cash flows associated with these liabilities equate to the carrying amount disclosed within the financial statements.

As of June 30, 2019, the maturity profile of the anticipated future contractual cash flows including interest in relation to the Group's borrowings, on an undiscounted basis and which, therefore differs from the carrying value, is as follows:

(in U.S. dollars, in thousands)	**Within 1 year**	**Between 1-2 years**	**Between 2-5 years**	**Over 5 years**	**Total contractual cash flows**	**Carrying amount**
Borrowings(1)(2)	(18,845)	(29,790)	(57,634)	(34,728)	(140,997)	(81,286)
	(18,845)	**(29,790)**	**(57,634)**	**(34,728)**	**(140,997)**	**(81,286)**

(1) Contractual cash flows include payments of principal, interest and other charges. Interest is calculated based on debt held at June 30, 2019 without taking account drawdowns of further tranches.

(2) In relation to the contractual maturities of the NovaQuest borrowings, there is variability in the maturity profile of the anticipated future contractual cash flows given the timing and amount of payments are calculated based on our estimated net sales of pediatric aGVHD.

11. Capital management

The Group's objective when managing capital is to safeguard its ability to continue as a going concern, so that it can provide returns for shareholders and benefits for other stakeholders. See Note 5(a) for the cash reserves of the Group as at the end of the financial reporting period.

12. Interests in other entities

The Group's subsidiaries as of June 30, 2019 and 2018 are set out below. Unless otherwise stated, they have share capital consisting solely of ordinary shares that are held directly by the Group, and the proportion of ownership interests held equals the voting rights held by the Group. The country of incorporation or registration is also their principal place of business, aside from BeiCell Ltd, which was incorporated on November 15, 2018 in the Cayman Islands however operates in Hong Kong.

	Country of incorporation	Class of shares	Equity holding	
			As of June 30,	
			2019	2018
			%	%
Mesoblast, Inc.	USA	Ordinary	100	100
Mesoblast International Sàrl (includes Mesoblast International Sàrl Singapore Branch)	Switzerland	Ordinary	100	100
Mesoblast Australia Pty Ltd	Australia	Ordinary	100	100
Mesoblast UK Ltd	United Kingdom	Ordinary	100	100
Mesoblast International (UK) Ltd	United Kingdom	Ordinary	100	100
BeiCell Ltd	Cayman Islands	Ordinary	100	N/A

13. Contingent assets and liabilities

a. Contingent assets

The Group did not have any contingent assets outstanding as of June 30, 2019 and June 30, 2018.

b. Contingent liabilities

(i) Central Adelaide Local Health Network Incorporated ("CALHNI") (formerly Medvet)

The Group acquired certain intellectual property relating to our MPCs, or Medvet IP, pursuant to an Intellectual Property Assignment Deed, or IP Deed, with Medvet Science Pty Ltd, or Medvet. Medvet's rights under the IP Deed were transferred to Central Adelaide Local Health Network Incorporated, or CALHNI, in November 2011. In connection with its use of the Medvet IP, on completion of certain milestones the Group will be obligated to pay CALHNI, as successor in interest to Medvet, (i) certain aggregated milestone payments of up to $2.2 million and single-digit royalties on net sales of products covered by the Medvet IP, for cardiac muscle and blood vessel applications and bone and cartilage regeneration and repair applications, subject to minimum annual royalties beginning in the first year of commercial sale of those products and (ii) single-digit royalties on net sales of the specified products for applications outside the specified fields.

(ii) Other contingent liabilities

The Group has entered into a number of other agreements with other third parties pertaining to intellectual property. Contingent liabilities may arise in the future if certain events or developments occur in relation to these agreements. As of June 30, 2019 the Group has assessed these contingent liabilities to be remote and specific disclosure is not required.

14. Commitments

a. Capital commitments

The Group did not have any commitments for future capital expenditure outstanding as of June 30, 2019 and June 30, 2018.

b. Lease commitments: Group as lessee

The Group leases various offices under non-cancellable operating leases. The leases have varying terms, escalation clauses and renewal rights. On renewal, the terms of the leases are renegotiated.

(in U.S. dollars, in thousands)	Total	Within one year	Later than one year but no later than three years	Later than three years but no later than five years	Later than five years
Operating leases	7,460	2,100	2,763	1,341	1,256
Total commitments	**7,460**	**2,100**	**2,763**	**1,341**	**1,256**

Lease commitments include amounts in AUD and Singapore dollars which have been translated to USD as of June 30, 2019 foreign exchange rates published by the Reserve Bank of Australia.

c. Purchase commitments

The Group did not have any purchase commitments as of June 30, 2019.

15. Events occurring after the reporting period

There were no other events that have occurred after June 30, 2019 and prior to the signing of this financial report that would likely have a material impact on the financial results presented.

16. Related party transactions

a. Parent entity

The parent entity within the Group is Mesoblast Limited.

b. Subsidiaries

Details of interests in subsidiaries are disclosed in Note 12 to the financial statements.

c. Key management personnel compensation

The aggregate compensation made to Directors and other members of key management personnel of the Group is set out below

(in U.S. dollars)	Year Ended June 30, 2019	2018
Short-term employee benefits	2,723,902	2,577,166
Long-term employee benefits	12,074	5,648
Post-employment benefits	45,878	66,539
Share based payments	297,423	(60,858)
	3,079,277	**2,588,495**

d. Transactions with other related parties

Accounts receivable from revenues, accounts payable to expenses and loans from subsidiaries as at the end of the fiscal year have been eliminated on consolidation of the Group.

e. Terms and conditions

All other transactions were made on normal commercial terms and conditions and at market rates, except that there are no fixed terms for the repayment of loans between the parties.

Outstanding balances are unsecured and are repayable in cash.

17. Share-based payments

The Company has adopted an Employee Share Option Plan ("ESOP") and a Loan Funded Share Plan ("LFSP") (together, "the Plans") to foster an ownership culture within the Company and to motivate senior management and consultants to achieve performance targets. Selected directors, employees and consultants may be eligible to participate in the Plans at the absolute discretion of the board of directors, and in the case of directors, upon approval by shareholders. Due to changes in the Australian taxation regime, the Company no longer issues new LFSP since July 1, 2015.

Grant policy

In accordance with the Company's policy, options and loan funded shares are typically issued in three equal tranches. For issues granted prior to July 1, 2015 the length of time from grant date to expiry date was typically 5 years. Grants since July 1, 2015, are issued with a seven year term.

Options issued to employees generally vest based on service or time conditions. In the year ended June 30, 2019, senior executives were issued options that vest based on performance conditions. For time based vesting options, the first tranche typically vests 12 months after grant date, the second tranche 24 months after grant date, and the third tranche 36 months after grant date.

The exercise price is determined by reference to the Company policy which is generally the volume weighted market price of a share sold on the ASX on the 5 trading days immediately before the Board approval date. In the case of options that have time based vesting conditions, the board of directors adds a 10% premium. Options with performance based vesting conditions are issued with no premium. The board of directors' policy is not to issue options at a discount to the market price. The same approach is used to determine the purchase price to acquire a loan-funded share for the purposes of the LFSP.

The aggregate number of options which may be issued pursuant to the ESOP must not exceed 10,000,000 with respect to US incentive stock options, and with respect to Australian residents, the limit imposed under the Australian Securities and Investments Commission Class Order 14/1000.

In addition, the LFSP which has not been issued since July 1, 2015, has the following characteristics:

On grant date, the Company issues new equity (rather than purchasing shares on market), and the loan funded shares are placed in a trust which holds the shares on behalf of the employee. The trustee issues a limited recourse, interest free, loan to the employee which is equal to the number of shares multiplied by the price. A limited-recourse loan means that the repayment amount will be the lesser of the outstanding loan value (the loan value less any amounts that may have already been repaid) and the market value of the shares that are subject to the loan. The price is the amount the employee must pay for each loan funded share if exercised.

The trustee continues to hold the shares on behalf of the employee until the employee chooses to settle the loan pertaining to the shares and all vesting conditions have been satisfied, at which point ownership of the shares is fully transferred to the employee.

Any dividends paid by the Company, while the shares are held by the trustee, are applied as a repayment of the loan at the after-tax value of the dividend.

a. Reconciliation of outstanding share based payments

Series	Grant Date	Expiry Date	Exercise Price	Opening Balance	Granted No. (during the year)	Exercised No. (during the year)	Lapsed/Forfeited* No. (during the year)	Closing Balance	Vested and exercisable No (end of year)
INC	7/12/2010	26/10/2018	USD 0.305	26,108	—	(26,108)	—	—	—
INC	7/12/2010	26/10/2019	USD 0.340	319,892	—	—	—	319,892	319,892
17/LF3	9/07/2012	8/07/2018	AUD 6.67	150,000	—	—	(150,000)	—	—
22/LF8	4/09/2013	27/08/2018	AUD 6.26	225,000	—	—	(225,000)	—	—
25a (i&ii)	1/01/2014	31/12/2018	AUD 6.36	650,000	—	—	(650,000)	—	—
25b	12/12/2014	31/10/2019	AUD 4.49	50,000	—	—	—	50,000	50,000
27/LF12	5/09/2014	30/06/2019	AUD 4.71	2,045,000	—	—	(1,790,000)		
27/LF12	5/09/2014	30/06/2019	AUD 4.71		—	—	(255,000)*	—	—
28/LF13	9/10/2014	8/10/2019	AUD 4.52	75,000	—	—	—	75,000	75,000
29	25/11/2014	24/11/2019	AUD 4.00	240,000	—	—		240,000	240,000
30c(1)	25/03/2015	20/01/2019	AUD 4.98	135,000	—	—	(135,000)	—	—
30d(1)	25/03/2015	25/01/2019	AUD 4.98	300,000	—	—	(300,000)	—	—
30f(1)	25/03/2015	25/01/2019	AUD 4.98	200,000	—	—	(200,000)	—	—
30h(1)	25/03/2015	30/06/2019	AUD 4.69	400,000	—	—	(400,000)	—	—
30i(1)	25/03/2015	30/06/2019	AUD 4.44	600,000	—	—	(600,000)	—	—
LF14	6/01/2015	16/12/2019	AUD 4.66	150,000	—	—	—	150,000	150,000
31b	12/05/2015	16/02/2020	AUD 4.28	200,000	—	—	—	200,000	200,000
32	10/07/2015	30/06/2022	AUD 4.20	2,458,334	—	—	(150,000)*	2,308,334	2,308,334
33	26/08/2015	16/08/2022	AUD 4.05	75,000	—	—	—	75,000	75,000
34	27/04/2016	6/03/2023	AUD 2.80	3,380,000	—	—	(186,666)*	3,193,334	3,193,334
34a	27/04/2016	17/04/2023	AUD 2.74	200,000	—	—	—	200,000	200,000
34b	31/10/2016	6/03/2023	AUD 2.80	200,000	—	—	—	200,000	200,000
35	30/06/2016	18/01/2021	AUD 2.20	1,500,000	—	—	—	1,500,000	1,500,000
36	6/12/2016	5/12/2023	AUD 1.31	1,885,000	—	(75,000)	(140,000)*	1,670,000	1,116,666
36a	6/12/2016	5/12/2023	AUD 1.19	4,400,000	—	(212,000)	—	4,188,000	3,000,502
36b	13/01/2017	12/01/2024	AUD 1.65	300,000	—	—	—	300,000	300,000
37	28/06/2017	27/06/2024	AUD 2.23	300,000	—	—	(150,000)*	150,000	100,000
38	16/09/2017	15/09/2024	AUD 1.54	100,000	—	—	—	100,000	33,334
38a	16/09/2017	15/09/2024	AUD 1.40	150,000	—	—	—	150,000	150,000
39	13/10/2017	12/10/2024	AUD 1.94	2,215,000	—	—	(236,667)*	1,978,333	668,330
39a	13/10/2017	12/10/2024	AUD 1.76	1,900,000	—	—	—	1,900,000	1,300,000
40	24/11/2017	23/11/2024	AUD 1.41	750,000	—	—	—	750,000	250,000
40a	24/11/2017	23/11/2024	AUD 1.28	750,000	—	—	—	750,000	—
41	18/06/2018	17/06/2025	AUD 1.52		200,000	—	—	200,000	66,667
42	11/07/2018	10/07/2025	AUD 1.56		200,000	—	—	200,000	—
43	18/07/2018	17/07/2025	AUD 1.87		5,970,000	—	(125,000)*	5,845,000	—
44	15/07/2018	14/07/2025	AUD 1.72		300,000	—	—	300,000	—
45	30/11/2018	29/11/2025	AUD 1.33		590,000	—	—	590,000	—
46	19/01/2019	18/01/2026	AUD 1.45		5,000	—	—	5,000	—
47	19/01/2019	18/01/2026	AUD 1.45		150,000	—	—	150,000	75,000
June 30, 2019				**26,329,334**	**7,415,000**	**(313,108)**	**(5,693,333)**	**27,737,893**	**15,572,059**
Weighted average share purchase price				AUD 2.68	AUD 1.79	AUD 1.16	AUD 4.58	AUD 2.06	AUD 2.35

(1) 30a to 30i were granted as remuneration for the repurchase and cancellation of 2,985,000 LFSP during the year ended 30 June 2015 (see Note 17(b)).

Series	Grant Date	Expiry Date	Exercise Price	Opening Balance	Granted No. (during the year)	Exercised No. (during the year)	Lapsed/Forfeited* No. (during the year)	Closing Balance	Vested and exercisable No (end of year)
INC	7/12/2010	26/10/2018	USD 0.305	154,064	—	(127,956)	—	26,108	26,108
INC	7/12/2010	26/10/2019	USD 0.340	447,848	—	(127,956)	—	319,892	319,892
17/LF3	9/07/2012	8/07/2018	AUD 6.69	150,000	—	—	—	150,000	150,000
19/LF5	25/01/2013-29/01/2013	24/01/2018-28/01/2018	AUD 6.29	50,000	—	—	(50,000)	—	—
20/LF6	24/05/2013	23/05/2018	AUD 6.36	425,000	—	—	(325,000)		
20/LF6	24/05/2013	23/05/2018	AUD 6.36		—	—	(100,000)*	—	—
21/LF7	3/09/2013	30/06/2018	AUD 5.92	1,865,000	—	—	(1,615,000)		
22/LF8	4/09/2013	27/08/2018	AUD 6.28	225,000	—	—	—	225,000	225,000
25a (i&ii)	1/01/2014	31/12/2018	AUD 6.38	650,000	—	—	—	650,000	650,000
25b	12/12/2014	31/10/2019	AUD 4.51	50,000	—	—	—	50,000	50,000
27/LF12	5/09/2014	30/06/2019	AUD 4.71	2,070,000	—	—	(25,000)*	2,045,000	2,045,000
27(iv)	25/08/2014	24/08/2019	AUD 4.67	75,000	—	—	(75,000)*	—	—
28/LF13	9/10/2014	8/10/2019	AUD 4.54	85,000	—	—	(10,000)*	75,000	75,000
29	25/11/2014	24/11/2019	AUD 4.02	240,000	—	—	—	240,000	240,000
30a	25/03/2015	30/06/2018	AUD 5.00	650,000	—	—	(650,000)	—	—
30b	25/03/2015	25/01/2018	AUD 5.00	235,000	—	—	(235,000)	—	—
30c	25/03/2015	25/01/2019	AUD 5.00	135,000	—	—	—	135,000	135,000
30d	25/03/2015	30/06/2019	AUD 5.00	300,000	—	—	—	300,000	300,000
30e	25/03/2015	23/07/2019	AUD 5.00	165,000	—	—	(165,000)	—	—
30f	25/03/2015	23/07/2019	AUD 5.00	200,000	—	—	—	200,000	200,000
30g	25/03/2015	20/01/2019	AUD 4.71	300,000	—	—	(300,000)*	—	—
30h	25/03/2015	25/01/2018	AUD 4.71	400,000	—	—	—	400,000	400,000
30i	25/03/2015	25/01/2019	AUD 4.46	600,000	—	—	—	600,000	600,000
30j	25/03/2015	30/06/2019	AUD 4.71	150,000	—	—	(150,000)*	—	—
LF14	6/01/2015	16/12/2019	AUD 4.66	150,000	—	—	—	150,000	150,000
31b	12/05/2015	16/02/2020	AUD 4.30	200,000	—	—	—	200,000	200,000
32	10/07/2015	30/06/2022	AUD 4.22	2,620,000	—	—	(161,666)*	2,458,334	1,683,336
33	26/08/2015	16/08/2022	AUD 4.07	91,667	—	—	(16,667)*	75,000	50,000
34	27/04/2016	6/03/2023	AUD 2.82	3,621,667	—	—	(241,667)*	3,380,000	2,299,982
34a	27/04/2016	17/04/2023	AUD 2.76	200,000	—	—	—	200,000	133,334
34b	31/10/2016	6/03/2023	AUD 2.82	200,000	—	—	—	200,000	200,000
35	30/06/2016	30/06/2019	AUD 2.20	1,500,000	—	—	—	1,500,000	1,500,000
36	6/12/2016	5/12/2023	AUD 1.33	2,045,000	—	(33,333)	(126,667)*	1,885,000	611,666
36a	6/12/2016	5/12/2023	AUD 1.21	4,400,000	—	—	—	4,400,000	1,495,002
36b	13/01/2017	12/01/2024	AUD 1.67	450,000	—	—	(150,000)*	300,000	300,000
37	28/06/2017	27/06/2024	AUD 2.23	—	300,000	—	—	300,000	100,000
38	16/09/2017	15/09/2024	AUD 1.54	—	100,000	—	—	100,000	—
38a	16/09/2017	15/09/2024	AUD 1.40	—	150,000	—	—	150,000	—
39	13/10/2017	12/10/2024	AUD 1.94	—	2,310,000	—	(95,000)*	2,215,000	—
39a	13/10/2017	12/10/2024	AUD 1.76	—	2,000,000	—	(100,000)*	1,900,000	200,000
40	24/11/2017	23/11/2024	AUD 1.41	—	750,000	—	—	750,000	—
40a	24/11/2017	23/11/2024	AUD 1.28	—	750,000	—	—	750,000	—
June 30, 2018				**25,100,246**	**6,360,000**	**(289,245)**	**(4,841,667)**	**26,329,334**	**14,339,320**
Weighted average share purchase price				AUD 3.35	AUD 1.74	AUD 0.52	AUD 4.97	AUD 2.68	AUD 3.39

(1) 30a to 30i were granted as remuneration for the repurchase and cancellation of 2,985,000 LFSP during the year ended 30 June 2015 (see Note 17(b)).

Series	Grant Date	Expiry Date	Exercise Price	Opening Balance	Granted No. (during the year)	Exercised No. (during the year)	Lapsed/Forfeited* No. (during the year)	Closing Balance	Vested and exercisable No (end of year)
INC	7/12/2010	26/10/2018	USD 0.305	154,064	—	—	—	154,064	154,064
INC	7/12/2010	26/10/2019	USD 0.340	447,848	—	—	—	447,848	447,848
INC	7/12/2010	25/04/2017	USD 0.444	127,956	—	(127,956)	—	—	—
INC	7/12/2010	2/05/2017	USD 0.444	127,956	—	(127,956)	—	—	—
16/LF2	24/02/2012	23/02/2017	USD 8.480	340,000	—	—	(170,000)		—
16/LF2	24/02/2012	23/02/2017	AUD 8.48		—	—	(170,000)*		—
17/LF3	9/07/2012	8/07/2018	AUD 6.69	250,000	—	—	(100,000)*	150,000	150,000
18/LF4	21/09/2012-29/10/2012	30/06/2017	AUD 6.70	1,948,333	—	—	(1,673,333)		
18/LF4	21/09/2012-29/10/2012	30/06/2017	AUD 6.70		—	—	(275,000)*	—	—
19/LF5	25/01/2013-29/01/2013	24/01/2018-28/01/2018	AUD 6.29	100,000	—	—	(50,000)*	50,000	50,000
20/LF6	24/05/2013	23/05/2018	AUD 6.36	595,000	—	—	(170,000)*	425,000	425,000
21/LF7	3/09/2013	30/06/2018	AUD 5.92	2,430,000	—	—	(565,000)*	1,865,000	1,865,000
22/LF8	4/09/2013	27/08/2018	AUD 6.28	225,000	—	—	—	225,000	225,000
23a	26/11/2013	10/10/2018	AUD 6.20	33,333	—	—	(33,333)*	—	—
24	17/12/2013	16/12/2018	AUD 6.25	25,000	—	—	(25,000)*	—	—
25a (i&ii)	1/01/2014	31/12/2018	AUD 6.38	650,000	—	—	—	650,000	650,000
25b	12/12/2014	31/10/2019	AUD 4.51	50,000	—	—	—	50,000	33,334
25	1/07/2014	6/04/2019	AUD 5.80	10,000	—	—	(10,000)*	—	—
26/LF11	24/07/2014	23/07/2019	AUD 4.71	125,000	—	—	(125,000)*	—	
27/LF12	5/09/2014	30/06/2019	AUD 4.71	2,865,000	—	—	(795,000)*	2,070,000	1,380,004
27(ii)	4/08/2014	3/08/2019	AUD 4.60	50,000	—	—	(50,000)*	—	—
27(iv)	25/08/2014	24/08/2019	AUD 4.67	75,000	—	—	—	75,000	50,000
28/LF13	9/10/2014	8/10/2019	AUD 4.54	235,000	—	—	(150,000)*	85,000	56,666
29	25/11/2014	24/11/2019	AUD 4.02	240,000	—	—	—	240,000	160,002
30a	25/03/2015	30/06/2018	AUD 5.00	650,000	—	—	—	650,000	650,000
30b	25/03/2015	25/01/2018	AUD 5.00	235,000	—	—	—	235,000	235,000
30c	25/03/2015	25/01/2019	AUD 5.00	135,000	—	—	—	135,000	135,000
30d	25/03/2015	30/06/2019	AUD 5.00	300,000	—	—	—	300,000	300,000
30e	25/03/2015	23/07/2019	AUD 5.00	165,000	—	—	—	165,000	165,000
30f	25/03/2015	23/07/2019	AUD 5.00	200,000	—	—	—	200,000	200,000
30g	25/03/2015	20/01/2019	AUD 4.71	300,000	—	—	—	300,000	200,000
30h	25/03/2015	25/01/2018	AUD 4.71	400,000	—	—	—	400,000	266,668
30i	25/03/2015	25/01/2019	AUD 4.46	600,000	—	—	—	600,000	600,000
30j	25/03/2015	30/06/2019	AUD 4.71	150,000	—	—	—	150,000	100,000
LF14	6/01/2015	16/12/2019	AUD 4.66	150,000	—	—	—	150,000	100,000
31a	27/04/2015	16/02/2020	AUD 4.73	20,000	—	—	(20,000)*	—	—
31b	12/05/2015	16/02/2020	AUD 4.30	200,000	—	—	—	200,000	200,000
32	10/07/2015	30/06/2022	AUD 4.22	3,840,000	—	—	(1,220,000)*	2,620,000	873,334
33	26/08/2015	16/08/2022	AUD 4.07	125,000	—	—	(33,333)*	91,667	41,667
34	27/04/2016	6/03/2023	AUD 2.82	5,140,000	—	(16,667)	(1,501,666)*	3,621,667	1,218,324
34a	27/04/2016	17/04/2023	AUD 2.76	200,000	—	—	—	200,000	66,667
34b	31/10/2016	6/03/2023	AUD 2.82	—	200,000	—	—	200,000	200,000
35	30/06/2016	30/06/2019	AUD 2.22	1,500,000	—	—	—	1,500,000	—
36	6/12/2016	5/12/2023	AUD 1.33	—	2,095,000	—	(50,000)*	2,045,000	—
36a	6/12/2016	5/12/2023	AUD 1.21	—	4,400,000	—	—	4,400,000	816,667
36b	13/01/2017	12/01/2024	AUD 1.67	—	450,000	—	—	450,000	150,000
June 30, 2017				**25,414,490**	**7,145,000**	**(272,579)**	**(1,843,333)**	**25,100,246**	**12,165,245**
Weighted average share purchase price				AUD 4.39	AUD 1.32	AUD 0.72	AUD 5.10	AUD 3.35	AUD 4.36

(1) 30a to 30i were granted as remuneration for the repurchase and cancellation of 2,985,000 LFSP during the year ended 30 June 2015 (see Note 17(b)).

The weighted average share price at the date of exercise of options exercised during the years ended June 30, 2019, 2018 and 2017 were AUD 2.06, AUD 1.46 and AUD 3.28 respectively. The weighted average remaining contractual life of share options and loan funded shares outstanding as of June 30, 2019, 2018 and 2017 were 4.53 years, 4.24 years and 4.09 years, respectively.

b. Existing share-based payment arrangements

General terms and conditions attached to share based payments

Share options pursuant to the employee share option plan and shares pursuant to loan funded share plan are generally granted in three equal tranches. For issues granted prior to July 1, 2015 the length of time from grant date to expiry date was typically 5 years. Grants since July 1, 2015, are issued with a seven year term. Vesting occurs either based on achievement of performance conditions or progressively over the life of the option/share with the first tranche vesting one year from grant date, the second tranche two years from grant date, and the third tranche three years from grant date. On cessation of employment the Company's board of directors determines if a leaver is a bad leaver or not. If a participant is deemed a bad leaver, all rights, entitlements and interests in any unexercised options or shares (pursuant to the loan funded share plan) held by the participant will be forfeited and will lapse immediately. If a leaver is not a bad leaver they may retain vested options and shares (pursuant to the loan funded share plan), however, they must be exercised within 60 days of cessation of employment (or within a longer period if so determined by the Company's board of directors), after which time they will lapse. Unvested options will normally be forfeited and lapse.

This policy applies to all issues shown in the above table with the exception of the following:

25a(i&ii)	Options were granted in two equal tranches and vested on the date that the option holder had direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.
INC.	As part of the acquisition of Mesoblast, Inc., Mesoblast, Inc. options were converted to options of the Company at a conversion ratio of 63.978. The Mesoblast, Inc. option exercise price per option was adjusted using the same conversion ratio. All options vested on acquisition date (December 7, 2010), and will expire according to their original expiry dates (with the exception of options held by directors which were limited to an expiry date not exceeding four years from acquisition).
31b	Options were granted in two equal tranches and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.
35	Incentive rights granted pursuant to the Equity Facility Agreement with Kentgrove Capital, dated June 30, 2016, had fully vested on the agreement date and will expire thirty six months after the date of the issue of the incentive right.
36 (a&b)	Options were granted in two or three equal tranches and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.
38a & 40a	Options were granted in one tranche and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.
39a	Options were granted in one or two equal tranches and will vest on the date that the option holder has direct involvement (to the reasonable satisfaction of the Company's board of directors) in the Company achieving certain confidential commercial objectives.

Modifications to share-based payment arrangements

During the year ended June 30, 2015, the Company repurchased an aggregate amount of $13.9 million (AUD 17.7 million) of loans under LFSP and correspondingly cancelled 2,985,000 of the Company's ordinary shares held in trust for certain employees of the Company. As remuneration for the repurchase of loans and cancellation of these ordinary shares under LFSP, the Company granted options to purchase 2,985,000 of the Company's ordinary shares at exercise prices ranging from AUD 4.44 to AUD 4.98 under ESOP 30a to 30i. As of March 25, 2015 (the "modification date"), the total incremental fair value granted as a result of these modifications was $0.6 million. During the year ended June 30, 2018, as a result of a fully underwritten institutional and retail entitlement offer to existing eligible shareholders (on a 1 for 12 basis) in September 2017, the exercise price of all outstanding options at the time was reduced by A$0.02 per option subject to the ESOP plan under clause 7.3. There were no modifications made to share-based payment arrangements during the year ended June 30, 2017 and June 30, 2019.

c. Fair values of share based payments

The weighted average fair value of share options granted during the years ended June 30, 2019, 2018 and 2017 were AUD 0.95, AUD 0.61 and AUD 1.46, respectively.

The fair value of all shared-based payments made has been calculated using the Black-Scholes model. This model requires the following inputs:

Share price at acceptance date

The share price used in valuation is the share price at the date at which the entity and the employee agree to a share-based payment arrangement, being when the entity and the employee have a shared understanding of the terms and conditions of the arrangement. This price is generally the volume weighted average share price for the five trading days leading up to the date.

Exercise price

The exercise price is a known value that is contained in the agreements.

Share price volatility

The model requires the Company's share price volatility to be measured. In estimating the expected volatility of the underlying shares our objective is to approximate the expectations that would be reflected in a current market or negotiated exchange price for the option or loan funded share. Historical volatility data is considered in determining expected future volatility.

Life of the option/share

The life is generally the time period from grant date through to expiry. Certain assumptions have been made regarding "early exercise" i.e. options exercised ahead of the expiry date, with respect to option series 14 and later. These assumptions have been based on historical trends for option exercises within the Company and take into consideration exercise trends that are also evident as a result of local taxation laws.

Dividend yield

The Company has yet to pay a dividend so it has been assumed the dividend yield on the shares underlying the options will be 0%.

Risk free interest rate

This has been sourced from the Reserve Bank of Australia historical interest rate tables for government bonds.

Model inputs

The model inputs for the valuations of options approved and granted during the year ended June 30, 2019 are as follows:

Series	Financial year of grant	Exercise/Loan price per share AUD	Share price at acceptance date AUD	Expected share price volatility	Life(1)	Dividend yield	Risk-free interest rate
41	2019	1.52	1.52	52.31%	5.8 yrs	0%	2.16%
42	2019	1.56	1.56	52.40%	6.1 yrs	0%	2.36%
43	2019	1.87	1.70	52.78%	5.9 yrs	0%	2.27%
44	2019	1.72	1.59	54.40%	5.6 yrs	0%	1.91%
45	2019	1.33	1.33	54.11%	6.1 yrs	0%	2.01%
46	2019	1.45	1.33	53.92%	5.8 yrs	0%	1.14%
47	2019	1.45	1.33	53.95%	5.8 yrs	0%	1.19%

(1) Expected life after factoring likely early exercise.

The closing share market price of an ordinary share of Mesoblast Limited on the ASX as of June 30, 2019 was AUD 1.48.

The model inputs for the valuations of options approved and granted during the year ended June 30, 2018 are as follows:

Series	Financial year of grant	Exercise/Loan price per share AUD	Share price at acceptance date AUD	Expected share price volatility	Life(1)	Dividend yield	Risk-free interest rate
37	2018	2.23	2.02	52.21%	5.8 yrs	0%	2.22%
38	2018	1.54	1.37	52.04%	5.8 yrs	0%	2.41%
38a	2018	1.40	1.37	52.56%	5.8 yrs	0%	2.27%
39	2018	1.94	1.34	52.49%	5.9 yrs	0%	2.16%
39a	2018	1.76	1.34	52.49%	5.9 yrs	0%	2.16%
40	2018	1.41	1.32	52.35%	5.8 yrs	0%	2.43%
40a	2018	1.28	1.32	52.35%	5.8 yrs	0%	2.43%

(1) Expected life after factoring likely early exercise.

The closing share market price of an ordinary share of Mesoblast Limited on the ASX as of June 30, 2018 was AUD 2.08.

The model inputs for the valuations of options approved and granted during the year ended June 30, 2017 are as follows:

Series	Financial year of grant	Exercise/Loan price per share AUD	Share price at acceptance date AUD	Expected share price volatility	Life(1)	Dividend yield	Risk-free interest rate
34b	2017	2.82	1.24	51.13%	4.6 yrs	0%	2.16%
36	2017	1.33	2.32	51.63%	5.5 yrs	0%	2.15%
36a	2017	1.21	2.32	51.63%	5.5 yrs	0%	2.15%
36b	2017	1.67	2.32	51.63%	5.6 yrs	0%	2.15%

(1) Expected life after factoring likely early exercise.

The closing share market price of an ordinary share of Mesoblast Limited on the ASX as of June 30, 2017 was AUD 1.08.

18. Remuneration of auditors

During the year the following fees were paid or payable for services provided by the auditor of the parent entity, its related practices and non-related audit firms:

(in U.S. dollars)	Year Ended June 30, 2019	2018	2017
a. PricewaterhouseCoopers Australia			
Audit and other assurance services			
Audit and review of financial reports	690,245	620,837	729,598
Other audit services[1]	—	92,403	42,306
Total remuneration of PricewaterhouseCoopers Australia	**690,245**	**713,240**	**771,904**
b. Network firms of PricewaterhouseCoopers Australia			
Audit and other assurance services			
Audit and review of financial reports	89,038	93,839	77,723
Total remuneration of Network firms of PricewaterhouseCoopers Australia	**89,038**	**93,839**	**77,723**
Total auditors' remuneration[2]	**779,283**	**807,079**	**849,627**

(1) Audit and review of financial reports and registration statements in connection with the filings on Form S-8 and F-3.
(2) All services provided are considered audit services for the purpose of SEC classification.

19. Losses per share

	Year Ended June 30, 2019	2018	2017
(Losses) per share			
(in cents)			
(a) Basic (losses) per share			
From continuing operations attributable to the ordinary equity holders of the company	(18.16)	(7.58)	(19.25)
Total basic (losses) per share attributable to the ordinary equity holders of the company	**(18.16)**	**(7.58)**	**(19.25)**
(b) Diluted (losses) per share			
From continuing operations attributable to the ordinary equity holders of the company	(18.16)	(7.58)	(19.25)
Total basic (losses) per share attributable to the ordinary equity holders of the company	**(18.16)**	**(7.58)**	**(19.25)**
(c) Reconciliation of (losses) used in calculating (losses) per share			
(in U.S. dollars, in thousands)			
Basic (losses) per share			
(Losses) attributable to the ordinary equity holders of the company used in calculating basic (losses) per share:			
From continuing operations	(89,799)	(35,290)	(76,815)
Diluted (losses) per share			
(Losses) from continuing operations attributable to the ordinary equity holders of the company:			
Used in calculating basic (losses) per share	(89,799)	(35,290)	(76,815)
(Losses) attributable to the ordinary equity holders of the company used in calculating diluted losses per share	(89,799)	(35,290)	(76,815)

	2019 Number	2018 Number	2017 Number
Weighted average number of ordinary shares used as the denominator in calculating basic losses per share	494,381,490	465,688,997	399,042,172
Weighted average number of ordinary shares and potential ordinary shares used in calculating diluted losses per share	494,381,490	465,688,997	399,042,172

Options granted to employees (see Note 17) are considered to be potential ordinary shares. These securities have been excluded from the determination of basic losses per shares. They have also been excluded from the calculation of diluted losses per share because they are anti-dilutive for the years ended June 30, 2019, 2018 and 2017. Shares that may be paid as contingent consideration have also been excluded from basic losses per share. They have also been excluded from the calculation of diluted losses per share because they are anti-dilutive for the years ended June 30, 2019, 2018 and 2017.

The calculations for the years ended June 30, 2018 and 2017 have been adjusted to reflect the bonus element in the entitlement offer to existing eligible shareholders which occurred during September 2018.

20. Parent entity financial information

a. Summary financial information

The parent entity financial information disclosure is an Australian Disclosure Requirement as required by *Corporations Regulations 2001*. The individual financial statements for the parent entity show the following aggregate amounts:

	As of June 30,	
(in U.S. dollars, in thousands)	**2019**	**2018**
Balance Sheet		
Current Assets	6,723	19,499
Total Assets	**643,708**	**676,385**
Current Liabilities	5,792	6,086
Total Liabilities	**5,878**	**6,186**
Shareholders' Equity		
Issued Capital	910,405	889,480
Reserves		
Foreign Currency Translation Reserve	(209,207)	(174,948)
Share Options Reserve	65,379	61,320
(Accumulated losses)	(128,747)	(105,653)
	637,830	**670,199**
Loss for the period	**(23,094)**	**(26,346)**
Total comprehensive loss for the period	**(23,094)**	**(26,346)**

b. Contingent liabilities of the parent entity

(i) Central Adelaide Local Health Network Incorporated ("CALHNI") (formerly Medvet)

Mesoblast Limited acquired certain intellectual property relating to our MPCs, or Medvet IP, pursuant to an Intellectual Property Assignment Deed, or IP Deed, with Medvet Science Pty Ltd, or Medvet. Medvet's rights under the IP Deed were transferred to Central Adelaide Local Health Network Incorporated, or CALHNI, in November 2011. In connection with its use of the Medvet IP, on completion of certain milestones Mesoblast Limited will be obligated to pay CALHNI, as successor in interest to Medvet, (i) certain aggregated milestone payments of up to $2.2 million and single-digit royalties on net sales of products covered by the Medvet IP, for cardiac muscle and blood vessel applications and bone and cartilage regeneration and repair applications, subject to minimum annual royalties beginning in the first year of commercial sale of those products and (ii) single-digit royalties on net sales of the specified products for applications outside the specified fields.

21. Segment information

Operating segments are identified on the basis of whether the allocation of resources and/or the assessment of performance of a particular component of the Company's activities are regularly reviewed by the Company's chief operating decision maker as a separate operating segment. By these criteria, the activities of the Company are considered to be one segment being the development of adult stem cell technology platform for commercialization, and the segmental analysis is the same as the analysis for the Company as a whole. The chief operating decision maker (Chief Executive Officer) reviews the consolidated income statement, balance sheet, and statement of cash flows regularly to make decisions about the Company's resources and to assess overall performance.

22. Summary of significant accounting policies

This note provides the principal accounting policies adopted in the preparation of these consolidated financial statements as set out below. These policies have been consistently applied to all the years presented, unless otherwise stated. The financial statements are for the consolidated entity consisting of Mesoblast Limited and its subsidiaries.

a. Principles of consolidation

i. Subsidiaries

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of Mesoblast Limited ("Company" or "Parent Entity") as of June 30, 2019 and the results of all subsidiaries for the year then ended. Mesoblast Limited and its subsidiaries together are referred to in this financial report as the Group or the consolidated entity.

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity.

Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The acquisition method of accounting is used to account for business combinations by the Group.

Intercompany transactions, balances and unrealized gains on transactions between Group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of the impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

ii. Employee share trust

The Group has formed a trust to administer the Group's employee share scheme. This trust is consolidated, as the substance of the relationship is that the trust is controlled by the Group.

b. Segment reporting

The Group predominately operates in one segment as set out in Note 21.

c. Foreign currency translation

(i) Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). The functional currency of Mesoblast Limited is the AUD. The consolidated financial statements are presented in USD, which is the Group's presentation currency.

(ii) Translations and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the transaction at period end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in net loss, except when they are deferred in equity as qualifying cash flow hedges and qualifying net investment hedges or attributable to part of the net investment in a foreign operation.

Non-monetary items that are measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was determined. Translation differences on assets and liabilities carried at fair value are reported as part of the fair value gain or loss. For example, translation differences on non-monetary assets and liabilities such as equities held at fair value through profit or loss are recognized in net loss as part of the fair value gain or loss and translation differences on non-monetary assets such as equities classified as financial assets at fair value are recognized in other comprehensive income.

(iii) Group companies

The results and financial position of all the Group entities (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for the balance sheets presented are translated at the closing rate at the date of that balance sheets;
- income and expenses for the statements of comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and all resulting exchange differences are recognized in other comprehensive income.

(iv) Other

On consolidation, exchange differences arising from the translation of any net investment in foreign entities, and of borrowings and other financial instruments designated as hedges of such investments, are recognized in other comprehensive income. When a foreign operation is sold or any borrowings forming part of the net investment are repaid, the associated exchange differences are reclassified to net loss, as part of the gain or loss on sale.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the foreign entities and translated at the closing rate.

d. Revenue recognition

We adopted IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018, using the modified retrospective approach. Revenue from contracts with customers is measured and recognized in accordance with the five step model prescribed by the standard.

First, contracts with customers within the scope of IFRS 15 are identified. Distinct promises within the contract are identified as performance obligations. The transaction price of the contract is measured based on the amount of consideration we expect to be entitled from the customer in exchange for goods or services. Factors such as requirements around variable consideration, significant financing components, noncash consideration, or amounts payable to customers also determine the transaction price. The transaction is then allocated to separate performance obligations in the contract based on relative standalone selling prices. Revenue is recognized when, or as, performance obligations are satisfied, which is when control of the promised good or service is transferred to the customer.

There was no cumulative impact of the adoption of IFRS 15 *Revenue from Contracts with Customers* on July 1, 2018.

Revenues from contracts with customers comprise commercialization and milestone revenue. We also have revenue from research and development tax incentives and interest revenue.

(i) Commercialization and milestone revenue

Commercialization and milestone revenue generally includes non-refundable up-front license and collaboration fees; milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones; as well as royalties on product sales of licensed products, if and when such product sales occur; and revenue from the supply of products.

Where such arrangements can be divided into separately identifiable components (each component constituting a separate earnings process), the arrangement consideration is allocated to the different components based on their relative fair values and recognized over the respective performance period in accordance with IAS 18 Revenue. Where the components of the arrangement cannot be divided into separate units, the individual deliverables are combined as a single unit of accounting and the total arrangement consideration is recognized over the estimated collaboration period. Such analysis requires considerable estimates and judgments to be made by us, including the relative fair values of the various elements included in such agreements and the estimated length of the respective performance periods.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, within current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, within non-current liabilities.

TiGenix arrangement

In December 2017, the Group entered into a patent license agreement with TiGenix NV, now a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda"), which granted Takeda exclusive access to certain of our patents to support global commercialization of the adipose-derived mesenchymal stem cell product, Alofisel®, a registered trademark of TiGenix, previously known as Cx601, a product candidate of Takeda, for the local treatment of fistulae. The agreement includes the right for Takeda to grant sub-licenses to affiliates and third parties.

As part of the agreement, the Group received €5.0 million ($5.9 million) before withholding tax as a non-refundable up-front payment and recognized this amount in revenue in December 2017 upon receipt. In December 2018, we received a milestone payment of €5.0 million ($5.9 million) before withholding tax, and recognized this amount in revenue in December 2017 as all performance obligations had been satisfied at that time. We are entitled to further payments up to €10.0 million when Takeda reaches certain product regulatory milestones. Additionally, we receive single digit royalties on net sales of Alofisel®.

No milestone revenue was recognized in relation to the patent license agreement with Takeda in the year ended June 30, 2019.

In the year ended June 30, 2018, the Group recognized $11.8 million in milestone revenue in relation to the Group's patent license agreement with Takeda. Within this $11.8 million, €5.0 million ($5.9 million) was recognized in relation to the non-refundable up-front payment received upon execution of the Group's patent license agreement with Takeda in December 2017 and €5.0 million ($5.9 million) was recognized in relation to further payments due within 12 months of the patent license agreement date for product Alofisel®. These amounts were recorded in revenue as there are no further performance obligations required in regards to these milestones.

JCR arrangement

In October 2013, the Group acquired all of Osiris' culture-expanded, MSC-based assets. These assets included assumption of a collaboration agreement with JCR, a research and development oriented pharmaceutical company in Japan. Revenue recognized under this model is limited to the amount of cash received or for which the Group is entitled to, as JCR has the right to terminate the agreement at any time.

Under the JCR Agreement, JCR is responsible for all development and manufacturing costs including sales and marketing expenses. Under the JCR Agreement, JCR has the right to develop our MSCs in two fields for the Japanese market: exclusive in conjunction with the treatment of hematological malignancies by the use of hematopoietic stem cells derived from peripheral blood, cord blood or bone marrow, or the First JCR Field; and non-exclusive for developing assays that use liver cells for non-clinical drug screening and evaluation, or the Second JCR Field. With respect to the First JCR Field, we are entitled to payments when JCR reaches certain commercial milestones and to escalating double-digit royalties. These royalties are subject to possible renegotiation downward in the event of competition from non-infringing products in Japan. With respect to the Second JCR Field, we are entitled to a double digit profit share. In October 2018, we expanded our partnership with JCR in Japan for wound healing in patients with Epidermolysis Bullosa ("EB"). We will receive royalties on TEMCELL product sales for EB. We apply the sales-based and usage-based royalty exception for licenses of intellectual property and therefore recognize royalty revenue at the later of when the subsequent sale or usage occurs and the associated performance obligation has been satisfied.

For the years ended June 30, 2019 and 2018, we recognized $5.0 million and $3.6 million, respectively, in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan, by our licensee JCR. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

For the year ended June 30, 2019, we recognized $1.0 million in cumulative net sales milestone revenue upon licensee, JCR, reaching milestones for sales of TEMCELL in Japan. For the year ended June 30, 2018, the Group recognized $1.5 million of milestone revenue from JCR. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

(ii) Interest revenue

Interest revenue is accrued on a time basis by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that asset's net carrying amount.

(iii) Research and development tax incentive

The Australian Government replaced the research and development tax concession with the research and development tax incentive from July 1, 2011. The provisions provide refundable or non-refundable tax offsets.

The research and development tax incentive applies to expenditure incurred and the use of depreciating assets in an income year commencing on or after July 1, 2011. The research and development tax incentive credit is available for our research and development activities in Australia as well as research and development activities outside of Australia to the extent such non-Australian based activities relate to intellectual property owned by our Australian resident entities do not exceed half the expenses for the relevant activities and are approved by the Australian government. A refundable tax offset is available to eligible companies with an annual aggregate turnover of less than A$20.0 million. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending. For the years ended June 30, 2019 and 2018, the rate of the refundable tax offset is 43.5%. For the year ended June 30, 2019, the Group has recognized loss of $0.1 million due to an adjustment of management's estimate of revenue for the year ended June 30, 2018. For years ended June 30, 2018 and 2017, the Group recognized income of $1.8 million and $1.5 million, respectively years ended June 30, 2019 and 2018.

The Group's research and development activities are eligible under an Australian government tax incentive for eligible expenditure from July 1, 2011. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. At each period end management estimates and recognizes the refundable tax offset available to the Group based on available information at the time.

The receivable for reimbursable amounts that have not been collected is reflected in trade and other receivables in the Group's consolidated balance sheets. Income associated with the research and development tax incentive is recorded in the Group's other operating income and expenses in the Group's consolidated income statement.

e. Research and development undertaken internally

The Group currently does not have any capitalized development costs. Research expenditure is recognized as an expense as incurred. Costs incurred on development projects, which consist of preclinical and clinical trials, manufacturing development, and general research, are recognized as intangible assets when it is probable that the project will, after considering its commercial and technical feasibility, be completed and generate future economic benefits and its costs can be measured reliably.

The expenditure capitalized comprises all directly attributable costs, including costs of materials, services, direct labor and an appropriate proportion of overheads. Other development costs that do not meet these criteria are expensed as incurred. Development costs previously recognized as expenses, are not recognized as an asset in a subsequent period and will remain expensed. Capitalized development costs are recorded as intangible assets and amortized from the point at which the asset is ready for use on a straight-line basis over its useful life.

f. Income tax

The income tax expense or benefit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Group's subsidiaries and associates operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, the deferred income tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting, nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred tax assets are recognized for deductible temporary differences and unused tax losses only if it is probable that future taxable amounts will be available to utilize those temporary differences and losses. Deferred tax assets are only recognized to the extent that there are sufficient deferred tax liabilities unwinding.

Deferred tax liabilities and assets are not recognized for temporary differences between the carrying amount and tax bases of investments in controlled entities where the parent entity is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets and liabilities and when the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

Current and deferred tax is recognized in net loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

g. Leases

Leases in which a significant portion of the risks and rewards of ownership are not transferred to the Group as lessee are classified as operating leases (Note 14). Payments made under operating leases (net of any incentives received from the lessor) are charged to profit or loss on a straight-line basis over the period of the lease.

h. Business combinations

The acquisition method of accounting is used to account for all business combinations, regardless of whether equity instruments or other assets are acquired. The consideration transferred for the acquisition of a subsidiary comprises the fair values of the assets transferred, the liabilities incurred and the equity interests issued by the Group. The consideration transferred also includes the fair value of any asset or liability resulting from a contingent consideration arrangement and the fair value of any pre-existing equity interest in the subsidiary. Acquisition-related costs are expensed as incurred. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are, with limited exceptions, measured initially at their fair values at the acquisition date. On an acquisition-by-acquisition basis, the Group recognizes any noncontrolling interest in the acquiree either at fair value or at the non-controlling interest’s proportionate share of the acquiree’s net identifiable assets.

The excess of the consideration transferred and the amount of any non-controlling interest in the acquiree over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts are less than the fair value of the net identifiable assets of the subsidiary acquired and the measurement of all amounts has been reviewed, the difference is recognized directly in net loss as a bargain purchase.

Where settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value as at the date of exchange. The discount rate used is the entity’s incremental borrowing rate, being the rate at which a similar borrowing could be obtained from an independent financier under comparable terms and conditions.

Contingent consideration is classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognized in profit or loss.

i. Impairment of assets

Goodwill and intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment or more frequently if events or changes in circumstances indicate that they might be impaired. Other assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognized for the amount by which the asset’s carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset’s fair value less costs to dispose and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (cash-generating units). Non-financial assets (other than goodwill) that have suffered impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

j. Cash and cash equivalents

For the purpose of presentation in the statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term and highly liquid investments with original maturities 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.

k. Trade and other receivables

Trade receivables and other receivables represent the principal amounts due at balance date less, where applicable, any provision for expected credit losses. The Group uses the simplified approach to measuring expected credit losses, which uses a lifetime expected credit loss allowance. Debts which are known to be uncollectible are written off in the consolidated income statement. All trade receivables and other receivables are recognized at the value of the amounts receivable, as they are due for settlement within 60 days and therefore do not require remeasurement.

l. Investments and other financial assets

(i) Classification

The Group classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through OCI or through profit or loss); and
- those to be measured at amortized cost

The classification depends on the Group's business model for managing the financial assets and the contractual terms of the cash flow. For assets measured at fair value, gains and losses will either be recorded in profit or loss or OCI. For investments in equity instruments that are not held for trading, this will depend on whether the group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income (FVOCI). See Note 5 for details about each type of financial asset.

(ii) Recognition and derecognition

Regular way purchases and sales of financial assets are recognized on trade-date, the date on which the Group commits to purchase or sell the asset. Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the Group has transferred substantially all the risks and rewards of ownership.

(iii) Measurement

At initial recognition, the Group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss (FVPL), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss. Financial assets with embedded derivatives are considered in their entirety when determining whether their cash flows are solely payment of principal and interest.

Details on how the fair value of financial instruments is determined are disclosed in Note 5(g).

Equity instruments

The group subsequently measures all equity investments at fair value. Where the Group has elected to present fair value gains and losses on equity investments in OCI, there is no subsequent reclassification of fair value gains and losses to profit or loss following the derecognition of the investment. Dividends from such investments continue to be recognized in profit or loss as other income when the group's right to receive payments is established.

Changes in the fair value of financial assets at FVPL are recognized in other gains/(losses) in the statement of profit or loss as applicable. Impairment losses (and reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value.

(iv) Impairment

For trade receivables, the group applies the simplified approach permitted by IFRS 9, which requires expected lifetime losses to be recognized from initial recognition of the receivables, see note 5(b) for further details.

m. Derivatives

Derivatives are initially recognized at fair value on the date a derivative contract is entered into and are subsequently remeasured to their fair value at the end of each reporting period.

Derivatives that do not qualify for hedge accounting

Certain derivative instruments do not qualify for hedge accounting. Changes in the fair value of any derivative instrument that does not qualify for hedge accounting are recognized immediately in profit or loss and are included in other income or other expenses.

n. Property, plant and equipment

Plant and equipment are stated at historical cost less accumulated depreciation and impairment. Cost includes expenditure that is directly attributable to the acquisition of the item.

Subsequent cost are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associates with the item will flow to the Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to profit and loss during the reporting period in which they are incurred.

Property, plant and equipment, other than freehold land, are depreciated over their estimated useful lives using the straight line method (see Note 6(a)).

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposal of plant and equipment are taken into account in determining the profit for the year.

o. Intangible assets

(i) Goodwill

Goodwill is measured as described in Note 22(h). Goodwill on acquisition of subsidiaries is included in intangible assets (Note 6(b)). Goodwill is not amortized but it is tested for impairment annually or more frequently if events or changes in circumstances indicate that it might be impaired, and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold.

Goodwill is allocated to cash generating units for the purpose of impairment testing. The allocation is made to those cash generating units or groups of cash generating units that are expected to benefit from the business combination in which the goodwill arose, identified according to operating segments (Note 21).

(ii) Trademarks and licenses

Trademarks and licenses have a finite useful life and are carried at cost less accumulated amortization and impairment losses.

(iii) In-process research and development acquired

In-process research and development that has been acquired as part of a business acquisition is considered to be an indefinite life intangible asset on the basis that it is incomplete and cannot be used in its current form. Indefinite life intangible assets are not amortized but rather are tested for impairment annually in the third quarter of each year, or whenever events or circumstances present an indication of impairment.

In-process research and development will continue to be tested for impairment until the related research and development efforts are either completed or abandoned. Upon completion of the related research and development efforts, management determines the remaining useful life of the intangible assets and amortizes them accordingly. In order for management to determine the remaining useful life of the asset, management would consider the expected flow of future economic benefits to the entity with reference to the product life cycle, competitive landscape, obsolescence, market demand, any remaining patent useful life and various other relevant factors.

In the case of abandonment, the related research and development efforts are considered impaired and the asset is fully expensed.

(iv) Current marketed products

Current marketed products contain products that are currently being marketed. The assets are recognized on our balance sheet as a result of business acquisitions or reclassifications from In-process research and development upon completion. Upon completion, when assets become available for use, assets are reclassified from in-process research and development to current marketed products at the historical value that they were recognized at within the in-process research and development category.

Upon reclassification to the current market products category management determines the remaining useful life of the intangible assets and amortizes them from the date they become available for use. In order for management to determine the remaining useful life of the asset, management would consider the expected flow of future economic benefits to the entity with reference to the product life cycle, competitive landscape, obsolescence, market demand, any remaining patent useful life and any other relevant factors.

Management have chosen to amortize all intangible assets with a finite useful life on a straight-line basis over the useful life of the asset. Current marketed products are tested for impairment in accordance with IAS 36 Impairment of Assets which requires testing whenever there is an indication that an asset may be impaired.

p. Trade and other payables

Payables represent the principal amounts outstanding at balance date plus, where applicable, any accrued interest. Liabilities for payables and other amounts are carried at cost which approximates fair value of the consideration to be paid in the future for goods and services received, whether or not billed. The amounts are unsecured and are usually paid within 30 to 60 days of recognition.

q. Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Fees paid on the establishment of loan facilities are recognized as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. If it is not probable, the fee is deferred until the draw down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalized as a prepayment for liquidity services and amortized over the period of the facility to which it relates.

Borrowings are removed from the balance sheet when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished or transferred to another party and the consideration paid, including any non-cash assets transferred of liabilities assumed, is recognized in profit or loss as other income or finance costs.

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

Hercules

On March 6, 2018, the Group entered into a loan and security agreement with Hercules, for a $75.0 million non-dilutive, four-year credit facility. We drew the first tranche of $35.0 million on closing and a further tranche of $15.0 million was drawn in January 2019, which resulted in an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument’s original effective interest rate. In the year ended June 30, 2019, we recognized a $0.4 million gain in the Income Statement as remeasurement of borrowing arrangements within finance costs. An additional $25.0 million may be drawn as certain

conditions and milestones are met. The loan matures in March 2022 with principal repayments commencing in October 2019 with the ability to defer the commencement of principal repayments up to 30 months to October 2020 if certain conditions and milestones are met. Interest on the loan is payable monthly in arrears on the 1st day of the month. At closing date, the interest rate was 9.45%. On March 22, 2018, June 14, 2018, September 27, 2018 and December 20, 2018, in line with the increase in the U.S. prime rate, the interest rate on the loan increased to 9.70%, 9.95%, 10.20% and 10.45%, respectively.

NovaQuest

On June 29, 2018, we drew the first tranche of $30.0 million of the principal amount from the $40.0 million secured loan with NovaQuest. There is a four-year interest only period, until July 2022, with the principal repayable in equal quarterly instalments over the remaining period of the loan. A $0.4 million loan administration fee is payable annually in June and is recognized as a current liability. The loan matures in July 2026. Interest on the loan will accrue at a fixed rate of 15% per annum.

All interest and principal payments will be deferred until after the first commercial sale of our allogeneic product candidate MSC-100-IV in pediatric patients with steroid refractory aGVHD, in the United States and other geographies excluding Asia ("pediatric aGVHD"). We can elect to prepay all outstanding amounts owing at any time prior to maturity, subject to a prepayment charge, and may decide to do so if net sales of pediatric aGVHD are significantly higher than current forecasts.

If there are no net sales of pediatric aGVHD, the loan is only repayable on maturity in 2026. If in any annual period 25% of net sales of pediatric aGVHD exceed the amount of accrued interest owing and, from 2022, principal and accrued interest owing ("the payment cap"), Mesoblast will pay the payment cap and an additional portion of excess sales which may be used for early prepayment of the loan. If in any annual period 25% of net sales of pediatric aGVHD is less than the payment cap, then the payment is limited to 25% of net sales of pediatric aGVHD. Any unpaid interest will be added to the principal amounts owing and shall accrue further interest. At maturity date, any unpaid loan balances are repaid.

Because of this relationship of net sales and repayments, changes in our estimated net sales may trigger an adjustment of the carrying amount of the financial liability to reflect the revised estimated cash flows. The carrying amount adjustment is recalculated by computing the present value of the revised estimated future cash flows at the financial instrument's original effective interest rate. The adjustment is recognized in the Income Statement in the period the revision is made. For the year ended June 30, 2019, a $0.7 million loss has been recognized by the Group in the Income Statement as remeasurement of borrowing arrangements within other operating income and expenses.

The carrying amount of the loan and security agreement with NovaQuest is subordinated to the Group's floating rate loan with the senior creditor, Hercules.

r. Provisions

Provisions are recognized when the Group has a present legal obligation as a result of a past event, it is probable that the Group will be required to settle the obligation, and a reliable estimate can be made of the amount of the obligation.

Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the end of the reporting period. The discount rate used to determine the present value is a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The increase in the provision due to the passage of time is recognized as interest expense.

Provisions are recorded on acquisition of a subsidiary, to the extent they relate to a subsidiary's contingent liabilities, if it relates to a past event, regardless of whether it is probable the amount will be paid.

s. Employee benefits

A liability is recognized for benefits accruing to employees in respect of wages and salaries, bonuses, annual leave and long service leave.

Liabilities recognized in respect of employee benefits which are expected to be settled within 12 months after the end of the period in which the employees render the related services are measured at their nominal values using the remuneration rates expected to apply at the time of settlement.

Liabilities recognized in respect of employee benefits which are not expected to be settled within 12 months after the end of the period in which the employees render the related services are measured as the present value of the estimated future cash outflows to be made by the Group in respect of services provided by employees up to reporting date.

The obligations are presented as current liabilities in the balance sheet if the entity does not have an unconditional right to defer settlement for at least twelve months after the reporting period, regardless of when the actual settlement is expected to occur.

Termination benefits are payable when employment is terminated by the Group before the normal retirement date, or when an employee accepts voluntary redundancy in exchange for these benefits. The Group recognizes termination benefits at the earlier of the following dates: when the Group can no longer withdraw the offer of those benefits and when the entity recognizes costs for a restructuring that is within the scope of IAS 37 and involves the payment of termination benefits.

t. Share-based payments

Share-based payments are provided to eligible employees, directors and consultants via the Employee Share Option Plan ("ESOP") and the Australian Loan Funded Share Plan ("LFSP"). The terms and conditions of the LFSP are in substance the same as the employee share options and therefore they are accounted for on the same basis.

Equity-settled share-based payments with employees and others providing similar services are measured at the fair value of the equity instrument at acceptance date. Fair value is measured using the Black-Scholes model. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions, and behavioral considerations. It does not make any allowance for the impact of any service and non-market performance vesting conditions. Further details on how the fair value of equity-settled share-based transactions has been determined can be found in Note 17.

The fair value determined at the acceptance date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on management's estimate of shares that will eventually vest, with a corresponding increase in equity. At the end of each period, the entity revises its estimates of the number of shared-based payments that are expected to vest based on the non-market vesting conditions. It recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to equity.

u. Contributed equity

Ordinary shares are classified as equity.

Transaction costs arising on the issue of equity instruments are recognized separately in equity. Transaction costs are the costs that are incurred directly in connection with the issue of those equity instruments and which would not have been incurred had those instruments not been issued.

v. Loss per share

(i) Basic losses per share

Basic losses per share is calculated by dividing:

- the loss attributable to equity holders of the Group, excluding any costs of servicing equity other than ordinary shares;
- by the weighted average number of ordinary shares outstanding during the fiscal year, adjusted for bonus elements in ordinary shares issued during the year.

(ii) Diluted losses per share

Diluted losses per share adjusts the figures used in the determination of basic earnings per share to take into account

- the after income tax effect of interest and other financing costs associated with dilutive potential ordinary shares; and
- the weighted average number of shares assumed to have been issued for no consideration in relation to dilutive potential ordinary shares.

w. Goods and services tax (“GST”)

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

Receivables and payables 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 Balance Sheet.

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

x. Rounding of amounts

Our company is of a kind referred to in ASIC Corporations (Rounding in Financial/Directors’ Reports) Instrument 2016/191, issued by the Australian Securities and Investments Commission, relating to the ‘rounding off’ of amounts in the financial report. Unless mentioned otherwise, amounts within this report have been rounded off in accordance with that Legislative Instrument to the nearest thousand dollars, or in certain cases, to the nearest dollar.

Australian Disclosure Requirements

Directors' Declaration

In the directors' opinion:

(a) the financial statements and Notes set out on pages 150 to 210 are in accordance with the *Corporations Act 2001*, including:

(i) Complying with Accounting Standards, the *Corporations Regulations 2001* and other mandatory professional reporting requirements, and

(ii) Giving a true and fair view of the consolidated entity's financial position as at June 30, 2019 and of its performance for the fiscal year ended on that date, and

(b) There are reasonable grounds to believe that the Group will be able to pay its debts as and when they become due and payable.

Note 1 'Basis of preparation' confirms that the financial statements also comply with International Financial Reporting Standards as issued by the International Accounting Standards Board.

The directors have been given the declarations by the chief executive officer and chief financial officer required by section 295A of the *Corporations Act 2001*.

This declaration is made in accordance with a resolution of the directors.

/s/ Joseph Swedish	/s/ Silviu Itescu
Joseph Swedish	Silviu Itescu
Chairman	Chief Executive Officer

Melbourne, August 30, 2019

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Item 19. Exhibits

Item	
1.1*	Constitution of Mesoblast Limited adopted on November 22, 2018.
1.2	Certificate of Registration of Mesoblast Limited (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.1	Form of Deposit Agreement between Mesoblast Limited and JPMorgan Chase Bank, N.A., as depositary, and Holders of the American Depositary Receipts (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.2	Form of American Depositary Receipt evidencing American Depositary Shares (included in Exhibit 4.1).
4.3	Clinical Trial Agreement by and between The National Heart, Lung, and Blood Institute and Mesoblast, Inc. dated July 28, 2014 (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.4†	Manufacturing Services Agreement by and between Mesoblast Limited and Lonza Walkersville, Inc. and Lonza Bioscience Singapore Pte. Ltd., dated September 20, 2011 (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.5	Purchase Agreement by and between Mesoblast International Sàrl and Osiris Therapeutics, Inc., dated October 10, 2013 (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.6	Amendment #1 to Purchase Agreement by and between Mesoblast International Sàrl and Osiris Therapeutics, Inc., dated December 17, 2014 (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.7†	License Agreement by and between Osiris Acquisition II, Inc. and JCR Pharmaceuticals Co., Ltd., dated August 26, 2003 (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.8†	Amendment 1 to License Agreement by and between Osiris Acquisition II, Inc. and JCR Pharmaceuticals Co., Ltd., dated June 27, 2005 (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.9	Technology Transfer and License Agreement by and between Case Western Reserve University and Osiris Therapeutics, Inc., dated January 1, 1993 (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.10	Amendment Number 1 to Technology Transfer and License Agreement by and between Case Western Reserve University and Osiris Therapeutics, Inc., dated November 3, 1993 (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.11	Amendment to the Technology Transfer and License Agreement by and between Case Western Reserve University and Osiris Therapeutics, Inc., dated October 18, 1999 (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.12	Third Amendment to Technology Transfer and License Agreement by and between Case Western Reserve University and Osiris Therapeutics, Inc., dated October 27, 2003 (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.13	Intellectual Property Assignment Deed by and between Mesoblast Limited and Medvet Science Pty Ltd, dated October 4, 2004 (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.14#	Loan Funded Share Plan Rules, as amended, and form of loan agreement thereunder (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.15#	Employee Share Option Plan Rules, and form of option agreement thereunder (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.16#	Employment Agreement, dated August 8, 2014, by and between Mesoblast Limited and Silviu Itescu (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.17	Sublease, by and between Mesoblast Limited and CIT Group Inc., dated September 27, 2011 (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).

4.18	Sublease, by and between Mesoblast Limited and Collins Place Pty Ltd, AMP Capital Investors Limited, and Australia and New Zealand Banking Group Limited, dated April 21, 2014 (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.19	Form of 2012 Deed of Indemnity, Insurance and Access (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.20	Form of 2014 Deed of Indemnity, Insurance and Access (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.21†	Patent License and Settlement Agreement with TiGenix S.A.U., dated December 14, 2017 (incorporated by reference to Exhibit 4.21 to the Company's Annual Report on Form 20-F filed with the SEC on August 31, 2018).
4.22†	Loan and Security Agreement by and among Mesoblast Limited, Mesoblast UK Limited, Mesoblast International (UK) Limited, Mesoblast, Inc., Mesoblast International Sarl and Hercules Capital, Inc., dated March 6, 2018 (incorporated by reference to Exhibit 4.22 to the Company's Annual Report on Form 20-F filed with the SEC on August 31, 2018).
4.23†	Loan and Security Agreement by and between Mesoblast Limited, Mesoblast UK Limited, Mesoblast, Inc., Mesoblast International (UK) Limited, Mesoblast International Sàrl and NQP SPV II, L.P., dated June 29, 2018 (incorporated by reference to Exhibit 4.23 to the Company's Annual Report on Form 20-F filed with the SEC on August 31, 2018).
4.24†	Development and Commercialization Agreement by and between Mesoblast Inc., Mesoblast International Sàrl and Tasly Pharmaceutical Group Co., Ltd. dated July 17, 2018 (incorporated by reference to Exhibit 4.24 to the Company's Annual Report on Form 20-F filed with the SEC on August 31, 2018).
4.25* ✓	Supplementary Agreement for Additional License by and between Mesoblast International Sarl and JCR Pharmaceuticals Co., Ltd., dated October 12, 2018.
4.26* ✓	First Amendment to Loan and Security Agreement by and among Mesoblast Limited, Mesoblast UK Limited, Mesoblast International (UK) Limited, Mesoblast, Inc., Mesoblast International Sarl and Hercules Capital, Inc., dated January 11, 2019
4.27* ✓	Second Supplementary Agreement for Additional License by and between Mesoblast International Sarl and JCR Pharmaceuticals Co., Ltd., dated June 5, 2019.
8.1*	List of Significant Subsidiaries of Mesoblast Limited.
10 *	Consent of independent registered public accounting firm.
12.1*	Certification of the Chief Executive Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
12.2*	Certification of the Chief Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
13.1*	Certification of the Chief Executive Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002
13.2*	Certification of the Chief Financial Officer pursuant to 18 U.S.C. section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002
99.1*	Appendix 4E preliminary final report for the twelve months to June 30, 2019.
99.2*	Auditor's independence declaration, dated August 30, 2019.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

#	Indicates management contract or compensatory plan.
*	Filed herewith.
†	Confidential treatment has been requested for portions of this exhibit. These portions have been omitted and have been filed separately with the Securities and Exchange Commission.
✓	Certain confidential portions of this exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions are not material and 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.

Mesoblast Limited

By:	/s/ Joseph R Swedish
Name:	Joseph R Swedish
Title:	Chairman
By:	/s/ Silviu Itescu
Name:	Silviu Itescu
Title:	Chief Executive Officer

Dated: August 30, 2019

Constitution

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Mesoblast Limited ACN 109 431 870

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Level 23 Rialto Towers 525 Collins Street
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minterellison.com

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Constitution of Mesoblast Limited

Preliminary

1. Defined terms

1.1 In this Constitution:

Adoption Date means the date on which this Constitution is adopted by the Company as its constitution.

Alternate Director means a person appointed as an alternate director under clause 74.

ASX means ASX Limited ABN 98 008 624 691 or the financial market known as the 'Australian Securities Exchange' that it operates, as the context requires.

ASX Listing Rules means the listing rules of ASX and any other rules of ASX applicable to the Company or the Shares while the Company is admitted to the Official List, each as amended or replaced from time to time, except to the extent of any express written waiver by ASX.

ASX Settlement means ASX Settlement Pty Limited ABN 49 008 504 532.

ASX Settlement Operating Rules means the operating rules of ASX Settlement as amended or replaced from time to time, except to the extent of any express written waiver by ASX Settlement.

Auditor means the Company's auditor for the time being.

Business Day has the same meaning as in the ASX Listing Rules.

Certificated Holding has the same meaning as in the ASX Settlement Operating Rules.

CHESS Holding has the same meaning as in the ASX Settlement Operating Rules.

Company means Mesoblast Limited ACN 109 431 870.

Constitution means the constitution of the Company as amended from time to time.

Corporations Act means the *Corporations Act 2001* (Cth) as amended or replaced from time to time and includes any regulations made under that Act and any exemption or modification to that Act applying to the Company.

Director means a person appointed to the position of a director of the Company and where appropriate, includes an Alternate Director.

Directors means all or some of the Directors acting as a board.

Direct Vote, in relation to a resolution or a meeting, includes a vote delivered to the Company by post, fax or other electronic means approved by the Directors.

Dividend includes bonus.

Executive Director has the meaning given by clause 81.3.

Issuer Sponsored Holding has the same meaning as in the ASX Settlement Operating Rules.

Listed, in relation to the Company, means if the Company is included in the Official List of ASX.

Managing Director means a Director appointed as managing director under clause 81.1.

Marketable Parcel has the same meaning as in the ASX Settlement Operating Rules in force from time to time.

Member means a person who is a member of the Company under the Corporations Act.

Non-Executive Director means a Director who is not an Executive Director.

Non-Marketable Parcel means a parcel of securities that is less than a Marketable Parcel.

Previous Constitution means the constitution of the Company in force immediately before the Adoption Date.

Proper ASTC transfer has the meaning given to it in the *Corporations Regulations 2001*(Cth).

Register means the register of Members of the Company.

Representative means a person appointed by a Member to act as its representative under clause 59.1.

Restricted Securities has the same meaning as in the ASX Listing Rules.

Seal means the Company's common seal.

Secretary means any person appointed by the Directors to perform any of the duties of a secretary of the Company and if more than one person is appointed, any one or more of such persons.

Shares means shares in the share capital of the Company.

1.2 In this Constitution, except where the context otherwise requires, an expression in a clause of this Constitution has the same meaning as in the Corporations Act. Where the expression has more than one meaning in the Corporations Act and a provision of the Corporations Act deals with the same matter as a clause of this Constitution, that expression has the same meaning as in that provision.

2. Interpretation

2.1 In this Constitution, except where the context otherwise requires:

(a) the singular includes the plural and vice versa, and a gender includes other genders;

(b) another grammatical form of a defined word or expression has a corresponding meaning;

(c) a reference to a clause, paragraph, schedule or annexure is to a clause or paragraph of, or schedule or annexure to, this Constitution, and a reference to this Constitution includes any schedule or annexure;

(d) a reference to a document or instrument includes the document or instrument as novated, altered, supplemented or replaced from time to time;

(e) a reference to **A$**, **$A**, **dollar** or **$** is to Australian currency; and

(f) the meaning of general words is not limited by specific examples introduced by **including**, **for example** or similar expressions.

2.2 Headings are for ease of reference only and do not affect interpretation.

2.3 The Corporations Act prevails over any inconsistency with:

(a) this Constitution;

(b) the ASX Listing Rules; and

(c) the ASX Settlement Operating Rules.

2.4 A reference in this Constitution to a Member being present at a meeting of Members is a reference to:

(a) a Member present in person physically or by electronic means; or

(b) a Member present by proxy, attorney or Representative; or

(c) other than in relation to any clause which specifies a quorum, a Member who has duly lodged a valid Direct Vote in relation to the general meeting in accordance with clause 54 of this Constitution.

3. Replaceable rules

The provisions of the Corporations Act that apply to certain companies as replaceable rules and any other rules or regulations in the legislation under which the Company was formed are in each case displaced by this Constitution in their entirety and do not apply to the Company.

4. Transitional provisions

This Constitution has the effect that:

(a) every Director, alternate director, senior manager and secretary in office as at the Adoption Date continues in office subject to, and is taken to have been appointed or elected under, this Constitution;

(b) the Directors are taken, on and from the Adoption Date, to have decided under clause 60.3 a number which is equal to the number of the persons in office as Executive Directors and Non-executive Directors immediately after the Adoption Date;

(c) any register maintained by the Company immediately before the Adoption Date is taken to be a register maintained under this Constitution;

(d) any Seal adopted by the Company before the Adoption Date is taken to be the Seal until another Seal is adopted by the Company under this constitution;

(e) for the purposes of clause 97.1(a) a cheque issued under a corresponding provision of the Previous Constitution is taken to have been issued under clause 97.1(a) any money held for a Member under the Previous Constitution is taken to be held in an account under clause 97.3 and any money held at the Adoption Date for a Member the Company regards as uncontactable is taken to be held in an account under clause 97.3; and

(f) unless a contrary intention appears in this Constitution, all persons, things, agreements and circumstances appointed, approved, created or delegated by or under the Previous Constitution continue to have the same status, operation and effect as if they had occurred under this Constitution on and after the Adoption Date.

Shares

5. Currency

5.1 Any amount payable to the holder of a Share, whether in relation to dividends, return of capital, participation in surplus assets of the Company or otherwise may be paid in the currency of a country other than Australia.

5.2 The Directors may fix a time on or before the payment date as the time at which the applicable exchange rate will be determined for that purpose.

6. Issue of Shares

6.1 Subject to the Corporations Act, the ASX Listing Rules and this Constitution, the Directors may issue and allot, or dispose of, Shares:

(a) on terms determined from time to time by the Directors;

(b) at an issue price that the Directors determine from time to time; and

(c) to Members whether in proportion to their existing shareholdings or otherwise, or to such other persons as the Directors may determine from time to time.

6.2 The Directors' power under clause 6.1 includes the power to:

(a) grant options over unissued Shares; and

(b) issue and allot Shares:

(i) with any preferential, deferred or special rights, privileges or conditions;

(ii) with any restrictions in regard to dividend, voting, return of capital or otherwise;

(iii) which are liable to be redeemed or converted;

(iv) which are bonus Shares for whose issue no consideration is payable to the Company; or

(v) which have any combination of the characteristics described in clauses 6.2(b)(i) to 6.2(b)(iv) inclusive.

7. Commission and brokerage

Any brokerage or commission which may be paid by the Company may be made in cash, by the issue and allotment of Shares, or the issue of debentures, or by a combination of any of those methods.

8. Trusts not recognised

8.1 Except as required by law, the ASX Settlement Operating Rules or as otherwise provided by this Constitution, the Company will not recognise any person as holding a Share on trust and the Company will not be bound to recognise any equitable, contingent, future or partial interest or any other right in respect of a Share except the registered holder's absolute right of ownership.

8.2 This clause 8 applies even if the Company has notice of the relevant trust, interest or right.

9. Joint holders

9.1 If two or more persons are registered as the holders of a Share, they are taken to hold the Share as joint tenants with benefit of survivorship and the person whose name appears first on the Register is the only joint holder entitled to receive notices from the Company.

9.2 Any one of the joint holders of a Share may give an effective receipt for any dividend or return of capital payable to the joint holders.

9.3 The Company is entitled to and in respect of CHESS Holdings, must:

(a) record the names of only the first three joint holders of a Share on the Register;

(b) regard the three joint holders of a Share appearing first on the Register as the registered holders of that Share to the exclusion of any other holders; and

(c) disregard the entitlement of any person to be registered on the Register as a holder if the name of the person would appear on the Register after the first three holders for that Share.

10. Share certificates

10.1 The Directors will not, unless they determine otherwise or the ASX Listing Rules require, issue a certificate to a Member for any Shares registered in the Member's name or record any holding as held on a certificated sub-register.

10.2 Any certificate for Shares must be issued and despatched in accordance with the Corporations Act, the ASX Listing Rules and the ASX Settlement Operating Rules.

10.3 Subject to the ASX Listing Rules, the Directors may in their absolute discretion elect whether to maintain a certificated sub-register for any class of Shares.

10.4 Subject to the ASX Listing Rules and the ASX Settlement Operating Rules, Shares may be held on any sub-register maintained by or on behalf of the Company or on any branch register kept by the Company.

10.5 The Directors may order worn out or defaced certificates to be cancelled and, if necessary, replaced by new certificates.

11. Variation of class rights

11.1 The rights attached to any class of Shares may be varied in accordance with the Corporations Act.

11.2 The provisions of this Constitution relating to general meetings apply, with necessary changes, to a meeting of a class of Members holding Shares in that class as if it was a general meeting except that:

(a) a quorum is two persons holding or representing by proxy whether or not the Member or Members they represent cast Direct Votes, attorney or Representative not less than 25% of the Shares of the class or, if there is one holder of Shares in the class, that holder or a proxy, attorney or representative of that holder; and

(b) any holder of Shares of the class present in person or by proxy whether or not the Member the proxy represents cast Direct Votes, attorney or Representative may demand a poll.

11.3 The rights conferred on the holders of any class of Shares are taken as not having been varied by the creation or issue of further Shares ranking equally with them.

12. Non-marketable parcels

12.1 If one or more Members hold less than a Marketable Parcel of Shares, the Directors may invoke the procedure for the sale of Shares under this clause 12 (**Procedure**).

12.2 To invoke the Procedure, the Directors must give each Member (or each Member whose Shares are not held in a CHESS Holding) who holds less than a Marketable Parcel of Shares (**Eligible Member**) written notice (**Notice of Divestiture**) that complies with this clause 12.

12.3 A Notice of Divestiture given to a Member must:

(a) state that the Shares referred to in the Notice of Divestiture are liable to be sold in accordance with the Procedure if the Member does not advise the Company before a specified date (**Relevant Date**) that the Member wishes to keep those Shares; and

(b) if the Member holds Shares in a CHESS Holding, contain a statement to the effect that if those Shares remain in a CHESS Holding after the Relevant Date, the Company may, without further notice, move those Shares from the CHESS Holding to an Issuer Sponsored Holding or a Certificated Holding for the purposes of divestment by the Company in accordance with the Procedure.

12.4 The Relevant Date must be six weeks or more after the date that the Notice of Divestiture is sent.

12.5 A copy of a Notice of Divestiture must be given to any other person required by the ASX Settlement Operating Rules.

12.6 If an Eligible Member on whom a Notice of Divestiture has been served, wants to keep the Shares referred to in the Notice of Divesture, the Eligible Member must give the Company written notice before the Relevant Date, advising the Company that the Member wants to keep those Shares or the member must increase their holding of Shares before the Relevant Date to a Marketable Parcel in each of which events the Company will not sell the Shares.

12.7 In addition to invoking the Procedure by giving a Notice of Divestiture under clause 12.2, the Directors may also initiate a sale of Shares held by a Member (also, **Eligible Member**) if the Eligible Member holds less than a Marketable Parcel of Shares and that holding was created by a

transfer of a parcel of Shares effected on or after the Adoption Date that was less than a Marketable Parcel at the time that the transfer was initiated or, in the case of a paper-based transfer, the transfer document was lodged with the Company:

(a) the Shares held by the Eligible Member may be sold as provided in clause 12.8; and

(b) the Directors may remove or change the Eligible Member's rights to vote or receive dividends in respect of those Shares. Any dividends withheld must be sent to the former holder after the sale when the former holder delivers to the Company such proof of title as the Directors accept.

12.8 If an Eligible Member on whom a Notice of Divestiture has been served does not give the Company written notice before the Relevant Date advising the Company that the Eligible Member wants to keep the Shares referred in the Notice of Divestiture or the Member has not increased their holding of Shares before the Relevant Date to a Marketable Parcel, or clause 12.7 applies to the Member the Company may:

(a) if the Member holds those Shares in a CHESS Holding, move those Shares from the CHESS Holding to an Issuer Sponsored Holding or a Certificated Holding; and

(b) in any case, sell those Shares in accordance with the Procedure.

12.9 Any Shares which may be sold under this clause 12 may be sold on the terms, in the manner (whether on-market, by private treaty, through a share sale facility established by, on behalf of, or at the request of the Company, or otherwise) and at the time or times determined by the Directors and, for the purposes of a sale under this clause 12, each Eligible Member:

(a) appoints the Company as the Eligible Member's agent for sale and to receive any disclosure document, including a financial services guide;

(b) authorises the Company to effect on the Eligible Member's behalf a transfer of the Shares sold and to deal with the proceeds of the sale of the Shares in accordance with clause 12.11;

(c) appoints the Company, its Directors and Secretaries jointly and severally as the Eligible Member's attorneys to execute any instrument or take other steps, in the Eligible Member's name and on the Eligible Member's behalf, as they or any of them may consider appropriate to transfer the Shares sold; and

(d) authorises each of the attorneys appointed under clause 12.9(c) to appoint an agent to do a thing referred to in clause 12.9(c).

12.10 The title of the transferee to Shares acquired under this clause 12 is not affected by an irregularity or invalidity in connection with the sale of Shares to the Transferee.

12.11 The proceeds of any sale of Shares under this clause 12 less any unpaid calls and interest (**Sale Consideration**) will be paid to the relevant Member or as that Member may direct.

12.12 The Company will hold the Sale Consideration in trust for the Member whose Shares are sold under this clause and will forthwith notify the Member in writing that the Sale Consideration in respect of the Member's Shares has been received by the Company and is being held by the Company pending instructions from the Member as to how it is to be dealt with. If the Member has been issued with a share certificate or certificates, the Member's instructions, to be effective, must be accompanied by the share certificate or certificates to which the Sale Consideration relates or, if the certificate or certificates has or have been lost or destroyed, by a statement and undertaking under subsection 1070D(5) of the Corporations Act.

12.13 Subject to the Corporations Act, the Company or the purchaser will bear all costs, including brokerage and stamp duty, associated with the sale of any Shares under this clause.

12.14 A Notice of Divestiture under clause 12.2 may only be given once in any 12 month period and may not be given during the offer period of a takeover bid for the Company.

12.15 If the Procedure has been invoked and there is an announcement of a takeover bid for Shares, no more sales of Shares may be made under this clause 12 until after the close of the offers made under the takeover. The Procedure may then be invoked again.

12.16 The Directors may, before a sale is effected under this clause 12, revoke a Notice of Divestiture or any step taken under clause 12.7 or suspend or terminate the Procedure, either generally or in specific cases.

12.17 If a Member is an Eligible Member in respect of more than one parcel of Shares, the Directors may treat the Member as a separate Eligible Member in respect of each of those parcels so that this clause 12 will operate as if each parcel was held by a different person.

Calls

13. General

13.1 Subject to the Corporations Act and the terms on which partly paid Shares are issued, the Directors may make calls on the holders of the Shares for any money unpaid on them.

13.2 A call is made when the resolution of the Directors authorising it is passed.

13.3 The Directors may revoke or postpone a call before its due date for payment.

13.4 The Directors may require a call to be paid by instalments.

13.5 The Company must comply with the Corporations Act and the ASX Listing Rules in relation to the dispatch and content of notices to Members on whom a call is made.

13.6 A Member to whom notice of a call is given in accordance with this clause 13 must pay to the Company the amount called in accordance with the notice.

13.7 Failure to send a notice of a call to any Member or the non-receipt of a notice by any Member does not invalidate the call.

13.8 Joint holders of Shares are jointly and severally liable to pay all calls in respect of their Shares.

14. Instalments and amounts which become payable

If:

(a) the Directors require a call to be paid by instalments; or

(b) an amount becomes payable by the terms of issue of Shares on allotment, or at a time or in circumstances specified in the terms of issue,

then:

(c) every instalment or the amount payable under the terms of issue is payable as if it were a call made by the Directors and as if they had given notice of it; and

(d) the consequences of late payment or non-payment of an instalment or the amount payable under the terms of issue are the same as the consequences of late payment or non-payment of a call.

15. Interest and expenses

If an amount called is not paid on or before the due date, the person liable to pay the amount must also pay:

(a) interest on the amount from the due date to the time of actual payment at a rate determined by the Directors (not exceeding 20% per annum); and

(b) all expenses incurred by the Company as a consequence of the non-payment,

but the Directors may waive payment of the interest and expenses in whole or in part. Interest accrues daily and may be capitalised monthly or at such other intervals as the Directors decide.

16. Recovery of amounts due

On the hearing of any action for the recovery of money due for any call, proof that:

(a) the name of the person sued was, when the call was made, entered in the Register as a holder or the holder of Shares in respect of which the call was made;

(b) the resolution making the call is duly recorded in the Directors' minute book; and

(c) notice of the call was given to the person sued,

will be conclusive evidence of the debt.

17. Differentiation

The Directors may, on the issue of Shares, differentiate between the holders as to the amount of calls to be paid and the times of payment.

18. Payment of calls in advance

18.1 The Directors may accept from a Member the whole or part of the amount unpaid on a Share before the amount accepted has been called.

18.2 The Company may:

(a) pay interest on any amount accepted, until the amount is payable under a call and at a rate (not exceeding 20% per annum) agreed between the Member and the Directors; and

(b) subject to any contract between the Company and the Member, repay all or any of the amount accepted in excess of the amount called on the Share.

18.3 Payment of an amount in advance of a call does not entitle the paying Member to any:

(a) dividend, benefit or advantage, other than the payment of interest under this clause 18; or

(b) voting right,

to which the Member would not have been entitled if it had paid the amount when it became due.

Lien and forfeiture

19. Lien

19.1 The Company has a first and paramount lien on every partly paid Share and dividends payable in respect of the Share for all money:

(a) due and unpaid to the Company, in respect of the Share;

(b) presently payable by a holder or the holder of the Share, or the holder's estate, to the Company in respect of the Share; or

(c) which the Company is required by law to pay (and has paid) in respect of the Share.

19.2 The lien extends to reasonable interest and expenses incurred because the amount is not paid.

19.3 If any law for the time being of any country, state or place imposes or purports to impose an immediate or contingent liability on the Company to make any payment or authorises a taxing authority or Government official to require the Company to make payment in respect of Shares or dividends or other moneys accruing due to the Member who holds the Shares:

(a) the Member or, if the Member is deceased, the Member's legal personal representative, indemnifies the Company in respect of any such payment or liability; and

(b) the Company:

(i) has a lien on the Shares and dividends and other moneys payable in respect of the Shares, whether the Shares are held by the Member solely or jointly with another person in respect of any payment made or liability incurred by the Company, together with reasonable expenses and interest on any payment made by the Company at a rate to be fixed by the Directors not exceeding 20% per annum from the date of payment by the Company to the date of repayment by the Member;

(ii) may set off amounts so paid by the Company against amounts payable by the Company to the Member as dividends or otherwise; and

(iii) may recover as a debt due from the Member or its legal personal representative the amount of all payments made by the Company together with reasonable expenses and interest at the rate and for the period referred to in clause 19.3(b)(i).

19.4 The Company may do all things which the Directors think necessary or appropriate to do under the ASX Listing Rules and the ASX Settlement Operating Rules to enforce or protect the Company's lien.

19.5 Unless the Directors determine otherwise, the registration of a transfer of a Share operates as a waiver of the Company's lien on the Share so far as it relates to amounts owing by the transferor or any predecessor in title.

19.6 The Directors may:

(a) declare a Share to be wholly or partly exempt from a lien; or

(b) waive or compromise all or part of any payment due to the Company.

20. Lien sale

If:

(a) the Company has a lien on a Share for money presently payable; and

(b) the Company has given the Member or the Member's executors or administrators (as the case may be) holding the Share written notice demanding payment of the money; and

(c) that Member fails to pay all of the money demanded,

then 14 or more days after giving the notice, the Directors may sell the Share in any manner determined by them.

21. Forfeiture notice

21.1 The Directors may at any time after a call or instalment becomes payable and remains unpaid by a Member, serve a notice on the Member requiring the Member to pay all or any of the following:

(a) the unpaid amount;

(b) any interest that has accrued; and

(c) all expenses incurred by the Company as a consequence of the non-payment.

21.2 The notice under clause 21.1 must:

(a) specify a day (not earlier than 14 days after the date of the notice) on or before which the payment required by the notice must be made; and

(b) state that if a Member does not comply with the notice, the Shares in respect of which the call was made or instalment is payable will be liable to be forfeited.

22. Forfeiture

22.1 If a Member does not comply with a notice served under clause 21, then any or all of the Shares in respect of which the notice was given may be forfeited under a resolution of the Directors.

22.2 Unpaid dividends in respect of forfeited Shares will also be forfeited.

22.3 On forfeiture, Shares become the property of the Company and forfeited Shares must be:

(a) sold, disposed of, or cancelled on terms determined by the Directors; or

(b) offered by public auction.

22.4 The Directors may, at any time before a forfeited Share is sold, disposed of or cancelled, annul the forfeiture of the Share on conditions determined by them.

22.5 Promptly after a Share has been forfeited:

(a) notice of the forfeiture must be given to the Member in whose name the Share was registered immediately before its forfeiture; and

(b) the forfeiture and its date must be noted in the Register.

22.6 Omission or neglect to give notice of or to note the forfeiture as specified in clause 22.5 will not invalidate a forfeiture.

23. Liability of former Member

23.1 The interest of a person who held Shares which are forfeited is extinguished but, the former Member remains liable to pay:

(a) all money (including interest and expenses) that was payable by the Member to the Company at the date of forfeiture in respect of the forfeited Shares; and

(b) interest from the date of forfeiture until payment of the money referred to in clause 23.1(a), of this clause at a rate determined by the Directors (not exceeding 20% per annum).

23.2 A former Member's liability to the Company ceases if and when the Company receives payment in full of all money (including interest and expenses) payable by the former Member in respect of the Shares. The liability may only be compromised, released or waived by the Directors.

24. Disposal of Shares

24.1 The Company may:

(a) receive the consideration (if any) given for a forfeited Share on any sale or disposition of the Share, or a Share sold under a lien sale;

(b) effect a transfer of the Share or execute or appoint a person to execute, a transfer of the Share in favour of a person to whom the Share is sold or disposed of; and

(c) register as the holder of the Share the person to whom the Share is sold.

24.2 The purchaser of the Share:

(a) is not bound to check the regularity of the sale or the application of the purchase price;

(b) obtains title to the Share despite any irregularity in the sale; and

(c) will not be subject to complaint or remedy by the former holder of the Share in respect of the purchase.

24.3 A statement signed by a Director and a Secretary that the Share has been regularly forfeited and sold or reissued or regularly sold without forfeiture to enforce a lien, is conclusive evidence of the matters stated as against all persons claiming to be entitled to the Share.

24.4 Subject to the terms on which a Share is on issue, the net proceeds of any sale made to enforce a lien or on forfeiture must be applied by the Company in the following order:

(a) in payment of the costs and expenses of the sale;

(b) in payment of all amounts (if any) secured by the lien or all money (if any) that was payable in respect of the forfeited Share; and

(c) where the Share was forfeited under clause 22.1, in payment of any surplus to the former Member whose Share was sold.

Transfer of Shares

25. General

25.1 Subject to this Constitution, a Member may transfer Shares held by that Member.

25.2 Subject to clause 25.3, Shares may be transferred by:

(a) a written transfer instrument in any usual or common form; or

(b) any other form approved by the Directors.

25.3 The Company may participate in any computerised or electronic system for market settlement, securities transfer and registration conducted in accordance with the Corporations Act, the ASX Listing Rules and the ASX Settlement Operating Rules, or corresponding laws or financial market rules in any other country.

25.4 If the Company participates in a system of the kind described in clause 25.3, then despite any other provision of this Constitution:

(a) Shares may be transferred, and transfers may be registered, in any manner required or permitted by the ASX Listing Rules or the ASX Settlement Operating Rules (or corresponding laws or financial market rules in any other country) applying in relation to the system;

(b) the Company must comply with and give effect to those rules; and

(c) the Company may, in accordance with those rules, decline to issue certificates for holdings of Shares.

25.5 A written transfer instrument must be:

(a) executed by the transferor or (where the Corporations Act permits) stamped by the transferor's broker;

(b) unless the Directors decide otherwise in the case of a fully paid Share, executed by the transferee or (where the Corporations Act permits) stamped by the transferee's broker; and

(c) in the case of a transfer of partly paid Shares, endorsed or accompanied by an instrument executed by the transferee or by the transferee's broker to the effect that the transferee agrees to accept the Shares subject to the terms and conditions on which the transferor held them, to become a Member and to be bound by the Constitution.

Subject to the Corporation Act, the written transfer instrument may comprise more than one document.

25.6 Except as required by the ASX Settlement Operating Rules:

(a) a transferor of Shares remains the holder of the Shares transferred until the transfer is registered and the name of the transferee is entered in the Register in respect of the Shares; and

(b) a transfer of Shares does not pass the right to any dividends on the Shares until such registration.

26. Transfer procedure

26.1 Except where the Directors determine (to comply with laws or financial market rules of a foreign country or the ASX Settlement Operating Rules), for a transfer of Shares that is not an ASX Settlement regulated transfer:

(a) the written transfer instrument must be left at the Company's registered office or another place acceptable to the Company;

(b) the instrument must be accompanied by a certificate for the Shares dealt with in the transfer where a certificate has been issued, unless the Directors waive production of the certificate on receiving satisfactory evidence of the loss or destruction of the certificate; and

(c) the Directors may require other evidence of the transferor's right to transfer the Shares.

26.2 For a transfer of Shares that is an ASX Settlement regulated transfer, a Share transfer must be effected in accordance with the ASX Listing Rules and the ASX Settlement Operating Rules.

26.3 The Company may charge a fee for registering a transfer of Shares if:

(a) the Company is not listed; or

(b) the fee is not prohibited by the ASX Listing Rules.

27. Right to refuse registration

27.1 The Directors may in their absolute discretion refuse to register any transfer of Shares or other securities where the Shares or other securities are not quoted by ASX. Where the Shares or other securities are quoted by ASX, the Directors may in their absolute discretion refuse to register any transfer in any of the circumstances permitted by the ASX Listing Rules.

27.2 The Directors must:

(a) except as permitted by ASX, refuse to register any transfer of Shares or other securities which are Restricted Securities if that transfer is or might be in breach of the ASX Listing Rules or any restriction agreement entered into by the Company under the ASX Listing Rules in relation to the Shares; and

(b) refuse to register any transfer where the Company is, or the Directors are, required to do so by the ASX Listing Rules.

27.3 Despite clauses 27.1 and 27.2, the Company must not refuse or fail to register or give effect to, or delay or in any way interfere with, a proper ASTC transfer of Shares or other securities quoted by ASX.

27.4 If a person has lodged a transfer which the Directors have refused to register, the Company must, within five Business Days after the date of lodgment, give to the lodging person written notice of the refusal and the reasons for it.

27.5 Subject to clause 27.3, Restricted Securities cannot be disposed of during the escrow period except as permitted by the ASX Listing Rules or ASX. The Company will refuse to acknowledge a disposal of Restricted Securities to the extent required under the ASX Listing Rules.

Transmission of Shares

28. Title on death

28.1 The legal personal representative of a deceased Member who was the sole holder of Shares is the only person whom the Company will recognise as having any title to the deceased Member's Shares.

28.2 If a deceased Member was a joint holder of Shares, the other joint holder is the only person whom the Company will recognise as having any title to the deceased Member's Shares.

28.3 The estate of the deceased Member will not be released from any liability to the Company in respect of the Shares.

28.4 The Company may register or give effect to a transfer to a transferee who dies before the transfer is registered.

29. Entitlement to transmission

29.1 A person who becomes entitled to a Share in consequence of the death, mental incapacity or bankruptcy of a Member may, subject to clause 27 and to producing to the Company evidence of its entitlement which is satisfactory to the Directors, elect to:

(a) be registered as the holder of the Share; or

(b) transfer the Share to some other person nominated by it.

29.2 If the person who has become entitled to a Share:

(a) elects to be registered as the holder, then the person must deliver or send to the Company a written notice of election signed by him or her; or

(b) elects to transfer the Share, then the person must effect a transfer of the Share.

29.3 An election to be registered as a holder of a Share under clause 29.1(a) or a transfer of a Share from a Member or deceased Member under this clause 29 is subject to the same limitations, restrictions and provisions of this Constitution as would apply if the election were a transfer or the transfer were made by the Member or deceased Member himself or herself.

29.4 A person who:

(a) has become entitled to a Share by operation of law; and

(b) has produced evidence of that person's entitlement which is satisfactory to the Directors,

is entitled to the dividends and other rights of the registered holder of the Share.

29.5 Where two or more persons are jointly entitled to any Share in consequence of the death of the registered holder, they will be considered to be joint holders of the Share.

29.6 Any person who is registered under this clause must indemnify the Company against all liabilities, costs, losses and expenses incurred by the Company as a result of registering the person.

30. Plebiscite to approve proportional takeover bids

30.1 In this clause 30:

Approving Resolution in relation to a Proportional Takeover Bid means a resolution to approve the Proportional Takeover Bid passed in accordance with clause 30.3.

Approving Resolution Deadline in relation to a Proportional Takeover Bid means the day that is 14 days before the last day of the bid period, during which the offers under the Proportional Takeover Bid remain open or a later day allowed by ASIC.

Proportional Takeover Bid means a takeover bid that is made or purports to be made under section 618(1)(b) of the Corporations Act in respect of securities in a class of securities of the Company.

Relevant Class in relation to a Proportionate Takeover Bid, means the class of securities in the Company in respect of which offers are made under the Proportional Takeover Bid.

30.2 Despite clauses 27 and 107, a transfer giving effect to a contract resulting from the acceptance of an offer made under a Proportional Takeover Bid must not be registered unless an Approving Resolution to approve the Proportional Takeover Bid has been passed or is taken to have been passed in accordance with clauses 30.3 to 30.8 inclusive.

30.3 Where offers have been made under a Proportionate Takeover Bid, the Directors must:

(a) call and arrange to hold a meeting of the persons entitled to vote on the Approving Resolution for the purpose of considering and, if thought fit, passing a resolution to approve the Proportional Takeover Bid; and

(b) ensure that the resolution is voted on in accordance with clauses 30.4 to 30.8 inclusive,

before the Approving Resolution Deadline.

30.4 The provisions of this Constitution relating to general meetings apply, with necessary changes, to a meeting that is called under clause 30.3, as if that meeting were a general meeting of the Company, except that:

(a) a meeting may be called and held on less than the notice period provided in the Corporations Act or this Constitution if the Board considers that should be done to ensure that the meeting is held before the Approving Resolution Deadline; and

(b) the holder of a security that carries no right to vote at a general meeting of the Company has one vote for each security held at a meeting called and arranged to be held under this clause 30.

30.5 The bidder under a Proportional Takeover Bid and any Associates of the bidder are not entitled to vote on the Approving Resolution and, if they do, their votes must not be counted.

30.6 Subject to clause 30.5, a person who, as at the end of the day on which the first offer under the Proportional Takeover Bid was made, held securities of the Relevant Class, is entitled to vote on the Approving Resolution relating to the Proportional Takeover Bid.

30.7 An Approving Resolution that has been voted on is taken to have been passed if the proportion that the number of votes in favour of the Approving Resolution bears to the total number of votes on the resolution is greater than 50%, and otherwise is taken to have been rejected.

30.8 If an Approving Resolution has not been voted on in accordance with clauses 30.3 to 30.7 inclusive as at the end of the day before the Approving Resolution Deadline, an Approving Resolution will be taken to have been passed in accordance with those clauses on the Approving Resolution Deadline.

Changes to Share capital

31. Alteration of share capital

The Directors may do anything required to give effect to any resolution altering or approving the reduction of the Company's Share capital, including, where a Member becomes entitled to a fraction of a Share or other security on a conversion of some or all of the Shares into a larger or smaller number or on a reduction of capital:

(a) causing the Company to make cash payments;

(b) determining that fractions may be disregarded to adjust the rights of all parties;

(c) appointing a trustee to deal with any fractions on behalf of Members; and

(d) rounding up each fractional entitlement to the nearest whole Share or security by capitalising any amount for capitalisation under clause 100 even though only some of the Members participate in the capitalisation.

32. Reductions of capital

32.1 Subject to the Corporations Act and the Listing Rules, the Company may reduce its share capital in any manner.

32.2 Without limiting the generality of clause 32.1, the Company when reducing its share capital may resolve that such reduction be effected wholly or in part by the distribution of specific assets (whether held in the name of the Company or in the name of any wholly owned subsidiary of the Company) and in particular fully paid shares, debentures, debenture stock or other securities of any other corporation or in any one or more of such ways.

32.3 If a difficulty arises in making a distribution of specific assets or the Directors otherwise so determine, the Directors may do all or any one or more of the following:

(a) deal with the difficulty as they think expedient;

(b) fix the value of all or any part of the specific assets for the purposes of the distribution;

(c) determine that cash will be paid to any Members on the basis of the fixed value in order to equitably adjust the rights of the Members; and

(d) vest any specific assets in trustees as the Directors consider expedient.

32.4 If a distribution of specific assets to a particular Member or Members is in the Directors' opinion contrary to any law, including any law applicable to the Member, or, in the Directors' opinion, impractical, the Directors may make a cash payment to the Member or Members on the basis of the cash amount of the reduction in share capital instead of the distribution of specific assets.

32.5 Where the Company pursuant to a reduction of its share capital distributes to its Members shares in another corporation:

(a) the Members will be deemed to have agreed to become members of that other corporation; and

(b) each of the Members appoints the Company or any of the Directors as its agent to execute any transfer of shares or other document required to facilitate or effect the distribution of shares to that Member.

33. Ancillary powers

If a distribution, transfer or issue of specific assets, shares or securities to a particular Member or Members is, in the Directors' discretion, considered impracticable or would give rise to parcels of securities which do not constitute marketable parcels, the Directors may cause the Company to make a cash payment to those Members or allocate the assets, shares or securities to a trustee to be sold on behalf of, and for the benefit of, those Members, instead of making the distribution, transfer or issue to those Members.

34. Buy-backs

Subject to the Corporations Act and the Listing Rules, the Company may buy Shares on terms and at times determined from time to time by the Directors.

Powers of attorney

35. Powers of attorney

35.1 If a Member executes or proposes to execute any document or do any act by or through an attorney which is relevant to the Company or the Member's shareholding in the Company, that Member must deliver the instrument appointing the attorney to the Company for notation.

35.2 The Company may require the Member to lodge a certified copy of the instrument for retention by the Company, and ask for whatever evidence it thinks appropriate that the power of attorney is effective and continues to be in force.

35.3 Any power of attorney granted by a Member will, as between the Company and the Member who granted the power of attorney:

(a) continue in force; and

(b) may be acted on,

unless express notice in writing of its revocation or of the death of the Member who granted it is lodged with the Company.

35.4 Where a Member proposes that an attorney represent the Member at a general meeting or adjourned meeting, the Member must comply with clause 57.1 of this Constitution.

General meetings

36. Calling general meeting

36.1 A Director may call a meeting of Members.

36.2 The Directors must call annual general meetings in accordance with the Corporations Act, to be held by the Company at times to be determined by the Directors.

36.3 Members may also request or call and arrange to hold general meetings in accordance with the procedures and requirements set out in the Corporations Act.

36.4 A general meeting may be held at two or more venues simultaneously using any technology that gives the Members as a whole a reasonable opportunity to participate.

37. Notice

37.1 Notice of a general meeting must be given in accordance with the Corporations Act to the persons referred to in clause 102.1.

37.2 Except as permitted by the Corporations Act, general meetings must be called on at least the minimum number of days' notice required by the Corporations Act (which at the Adoption Date is 28 days) and otherwise in accordance with the procedures set out in the Corporations Act.

37.3 Subject to the requirements of the Corporations Act, the content of a notice of general meeting called by the Directors must be decided by the Directors.

38. Business

38.1 Unless the Corporations Act provides otherwise:

(a) no business may be transacted at a general meeting unless the general nature of the business is stated in the notice calling the meeting; and

(b) except with the approval of the Directors or the chairperson, no person may move an amendment to a proposed resolution the terms of which are set out in the notice calling the meeting or to a document which relates to such a resolution and a copy of which has been made available to Members to inspect or copy.

38.2 The Directors may postpone or cancel any general meeting (other than a meeting requested or called by Members under clause 36.3) at any time before the day of the meeting. The Directors must give notice of the postponement or cancellation to all persons entitled to receive notices of a general meeting.

38.3 An accidental omission to send a notice of a general meeting (including a proxy appointment form) or the postponement of a general meeting to any Member or the non-receipt of a notice (or form) by any Member does not invalidate the proceedings at or any resolution passed at the general meeting.

38.4 A person's attendance at the general meeting waives any obligation the person may have to:

(a) a failure to give notice, or the giving of a defective notice, of the meeting unless the person at the beginning of the meeting objects to the holding of the meeting; and

(b) the consideration of a particular matter at the meeting which is not within the business referred to in the notice of meeting, unless the person objects to considering the matter when it is presented.

Proceedings at general meetings

39. Member

In clauses 40, 41, 42, 43, 44, 47 and 49, **Member** includes a Member present in person or by proxy (whether or not the Member or Members they represent cast Direct Votes), attorney or Representative.

40. Quorum

40.1 No business may be transacted at a general meeting unless a quorum of Members is present at the commencement of business.

40.2 A quorum of Members is two Members unless there are less than two Members, in which event a quorum is those Members.

40.3 If a quorum is not present within 30 minutes after the time appointed for a general meeting:

(a) the general meeting is automatically dissolved if it was requested or called by Members; or

(b) in any other case:

(i) it will stand adjourned to the same time and place seven days after the meeting, or to another day, time and place determined by the Directors; and

(ii) if at the adjourned general meeting a quorum is not present within 30 minutes after the time appointed for the general meeting the general meeting is automatically dissolved.

41. Chairperson

41.1 The chairperson, or in the chairperson's absence the deputy chairperson, of Directors' meetings will be the chairperson at every general meeting.

41.2 If:

(a) there is no chairperson or deputy chairperson; or

(b) neither the chairperson nor deputy chairperson is present within 15 minutes after the time appointed for holding the general meeting; or

(c) the chairperson and deputy chairperson are unwilling to act as chairperson of the general meeting,

the Directors present may elect a chairperson of the general meeting of the Members.

41.3 If no chairperson is elected in accordance with clause 41.2, then:

(a) the Members may elect one of the Directors present as chairperson; or

(b) if no Director is present or is willing to take the chair, the Members may elect one of the Members present as chairperson.

41.4 At any time during a meeting and in respect of any specific item or items of business, the chairperson may elect to vacate the chair in favour of another person nominated by the chairperson (which person must be a Director unless no Director is present or is willing to act). That person is to be taken to be the chairperson and will have all the powers of the chairperson (other than the power to adjourn the meeting), during the consideration of that item of business or those items of business.

41.5 If there is a dispute at a general meeting about a question of procedure, the chairperson may determine the question.

42. General conduct

42.1 The general conduct of each general meeting of the Company and the procedures to be adopted at the meeting will be determined by the chairperson, including the procedure for the conduct of the election of Directors.

42.2 The chairperson may, at any time the chairperson considers it necessary or desirable for the proper and orderly conduct of the meeting:

(a) impose a limit on the time that a person may speak on each motion or other item of business and terminate debate or discussion on any business, question, motion or resolution being considered at the meeting and require the business, questions, motion or resolution to be put to a vote of the Members present; and

(b) adopt any procedures for casting or recording votes at the meeting whether on a show of hands or on a poll, including the appointment of scrutineers.

42.3 A decision by the chairperson under clause 42.1 or 42.2 is final.

43. Postponement and Adjournment

43.1 The chairperson may postpone the meeting before it has started, whether or not a quorum is present, if, at the time and place appointed for the meeting, he or she considers that:

(a) there is not enough room for the number of Members who wish to attend the meeting; or

(b) a postponement is necessary in light of the behaviour of persons present or for any other reason so that the business of the meeting can be properly carried out.

43.2 A postponement under clause 43.1 will be to another time, which may be on the same day as the meeting, and may be to another place (and the new time and place will be taken to be the time and place for the meeting as if specified in the notice which called the meeting originally).

43.3 The chairperson may at any time during the course of the meeting:

(a) adjourn the meeting or any business, motion, question or resolution being considered or remaining to be considered by the meeting either to a later time at the same meeting or to an adjourned meeting; and

(b) for the purpose of allowing any poll to be taken or determined, suspend the proceedings of the meeting for such period/s as he or she decides without effecting an adjournment. No business may be transacted and no discussion may take place during any suspension of proceedings unless the chairperson otherwise allows.

43.4 The chairperson's rights under clauses 43.1 and 43.3 are exclusive and, unless the chairperson requires otherwise, no vote may be taken or demanded by the members present about any postponement, adjournment or suspension of proceedings.

43.5 Only unfinished business may be transacted at a meeting resumed after an adjournment.

43.6 Where a meeting is postponed or adjourned under this clause 43, notice of the postponed or adjourned meeting must be given to ASX, but except as provided by clause 43.8, need not be given to any other person.

43.7 Where a meeting is postponed or adjourned, the Directors may, by notice to ASX, postpone, cancel or change the place of the postponed or adjourned meeting.

43.8 Where a meeting is postponed or adjourned for 30 days or more, notice of the postponed or adjourned meeting must be given as in the case of the original meeting.

44. Decisions

44.1 Subject to the Corporations Act in relation to special resolutions, a resolution is carried if a majority of the votes cast on the resolution are in favour of the resolution.

44.2 A resolution put to the vote of a meeting is decided on a show of hands unless a poll is demanded by:

(a) at least 5 Members entitled to vote on the resolution; or

(b) Members with at least 5% of the votes that may be cast on the resolution on a poll; or

(c) the chairperson.

44.3 A poll:

(a) may be demanded:

(i) before a vote is taken; or

(ii) in the case of a vote taken on a show of hands, immediately before or immediately after, the results of the vote are declared; and

(b) must be demanded if:

(i) a vote by show of hands is taken on the resolution; and

(ii) appointments of proxies have been received specifying the way the proxies are to vote on the resolution (whether or not as a Direct Vote); and

(iii) votes cast in accordance with the appointments of proxies referred to in clause 44.3(b)(ii) could change the outcome of the vote on the resolution.

44.4 Unless a poll is demanded:

(a) a declaration by the chairperson that a resolution has been carried, carried by a specified majority, or lost; and

(b) an entry to that effect in the minutes of the meeting,

are conclusive evidence of the fact without proof of the number or proportion of the votes in favour of or against the resolution.

44.5 The demand for a poll may be withdrawn.

44.6 A decision of a general meeting may not be impeached or invalidated on the ground that a person voting at the meeting was not entitled to do so.

45. Taking a poll

45.1 Subject to clause 45.5, a poll will be taken when and in the manner that the chairperson directs. No notice need be given of any poll.

45.2 The result of the poll will determine whether the resolution on which the poll was demanded is carried or lost.

45.3 The chairperson may determine any dispute about the admission or rejection of a vote, and such determination, if made in good faith, will be final and conclusive.

45.4 A poll cannot be demanded on any resolution concerning the election of the chairperson of a general meeting.

45.5 A poll demanded by the chairperson on any resolution concerning the adjournment of a general meeting must be taken immediately.

45.6 After a poll has been demanded at a general meeting, the general meeting may continue for the transaction of business other than the question on which the poll was demanded.

46. Casting vote of chairperson

The chairperson does not have a casting vote (in addition to the chairperson's votes as a Member, proxy, attorney or Representative) on a show of hands or on a poll.

47. Admission to general meetings

47.1 The chairperson of a general meeting may refuse admission to a person, or require a person to leave and not return to, a meeting if the person:

(a) refuses to permit examination of any article in the person's possession; or

(b) is in possession of any:

(i) electronic or recording device;

(ii) placard or banner; or

(iii) other article,

which the chairperson considers to be dangerous, offensive or liable to cause disruption; or

(c) causes any disruption to the meeting including by refusal to comply with a request of the chairman to turn off a mobile telephone, personal communication device or similar device; or

(d) who behaves or threatens to behave in a dangerous, offensive or disruptive way.

47.2 The chairperson may delegate the powers conferred by clause to any person he or she thinks fit.

47.3 A person, whether a Member or not, requested by the directors or the chairperson to attend a general meeting is entitled to be present and, at the request of the chairperson, to speak at the meeting.

47.4 If the chairperson of a general meeting considers that there is not enough room for the Members who wish to attend the meeting, he or she may arrange for any person whom he or she considers cannot be seated in the main meeting room to observe or attend the general meeting in a separate room. Even if the Members present in the separate room are not able to participate in the conduct of the meeting, the meeting will nevertheless be treated as validly held in the main room.

47.5 If a separate meeting place is linked to the main place of a general meeting by an instantaneous audio-visual communication device which, by itself or in conjunction with other arrangements:

(a) gives the general body of Members in the separate meeting place a reasonable opportunity to participate in proceedings in the main place;

(b) enables the chairperson to be aware of proceedings in the other place; and

(c) enables the Members in the separate meeting place to vote on a show of hands or on a poll,

a Member present at the separate meeting place is taken to be present at the general meeting and entitled to exercise all rights as if he or she was present at the main place.

47.6 If, before or during the meeting, any technical difficulty occurs where one or more of the matters set out in clause 47.5 is not satisfied, the chairperson may:

(a) adjourn the meeting until the difficulty is remedied; or

(b) continue to hold the meeting in the main place (and any other place which is linked under clause 47.5 and transact business, and no member may object to the meeting being held or continuing.

(c) Nothing in this clause 47 is to be taken to limit the powers conferred on the chairperson by law.

48. Auditor's right to be heard

The Auditor is entitled to:

(a) attend any general meeting of the Company;

(b) be heard at any general meeting of the Company on any part of the business of the meeting that concerns the Auditor in their capacity as auditor, even if:

(i) the Auditor retires at the general meeting; or

(ii) Members pass a resolution to remove the Auditor from office; and

(c) authorise a person in writing to attend and speak at any general meeting as the Auditor's representative.

Votes of Members

49. Entitlement to vote

49.1 Subject to this Constitution and to any rights or restrictions attaching to any class of Shares:

(a) every Member may vote;

(b) subject to clause 53.4 and the Corporations Act, on a show of hands every Member has one vote; and

(c) on a poll every Member has:

(i) for each fully paid Share held by the Member, one vote; and

(ii) for each partly paid Share held by the Member, a fraction of a vote equivalent to the proportion which the amount paid (not credited) is of the total amounts paid and payable, whether or not called (excluding amounts credited), on the Share. Without limiting the generality of clause 18.3, an amount paid on a Share in advance of a call is not to be taken as paid for the purposes of this clause.

49.2 During a breach of the ASX Listing Rules relating to Shares which are Restricted Securities, or a breach of a restriction agreement, the holder of the relevant Restricted Securities is not entitled to any voting rights in respect of those Restricted Securities.

49.3 If a Member:

(a) dies; or

(b) through mental or physical infirmity, is incapable of managing the Member's affairs,

and a personal representative, trustee or other person is appointed under law to administer the Member's estate or property, the personal representative, trustee or person so appointed may exercise any rights of the Member in relation to a general meeting as if the personal representative, trustee or person (as the case may be) was a Member.

49.4 If, under the Corporations Act or the Listing Rules, a notice calling a meeting and proposing a resolution specifies that:

(a) a Member must not vote in favour of the resolution;

(b) a Member must not vote on the resolution; or

(c) a vote on the resolution by the Member will be disregarded,

and the Member or a person acting as the Member's proxy, attorney or representative does tender a vote, in the case of paragraph (a), in favour of, or in the case of paragraph (b) or (c), on, the resolution, their vote must not be counted.

49.5 Where the Corporations Act or the Listing Rules prohibits a Member from voting in favour of a resolution, this does not prohibit the Member from voting against the resolution.

50. Unpaid calls

A Member is entitled to:

(a) vote; or

(b) be counted in a quorum,

only in respect of Shares on which all calls due and payable have been paid.

51. Joint holders

51.1 If two or more joint holders purport to vote, the vote of the joint holder whose name appears first in the Register will be accepted, to the exclusion of the other joint holder or holders.

51.2 For the purposes of this clause 51, several executors or administrators of a deceased Member in whose sole name any Shares are registered will be taken to be joint holders of those Shares.

52. Objections

52.1 An objection to the qualification of a voter may only be raised at the general meeting or adjourned general meeting at which the voter tendered their vote.

52.2 An objection must be referred to the chairperson of the general meeting for decision, whose decision is final.

52.3 A vote which the chairperson does not disallow under an objection is valid for all purposes.

53. Votes by proxy

53.1 A Member who is entitled to vote at a general meeting of the Company may appoint not more than two proxies to attend and vote at the general meeting on that Member's behalf.

53.2 A proxy need not be a Member.

53.3 If a Member appoints one proxy, that proxy may, subject to the Corporations Act, vote on a show of hands.

53.4 If a Member appoints two proxies and the appointment does not specify the proportion or number of the Member's votes each proxy may exercise, each proxy may exercise half the votes. However, neither proxy may vote on a show of hands.

53.5 A proxy may demand or join in demanding a poll.

53.6 Subject to the Corporations Act, a proxy may vote or abstain as he or she chooses.

53.7 If:

(a) a Member nominates the chairperson of the meeting as the Member's proxy; or

(b) the chairperson is to act as proxy under clause 56 or otherwise under a default appointment according to the terms of the proxy form,

then the person acting as chairperson in respect of an item of business at the meeting must act as proxy under the appointment in respect of that item of business.

53.8 A proxy's authority to speak and attend for a Member at a meeting is suspended while the Member is present in person or by representative at the meeting unless the Member otherwise decides and informs the Company in writing prior to the start of the meeting, in which event the Member's authority to speak or vote at the meeting is suspended while the proxy is present at the meeting.

54. Direct Votes

54.1 The Directors may determine that at any meeting of Members or class meeting, a Member who is entitled to attend and vote on a resolution at that meeting is entitled to a Direct Vote in respect of that resolution.

54.2 The Directors may prescribe regulations, rules and procedures in relation to Direct Voting, including specifying the form, method and timing of giving a Direct Vote at a meeting in order for the vote to be valid.

55. Document appointing proxy

55.1 An appointment of a proxy is valid if it is signed by the Member making the appointment and contains the information required by subsection 250A(1) of the Corporations Act.

55.2 For the purposes of clause 55.1, an appointment received at an electronic address will be taken to be signed by the Member if:

(a) a personal identification code allocated by the Company to the Member has been input into the appointment; or

(b) the appointment has been verified in another manner approved by the Directors.

55.3 The Company may send a proxy appointment form to Members in a form which has been approved by the Directors or by the chairperson and the Managing Director.

55.4 A proxy's appointment is valid at an adjourned general meeting.

55.5 A proxy or attorney may be appointed for all meetings or for any number of general meetings or for a particular purpose.

55.6 Unless otherwise provided for in the proxy's appointment or in any instrument appointing an attorney, the appointment of the proxy or the attorney will be taken to confer authority:

(a) to vote on:

(i) any amendment moved to the proposed resolutions and on any motion that the proposed resolutions not be put or any similar motion; and

(ii) any procedural motion, including any motion to elect the chairperson, to vacate the chair or to adjourn the general meeting,

even though the appointment may specify the way the proxy or attorney is to vote on a particular resolution; and

(b) to vote on any motion before the general meeting whether or not the motion is referred to in the appointment,

(c) except where any such vote, if cast, would constitute an offence under the Corporations Act.

56. Proxy in blank

If a proxy appointment is signed by the Member but does not name the proxy or proxies in whose favour it is given, the chairperson may either act as proxy or complete the proxy appointment by inserting the name or names of one or more Directors or a Secretary.

57. Lodgement of proxy

57.1 Subject to clause 57.3, the appointment of a proxy or attorney must be received by the Company, at least 48 hours (unless reduced in the notice of meeting to which the appointment relates) before the general meeting (or the resumption of an adjourned general meeting) at which the appointee is to attend and vote.

57.2 If the appointment purports to be executed under a power of attorney or other authority, the original document or a certified copy of it must be received by the Company at least 48 hours (unless reduced in the notice of meeting to which the appointment relates) before the general meeting (or the resumption of an adjourned general meeting).

57.3 The Company receives an appointment of a proxy or attorney or other authority under which it was signed when they are received at:

(a) the Company's registered office;

(b) a facsimile number at the Company's registered office; or

(c) a place, facsimile number or electronic address specified for that purpose in the notice of general meeting.

58. Validity

58.1 A vote cast in accordance with an appointment of proxy or power of attorney is valid even if before the vote was cast the appointor:

(a) died;

(b) became mentally incapacitated;

(c) revoked the proxy or power; or

(d) transferred the Shares in respect of which the vote was cast,

unless the Company received written notification of the death, mental incapacity, revocation or transfer before the relevant general meeting or adjourned general meeting.

58.2 Notwithstanding any other clause of this Constitution, a vote cast or purported to be cast by a person in circumstances which would constitute an offence under the Corporations Act is invalid and will not be counted by the Company on any vote, whether by proxy, in person, on a poll or by any other means .

59. Representatives of bodies corporate

59.1 Any Member or proxy that is a body corporate may appoint an individual as its representative as provided by the Corporations Act.

59.2 The appointment of a Representative may set out restrictions on the Representative's powers.

59.3 The original form of appointment of a Representative, a certified copy of the appointment, or a certificate of the body corporate evidencing the appointment of a Representative is prima facie evidence of a Representative having been appointed.

59.4 The chairperson of a general meeting may permit a person claiming to be a Representative to exercise the body's powers even if he or she has not produced a certificate or other satisfactory evidence of his or her appointment.

Appointment and removal of Directors

60. Number of Directors

60.1 Subject to the Corporations Act, the Company may by resolution passed at a general meeting increase the minimum number of Directors or increase or reduce the maximum number of Directors.

60.2 Until the Company resolves otherwise in accordance with clause 60.1 there will be:

(a) a minimum of three Directors; and

(b) a maximum of 10 Directors.

60.3 Subject to any resolution of the Members determining the maximum and minimum numbers of Directors, the Directors may from time to time determine the respective numbers of Executive and Non-Executive Directors.

61. Qualification

61.1 Neither a Director nor an Alternate Director has to hold any Shares.

61.2 In addition to the circumstances which disqualify a person from managing a corporation according to the Corporations Act, no person who has been an insolvent under administration within the previous five years is eligible to become a Director.

61.3 A Director (and an Alternate Director when acting as a Director) is entitled to notice of all general meetings and meetings of the holders of any class of Shares.

62. Power to remove and appoint

62.1 Subject to the provisions of this Constitution, the Company may appoint a person as a Director by resolution passed in general meeting.

62.2 A Director appointed or elected at a general meeting is taken to have been appointed or elected with effect from immediately after the end of that general meeting unless the resolution by which the Director was appointed or elected specifies a different time.

62.3 If the conduct or position of any Director is such that continuance in office appears to the majority of the Directors to be prejudicial to the interests of the Company, a majority of Directors at a meeting of the Directors specifically called for that purpose may suspend that Director.

62.4 A suspended Director may not take any part in the business or affairs of the Company until the suspension has been terminated.

62.5 Within 14 days of the suspension of a Director, the Directors must call a general meeting, at which the Members may consider a resolution to remove the Director from office.

62.6 If a resolution to remove a suspended Director from office is not carried at the general meeting called to consider the matter, the suspension of the Director is terminated and the Director is reinstated in his or her office.

63. Additional and casual Directors

63.1 Subject to clause 60, only the Directors may appoint any person as a Director to fill a casual vacancy or as an addition to the existing Directors.

63.2 Unless the Director is the Managing Director and the ASX Listing Rules do not require that Director to be subject to retirement as set out in this clause, a Director appointed under clause 63.1 will hold office until the end of the next annual general meeting of the Company, at which the Director may be re-elected.

64. Retirement of Directors

64.1 No Director, who is not the Managing Director, may hold office for a continuous period in excess of three years or until the third annual general meeting following the Director's appointment or election, whichever is the longer, without submitting for re-election. If no such director would be required to submit for re-election but the ASX Listing Rules require an election of Directors to be held, the Director to retire will be the Director who has been longest in office since their last election, but, as between persons who became Directors on the same day, the one to retire will (unless they otherwise agree among themselves) be determined by lot.

64.2 A retiring Director remains in office until the end of the meeting at which the Director retires or vacates office, and will be eligible for re-election at the meeting.

65. Eligibility for election as Director

65.1 A person is eligible for election to the office of a Director at a general meeting only if:

(a) the person is in office as a Director immediately before the meeting;

(b) the person has been nominated by the Directors for election at that meeting;

(c) where the person is a Member, the person has, at least 35 Business Days but no more than 90 Business Days before the meeting, given the Company a notice signed by the person stating the person's desire to be a candidate for election at the meeting; or

(d) where the person is not a Member, a Member intending to nominate the person for election at that meeting has, at least 35 Business Days but no more than 90 Business Days before the meeting, given the Company a notice signed by the Members stating the Member's intention to nominate the person for election, and a notice signed by the person stating the person's consent to the nomination.

65.2 Clause 65.1(a) applies to elections of Directors at a general meeting that is a ***spill meeting*** as defined in section 250V(1) of the Corporations Act, to the extent permitted by the Corporations Act.

66. Vacation of office

The office of a Director immediately becomes vacant if the Director:

(a) ceases to be a Director by virtue of the Corporations Act;

(b) is prohibited by the Corporations Act from holding office or continuing as a Director;

(c) is liable to pay a call but does not pay the call within 21 days after the date on which it is payable;

(d) is prohibited from holding or is removed from the office of Director by an order made under the Corporations Act;

(e) becomes bankrupt or makes any general arrangement or composition with his or her creditors;

(f) cannot fully participate in the management of the Company because of his or her mental incapacity or is a person whose estate is liable to have a person appointed, under the law relating to the administration of estates of persons who through mental or physical infirmity are incapable of managing their affairs, to administer it, or becomes in the opinion of the Directors incapable of performing his or her duties;

(g) resigns from his or her office of Director by notice in writing to the Company; or

(h) is absent from Directors' meetings for six consecutive months without leave of absence from the Directors.

Remuneration of Directors

67. Remuneration of Non-Executive Directors

67.1 Subject to the ASX Listing Rules, the Directors as a whole (other than Executive Directors) may be paid or provided remuneration for their services the total amount or value of which must not exceed each year an aggregate maximum approved for the purposes of clause 15.4(a) of the Previous Constitution or such higher maximum amount determined from time to time by the Company in general meeting.

67.2 When calculating a Director's remuneration for the purposes of the aggregate maximum under clause 67.1, any amount paid by the Company or a related body corporate:

(a) to a superannuation, retirement or pension fund for a Director so that the Company is not liable to pay the superannuation guarantee charge or similar statutory charge is to be included; and

(b) for any insurance premium paid or agreed to be paid for a Director under clause 67.7 is to be excluded.

67.3 Subject to the ASX Listing Rules, the aggregate maximum sum will be divided among the Non-Executive Directors in such proportion and manner as the Directors agree and, in default of agreement, equally and shall be deemed to accrue from day to day.

67.4 Non-Executive Directors may not be paid a commission on or a percentage of profits or operating revenue.

67.5 If a Non-Executive Director is required to perform services for the Company which in the opinion of the Directors, are outside the scope of the ordinary duties of a Director, the Company may pay or provide the Director remuneration determined by the Directors which may be either in addition to or instead of the Director's remuneration under clause 67.1. Any remuneration paid or provided under this clause 67.5 does not form part of the aggregate maximum sum of Directors' remuneration permitted under clause 67.1.

67.6 Non-Executive Directors may also be paid all travelling, hotel and other expenses properly incurred by them in attending and returning from meetings of the Directors or any committee of the Directors or general meetings of the Company or otherwise in connection with the Company's business.

67.7 The Company may also pay a premium for a contract insuring a person who is or has been a Non-Executive Director against liability incurred by the person as a Director, except in circumstances prohibited by the Corporations Act.

67.8 Shares, options, rights and other share-based payments may be provided to Non-Executive Directors as part of their remuneration under clauses 67.3 and 67.4 according to the rules of any share plan for the remuneration of Non-Executive Directors that may be introduced by the Company, subject to the ASX Listing Rules and requirements of the Corporations Act. The value of any such Shares, options, rights and other share-based payments will not be included in the aggregate maximum under clause 67.1.

68. Remuneration of Executive Directors

68.1 The remuneration of an Executive Director may from time to time be fixed by the Directors. The remuneration may be by way of salary or commission or participation in profits or by all or any of these modes but may not be by commission on, or a percentage of, operating revenue.

68.2 The Company may reimburse an Executive Director for his or her expenses properly incurred as a Director or in the course of his or her office.

68.3 Except in circumstances prohibited by the Corporations Act, the Company may pay a premium for a contract insuring a person who is or has been an Executive Director against liability incurred by the person as a Director.

69. Retirement benefits

69.1 Subject to the Corporations Act, the Company may give a person a benefit in connection with a Director's retirement from a managerial or executive office in the Company or a related body corporate of the Company.

69.2 Subject to the Corporations Act, the Company may enter into an agreement or contract with a person for the giving to the person or any other person of a benefit in connection with a Director's retirement from a managerial or executive office in the Company or a related body corporate of the Company.

Powers and duties of Directors

70. Directors to manage Company

70.1 The business of the Company is managed by or under the direction of the Directors who may exercise all powers of the Company that this Constitution, the Corporations Act or the ASX Listing Rules do not require to be exercised by the Company in general meeting.

70.2 Without limiting the generality of clause 70.1, the Directors may exercise all the powers of the Company to:

(a) borrow money;

(b) charge any property or business of the Company or all or any of its uncalled capital;

(c) issue debentures or give any other security for a debt, liability or obligation of the Company or of any other person; and

(d) guarantee or to become liable for the payment of money or the performance of any obligation by or of any other person.

Proceedings of Directors

71. Directors' meetings

71.1 Any Director may call a meeting of the Directors.

71.2 A Directors' meeting must be called by giving not less than 48 hours' notice of such meeting to each Director, unless the Directors unanimously agree otherwise. The notice may be in writing or given using any technology consented to by all the Directors. The consent may be a standing one.

71.3 An accidental omission to send a notice of a meeting of Directors to any Director or the non-receipt of such a notice by any Director does not invalidate the proceedings, or any resolution passed, at the meeting.

71.4 Subject to the Corporations Act, a Directors' meeting may be held by the Directors communicating with each other by any technological means consented to by all the Directors. The consent may be a standing one.

71.5 The Directors need not all be physically present in the same place for a Directors' meeting to be held.

71.6 A Director who participates in a meeting held in accordance with clause 71.4 is taken to be present and entitled to vote at the meeting.

71.7 A Director can only withdraw his or her consent under clause 71.4 to the means of communication between Directors proposed for a Directors' meeting if the Director does so at least 48 hours before the meeting.

71.8 Clause 71.4 applies to meetings of Directors' committees as if all committee members were Directors.

71.9 The Directors may meet together, adjourn and regulate their meetings as they think fit.

71.10 A quorum for meetings of Directors may be fixed by the Directors and unless so fixed, is three Directors present. The quorum must be present at all times during the meeting.

71.11 Where a quorum cannot be established for the consideration of a particular matter at a meeting of Directors, one or more of the Directors may call a general meeting of Members to deal with the matter.

72. Decisions

72.1 Questions arising at a meeting of Directors are to be decided by a majority of votes of the Directors present and voting and, subject to the Corporations Act, each Director has one vote.

72.2 Subject to the ASX Listing Rules, in the case of an equality of votes, the chairperson of a meeting does not have a casting vote in addition to his or her deliberative vote.

72.3 An Alternate Director has one vote for each Director for whom he or she is an alternate. If an Alternate Director is a Director, he or she also has a vote as a Director.

73. Directors' interests

73.1 Where required by the Corporations Act, a Director must give the Directors notice of any material personal interest in a matter that relates to the affairs of the Company.

73.2 Subject to the provisions of this clause 73, a Director or a body or entity in which a Director has a direct or indirect interest may:

(a) enter into any agreement or arrangement with the Company;

(b) hold any office or place of profit other than as auditor in the Company; and

(c) act in a professional capacity other than as auditor for the Company,

and the Director or the body or entity can receive and keep beneficially any remuneration, profits or benefits under any agreement or arrangement with the Company or from holding an office or place of profit in or acting in a professional capacity with the Company.

73.3 The fact that a Director holds office as a director, and has fiduciary obligations arising out of that office:

(a) will not void or render voidable a contract made by a Director with the Company;

(b) will not void or render voidable a contract or arrangement entered into by or on behalf of the Company and in which the Director may have any interest; and

(c) will not require the Director to account to the Company for any profit realised by or under any contract or arrangement entered into by or on behalf of the Company and in which the Director may have any interest.

73.4 A Director may be or become a director or other officer of, or otherwise be interested in:

(a) any related body corporate of the company; or

(b) any other body corporate promoted by the Company or in which the Company may be interested as a vendor, shareholder or otherwise,

and is not accountable to the Company for any remuneration or other benefits received by the Director as a director or officer of, or from having an interest in, that body corporate.

73.5 A Director who has a material personal interest in a matter that is being considered at a Directors' meeting must not:

(a) be present while the matter is being considered at the meeting; or

(b) vote on the matter,

unless permitted to do so by the Corporations Act, in which case the Director may:

(c) be counted in determining whether or not a quorum is present at any meeting of Directors considering that contract or arrangement or proposed contract or arrangement;

(d) sign or countersign any document relating to that contract or arrangement or proposed contract or arrangement; and

(e) vote in respect of, or in respect of any matter arising out of, the contract or arrangement or proposed contract or arrangement.

73.6 A Director must give to the Company such information about the Shares or other securities in the Company in which the Director has a relevant interest and at the times that the Secretary requires, to enable the Company to comply with any disclosure obligations it has under the Corporations Act or the ASX Listing Rules.

74. Alternate Directors

74.1 A Director may, with the approval of the Directors, appoint one or more persons as his or her alternate.

74.2 An Alternate Director is entitled to notice of Directors' meetings while he or she is acting in that capacity and, if the appointor is not present at a meeting, is entitled to attend, be counted in a quorum and vote as a Director.

74.3 An Alternate Director is an officer of the Company and is not an agent of the appointor.

74.4 The provisions of this Constitution which apply to Directors also apply to Alternate Directors, except that Alternate Directors are not entitled in that capacity to any remuneration from the Company.

74.5 The appointment of an Alternate Director may be revoked at any time by the appointor or by the other Directors.

74.6 An Alternate Director's appointment ends automatically when his or her appointor ceases to be a Director.

74.7 Any appointment or revocation under this clause must be effected by written notice delivered to the Secretary.

74.8 An Alternate Director does not have an interest in a contract or arrangement or a material personal interest in a matter by reason only of the fact that his or her appointor has such an interest.

75. Remaining Directors

75.1 The Directors may act even if there are vacancies on the board.

75.2 If the number of Directors is not sufficient to constitute a quorum at a Directors' meeting, the Director or Directors may act only to:

(a) appoint a Director or Directors; or

(b) call a general meeting.

76. Chairperson

76.1 The Directors may elect a Director as chairperson of Directors' meetings and may determine the period for which the chairperson will hold office.

76.2 If no chairperson is elected or if the chairperson is not present at any Directors' meeting within 10 minutes after the time appointed for the meeting to begin, the Directors present must elect a Director to be chairperson of the meeting.

76.3 The Directors may elect a Director as deputy chairperson to act as chairperson in the chairperson's absence.

77. Delegation

77.1 The Directors may delegate any of their powers, other than those which by law must be dealt with by the Directors as a board, to:

(a) a committee or committees;

(b) a Director or Directors;

(c) an employee or employees of the Company; or

(d) any other person.

77.2 The Directors may at any time revoke any delegation of power under clause 77.1.

77.3 A committee may be authorised by the Directors to sub-delegate all or any of the powers for the time being vested in it.

77.4 Meetings of any committee of Directors will be governed by the provisions of this Constitution which deal with Directors' meetings so far as they are applicable and are not inconsistent with any directions of the Directors. The provisions apply as if each member was a Director.

78. Written resolutions

78.1 If:

(a) all the Directors who are eligible to vote on a resolution (other than any Director on leave of absence approved by the Directors, any Director who disqualifies himself or herself from considering the resolution in question and any Director who would be prohibited by the Act from voting on the resolution in question) sign or consent to a resolution set out or identified in a document; and

(b) the Directors who sign or consent to the resolution would have constituted a quorum at a meeting of Directors held to consider that resolution,

then a resolution in those terms is taken to have been passed by the Directors without a meeting. The resolution is passed when the last Director signs or provides their consent.

78.2 For the purposes of clause 78.1, separate copies of a document may be used for signing or the provision of consent by the Directors if the wording of the resolution is identical in each copy.

78.3 Any document referred to in this clause may be a document in the form of a facsimile transmission, electronic notification, or produced by other electronic or mechanical means.

78.4 A Director may consent to a resolution by:

(a) signing the document containing the resolution (or a copy of the document):

(b) sending the consent in any document produced under the name of the Director with the Director's authority;

(c) delivering to the Company's registered office a written document addressed to the company secretary or the chairperson of Directors, signifying assent to the resolution and either setting out its terms or otherwise clearly identifying the resolution;

(d) telephoning the secretary or the chairperson of Directors and signifying assent to the resolution and clearly identifying its terms; or

(e) any other means approved from time to time by the Directors.

78.5 If a resolution is taken to have been passed in accordance with this clause 78, the minutes must record that fact.

78.6 This clause 78 applies to meetings of Directors' committees as if all members of the committee were Directors.

78.7 Any document referred to in this clause 78 must be sent to every Director who is entitled to vote on the resolution.

79. Validity of acts of Directors

79.1 An act done by a Director is effective even if their appointment, or the continuance of their appointment, is invalid because the Company or Director did not comply with this Constitution or any provision of the Corporations Act.

79.2 Clause 79.1 does not deal with the question whether an effective act by a director:

(a) binds the company in its dealings with other people; or

(b) makes the company liable to another person.

80. Minutes

80.1 The Directors must cause minutes to be made of:

(a) the names of the Directors present at all Directors' meetings and meetings of Directors' committees;

(b) all proceedings and resolutions of general meetings, Directors' meetings and meetings of Directors' committees;

(c) all resolutions passed in accordance with clause 78;

(d) appointments of officers, but only if the Directors resolve that a minute of the appointment should be made; and

(e) all disclosures of interests made in accordance with the Corporations Act.

80.2 Minutes must be signed by the chairperson of the meeting or by the chairperson of a future meeting, and if so signed will be conclusive evidence of the matters stated in such minutes.

Executive Directors

81. Appointment

81.1 The Directors may appoint one Director to the office of Managing Director on such terms as they think fit.

81.2 The Directors may appoint one or more Directors to any other full-time executive position in the Company on such terms as they think fit.

81.3 A Director appointed under clause 81.1 or 81.2, and a Director (however appointed) occupying for the time being a full-time executive position in the Company or a related body corporate of the Company, is referred to in this Constitution as an Executive Director.

81.4 The Directors may, subject to the terms of the Executive Director's employment contract, suspend, remove or dismiss him or her from executive office and appoint another Director in that place.

81.5 If an Executive Director ceases to be a Director, his or her appointment as an Executive Director terminates automatically.

81.6 If an Executive Director ceases to hold an executive office in the Company, then, unless the Directors resolve otherwise, he or she also ceases to be a Director from the same date.

81.7 If an Executive Director is suspended from executive office of the Company or of a related body corporate of the Company, his or her duties and obligations as Director are suspended for the same period.

81.8 A Managing Director is not subject to retirement under clause 64 and is not to be taken into account in determining the rotation of retirement of Directors. Any other Executive Directors are subject to retirement under clause 64.

82. Powers of Executive Directors

82.1 The Directors may confer on an Executive Director any powers exercisable by the Directors, subject to any terms and restrictions determined by the Directors.

82.2 The Directors may authorise an Executive Director to sub-delegate all or any of the powers vested in him or her.

82.3 Any power conferred under this clause may be concurrent with but not to the exclusion of the Directors' powers.

82.4 The Directors may at any time withdraw or vary any of the powers conferred on an Executive Director.

Local management

83. General

83.1 The Directors may provide for the management and transaction of the affairs of the Company in any place and in such manner as they think fit.

83.2 Without limiting clause 83.1, the Directors may:

(a) establish local boards or agencies for managing any of the affairs of the Company in a specified place and appoint any persons to be members of those local boards or agencies; and

(b) delegate to any person appointed under clause 83.2(a) any of the powers, authorities and discretions which may be exercised by the Directors under this Constitution,

on any terms and subject to any conditions determined by the Directors.

83.3 The Directors may at any time revoke or vary any delegation under this clause 83.

84. Appointment of attorneys and agents

84.1 The Directors may from time to time by resolution or power of attorney appoint any person to be the attorney or agent of the Company:

(a) for the purposes;

(b) with the powers, authorities and discretions (not exceeding those exercisable by the Directors under this Constitution);

(c) for the period; and

(d) subject to the conditions,

determined by the Directors.

84.2 An appointment by the Directors of an attorney or agent of the Company may be made in favour of:

(a) any member of any local board established under this Constitution;

(b) any company;

(c) the members, directors, nominees or managers of any company or firm; or

(d) any fluctuating body of persons whether nominated directly or indirectly by the Directors.

84.3 A power of attorney may contain such provisions for the protection and convenience of persons dealing with an attorney as the Directors think fit.

84.4 An attorney or agent appointed under this clause 84 may be authorised by the Directors to sub-delegate all or any of the powers authorities and discretions for the time being vested in it.

Secretary

85. Secretary

85.1 There must be at least one Secretary of the Company appointed by the Directors on conditions determined by them.

85.2 The Secretary is entitled to attend all Directors' and general meetings.

85.3 The Directors may, subject to the terms of the Secretary's employment contract, suspend, remove or dismiss the Secretary.

Seals

86. Common Seal

86.1 If the Company has a Seal:

(a) the Directors must provide for the safe custody of the Seal;

(b) it must not be used except with the authority of the Directors or a Directors' committee authorised to permit use of the Seal;

(c) every document to which the Seal is affixed must be signed by a Director and be countersigned by another Director, the Secretary or another person appointed by the Directors to countersign the document; and

(d) the Directors may determine by resolution either generally or in any particular case that the signature of any Director or the Secretary to a document to which the Seal or a duplicate seal or certificate seal is affixed may be a facsimile applied to the document by specified mechanical means.

86.2 Without limiting the generality of section 127 or Part 2B.2 of the Corporations Act, the Company may execute a document if the Seal is fixed to the document and the fixing of the Seal is witnessed by any of the persons referred to in section 127(2)(a) or (b) of the Corporations Act.

87. Duplicate Seal

If the Company has a Seal, the Company may have one or more duplicate seals of the Seal each of which:

(a) must be a facsimile of the Seal with the addition on its face of the words **Duplicate Seal**; and

(b) must only be used with the authority of the Directors or a Directors' committee.

Inspection of records

88. Times for inspection

88.1 Except as otherwise required by the Corporations Act, the Directors may determine whether and to what extent, and at what times and places and under what conditions, the financial records and other documents of the Company or any of them will be open for inspection by Members other than Directors.

88.2 A Member other than a Director does not have the right to inspect any financial records or other documents of the Company unless the Member is authorised to do so by a court order or a resolution of the Directors.

Dividends and reserves

89. Dividends

The Directors may by resolution either:

(a) declare a dividend and may fix the amount, the time for and method of payment; or

(b) determine a dividend or interim dividend is payable and fix the amount and the time for and method of payment.

90. Amend resolution to pay dividend

If the Directors determine that a dividend or interim dividend is payable under clause 89(b), they may amend or revoke the resolution to pay the dividend or interim dividend before the record date notified to ASX for determining entitlements to that dividend or interim dividend.

91. No interest

Interest is not payable by the Company on a dividend.

92. Reserves

92.1 The Directors may set aside out of any amount available for distribution as a dividend such amounts by way of reserves as they think appropriate before declaring a dividend or determining to pay a dividend.

92.2 If the Directors resolve to declare a dividend or determine to pay a dividend, or state in the minutes of a meeting of Directors their intention to do so subject to the occurrence of a future event:

(a) by such resolution or minutes the Directors will be taken to have set aside the amount available for distribution as a dividend as a reserve; and

(b) such amount will not be appropriated in the accounts of the Company against losses or appropriated or applied for any other purpose, except pursuant to a resolution approved by the Directors.

92.3 In any case other than that referred to in clause 92.1 or clause 92.2, any amount available for distribution, including retained earnings or profits, will not be taken to be appropriated or applied against losses or for any other purpose except pursuant to a resolution of the Directors.

92.4 The Directors may apply the reserves for any purpose for which an amount available for distribution as a dividend may be properly applied.

92.5 Pending any application or appropriation of the reserves, the Directors may invest or use the reserves in the business of the Company or in other investments as they think fit.

92.6 The Directors may carry forward any undistributed amount available for distribution as a dividend without transferring them to a reserve.

93. Dividend entitlement

93.1 Subject to the rights of persons (if any) entitled to Shares with special rights as to dividends:

(a) all fully paid Shares on which any dividend is declared or paid, are entitled to participate in that dividend equally; and

(b) each partly paid Share is entitled to a fraction of the dividend declared or paid on a fully paid Share of the same class, equivalent to the proportion which the amount paid (not credited) on the Share bears to the total amounts paid and payable, whether or not called, (excluding amounts credited) on the Share.

93.2 An amount paid on a Share in advance of a call is not to be taken as paid for the purposes of clause 93.1.

93.3 Unless otherwise determined by the Directors, Shares rank for dividends from their date of allotment.

93.4 Subject to the ASX Settlement Operating Rules, the Directors may fix a record date for a dividend, with or without suspending the registration of transfers from that date.

93.5 Subject to the ASX Settlement Operating Rules, a dividend in respect of a Share must be paid to the person who is registered, or entitled to be registered, as the holder of the Share:

(a) where the Directors have fixed a record date in respect of the dividend, on that date; or

(b) where the Directors have not fixed a record date in respect of that dividend, on the date fixed for payment of the dividend,

(c) and a transfer of a Share that is not registered on or before that date is not effective, as against the Company, to pass any right to the dividend.

93.6 Subject to the Corporations Act and the ASX Settlement Operating Rules, a transfer of Shares registered after the record date notified to ASX for determining entitlements to a dividend paid or payable in respect of the transferred Shares, does not pass the right to that dividend.

94. Restricted securities

During a breach of the ASX Listing Rules relating to Shares which are Restricted Securities, or a breach of a restriction agreement, the holder of the relevant Restricted Securities is not entitled to any dividend in respect of those Restricted Securities.

95. Deductions from dividends

The Directors may deduct from a dividend payable to a Member all sums presently payable by the Member to the Company on account of calls or otherwise in relation to Shares in the Company.

96. Distribution of assets

96.1 The Directors may resolve that a dividend will be paid wholly or partly by the transfer or distribution of specific assets, including fully paid shares in, or debentures of, any other corporation.

96.2 If a difficulty arises in making a transfer or distribution of specific assets, the Directors may:

(a) deal with the difficulty as they consider expedient;

(b) fix the value of all or any part of the specific assets for the purposes of the distribution;

(c) determine that cash will be paid to any Members on the basis of the fixed value in order to adjust the rights of all the Members; and

(d) vest any such specific assets in trustees as the Directors consider expedient.

96.3 If a transfer or distribution of specific assets to a particular Member or Members is in the Directors opinion contrary to any law including any law applicable to the Member, or, in the Directors' opinion, impracticable, the Directors may make a cash payment to the Member or Members on the basis of the cash amount of the dividend instead of the transfer or distribution of specific assets.

96.4 Where the Company pays a dividend (interim or final) by the transfer of shares in another corporation:

(a) the Members receiving the dividend will be taken to have agreed to become members of that corporation; and

(b) each of those Members appoints the Company or any of the Directors as its agent to execute any transfer of shares or other document required to facilitate or effect the distribution and transfer of the shares to the Member.

97. Payment

97.1 Any dividend or other money payable in respect of Shares may be paid:

(a) by cheque sent through the mail directed to:

(i) by the address of the Member shown in the Register or to the address of the joint holder of Shares shown first in the Register; or

(ii) by an address which the Member has, or joint holders have, in writing notified the Company as the address to which dividends should be sent;

(b) by electronic funds transfer to an account with a bank or other financial institution nominated by the Member and acceptable to the Company; or

(c) by any other means determined by the Directors,

and is at the risk of the Member who is (or joint holders one of whom is) the intended recipient as soon as it is given, posted or transferred, as applicable.

97.2 Any joint holder may give an effectual receipt for any dividend or other money paid in respect of Shares held by holders jointly.

97.3 If the Directors decide that payments will be made by electronic transfer into an account (of a type approved by the Directors) nominated by a Member, but no such account is nominated by the Member or an electronic transfer into a nominated account is rejected or refunded, the Company may credit the amount payable to an account of the Company to be held until the Member nominates a valid account.

97.4 Where a Member does not have a registered address or the Company believes that a Member is not known at the Member's registered address, the Company may credit an amount payable in respect of the Member's Shares to an account of the Company to be held until the Member claims the amount payable or nominates an account into which a payment may be made.

97.5 An amount credited to an account under clause 97.3 or 97.4 is to be treated as having been paid to the Member at the time it is credited to that account. The Company will not be a trustee of the money and no interest will accrue on the money.

97.6 If a cheque for an amount payable under clause 97.1 is not presented for payment for 11 calendar months after issue or an amount is held in an account under clause 97.3 or 97.4 for 11 calendar months, the Directors may reinvest the amount, after deducting reasonable expenses, into Shares on behalf of, and in the name of, the Member concerned and may stop payment on the cheque. The Shares may be acquired on market or by way of new issue at a price the Directors accept is market price at the time. Any residual sum which arises from the reinvestment may be carried forward or donated to charity on behalf of the Member, as the Directors decide. The Company's liability to pay the relevant amount is discharged by an application under this clause 97.6. The Directors may do anything necessary or desirable (including executing any document) on behalf of the Member to effect the application of an amount under this clause 97.6. The Directors may determine other rules to regulate the operation of this clause 97.6 and may delegate their power under this clause 97.6 to any person.

98. Election to reinvest dividend

The Directors may:

(a) establish a plan under which Members or any class of Members may elect to reinvest cash dividends paid or payable by the Company by acquiring by way of issue or transfer (or both) Shares or other securities; and

(b) vary, suspend or terminate the arrangements established under clause 98(a).

99. Election to accept Shares in lieu of dividend

99.1 The Directors may resolve, in respect of any dividend which it is proposed to pay on any Shares, that holders of those Shares may elect to:

(a) forego their right to share in the proposed dividend or part of the proposed dividend; and

(b) instead receive an issue of Shares credited as fully paid or a transfer of fully paid Shares (or both).

99.2 If the Directors resolve to allow the election provided for in clause 99.1, each holder of Shares conferring a right to share in the proposed dividend may, by notice in writing to the Company given in such form and within such period as the Directors may decide, elect to:

(a) forego the dividend which otherwise would have been paid to the holder on such of the holder's Shares conferring a right to share in the proposed dividend as the holder specifies in the notice of election; and

(b) receive instead Shares to be issued or transferred (or both) to the holder credited as fully paid, on and subject to such terms and conditions as the Directors may determine.

99.3 Following the receipt of duly completed notices of election under clause 99.1(b), the Directors must:

(a) appropriate from any amount available for distribution to Members an amount equal to the aggregate issue price (if any) of the Shares to be issued credited as fully paid or transfer fully paid Shares to those holders of Shares who have given such notices of election; and

(b) apply the amount (if any) in paying up in full the number of Shares required to be so issued, or paying the purchase price of Shares required to be so transferred.

99.4 The Directors may rescind, vary or suspend a resolution of the Directors made under clause 99.1 and the arrangements implemented under the resolution.

99.5 The powers given to the Directors by this clause 99 are additional to the provisions for capitalisation of amounts available for distribution to Members provided for by this Constitution. If the Directors exercise their power to capitalise amounts available for distribution to Members under clause 100 then any Member who has elected to participate in arrangements established under this clause 99 is deemed, for the purpose of determining the Member's entitlement to share in the capitalised sum, not to have so elected.

100. Capitalisation of amounts available for distribution

100.1 The Directors may resolve:

(a) to capitalise any sum available for distribution to Members; and

(b) that:

(i) no Shares be issued and no amounts unpaid on Shares be paid up on capitalisation of the sum; or

(ii) the sum be applied in any of the ways mentioned in clause 100.2 for the benefit of Members in the proportions in which the members would have been entitled if the sum had been distributed by way of Dividend.

100.2 The ways in which a sum may be applied for the benefit of Members under clause 100.1(b)(ii) are:

(a) in paying up any amounts unpaid on Shares held or to be held by Members;

(b) in paying up in full unissued Shares or debentures to be issued to Members as fully paid; or

(c) partly as mentioned in clause 100.2(a) and partly as mentioned in clause 100.2(b).

100.3 To the extent necessary to adjust the rights of the Members among themselves, the Directors may:

(a) make cash payments in cases where Shares or debentures become issuable in fractions; and

(b) authorise any person to make, on behalf of all the Members entitled to a benefit on the capitalisation, an agreement with the Company providing for:

(i) the issue to them, credited as fully paid up, of any such further Shares or debentures; or

(ii) the payment by the Company on their behalf of the amount or any part of the amount remaining unpaid on their existing Shares by the application of their respective proportions of the sum resolved to be capitalised,

and any agreement made under the authority of clause 100.3(b) is effective and binding on all the Members concerned.

Notices

101. Service of notices

101.1 Notice may be given by the Company to any person who is entitled to notice under this Constitution by:

(a) serving it on the person; or

(b) sending it by post, courier, facsimile transmission or electronic notification to the person at the person's address shown in the Register or the address supplied by the person to the Company for sending notices to the person; or

(c) (except in the case of a notice of meeting of Members which is required to be given individually to each Member entitled to vote at the meeting and to each Director), advertising in one or more newspapers published daily (except on weekends) throughout Australia as determined by the Directors.

101.2 A notice sent by post or courier is taken to be served:

(a) by properly addressing, prepaying and posting or directing the delivery of the notice; and

(b) on the day after the day on which it was posted or given to the courier for delivery.

101.3 A notice sent by facsimile transmission or electronic notification is taken to be served:

(a) by properly addressing the facsimile transmission or electronic notification and transmitting it; and

(b) on the day of its transmission except if transmitted after 5.00pm in which case is taken to be served on the next day.

101.4 A notice given by advertisement is taken to be served on the date on which the advertisement first appears in a newspaper.

101.5 A notice may be served by the Company on joint holders under clause 101.1(a) or 101.1(b) by giving the notice to the joint holder whose name appears first in the Register.

101.6 Every person who is entitled to a Share by operation of law and who is not registered as the holder of the Share is taken to receive any notice served in accordance with this clause by advertisement or on that person from whom the first person derives title.

101.7 A Share certificate, cheque, warrant or other document may be delivered by the Company either personally or by sending it:

(a) in the case of a Member whose address recorded in the Register is not in Australia, by airmail post, facsimile transmission, electronic notification or in another way that ensures that it will be received quickly, as appropriate; and

(b) in any other case by ordinary post,

and is at the risk of the addressee as soon as it is given or posted.

A Member whose address recorded in the Register is not in Australia may specify in writing an address in Australia for the purposes of clause 101.

101.8 A certificate in writing signed by a Director, Secretary or other officer of the Company, or by any person that the Company has engaged to maintain the Register, that a document or its envelope or wrapper was addressed and stamped and was posted or given to a courier is conclusive evidence of posting or delivery by courier.

101.9 The signature to a written notice given by the Company may be written, printed or affixed in any other manner permitted by the Corporations Act.

101.10 All notices sent by post outside Australia must be sent by prepaid airmail post.

101.11 A notice sent by post, courier, facsimile transmission or electronic notification to a Member's address shown in the Register or the address supplied by the Member to the Company for the purpose of sending notices to the Member is deemed to have been served notwithstanding that the Member has died, whether or not the Company has notice of his or her death.

101.12 The provisions of this clause relating to notices apply, to the extent that they can and with any necessary changes, to sending any communication or document.

102. Persons entitled to notice

102.1 Notice of every general meeting must be given to:

(a) every Member;

(b) every Director and Alternate Director;

(c) ASX; and

(d) the Auditor.

102.2 No other person is entitled to receive notice of a general meeting.

Audit and financial records

103. Company to keep financial records

103.1 The Directors must cause the Company to keep written financial records and to prepare financial documents and reports in accordance with the requirements of the Corporations Act and the ASX Listing Rules.

103.2 The Directors must cause the financial records and financial documents of the Company to be audited in accordance with the requirements of the Corporations Act and the ASX Listing Rules.

Winding up

104. Winding up

104.1 Nothing in this clause prejudices the rights of the holders of Shares issued on special terms and conditions.

104.2 If the Company is wound up, the liquidator may, with the sanction of a special resolution of the Company:

(a) divide among the Members in kind all or any of the Company's assets; and

(b) for that purpose, determine how he or she will carry out the division between the different classes of Members,

but may not require a Member to accept any Shares or other securities in respect of which there is any liability.

104.3 The liquidator may, with the sanction of a special resolution of the Company, vest all or any of the Company's assets in a trustee on trusts determined by the liquidator for the benefit of the contributories.

Indemnity

105. Indemnity

105.1 To the extent permitted by law and subject to the restrictions in section 199A of the Corporations Act and any other applicable law, the Company indemnifies every person who is or has been an officer of the Company against any liability (other than for legal costs) incurred by that person as an officer of the Company (including liabilities incurred by the officer as a director or secretary of a subsidiary of the Company where the Company requested the officer to accept that appointment).

105.2 To the extent permitted by law and subject to the restrictions in section 199A of the Corporations Act and any other applicable law, the Company indemnifies every person who is or has been an officer of the Company against reasonable legal costs incurred in defending an action for a liability incurred or allegedly incurred by that person as an officer of the Company (including such legal costs incurred by the officer as an officer of a subsidiary of the Company where the Company requested the officer to accept that appointment).

105.3 The amount of any indemnity payable under clause 105.1 or 105.2 will include an additional amount (**GST Amount**) equal to any GST payable by the officer being indemnified (**Indemnified Officer**) in connection with the indemnity (less the amount of any input tax credit claimable by the Indemnified Officer in connection with the indemnity). Payment of any indemnity which includes a GST Amount is conditional upon the Indemnified Officer providing the Company with a GST tax invoice for the GST Amount.

105.4 The Directors may agree to advance to an officer an amount which it might otherwise be liable to pay to the officer under clause 105.1 on such terms as the Directors' think fit but which are consistent with this clause, pending the outcome of any findings of a relevant court or tribunal which would have a bearing on whether the Company is in fact liable to indemnify the officer under clause 105.1. If after the Company makes the advance, the Directors form the view that the Company is not liable to indemnify the officer, the Company may recover any advance from the officer as a debt due by the officer to the Company.

105.5 The Company may enter into a deed with any officer (including without limitation any officer or other person who is director or secretary of a subsidiary of the Company where the Company requested the officer or other person to accept that appointment) to give effect to the rights conferred by this clause 105 or the exercise of a discretion under this clause 105 on such terms as the Directors think fit which are not inconsistent with this clause 105.

105.6 For the purposes of this clause 105, **officer** means:

(a) a Director;

(b) a Secretary;

(c) an officer as defined under the Corporations Act; or

(d) full-time employees of the Company as determined by the Directors.

106. Shareholder disclosure

If a Member has entered into any arrangement restricting the transfer or other disposal of Shares and those arrangements are of the nature of arrangements which the Company is required to disclose under the ASX Listing Rules, then the Member must provide to the Company such information that the Company requires and within the time that the Company requires, to comply with the Company's disclosure obligations.

ASX Listing Rules

107. ASX Listing Rules

107.1 If, and for such time only as, the Company is Listed, the following rules apply.

(a) Notwithstanding anything contained in this Constitution, if the ASX Listing Rules prohibit an act being done, the act shall not be done.

(b) Nothing contained in this Constitution prevents an act being done that the ASX Listing Rules require to be done.

(c) If the ASX Listing Rules require an act to be done or not to be done, authority is given for that act to be done or not to be done (as the case may be).

(d) If the ASX Listing Rules require this Constitution to contain a provision and it does not contain such a provision, this Constitution is deemed to contain that provision.

(e) If the ASX Listing Rules require this Constitution not to contain a provision and it contains such a provision, this Constitution is deemed not to contain that provision.

(f) If any provision of this Constitution is or becomes inconsistent with the ASX Listing Rules, this Constitution is deemed not to contain that provision to the extent of the inconsistency.

107.2 For the avoidance of doubt, the rules set out in clause 107.1 above have no operation or effect unless and until the Company is Listed and those rules will cease to have any operation or effect at such time, if any, as the Company is no longer Listed.

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

Execution Copy CONFIDENTIAL

Supplementary Agreement for Additional License

This Supplementary Agreement (this "Agreement") is made and entered into as of 12th day of October, 2018 by and between JCR Pharmaceuticals Co., Ltd., a corporation duly organized and existing under the laws of Japan having its office at 3-19 Kasuga-cho, Ashiya, Hyogo 659-0021, Japan ("JCR") and Mesoblast International Sarl, a company duly organized and existing under the laws of Switzerland having its office at Route de Pre-Bois 20 c/o Accounting & Management Service SA 1217 Meyrin, Switzerland and Mesoblast Limited, a company duly organized and existing under the laws of Australia having its office at Level 3955 Collins Street, Melbourne, Victoria 3000, Australia (collectively "Mesoblast").

BACKGROUND

Whereas, JCR and Osiris and Osiris Acquisition II, Inc. ("Osiris") were parties to a License Agreement dated August 26, 2003, as amended by Amendment 1 to License Agreement as of June 27, 2005 (collectively, the "First License Agreement"), wherein JCR has an exclusive license in Japan to develop and market certain medical products for specified fields under certain Osiris' patents and technical information,

Whereas, Mesoblast has acquired from Osiris the First License Agreement, together with substantially all of Osiris' business, assets and technical information and patents to which the First License Agreement relates,

Whereas, JCR has successfully launched commercial sale in Japan of certain medical product for graft versus host disease known as TEMCELL® HS Inj. under the First License Agreement, which product consists of human mesenchymal stem cells derived from bone marrow, and

Whereas, JCR is willing to obtain an additional license to develop and commercialize said product for the therapeutic use for epidermolysis bullosa,

NOW, THEREFORE, in consideration of mutual covenants and other good and valuable consideration, the Parties hereto agree as follows:

Section 1. Definitions
The words, wherever appear in this Agreement, shall have the following meaning:

1.1 "Affiliate", "Person", "Product", "Sublicensee", "Territory" and "Third Party" shall have the respective meaning as defined in Section 1 of the First License Agreement.

1.2 "Additional Field" means experimental, diagnostic and therapeutic use of JCR Product or Mesoblast Product for epidermolysis bullosa.

1.3 "JCR Product" means that certain Product known as TEMCELL® HS Inj., that is approved and commercialized as of the date hereof for graft versus host disease in the Territory, and any modification thereof, which consists of mesenchymal stem cells acquired and cultivated from human bone marrow.

1.4 "JCR Know-How" means scientific or technical information and other data (including safety and/or efficacy data) related to the JCR Product for use in the Additional Field, which JCR has a right to grant licenses to others without breaching the terms of an agreement or contract with any Third Party [***] for the Additional Field.

1.5 "JCR Safety Data" means post-marketing safety data of JCR Product as now or hereafter may be obtained by JCR, which JCR has a right to disclose and make available to others without breaching the terms of an agreement or contract with any Third Party.

1.6 “Mesoblast Patents” means such patents filed or issued in Japan, owned and controlled by Mesoblast which have valid claims covering the Additional Field, including those patent rights described in Appendix A hereto.

1.7 “Mesoblast Product” means that certain Product or Products (other than JCR Product) developed, owned, or controlled by Mesoblast or its Affiliates and any modification thereof, which consists of human mesenchymal stem cells derived from bone marrow including, without limitation, that Product known as MSC-100-IV (remestemcel-L).

1.8 “Net Sales” means (a) with respect to JCR Product sold for Additional Field in the Territory, the gross amount invoiced by JCR, its Affiliates, Sublicensees or co-marketers for such JCR Product and (b) with respect to Mesoblast Product the gross amount invoiced by Mesoblast, its Affiliates, sublicensees or co-marketers for such Mesoblast Product less in each case (a) and (b) deductions for: (i) trade, quantity and/or cash discounts, allowances and rebates actually allowed or given; (ii) freight, shipping, insurance and other transportation expenses (if separately identified in such invoice); (iii) credits or refunds actually allowed for rejections or defects of such Product, outdated or returned Product, or because of rebates or retroactive price reductions; (iv) sales, value added, excise taxes, tariffs and duties, and other taxes directly related to the sale, to the extent that such items are separately identified in such invoice and are paid by the purchaser of Product.

1.9 “Osiris Know-How” means any proprietary and non-public technical information, data and know-how originally developed by Osiris and later assigned to Mesoblast which are inextricably incorporated or adopted into JCR’s current manufacturing process of JCR Product.

1.10 “Party” means Mesoblast or JCR and, when used in the plural, means Mesoblast and JCR.

1.11“Regulatory Approval” means an official marketing approval which Minister of Health, Labour and Welfare may issue for commercial sale of JCR Product for Additional Field in the Territory (including any pricing or other approvals necessary to initiate commercial sales thereof).

Section 2. Grant of Licenses

2.1 Mesoblast hereby grants to JCR and its Affiliates an exclusive royalty-bearing license in the Territory, with the right to grant sublicenses, under the Mesoblast Patents and Osiris Know-How in order to develop, register and to obtain Regulatory Approval, use, make, have made, import, offer to sell, sell and have sold JCR Products for use in the Additional Field in the Territory.

2.2 JCR hereby grants to Mesoblast and its Affiliates a non-exclusive license and right to utilize JCR Know-How in order to develop, register, use, make, have made, import, export, offer to sell, sell and have sold Mesoblast Product outside of the Territory as well as a non-exclusive license and right to utilize JCR Safety Data for regulatory purpose in relation to Mesoblast Product outside of the Territory, provided that (i) disclosure and transmittal of JCR Know-How to Mesoblast shall be made at such time and in such manner as JCR may from time to time deem reasonable but no less often than as otherwise required under Section 3.4 (Reporting) of the First License Agreement and (ii) provision of JCR Safety Data shall be made in accordance with the Safety Data Exchange Agreement (“SDEA”) to be executed by the parties contemporaneously herewith. The foregoing licenses and rights (a) shall be royalty-free and fully-paid for practice in U.S.A., and (b) shall be subject to a running royalty at the rate of [***] of Net Sales of Mesoblast Product labeled and sold for the Additional Field in any other country outside of both the Territory and the U.S.A, which running royalty shall be payable to JCR in a manner consistent with the logistics set forth in Section 3 with respect to JCR’s payment of its royalty to Mesoblast on a *mutatis mutandis* basis and accrue country by country during the [***] year period beginning from the date of first commercial sale of any Mesoblast Product for the Additional Field in such country outside of both the Territory and the U.S.A.

2.3 JCR Know-How and JCR Safety Data shall be transmitted "AS IS" to Mesoblast in Japanese language. Except as otherwise expressly provided to the contrary in the SDEA, all costs for translation to another language shall be borne by Mesoblast.

Section 3. Royalties

3.1 In consideration of the license granted under Section 2.1 above, JCR, contingent upon the Regulatory Approval having been obtained with respect to the JCR Product for the Additional Field, shall pay to Mesoblast the running royalty equal to [***] of the Net Sales of the JCR Product sold by JCR, its Affiliates, co-marketers and Sublicensees for Additional Field in the Territory during the Term of this Agreement.

Notwithstanding the above, in the event that a Third Party sells any products similar to or competitive with JCR Product for the Additional Field in the Territory that do not infringe any of Mesoblast Patents in the Territory and such sales are at least [***] of Net Sales, the Parties shall negotiate to reduce the percentage amount of royalties payable to Mesoblast.

3.2 All royalty payments shall be paid quarterly within sixty (60) days of the end of each calendar quarter. Each such payment shall be accompanied by a statement of the amount of gross sales of the JCR Product, the calculation of Net Sales, the number of units of the JCR Product sold during such quarter, the amount of royalties due on such Net Sales of the JCR Product for the Additional Field, the conversion rates used in converting to United States Dollars and any other information reasonably requested by Mesoblast to enable Mesoblast to determine the amount owed hereunder.

3.3 JCR shall remit all payments required under this Agreement by wire transfer to the bank account as designated by Mesoblast from time to time in United States Dollars. Whenever for the purpose of calculating royalties from foreign currency shall be required, such conversion shall be at the rate of exchange of the last business day of the applicable calendar quarter as published by a reputable bank in Japan.

Section 4. Records and Inspection

4.1 JCR and its Affiliates and its Sublicensees and co-marketers shall keep complete and accurate records pertaining to the sale of JCR Products for Additional Field in the Territory and covering all transactions from which Net Sales are derived for a period of three calendar years after the year in which sales occurred, and in sufficient detail to permit Mesoblast to confirm the accuracy of royalty payments due hereunder.

4.2 At the request and expense (except as provided below) of Mesoblast, JCR and its Affiliates and its Sublicensees and co-marketers shall permit an independent certified public accountant appointed by Mesoblast and reasonably acceptable to JCR, at reasonable times and upon reasonable notice, to examine those records and all other material documents relating to or relevant to Net Sales in the possession or control of JCR and/or its Affiliates or its Sublicensees and co-marketers, for a period of three years after such royalties have accrued. Said accountant shall not disclose to Mesoblast any information other than information relating to said reports, royalties and payments. If, as a result of any inspection of the books and records of JCR or its Affiliates or its Sublicensees and co-marketers it is shown that JCR's royalty payments under this Agreement were less than the amount which should have been paid, then JCR shall make all payments required to be made to eliminate any discrepancy revealed by said inspection within forty-five (45) days after Mesoblast's demand therefor. Furthermore if the royalty payment was less than the amount which should have been paid by an amount in excess of [***] of the royalty payment actually made during the period in question, JCR shall also reimburse Mesoblast for the cost of such inspection.

4.3 Mesoblast shall undertake the reciprocal obligations as those JCR bears and JCR shall have the reciprocal rights as those Mesoblast holds as stipulated in Sections 4.1 and 4.2 above, with respect to the royalty payable to JCR under Section 2.2 hereof.

Section 5. Confidentiality

5.1 Mesoblast shall be bound by the same confidentiality obligations as those stipulated on its part to be performed or observed in Section 9 of the First License Agreement, which obligations shall be applicable to JCR Know-How and JCR Safety Data. For clarity, Mesoblast may use and disclose the JCR Know-How and JCR Safety Data to the extent reasonably necessary to exercise the license set forth in Section 2.2, but subject to reasonable protective measures and safeguards under the circumstances of such use or disclosure.

Section 6. Term and Termination

6.1 This Agreement shall take effect upon the date of execution and it shall continue to be in full force and effect until the later of (a) 24th of February, 2031 or (b) tenth anniversary of the first commercial sale of JCR Product for Additional Field in the Territory. It is understood that expiration or termination of this Agreement shall not affect the license or right hitherto granted to Mesoblast under Section 2.2 hereinabove, provided that Mesoblast shall perform and observe any obligations on its part to be performed or observed under this Agreement.

6.2 Sections 10.2 through 10.7 of the First License Agreement shall be deemed to have been incorporated into this Agreement by reference, provided that the term, “Osiris” shall be read as “Mesoblast”, the term, “Product” shall read as “JCR Product” and the term, “Field” shall be read as “Additional Field” and the cure period in Section 10.2 shall remain unchanged.

Section 7. Miscellaneous

7.1 Sections 7 and 8, Section 11, Sections 12.1 through 12.3, Sections 12.5 through 12.10, and Sections 12.14 through 12.16 of the First License Agreement shall be deemed to have been incorporated into this Agreement by reference, provided that the term, “Osiris” shall be read as “Mesoblast” and the term, “Product” shall be read as “JCR Product”.

7.2 This Agreement constitutes the entire agreement between the Parties hereto with respect to the license of Mesoblast Patents and Osiris Know-How for Additional Field and other subject matter stipulated herein, which shall supersede all previous agreements and discussions between the Parties hereto, whether written or oral.

7.3 The First License Agreement, which shall be applicable only to Field 1 and Field 2 defined therein, shall remain valid and unchanged.

7.4 [***].

Signatures appear on following page

IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed as of the date hereof by a duly authorized representative.

For and on behalf of
Mesoblast International Sarl

By: _____
Name: _____
Title: _____
Date: _____

For and on behalf of
Mesoblast Limited

By: _____
Name: _____
Title: _____
Date: _____

For and on behalf of
JCR Pharmaceuticals, Co., Ltd.

By: _____
Name: _____
Title: _____
Date: _____

Appendix A

Mesoblast Patents

[***]

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

Execution Version

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of January 11, 2019 (the "**Amendment Effective Date**"), is made by and among Mesoblast Limited ACN 109 431 870, an Australian listed public company ("**Parent**" and "**Guarantor**"), Mesoblast UK Limited, a company incorporated in England and Wales with registered number 07596260 whose registered address is 5 New Street Square, London, EC4A 3TW, United Kingdom ("**Mesoblast UK**"), Mesoblast, Inc., a Delaware corporation ("**Mesoblast USA**"), Mesoblast International (UK) Limited, a company incorporated in England and Wales with registered number 09630007 whose registered address is 5 New Street Square, London, EC4A 3TW, United Kingdom ("**Mesoblast Intl UK**"), Mesoblast International Sàrl, a company organized under the laws of Switzerland ("**Mesoblast SUI**") and each of Parent's Subsidiaries that delivers a Joinder Agreement pursuant to Section 7.13 of the Loan and Security Agreement (together with Mesoblast USA, Mesoblast UK, Mesoblast Intl UK and Mesoblast SUI, collectively referred to as the "**Borrowers**" and each, a "**Borrower**"), the several banks and other financial institutions or entities from time to time parties to the Loan and Security Agreement (collectively, referred to as "**Lender**") and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and Lender (in such capacity, the "**Agent**").

The Loan Parties, Lender and Agent are parties to a Loan and Security Agreement dated as of March 6, 2018 (as amended, restated, modified or otherwise supplemented from time to time, the "**Loan and Security Agreement**"). The Loan Parties have requested that Lender agree to certain amendments to the Loan and Security Agreement. Lender has agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Amendments to the Loan and Security Agreement. The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:

(a) New Definitions. The following definitions are added to Section 1.1 in their proper alphabetical order:

"First Amendment" means that certain First Amendment to Loan and Security Agreement dated as of the First Amendment Effective Date among the Loan Parties, Agent and Lender, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"First Amendment Effective Date" means January 11, 2019.

"Performance Milestone IV" means satisfaction of each of the following events: (a) [***]; (b) the [***]; and (c) [***] or [***] has publicly announced that [***] has [***].

"Phase 3 CLBP Study" means the Phase 3 study of MPC-06-ID assessing the safety and efficacy of rexlemestrocel-L (alone or combined with hyaluronic acid) in patients with chronic low back pain associated with moderate radiographic degenerative changes of a disc (CLBP), clinicaltrials.gov identifier NCT02412735.

"Remestemcel-L" means the product candidate MSC-100-IV (remestemcel-L) for the treatment of pediatric patients with steroid-refractory acute Graft versus Host Disease (GvHD).

"Three Months Liquidity" means, as of a date of determination, the sum of (x) the prior three (3) months (reported as of the end of a calendar month) of Net Operating Cash Burn (as defined and reported in Borrower's Financial Statements provided to Agent under Section 7.1(a) and calculated in a manner consistent with "Net Operating Cash Burn" as reported by Borrower in such Financial Statements delivered as of the First Amendment Effective Date) *plus* (y) the prior three (3) months (reported as of the end of a calendar month) of Net Investing Cash Burn (as defined and reported in Borrower's Financial Statements provided to Agent under Section 7.1(a) and calculated in a manner consistent with "Net Investing Cash Burn" as reported by Borrower in such Financial Statements delivered as of the First Amendment Effective Date), *excluding*, the effect of extraordinary, non-recurring, not regularly scheduled or onetime proceeds, amounts and payments (including but not limited to upfront or milestone proceeds and payments in connection with acquisitions, etc.) permitted under this Agreement; which calculation of "Three Months Liquidity" is subject to verification by Agent in its reasonable discretion (including supporting documentation reasonably requested by Agent).

"Tranche 3A" has the meaning set forth in Section 2.2(a)(iii).

"Tranche 3B" has the meaning set forth in Section 2.2(a)(iii).

"Unrestricted Cash" means Cash held by the Loan Parties in account(s) subject to an Account Control Agreement in favor of Agent.

(b) Amended and Restated Definitions. The following definitions are hereby amended and restated as follows:

" "Amortization Date" means October 1, 2019; provided however, if the Interest Only Extension Conditions 1 are satisfied, then April 1, 2020; provided further, if the Interest Only Extension Conditions 2 are satisfied, then October 1, 2020; and, provided further, if the Interest Only Extension Conditions 2 Grace Period is granted and clauses (a), (b), (c)(y)(ii), (d), and (e) of the Interest Only Extension Conditions 2 are satisfied, at Agent's reasonable discretion, the Amortization Date shall be extended in monthly increments (not to exceed, in the aggregate, the number of days granted for such Interest Only Extension Conditions 2 Grace Period)."

"Interest Only Extension Conditions 1" means satisfaction of each of the following:

(a) no Event of Default shall have occurred and is continuing;

(b) [***] has [***];

(c) [***] or [***] has publicly announced [***], subject to reasonable verification by Agent (including supporting documentation reasonably requested by Agent);

(d) [***] has [***], in each case after [***] but prior to [***], subject to reasonable verification by Agent (including supporting documentation reasonably requested by Agent); and

(e) if, and only if, [***] has occurred prior to [***]."

"Interest Only Extension Conditions 2" means satisfaction of each of the following:

(a) no Event of Default shall have occurred and is continuing;

(b) the Interest Only Extension Conditions 1 shall have been satisfied;

(c) either (x) [***], or (y) on or prior to [***], (i) [***], and (ii) if, and only if, a [***], at Agent's reasonable discretion, Borrower may have up to an additional [***] to satisfy the requirements of this clause (c)(y) (the "Interest Only Extension Conditions 2 Grace Period");

(d) [***] has [***], in each case as permitted under this Agreement, so long as at least [***], in each case after [***] but prior to [***], inclusive of [***], subject to reasonable verification by Agent (including supporting documentation reasonably requested by Agent); and

(e) Agent has received evidence satisfactory to Agent that [***]."

(c) Section 2.2(a)(iii). Section 2.2(a)(iii) is hereby amended and restated as follows:

"*Tranche 3*. (X) Subject to the terms and conditions of this Agreement and the First Amendment, Lender will severally (and not jointly) make in an amount not to exceed its respective Term Commitment, and Borrower agrees to draw, a Term Loan Advance of Fifteen Million Dollars ($15,000,000) on the First Amendment Effective Date ("Tranche 3A"). (Y) Subject to the terms and conditions of this Agreement and conditioned on [***], on or before [***], Borrower may request one or more additional Term Loan Advances in an aggregate principal amount up to Twenty-Five Million Dollars ($25,000,000) ("Tranche 3B" and, together with Tranche 3A, "Tranche 3") in minimum increments of Five Million Dollars ($5,000,000)."

(d) Section 7.14. Section 7.14 is hereby amended and restated as follows:

"Financial Covenant (Minimum Cash). At all times following the funding of Tranche 3A and prior to achievement of Performance Milestone IV, the Loan Parties shall maintain Unrestricted Cash plus the amount of the Loan Parties' accounts payable under GAAP or IFRS not paid after the 120th day following the invoice date for such accounts payable in an amount greater than or equal to Three Months Liquidity, subject to reasonable verification by Agent (including supporting documentation requested by Agent). Borrower shall provide Agent evidence of compliance with this Section 7.14 in each Compliance Certificate and upon request in form and substance reasonably acceptable to Agent and supporting documentation reasonably requested by Agent."

(e) Section 9.2. Section 9.2 is hereby amended and restated as follows:

"Any Loan Party breaches or defaults in the performance of any covenant or Secured Obligation under this Agreement, or any of the other Loan Documents, and (a) with respect to a default under any covenant under this Agreement (other than under Sections 2.6 (solely with respect to prepayments relating to the [***]), 4.4, 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.11, 7.12, 7.14, 7.15, 7.17, 7.18, 7.20, 7.21, 7.22 or 7.23) or any other Loan Document, such default continues for more than fifteen (15) days after the earlier of the date on which (i) Agent or Lender has given notice of such default to the Loan Parties and (ii) any Loan Party has actual knowledge of such default or (b) with respect to a default under any of Sections 2.6 (solely with respect to prepayments relating to the [***]), 4.4, 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.11, 7.12, 7.14, 7.15, 7.17, 7.18, 7.20, 7.21, 7.22 or 7.23, the occurrence of such default; or"

(f) Compliance Certificate. Exhibit F of the Loan and Security Agreement, the Compliance Certificate, is hereby amended and restated in its entirety with Annex A hereto.

(g) Commitments. Schedule 1.1 of the Loan and Security Agreement, the Schedule of Commitments, is hereby amended and restated in its entirety with Annex B hereto.

(h) References Within Loan and Security Agreement. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. The Loan Parties shall have paid (i) [***], which fee has been paid to Agent as of the Amendment Effective Date, (ii) the Tranche 3 Facility Charge applicable to Tranche 3A, (iii) all invoiced costs and expenses then due in accordance with Section 5(e), and (iv) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Agent shall have received this Amendment, executed by Agent, Lender, and the Loan Parties.

(c) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

(d) **Officer's Certificates**. Agent shall have received:

(i) certified copies of resolutions (or, in the case of Parent, an extract thereof) of each of the Loan Parties' (other than Mesoblast SUI) respective Boards of Directors (and shareholder, with respect to Mesoblast UK and Mesoblast Intl UK) evidencing (i) approval of the Term Loan Advance and other transactions evidenced by this Amendment; (ii) authorizing a specified person or persons to execute this Amendment; (iii) authorizing a specified person or persons, on its behalf, to sign and/or dispatch all documents and notices (including, if relevant, any Advance Request or other relevant notice) to be signed and/or dispatched by it under or in connection with this Amendment; and (iv) (with respect to Parent) (A) including a statement of corporate benefit; (B) acknowledging that the Board of Directors are acting for a proper purpose and that this Amendment is in the best interests of that Loan Party and for its commercial benefit; and (C) acknowledging that the relevant Loan Party was solvent and there were reasonable grounds to expect that the relevant Loan Party would continue to be solvent after executing and complying with its obligations under the Loan Documents (including the Loan and Security Agreement, as amended by this Amendment);

(ii) certificates (as customary in the jurisdiction of Mesoblast UK and Mesoblast Intl UK and containing specimen signatures) of a director confirming that guaranteeing or securing the Term Loan Advance would not cause any guaranteeing or similar limit binding on Mesoblast UK and Mesoblast Intl UK to be exceeded and certifying that each copy document relating to it specified in this Section, is correct, complete and the original of such copy document, is in full force and effect and has not been amended or superseded as at a date no earlier than the Amendment Effective Date;

(iii) in respect to any UK PSC Loan Party, a copy of the PSC Register together with confirmation from an authorized officer that no "warning notice" or "restrictions notice" (in each case as defined in Schedule 1B of the Companies Act 2006) has been issued in respect of the shares pledged as Collateral and no circumstances exist on the Amendment Effective Date which entitle that UK PSC Loan Party to issue any such notice;

(iv) verification certificates (as customary in the jurisdiction of Parent and containing specimen signatures) of a director confirming that (i) there will be no contravention of, and neither is it prohibited by, Chapter 2E or Chapter 2J.3 of the Australian Corporations Act from entering into and delivering this Amendment and performing any of its obligations under this Amendment; (ii) the relevant Loan Party is solvent and there are reasonable grounds to expect that the relevant Loan Party would continue to be solvent after executing and complying with its obligations under the Loan Documents (including the Loan and Security Agreement, as amended by this Amendment); (iii) guaranteeing or securing the Term Loan Advance would not cause any guaranteeing or similar limit binding on it to be exceeded; and (iv) each copy document relating to it specified in this Section 4, is correct, complete and the original of such copy document, is in full force and effect and has not been amended or superseded as at a date no earlier than the Amendment Effective Date;

(v) certificates (as customary in the jurisdiction of Mesoblast SUI and Mesoblast USA) containing specimen signatures of the authorized person or persons who may, on such Loan Party's behalf, sign and/or dispatch all documents and notices under or in connection with the Loan Documents;

(vi) certified copies of the constitutional documents and the bylaws, as amended through the Amendment Effective Date, of each Loan Party in form and substance satisfactory to Agent; and

(vii) certified copies of certificates of good standing (or foreign equivalent or insolvency search, as applicable) for each Loan Party from its jurisdiction of organization and similar certificates from all other jurisdictions in which it does business and where the failure to be qualified could have a Material Adverse Effect.

SECTION 4 Representations and Warranties. To induce Agent and Lender to enter into this Amendment, each Loan Party hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; *provided*, *however*, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; (b) that there has not been and there does not exist a Material Adverse Effect; and (c) other than as updated on the Perfection Certificate to be delivered to Agent within fifteen (15) Business Days of the Amendment Effective Date as set forth in Section 6 below, that the information included in the Perfection Certificate delivered to Agent on the Closing Date remains true and correct. For the purposes of this Section 4, (i) each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true, correct and complete as of such earlier date).

SECTION 5 Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation; No Novation**.

(i) Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. Lender's and Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future.

(ii) Each Loan Party hereby expressly reaffirms the grant of security under Section 3.1 of the Loan and Security Agreement, the English Security Documents, the Swiss Security Documents, the Pledge Agreement, the IP Security Agreement and any other Loan Document to which that Loan Party is a party and hereby expressly reaffirms that, with effect from (and including) the Amendment Effective Date, such grant of security in the Collateral: (x) remains in full force and effect notwithstanding the amendments expressly referenced herein; and (y) secures all Secured Obligations under the Loan and Security Agreement, as amended by this Amendment, and the other Loan Documents, including without limitation any Term Loan Advances funded on or after the Amendment Effective Date, as of the date hereof.

(iii) Each Loan Party hereby (x) consents to the execution and delivery of this Amendment and the consummation of the transactions described herein; (y) expressly ratifies and confirms that, with effect from (and including) the Amendment Effective Date, the guaranty set out in Section 12 of the Loan and Security Agreement and, solely with respect to Parent, the guarantee granted under clause 12 of the Australian law governed Security Trust Deed (collectively the "guaranty") shall remain in full force and effect notwithstanding the amendments expressly referenced herein with respect to the Secured Obligations now or hereafter outstanding under the Loan and Security Agreement, as amended by this Amendment, and each other Loan Document; and (z) expressly ratifies and confirms that the guaranty extends to all new obligations assumed by any Loan Party under the Loan Documents as amended by this Amendment, (including but not limited to any new obligations under the Loan and Security Agreement, as amended by this Amendment), subject only to the guaranty limitations set out in Section 12 of the amended and restated Loan and Security Agreement and, solely with respect to Parent, the guarantee limitations set out under clause 12 of the Australian law governed Security Trust Deed. Each Loan Party acknowledges that, notwithstanding anything to the contrary contained herein or in any other document evidencing any Secured Obligations to Agent and Lender or any other Secured Obligations, or any actions now or hereafter taken by Agent and Lender with respect to any Secured Obligations, such guaranty (i) is and shall continue to be a primary obligation of such Guarantor and such other Loan Party, (ii) is and shall continue to be an absolute, unconditional, continuing and irrevocable guaranty of payment, and (iii) is and shall continue to be in full force and effect in accordance with its terms. Nothing contained herein to the contrary shall release, discharge, modify, change or affect the original liability of Guarantor and such other Loan Party under such guaranty.

(iv) This Amendment is not a novation and the terms and conditions of this Amendment shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. Nothing in this Amendment is intended, or shall be construed, to constitute an accord and satisfaction of any Loan Party's Secured Obligations under or in connection with the Loan and Security Agreement and any other Loan Document or to modify, affect or impair the perfection or continuity of Agent's security interest in, (on behalf of itself and Lender) security titles to or other liens on any Collateral for the Secured Obligations.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) **Release**. In consideration of the agreements of Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each Loan Party, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Agent and each Lender, and their respective successors and assigns, and their respective present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lender and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which each Loan Party, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan and Security Agreement, or any of the other Loan Documents or transactions thereunder or related thereto (collectively, the "**Released Claims**"). Each Loan Party understands, acknowledges and agrees that the release set forth above (the "**Release**") may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Each Loan Party agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above. Without limiting the generality of the foregoing, each Loan Party hereby waives the provisions of any statute or doctrine that prevents a general release from extending to claims unknown by the releasing party, including, without limitation, California Civil Code Section 1542, which provides:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

Each Loan Party acknowledges that the agreements in this Section are intended to be in full satisfaction of all or any alleged injuries or damages arising in connection with the Released Claims. Each Loan Party acknowledges that the Release constitutes a material inducement to Agent and Lender to enter into this Amendment and that Agent and Lender would not have done so but for Agent's and Lender's expectation that the Release is valid and enforceable in all events.

(d) **No Reliance**. The Loan Parties hereby acknowledge and confirm to Agent and Lender that the Loan Parties are executing this Amendment on the basis of their own investigation and for their own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) **Costs and Expenses**. The Loan Parties agree to pay to Agent as required under the Loan Agreement, after giving effect to this Amendment, the reasonable and documented out-of-pocket fees and expenses of Agent and Lender party hereto and the reasonable and documented out-of-pocket fees and disbursements of counsel to Agent and Lender party hereto in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(f) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) **Governing Law**. **THIS AMENDMENT HAS BEEN NEGOTIATED AND DELIVERED TO AGENT AND LENDER IN THE STATE OF CALIFORNIA, AND SHALL HAVE BEEN ACCEPTED BY AGENT AND LENDER IN THE STATE OF CALIFORNIA. PAYMENT TO AGENT AND LENDER BY THE LOAN PARTIES OF THE SECURED OBLIGATIONS IS DUE IN THE STATE OF CALIFORNIA. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF CALIFORNIA, EXCLUDING CONFLICT OF LAWS PRINCIPLES THAT WOULD CAUSE THE APPLICATION OF LAWS OF ANY OTHER JURISDICTION.**

(h) **Complete Agreement; Amendments**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents.

(i) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

SECTION 6 Post-Close Obligation. Parent covenants and agrees to deliver to Agent within fifteen (15) Business Days of the Amendment Effective Date, a revised Perfection Certificate updated as of such date, duly executed by Parent. Each Loan Party agrees that the failure to comply with this Section 6 shall be deemed an immediate Event of Default.

[Balance of Page Intentionally Left Blank; Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWERS:

MESOBLAST UK LIMITED

By: _____
Name: Silviu Itescu
Title: Director

MESOBLAST, INC.

By: _____
Name: Silviu Itescu
Title: Sole Director

MESOBLAST INTERNATIONAL (UK) LIMITED

By: _____
Name: Silviu Itescu
Title: Director

MESOBLAST INTERNATIONAL SÀRL

_____
Place and Date

By: _____
Name: Silviu Itescu
Title: _____

GUARANTOR:

Executed by **Mesoblast Limited** in accordance with
Section 127 of the *Corporations Act 2001* (Cth)

Signature of director	Signature of director/company secretary (Please delete as applicable)
Name of director (print)	Name of director/company secretary (print)

Accepted in Palo Alto, California:

AGENT:

HERCULES CAPITAL, INC.

Signature: _____

Print Name: _____

Title: _____

LENDER:

HERCULES CAPITAL, INC.

Signature: _____

Print Name: _____

Title: _____

ANNEX A

EXHIBIT F

COMPLIANCE CERTIFICATE

Hercules Capital, Inc. (as "Agent")
400 Hamilton Avenue, Suite 310
Palo Alto, CA 94301

Reference is made to that certain Loan and Security Agreement dated as of March 6, 2018 and the Loan Documents (as defined therein) entered into in connection with such Loan and Security Agreement all as may be amended from time to time (hereinafter referred to collectively as the "Loan Agreement") by and among Hercules Capital, Inc. (the "Agent"), the several banks and other financial institutions or entities from time to time party thereto (collectively, the "Lender") and Hercules Capital, Inc., as agent for Lender (the "Agent") and [*insert name of main borrower]* (the "Company") as Borrower and each other Borrower and Guarantor party thereto. All capitalized terms not defined herein shall have the same meaning as defined in the Loan Agreement.

The undersigned is an Officer of the Company, knowledgeable of all Company financial matters, and is authorized to provide certification of information regarding the Company; hereby certifies, in such capacity, that in accordance with the terms and conditions of the Loan Agreement, except as set forth below, (i) each Loan Party is in compliance for the period ending _____ of all covenants, conditions and terms and (ii) hereby reaffirms that all representations and warranties contained therein are true and correct in all material respects on and as of the date of this Compliance Certificate with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date. The undersigned further certifies the attached financial statements are prepared in accordance with GAAP or IFRS, as applicable (except for the absence of footnotes with respect to unaudited financial statement and subject to normal year-end adjustments) and are consistent from one period to the next except as explained below.

Exceptions:

REPORTING REQUIREMENT	**REQUIRED**	**CHECK IF ATTACHED**
Monthly reporting	Monthly within 30 days	
Interim Financial Statements	Quarterly within 60 days	
Audited Financial Statements	FYE within 90 days	

ACCOUNTS

The undersigned hereby also confirms the below disclosed accounts represent all depository accounts and securities accounts presently open in the name of each Loan Party or Subsidiary, as applicable.

Have any depository or securities accounts been opened since the last Compliance Certificate? YES/NO

Cash Management (7.12(b)):

(A) Cash held by Mesoblast USA in accounts in the United States subject to an Account Control Agreement in favor of Agent: $_____

(B) outstanding Secured Obligations: $_____ *multiplied by* 1.20 = $_____

(C) accounts payable older than 90 days of invoice date and unpaid = $_____

(D) all Cash (excluding amounts held in Excluded Accounts) of Parent and its consolidated subsidiaries $_____ *multiplied by* 0.75 = %_____

Is (A) greater than or equal to *either* (B) plus (C) or (D)?

___Yes (in compliance); ___ No (not in compliance)

Are the Loan Parties in compliance with Section 7.12 based on the below disclosed depository accounts and securities accounts? YES/NO

		Depository AC #	Financial Institution	Account Type (Depository / Securities)	Last Month Ending Account Balance	Purpose of Account
LOAN PARTY Name/Address:						
	1					
	2					
	3					
	4					
	5					
	6					
	7					

LOAN PARTY/ SUBSIDIARY Name/Address						
	1					
	2					
	3					
	4					
	5					
	6					
	7					

Minimum Cash (7.14)

(a) The amount of Unrestricted Cash as of the date hereof: $_____

(b) The amount of the Loan Parties' accounts payable under GAAP or IFRS not paid after the 120th day following the invoice date for such accounts payable: $_____

(c) Clause (a) *plus* clause (b) is: $_____

(d) Prior 3 months (reported as of the end of a calendar month) of Net Operating Cash Burn: $_____

(e) Prior 3 months (reported as of the end of a calendar month) of Net Investing Cash Burn: $_____

(f) Clause (d) *plus* clause (e) is: $_____

(g) Sum of extraordinary, non-recurring, not regularly scheduled or onetime proceeds and amounts (including but not limited to upfront or milestone proceeds) from business development transactions permitted under this Agreement $_____

(h) Clause (f) *minus* clause (g) is: $_____

Is the amount reported in clause (c) equal to or greater than the amount reported in clause (h)?
__ Yes; __ No

If No: not in compliance.

INSURANCE

Have the Loan Parties amended or entered into any new insurance policies? YES/NO

Very Truly Yours,

[SIG BLOCK TO BE ADDED]

ANNEX B

SCHEDULE 1.1

COMMITMENTS

LENDER	TRANCHE	TERM COMMITMENT	HMRC Treaty Passport scheme reference number and jurisdiction of tax residence (if applicable)
Hercules Capital, Inc.	1	$22,750,000	13/H/370777/DTTP United States
Hercules Capital Funding Trust 2018-1	1	$12,250,000	N/A United States
Hercules Capital, Inc.	2	$15,000,000*	13/H/370777/DTTP United States
Hercules Capital, Inc.	3A	$15,000,000	13/H/370777/DTTP United States
Hercules Capital, Inc.	3B	$25,000,000**	13/H/370777/DTTP United States
TOTAL COMMITMENTS		$75,000,000*	

* Tranche 2 was undrawn at the end of the availability period for Tranche 2.

** [***].

Exhibit 4.27

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, IS OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

Execution Copy CONFIDENTIAL

Second Supplementary Agreement for Additional License

This Second Supplementary Agreement (this "Agreement") is made and entered into as of the 5th day of June by and between JCR Pharmaceuticals Co., Ltd., a corporation duly organized and existing under the laws of Japan having its office at 3-19 Kasuga-cho, Ashiya, Hyogo 659-0021, Japan ("JCR") and Mesoblast International Sarl, a company duly organized and existing under the laws of Switzerland having its office at Route de Pre-Bois 20 c/o Accounting & Management Service SA 1217 Meyrin, Switzerland and Mesoblast Limited, a company duly organized and existing under the laws of Australia having its office at Level 38 55 Collins Street, Melbourne, Victoria 3000, Australia (collectively "Mesoblast").

BACKGROUND

Whereas, JCR and Osiris and Osiris Acquisition II, Inc. ("Osiris") were parties to a License Agreement dated August 26, 2003, as amended by Amendment 1 to License Agreement as of June 27, 2005 (collectively, the "First License Agreement"), wherein JCR has an exclusive license in Japan to develop and market certain medical products for specified fields under certain Osiris' patents and technical information,

Whereas, Mesoblast has acquired from Osiris the First License Agreement, together with substantially all of Osiris' business, assets and technical information and patents to which the First License Agreement relates,

Whereas, JCR has successfully launched commercial sale in Japan of certain medical product for graft versus host disease known as TEMCELL® HS Inj. under the First License Agreement, which product consists of human mesenchymal stem cells derived from bone marrow (as defined further below, the "JCR Product"), and

Whereas, JCR and Mesoblast have entered into Supplementary Agreement for Additional License dated 12th day of October, 2018 to develop and commercialize JCR Product for the therapeutic use for epidermolysis bullosa ("First Supplementary Agreement"),

Whereas, JCR is willing to obtain another additional license to develop and commercialize JCR Product for the therapeutic use for neonatal hypoxic ischemic encephalopathy ("HIE"),

NOW, THEREFORE, in consideration of mutual covenants and other good and valuable consideration, the Parties hereto agree as follows:

Section 1. Definitions
The words, wherever appear in this Agreement, shall have the following meaning:

1.1 "Affiliate", "Person", "Product", "Sublicensee", "Territory" and "Third Party" shall have the respective meaning as defined in Section 1 of the First License Agreement.

1.2 "JCR Product" means that certain Product known as TEMCELL® HS Inj., that is approved and commercialized as of the date hereof for graft versus host disease in the Territory, and any modification thereof, which consists of mesenchymal stem cells acquired and cultivated from human bone marrow.

1.3 “JCR Know-How” means scientific or technical information and other data (including safety and/or efficacy data) related to the JCR Product for use in the Second Additional Field, which JCR has a right to grant licenses to others without breaching the terms of an agreement or contract with any Third Party.

1.4 “JCR Safety Data” means post-marketing safety data of JCR Product as now or hereafter may be obtained by JCR, which JCR has a right to disclose and make available to others without breaching the terms of an agreement or contract with any Third Party.

1.5 “Mesoblast Patents” means such patents filed or issued in Japan, owned and controlled by Mesoblast which have valid claims covering the Second Additional Field, including those patent rights described in Appendix A hereto.

1.6 “Mesoblast Product” means that certain Product or Products (other than JCR Product) developed, owned, or controlled by Mesoblast or its Affiliates and any modification thereof, which consists of human mesenchymal stem cells derived from bone marrow including, without limitation, that Product known as MSC-100-IV (remestemcel-L).

1.7 “Net Sales” means (a) with respect to JCR Product sold for Second Additional Field in the Territory, the gross amount invoiced by JCR, its Affiliates, Sublicensees or co-marketers for such JCR Product and (b) with respect to Mesoblast Product the gross amount invoiced by Mesoblast, its Affiliates, sublicensees or co-marketers for such Mesoblast Product less in each case (a) and (b) deductions for: (i) trade, quantity and/or cash discounts, allowances and rebates actually allowed or given; (ii) freight, shipping, insurance and other transportation expenses (if separately identified in such invoice); (iii) credits or refunds actually allowed for rejections or defects of such Product, outdated or returned Product, or because of rebates or retroactive price reductions; (iv) sales, value added, excise taxes, tariffs and duties, and other taxes directly related to the sale, to the extent that such items are separately identified in such invoice and are paid by the purchaser of Product.

1.8 “Osiris Know-How” means any proprietary and non-public technical information, data and know-how originally developed by Osiris and later assigned to Mesoblast which are inextricably incorporated or adopted into JCR’s current manufacturing process of JCR Product.

1.9 “Party” means Mesoblast or JCR and, when used in the plural, means Mesoblast and JCR.

1.10 “Regulatory Approval” means an official marketing approval which Minister of Health, Labour and Welfare may issue for commercial sale of JCR Product for Second Additional Field in the Territory (including any pricing or other approvals necessary to initiate commercial sales thereof).

1.11 “Second Additional Field” means experimental, diagnostic and therapeutic use of JCR Product or Mesoblast Product for HIE.

Section 2. Grant of Licenses

2.1 Mesoblast hereby grants to JCR and its Affiliates an exclusive royalty-bearing license in the Territory, with the right to grant sublicenses, under the Mesoblast Patents and Osiris Know-How in order to develop, register and to obtain Regulatory Approval, use, make, have made, import, offer to sell, sell and have sold JCR Products for use in the Second Additional Field in the Territory.

2.2 JCR hereby grants to Mesoblast and its Affiliates a non-exclusive license and right to utilize JCR Know-How in order to develop, register, use, make, have made, import, export, offer to sell, sell and have sold Mesoblast Product outside of the Territory as well as a non-exclusive license and right to utilize JCR Safety Data for regulatory purpose in relation to Mesoblast Product outside of the Territory, provided that (i) disclosure and transmittal of JCR Know-How to Mesoblast shall be made at such time and in such manner as JCR may from time to time deem reasonable but no less often than as otherwise required under Section 3.4 (Reporting) of the First License Agreement and (ii) provision of JCR Safety Data shall be made in accordance with the Safety Data Exchange Agreement ("SDEA"). The foregoing licenses and rights (a) shall be royalty-free and fully-paid for practice in U.S.A., and (b) shall be subject to a running royalty at the rate of [***] of Net Sales of Mesoblast Product labeled and sold for the Second Additional Field in any other country outside of both the Territory and the U.S.A, which running royalty shall be payable to JCR in a manner consistent with the logistics set forth in Section 3 with respect to JCR's payment of its royalty to Mesoblast on a *mutatis mutandis* basis and accrue country by country during the [***] year period beginning from the date of first commercial sale of any Mesoblast Product for the Second Additional Field in such country outside of both the Territory and the U.S.A.

2.3 JCR Know-How and JCR Safety Data shall be transmitted "AS IS" to Mesoblast in Japanese language. Except as otherwise expressly provided to the contrary in the SDEA, all costs for translation to another language shall be borne by Mesoblast.

2.4 Mesoblast will not grant any third party a license to Mesoblast's patent family entitled [***] to develop, register and to obtain Regulatory Approval, use, make, have made, import, offer to sell, sell and have sold a Product for use in the Second Additional Field in the Territory.

Section 3. Royalties

3.1 In consideration of the license granted under Section 2.1 above, JCR, contingent upon the Regulatory Approval having been obtained with respect to the JCR Product for the Second Additional Field, shall pay to Mesoblast the running royalty equal to [***] of the Net Sales of the JCR Product sold by JCR, its Affiliates, co-marketers and Sublicensees for Second Additional Field in the Territory during the Term of this Agreement.

Notwithstanding the above, in the event that (i) a Third Party sells any products similar to or competitive with JCR Product for the Second Additional Field in the Territory that do not infringe any of Mesoblast Patents in the Territory and such sales are at least [***] of Net Sales or (ii) NHI listed price applicable to JCR Product for the Second Additional Field is decreased from the initial NHI price by [***] or more by the regulatory authority in the Territory, the Parties shall negotiate to reduce the percentage of royalties payable to Mesoblast for Net Sales.

3.2 All royalty payments shall be paid quarterly within sixty (60) days of the end of each calendar quarter. Each such payment shall be accompanied by a statement of the amount of gross sales of the JCR Product, the calculation of Net Sales, the number of units of the JCR Product sold during such quarter, the amount of royalties due on such Net Sales of the JCR Product for the Second Additional Field, the conversion rates used in converting to United States Dollars and any other information reasonably requested by Mesoblast to enable Mesoblast to determine the amount owed hereunder.

3.3 JCR shall remit all payments required under this Agreement by wire transfer to the bank account as designated by Mesoblast from time to time in United States Dollars. Whenever for the purpose of calculating royalties from foreign currency shall be required, such conversion shall be at the rate of exchange of the last business day of the applicable calendar quarter as published by a reputable bank in Japan.

Section 4. Records and Inspection

4.1 JCR and its Affiliates and its Sublicensees and co-marketers shall keep complete and accurate records pertaining to the sale of JCR Products for Second Additional Field in the Territory and covering all transactions from which Net Sales are derived for a period of three calendar years after the year in which sales occurred, and in sufficient detail to permit Mesoblast to confirm the accuracy of royalty payments due hereunder.

4.2 At the request and expense (except as provided below) of Mesoblast, JCR and its Affiliates and its Sublicensees and co-marketers shall permit an independent certified public accountant appointed by Mesoblast and reasonably acceptable to JCR, at reasonable times and upon reasonable notice, to examine those records and all other material documents relating to or relevant to Net Sales in the possession or control of JCR and/or its Affiliates or its Sublicensees and co-marketers, for a period of three years after such royalties have accrued. Said accountant shall not disclose to Mesoblast any information other than information relating to said reports, royalties and payments. If, as a result of any inspection of the books and records of JCR or its Affiliates or its Sublicensees and co-marketers it is shown that JCR's royalty payments under this Agreement were less than the amount which should have been paid, then JCR shall make all payments required to be made to eliminate any discrepancy revealed by said inspection within forty-five (45) days after Mesoblast's demand therefor. Furthermore if the royalty payment was less than the amount which should have been paid by an amount in excess of [***] of the royalty payment actually made during the period in question, JCR shall also reimburse Mesoblast for the cost of such inspection.

4.3 Mesoblast shall undertake the reciprocal obligations as those JCR bears and JCR shall have the reciprocal rights as those Mesoblast holds as stipulated in Sections 4.1 and 4.2 above, with respect to the royalty payable to JCR under Section 2.2 hereof.

Section 5. Confidentiality

5.1 Mesoblast shall be bound by the same confidentiality obligations as those stipulated on its part to be performed or observed in Section 9 of the First License Agreement, which obligations shall be applicable to JCR Know-How and JCR Safety Data. For clarity, Mesoblast may use and disclose the JCR Know-How and JCR Safety Data to the extent reasonably necessary to exercise the license set forth in Section 2.2, but subject to reasonable protective measures and safeguards under the circumstances of such use or disclosure.

Section 6. Term and Termination

6.1 This Agreement shall take effect upon the date of execution and it shall continue to be in full force and effect until the later of (a) 24th of February, 2031 or (b) tenth anniversary of the first commercial sale of JCR Product for Second Additional Field in the Territory. It is understood that expiration or termination of this Agreement shall not affect the license or right hitherto granted to Mesoblast under Section 2.2 hereinabove, provided that Mesoblast shall perform and observe any obligations on its part to be performed or observed under this Agreement.

6.2 Sections 10.2 through 10.7 of the First License Agreement shall be deemed to have been incorporated into this Agreement by reference, provided that the term, "Osiris" shall be read as "Mesoblast", the term, "Product" shall read as "JCR Product" and the term, "Field" shall be read as "Second Additional Field" and the cure period in Section 10.2 shall remain unchanged.

Section 7. Miscellaneous

7.1 Sections 7 and 8, Section 11, Sections 12.1 through 12.3, Sections 12.5 through 12.10, and Sections 12.14 through 12.16 of the First License Agreement shall be deemed to have been incorporated into this Agreement by reference, provided that the term, "Osiris" shall be read as "Mesoblast" and the term, "Product" shall be read as "JCR Product".

7.2 This Agreement constitutes the entire agreement between the Parties hereto with respect to the license of Mesoblast Patents and Osiris Know-How for Second Additional Field and other subject matter stipulated herein, which shall supersede all previous agreements and discussions between the Parties hereto, whether written or oral.

7.3 The First License Agreement, which shall be applicable only to Field 1 and Field 2 defined therein and the First Supplementary Agreement which shall be applicable only to the Additional Field each shall remain valid and unchanged.

7.4 [***].

Signatures appear on following page

IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed as of the date hereof by a duly authorized representative.

For and on behalf of
Mesoblast International Sarl

By: _____
Name: _____
Title: _____
Date: _____

For and on behalf of
Mesoblast Limited

By: _____
Name: _____
Title: _____
Date: _____

For and on behalf of
JCR Pharmaceuticals, Co., Ltd.

By: _____
Name: Shin Ashida
Title: Chairman, President & CEO
Date: _____

Appendix A

Mesoblast Patents

[***]

Exhibit 8.1

Subsidiaries of Mesoblast Limited

Legal Entity	**Jurisdiction of Organization**
Mesoblast International Sarl	Switzerland
Mesoblast UK Limited	United Kingdom
Mesoblast, Inc.	United States

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form F-3 (No. 333-219210) and Form S-8 (Nos. 333-210935 and 333-220988) of Mesoblast Limited of our report dated August 30, 2019 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers
Melbourne, Australia
August 30, 2019

Exhibit 12.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Silviu Itescu, certify that:

1. I have reviewed this annual report on Form 20-F of Mesoblast Limited (the "Company");

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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 officer(s) 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: August 30, 2019

By: /s/ Silviu Itescu

Silviu Itescu
Chief Executive Officer

Exhibit 12.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Josh Muntner, certify that:

1. I have reviewed this annual report on Form 20-F of Mesoblast Limited (the "Company");

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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 officer(s) 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: August 30, 2019

By: /s/ Josh Muntner
Josh Muntner
Chief Financial Officer

Exhibit 13.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Mesoblast Limited (the "Company") on Form 20-F for the year ended June 30, 2019 as filed on the date hereof (the "Report") "), I, Silviu Itescu, Chief Executive Officer for the Company, certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge: I, Silviu Itescu, certify that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 30, 2019

By: /s/ Silviu Itescu

Silviu Itescu
Chief Executive Officer

Exhibit 13.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Mesoblast Limited (the "Company") on Form 20-F for the year ended June 30, 2019 as filed on the date hereof (the "Report"), I, Josh Muntner, Chief Financial Officer for the Company, certify pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

I, Josh Muntner, certify that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 30, 2019

By: /s/ Josh Muntner
Josh Muntner
Chief Financial Officer

Appendix 4E

Preliminary final report for the twelve months to 30 June 2019

Name of entity

MESOBLAST LIMITED **ABN 68 109 431 870**

1. Reporting period

Report for the financial year ended	30 June 2019
Previous corresponding period is the financial year ended	30 June 2018

2. Results for announcement to the market

	Up/down	% change		Amount reported for the year ended 30 June 2019 USD'000
Revenues from ordinary activities *(item 2.1)*	Down	4%	to	16,722
Loss from ordinary activities after tax attributable to members (*item 2.2*)	Up*	154%	to	89,799
Net loss for the period attributable to members *(item 2.3)*	Up*	154%	to	89,799

**increase in loss*

There are no dividends being proposed or declared for the period *(item 2.4 and 2.5)*

Commentary related to the above results

Please refer to 'Item 5.A Operating results' within the Form 20-F for the year ended 30 June 2019.

3. Net tangible assets per security

	30 June 2019	30 June 2018
Net tangible (liability)/asset backing per ordinary security (in USD cents)	(8.71) cents	4.88 cents

A large proportion of the company's assets are intangible in nature, consisting of intellectual property and goodwill relating to the acquisition of Mesoblast, Inc and culture-expanded Mesenchymal Stem Cells technology. These assets and the associated provision for contingent consideration are excluded from the calculation of net tangible assets per security. The deferred tax liability has also been excluded from the calculation to the extent it relates to future tax obligations as a result of the intellectual property assets deriving revenue at some point in the future. This deferred tax liability has arisen as a result of the intellectual property being acquired.

4. Other documents accompanying this Appendix 4E

This Appendix 4E should be read in conjunction with the Mesoblast annual report on the form 20-F, which includes:

- Item 18 Financial Statements; and
- Other sections as tabled below.

This preliminary final report and the associated Directors' Report are found throughout the various sections of the accompanying Mesoblast annual report on the form 20-F.

The following table has been provided to assist readers to locate each section of the Directors' Report within the accompanying annual report on the form 20-F.

Sections of Directors' Report	**Form 20-F Reference**
Principal activities	Item 5.A Operating Results See subheading – "Financial Overview"
Review of operations and activities	Item 4.B Business Overview Item 5.A Operating Results
Business strategies and prospects for future years	Item 4.B Business Overview
Business risks	Item 3.D Risk Factors
Significant changes in the state of affairs	Item 5.A Operating Results See subheading – "Significant changes in the state of affairs"
Matters subsequent to the end of the financial year	Item 8.B Significant Changes
Likely developments and expected results of operations	Item 5.A Operating Results See subheading – "Likely developments and expected results of operations"
Environmental regulations	Item 5.A Operating Results See subheading – "Environmental regulations"
Dividends	Item 4.B Business Overview See subheading – "Dividends"
Information on directors	Item 6.A Directors and Senior Management See subheading – "Board of Directors"
Remuneration report	The Remuneration report starts at Item 6 and ends part way through Item 6.B as indicated
Indemnification of officers	Item 6.B Compensation See subheading – "Indemnification of officers"
Proceedings on behalf of the group	Item 6.B Compensation See subheading – "Proceedings on our behalf"
Non-Audit Services	Item 6.B Compensation See subheading – "Non-audit services"
Auditor's independence declaration	Exhibits 99.2
Directors' Resolution	Item 6.B Compensation See subheading – "Directors' resolution"

5. Audited Financial Report 2019

This preliminary final report has been based on accounts which have been audited. The independent auditors report includes the following statement:

We draw attention to Note 1(i) in the financial report, which indicates that the Group incurred net cash outflows from operations during the year ended 30 June 2019 of $57.8 million. As a result, the Group is dependent on raising funds through entering strategic and commercial transactions, equity-based or debt-based financings. These conditions, along with other matters set forth in Note 1(i), indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

A copy of the audited Financial Statements for the year ended 30 June 2019 is included in Item 18 Financial Statements within the Form 20-F.

- End of Appendix 4E -

This page is required for Australian Disclosure Requirements and has been intentionally left blank.