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, 2017

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
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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	Name of each exchange on which registered
American Depositary Shares, each representing five Ordinary Shares*	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.

428,221,398 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

☐ Yes ☒ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, or an emerging growth company. See definitions 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. 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$" or "Australian dollar" refers to the legal currency of Australia.
- "IFRS" refers to the International Financial Reporting Standards as issued by the International Accounting Standards Board, or IASB.
- "AIFRS" refers to the Australian equivalents to International Financial Reporting Standards as issued by the Australian Accounting Standards Board, or AASB.
- "U.S. GAAP" refers to the Generally Accepted Accounting Principles in the United States.
- "FDA" refers to the United States Food and Drug Administration.
- "NIH" refers to the United States National Institutes of Health.
- "US$" 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 that relate to future events or our future financial performance and involve 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," "targets," "likely," "will," "would," "could," 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;
- 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 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, 2017, 2016 and 2015 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 thousands except per share information)	**2017**	**2016**	**2015**	**2014**	**2013**
Consolidated Income Statement Data:					
Revenue:					
Commercialization revenue	$ 1,444	$ 37,969	$ 15,004	$ 15,004	$ 18,685
Milestone revenue	500	3,500	2,000	—	—
Interest revenue	468	1,079	2,757	8,386	10,616
Total revenue	**2,412**	**42,548**	**19,761**	**23,390**	**29,301**
Research & development	(58,914)	(50,013)	(62,649)	(50,929)	(48,513)
Manufacturing commercialization	(12,065)	(29,763)	(23,783)	(25,434)	(23,082)
Management and administration	(23,007)	(22,500)	(29,540)	(24,403)	(22,899)
Fair value remeasurement of contingent consideration(1)	(130)	28,112	(15,336)	(4,327)	—
Impairment of intangible assets	—	(61,919)	—	—	—
Other operating income and expenses	1,489	2,714	15,303	6,173	4,543
Loss before income tax	**(90,215)**	**(90,821)**	**(96,244)**	**(75,530)**	**(60,650)**
Income tax benefit/(expense)	13,400	86,694	—	(4)	(1,470)
Loss attributable to the owners of Mesoblast Limited	**$ (76,815)**	**$ (4,127)**	**$ (96,244)**	**$ (75,534)**	**$ (62,120)**
Losses per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**Cents**	**Cents**
Basic - losses per share	(19.43)	(1.14)	(29.99)	(23.65)	(21.02)
Diluted - losses per share	(19.43)	(1.14)	(29.99)	(23.65)	(21.02)

(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, 2015, 2014 and 2013.

(in thousands except shares information)	2017	2016	As of June 30, 2015	2014	2013
Consolidated Balance Sheet Data:					
Cash and cash equivalents	45,761	80,937	110,701	185,003	292,449
Total current assets	63,609	88,823	122,460	191,931	307,789
Total assets	655,686	684,018	781,766	847,153	819,663
Total current liabilities	36,670	29,415	48,407	40,199	46,921
Total liabilities	138,920	155,857	313,779	308,594	235,071
Equity:					
Issued capital (428,221,398; 381,363,137; 336,997,729; 321,640,094 and 316,468,901 ordinary shares (no par value) issued as of June 30, 2017, 2016, 2015, 2014 and 2013, respectively)	830,425	770,272	709,191	662,722	642,378
Reserves	31,243	25,976	22,756	43,553	34,396
(Accumulated loss)/retained earnings	(344,902)	(268,087)	(263,960)	(167,716)	(92,182)
Total equity	516,766	528,161	467,987	538,559	584,592

(in thousands)	2017	2016	Year ended June 30, 2015	2014	2013
Cash Flow Data:					
Net cash (outflows) in operating activities	(95,471)	(87,996)	(101,036)	(74,906)	(55,746)
Net cash inflows/(outflows) in investing activities	142	(1,727)	(5,064)	(38,202)	(4,801)
Net cash inflows in financing activities	60,005	62,066	45,852	2,196	174,415
Net (decrease)/increase in cash and cash equivalents	**(35,324)**	**(27,657)**	**(60,248)**	**(110,912)**	**113,868**

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 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. For the year ended June 30, 2017, we had a comprehensive loss of $76.5 million. Our net loss for the year ended June 30, 2017 was $76.8 million. As of June 30, 2017, we have an accumulated deficit of $344.9 million since our inception. We do not know whether or when we will become profitable. Our losses have resulted principally from costs incurred in our manufacturing and clinical development activities.

We anticipate that our expenses will increase in the future as we move toward commercialization, including the scaling up of our manufacturing activities. 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 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 anticipate generating revenues from product sales for the foreseeable future (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 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 infrastructure;
- 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 and know-how;
- 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 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, domestic or foreign, 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, 2017, our cash and cash equivalents were $45.8 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 Congestive Heart Failure ("CHF")), MPC-06-ID (Chronic Low Back Pain ("CLBP")), MSC-100-IV (acute Graft versus Host Disease ("aGVHD")) and MPC-300-IV (inflammatory conditions) product candidates;
- initiate and advance our product candidates into larger and more expensive 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 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; and
- seek to attract and retain skilled personnel.

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 collaborations, 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(ii) 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 entering into an arrangement with a third party partner on one or more of our four Tier 1 product candidates that would result in non-dilutive funding and/or raising further capital, together with various cost containment and deferment strategies being completed including the reprioritization of certain projects.

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.

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 cells ("MLC") 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 stem cell products have been approved in the United States.

Other than with respect to sales of TEMCELL by our licensee JCR in Japan, we have not commercially marketed, distributed or sold any products, either ourselves or through a licensee. 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 MLC 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 MLC 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 than other, better known or extensively studied pharmaceutical or other product candidates to develop. 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. At the moment, no other industrially manufactured stem cell products have been approved in the United States, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or elsewhere.

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

Other than with respect to TEMCELL our licensed product in Japan, we have not obtained any regulatory approvals for a product, either ourselves or through a licensee. We must conduct extensive testing of our product candidates to demonstrate their safety and efficacy, including both preclinical animal testing and 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 we or they 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 for 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 the Phase 3 CHF trial from Teva Pharmaceutical Industries Ltd;
- 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 prospective clinical 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;
- 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 the testing, validation, manufacturing and delivery of the product candidates to the clinical 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 the product candidates that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- disagreements 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, especially for indications such as aGVHD which are designated as orphan or niche markets, 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. More specifically, certain of our product candidates, including MSC-100-IV for aGVHD, target indications with relatively small patient populations, which can prolong the clinical trial timeline for the regulatory process if sufficient patients cannot be enrolled in a timely manner. As a result, 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.

In addition, our planned clinical trials targeting more prevalent indications, such as our product candidates for CLBP, MPC-06-ID, and CHF, MPC-150-IM, may require the recruitment of several thousand patients. If there are delays in accumulating the required number of trial subjects or, in trials where clinical events are a primary endpoint, 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;
- ability to monitor patients adequately during and after treatment; and
- the degree of treatment effect in event-driven trials.

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 participate in 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 and CROs;
- standards within different jurisdictions for conducting clinical trials and resulting patients;
- our inability to locate 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
- 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.

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 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, even 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 other 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 treat 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 MSC-100-IV, which will focus on steroid-refractory 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 during our Phase 3 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.

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 (other than TEMCELL our licensed product in Japan), 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, and creates an accelerated approval pathway for such products. As this is a new law, it is not clear yet what impact it will have on the operation of our business. It is also unclear how and when the FDA will fully implement 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;
- the inability to obtain sufficient quantities of the product candidates required for clinical trials;
- 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. In addition, regulatory approval does not specify pricing or reimbursement which may not match our expectations based on the results of our clinical data.

We are seeking an expedited approval path for cellular medicines designated as Regenerative Medicine Advanced Therapies ("RMAT") under the 21st Century Cures Act. This is a new designation category, and there is no certainty that our products will receive this designation or that it will accelerate approval.

The FDA has not yet issued formal guidance under the Cures Act and there is no certainty as to whether any of our product candidates will receive RMAT designation under the Cures Act or that receiving such designation will provide an expedited pathway to approval. While the Cures Act offers several benefits to drugs designated as RMATs, including eligibility for increased agency support and advice during development, priority review on filing, accelerated approval based on potential surrogate endpoints, and for 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 our drug candidates or, if applicable, accelerate marketing approval.

Even if we obtain regulatory approval for a product candidate, 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 MLCs, is frequently misunderstood by the public. Negative public attitudes toward stem cell therapy could also result in greater governmental regulation of stem cell therapies, which could harm our business. The use of these 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. 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 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.

Fast track designation by the FDA may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

If a drug is intended for the treatment of a serious or life-threatening condition or disease and the applicable nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. Our MSC-100-IV product candidate has received fast track designation for the treatment of aGVHD by the FDA. We may in the future seek fast track designation for other of our product candidates as appropriate in the United States. For any product candidate that receives fast track designation, we may

not experience a faster development, review or approval process compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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 European Union 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 MSC-100-IV product candidate has received orphan drug designation for the treatment of aGVHD by the FDA. 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.

Breakthrough therapy designation by the FDA may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

We have in the past and may in the future apply for breakthrough therapy designation for our product candidates, as appropriate, in the United States. A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and for which preliminary clinical evidence indicates substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the applicant can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA may, in some cases, also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our products or product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree. In any event, the receipt of a breakthrough therapy designation for a product or product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. We have in the past been denied breakthrough designation for certain of our product candidates. In addition, even if one or more of our products or product candidates does qualify as a breakthrough therapy, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

We may face competition from biosimilars due to the changing 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 new 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 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, with the attendant competitive pressure and consequences.

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 other 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 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 MLC product candidates in our 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 cells, 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.

Further, we have made significant advances in the development of 3-dimensional ("3D"), bioreactor based production for MLCs, the goal of which is to allow us to produce our products at commercial scale. There is no guarantee that we will successfully complete this process, 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 two-dimensional, or

2D, manufacturing processes. In the event our transition to 3D manufacturing is unsuccessful, we may not be able to produce 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 certain 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 MLC 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 MLC product candidates. Relying on Lonza as our sole source to manufacture our MLC 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; 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 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 MLC-containing bone marrow from donors, for which we currently rely on Lonza. MLCs 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 will 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 general market availability 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 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 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.

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 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 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 no sales and marketing infrastructure and, as a company, have limited sales, marketing or distribution 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 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 lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more diversified product lines; 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 clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. 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 the stem cell industry and/or those with collaboration arrangements and other third party payors. 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.

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 recent change in the administration the Affordable Care Act may be repealed or significantly amended. 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 there are changes in policy limit reimbursements that we are able to receive through federal programs, it could negatively impact reimbursement levels from 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 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 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 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 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 therapy, 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 do not clearly demonstrate the efficacy of our product candidates, 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 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. 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 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, and we have a collaborator, JCR, with rights to develop and distribute products based on our MSC technology 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 into such markets. We may, therefore, 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, a referendum was held on the United Kingdom's membership in the European Union, the outcome of which was a vote in favor of leaving the European Union. 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 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;
- 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, 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.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that switches the U.S. patent system from a "first to invent" to a "first inventor to file" system, and affect the way patent applications will be prosecuted and may also affect patent litigation. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO issued Final Rules and Guidelines governing first-inventor-to-file in February 2013, and continues to develop and implement additional regulations and procedures to govern administration of the Leahy-Smith Act. Many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular the first-to-file provisions, only became effective on March 16, 2013. The full effect of these changes are currently unclear as the USPTO has not yet adopted all pertinent final rules and regulations, the courts have yet to address these provisions and the applicability of the Leahy-Smith Act and new regulations on specific patents, including our patents discussed herein, have not been determined and would need to be reviewed. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. As a result, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, or it could cause us to lose patent rights if we fail to timely file patent applications and another party files on an invention before we do, all of which could have a material adverse effect on our business and financial condition.

On June 13, 2013, the U.S. Supreme Court decision in Association for *Molecular Pathology v. Myriad Genetics, Inc.*, held that isolated DNA sequences are not patentable because they constitute a product of nature. The Supreme Court did not address stem cells in particular, and as a result, it is not yet clear what, if any, impact this Supreme Court decision or future decisions will have on the operation of our business.

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 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 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, 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. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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 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 laws. 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. ("Osiris") 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, 2017, our cumulative operating losses have a total potential tax benefit of $113.1 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. 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 provided by Section 382 of the Internal Revenue Code of 1986. Our carry forward net operating losses in the U.S. 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. We currently project to benefit from these incentives in future taxable years. We recognized income of $1.5 million and $3.8 million, respectively, from the Research and Development Tax Incentive program for the years ended June 30, 2017 and 2016. To the extent our research and development expenditures are deemed to be “ineligible,” then our grants would decrease.

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 grants 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. The review panel's recommendation, which has not been adopted or implemented as of the date of this Annual Report, would reduce the amount of the grants available to a maximum of A$2.0 million per annum for companies with an annual aggregate turnover of less than A$20.0 million, such as us. A final Australian federal government response to its review of the Research and Development Tax Incentive program has not yet been released or implemented as of the date of this Report. If the Research and Development Tax program incentives are revoked or modified, such as was recommended by the review panel, or if we are no longer eligible for such incentives, our business, results of operations and financial condition may be adversely affected.

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 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* (“HITECH”), 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. 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 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 Data Protection Directive, Canada's *Personal Information Protection and Electronic Documents Act* and other data protection, privacy and similar national, state/provincial and local laws 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.

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. We participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under these anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

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

We 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 United States and (c) our business must be administered principally outside the United States. 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 United States generally accepted accounting principles, 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.

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 new compliance initiatives.

As a company whose ADSs have recently begun to be publicly traded in the United States, we have incurred and will continue to incur significant legal, accounting, insurance and other expenses that we did not previously incur. In addition, 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 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 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 and may further restrict the ability of our shareholders to obtain a premium from such transactions, and which will also impact the value of the ADSs.

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 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 Global Select Market 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.

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 will 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 no or 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. In the event securities or industry analysts initiate coverage, 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. In the past, following periods of volatility in the market price of a company’s securities, shareholders often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of senior management and, if adversely determined, could have a material adverse effect on our results of operations and financial condition.

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 95% of our cash and cash equivalents as of June 30, 2017 were denominated in U.S. dollars and 5% 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.

Further, any significant change in the value of the Australian dollar may have a material adverse effect on the value of our ADSs in U.S. dollars. 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.

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 Global Select Market, we will be permitted to, and plan to, follow certain home country corporate governance practices in lieu of certain Nasdaq Global Select Market 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 *Securities Exchange Act of 1934*, as amended (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, 2017, 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 Australian research and development tax incentive credits and other active 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. 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. holders 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. holder 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. holders if we were classified as a PFIC, see Item 10.E- "Taxation — 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 United States. 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 United States. 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 United States 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 United States 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.

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

Important Corporate Developments

Fiscal year 2017 to date of annual report

August	Announced an entitlement offer of ordinary shares to all existing eligible shareholders in Australia and New Zealand and institutional shareholders in certain other countries in private placements. The entitlement offer is underwritten by an Australian investment bank and is expected to raise gross proceeds of approximately A$50.7 million.
	Announced plans to achieve an accelerated market entry of product candidate MPC-150-IM in the treatment of patients with the most advanced stages of chronic heart failure, defined as New York Heart Association stages Class III and Class IV.
	Results from the Phase 2a trial in patients with post-traumatic osteoarthritis published in peer-reviewed journal Arthritis Research and Therapy.
June	Results from Phase 2 trial in patients with biologic refractory rheumatoid arthritis were selected by peer review and presented at the European League Against Rheumatism (EULAR) Annual European Congress of Rheumatology.
April	Phase 3 trial of product candidate MPC-150-IM in patients with moderate to advanced chronic heart failure was successful in the pre-specified interim futility analysis of the efficacy endpoint in the trial's first 270 patients. The trial's Independent Data Monitoring Committee formally recommended that the trial should continue as planned
	Received A$3.7 million from the Australian Government for Research & Development activities conducted during the 2016 financial year.
	FDA cleared the commencement of a 24-patient trial sponsored and funded by the Boston Children's Hospital and combining Mesoblast's MPCs with corrective heart surgery in children under the age of 5 with hypoplastic left heart syndrome.
March	Successfully completed a fully underwritten institutional placement of 26.25 million new shares for gross proceeds of approximately $40 million.
	Results from the Phase 2 trial in patients with chronic low back pain due to intervertebral disc degeneration showed that a single intra-discal injection of 6 million MPCs resulted in meaningful improvements in both pain and function that were durable for at least 36 months.
	FDA granted a Fast Track designation for the use of MSC-100-IV to achieve improved overall response rate in children with steroid refractory acute graft versus host disease.
February	39-week data from the Phase 2 trial in patients with rheumatoid arthritis resistant to anti-Tumor Necrosis Factor agents showed that a single intravenous infusion of the product candidate MPC-300-IV was well tolerated and demonstrated a durable improvement in clinical symptoms, physical function, and disease activity relative to placebo over this period of follow-up.
	Results of a new study published in the peer-reviewed journal *Stem Cell Research & Therapy* showed that a single intravenous infusion of 150 million of the Company's proprietary allogeneic "off-the-shelf" STRO-3 immunoselected MPCs significantly improved clinical disease severity, reduced joint cartilage erosions, and improved synovial inflammation and histopathology in a large animal model of early rheumatoid arthritis.
December	Entered into an equity purchase agreement with Mallinckrodt Pharmaceuticals to exclusively negotiate a commercial and development partnership for MPC-06-ID in the treatment or prevention of moderate/severe chronic low back pain due to disc degeneration and MSC-100-IV in the treatment of acute graft versus host disease. As consideration, Mallinckrodt purchased approximately 20.04 million of Mesoblast's ordinary shares.
	MD Anderson Cancer Center and the United States National Institutes of Health (NIH) agreed to fund a clinical trial combining MPC-based expansion and ex-vivo fucosylation of hematopoietic stem cells for cord blood transplantation in cancer patients.

November	Phase 3 trial of product candidate MSC-100-IV used as front-line therapy in children with steroid-resistant acute graft versus host disease was successful in a pre-specified interim futility analysis.
October	Received the Frost & Sullivan Asia Pacific 2016 Cell Therapy Company of the Year Award.
	Results from the Phase 2 trial of product candidate, MPC-300-IV, in patients with diabetic kidney disease published in the peer-reviewed journal *EBioMedicine*.
September	Mr William (Bill) A. Burns, former Chief Executive Officer (CEO) of Roche Pharmaceuticals, appointed Vice Chairman of Mesoblast
August	Intellectual property portfolio covering the use of its mesenchymal precursor cells in the treatment of rheumatic diseases, including rheumatoid arthritis, strengthened by the granting of a key patent by the United States Patent and Trademark Office.
	Results from Phase 2 trial in biologic refractory rheumatoid arthritis showed that a single intravenous infusion of product candidate, MPC-300-IV, was well tolerated and demonstrated a dose-related improvement in clinical symptoms, physical function and disease activity relative to placebo through the 12 week primary endpoint.
	24 month results from phase 2 trial of chronic low back pain product candidate MPC-06-ID presented at the 24th Annual Scientific Meeting of the Spine Intervention Society and received the 2016 Best Basic Science Abstract award.
July	Announced plans for an early interim analysis on its Phase 3 chronic heart failure trial, projections for annualized cash burn and the establishment of an equity facility to provide up to A$120 million funding at the Company's discretion for up to three years.

Fiscal year 2016

June	Worldwide rights to mesenchymal precursor cell technology platform for the cardiovascular field regained from Teva Pharmaceutical Industries Ltd and agreement by the FDA for the use of a second navigational catheter system in Phase 3 program for advanced heart failure.
May	Received A$6.2 million from the Australian Government for Research & Development activities during the 2015 fiscal year.
April	Results from Phase 2a trial in patients with post-traumatic knee injury to the anterior cruciate ligament showed that a single intra-articular injection of product candidate, MPC-75-IA, resulted in improvement in pain, function, cartilage thickness, and joint structure over 24 months.
March	United States Patent and Trademark Office granted a key patent covering the use of the Company's proprietary mesenchymal precursor cells for the treatment or prevention of a broad range of rheumatic conditions, including rheumatoid arthritis.
	Exclusively licensed patented technology developed at Harvard Medical School for the modification of mesenchymal lineage adult stem cells to enhance their natural homing properties to sites of excessive inflammation.
February	Mesoblast's licensee in Japan, JCR Pharmaceuticals Co Ltd ("JCR"), launched TEMCELL® HS. Inj. ("TEMCELL"), a registered trademark of JCR, for the treatment of acute graft versus host disease in children and adults in Japan. TEMCELL. is the first allogeneic cell therapy to be fully approved in Japan.
	Results presented from Expanded Access Program showing that use of MSC-100-IV demonstrated clinically meaningful responses and associated significantly increased survival in children with steroid-refractory acute graft versus host disease.
	Results from the first cohort of Phase 2 trial in rheumatoid arthritis patients who have previously failed one or more biologic agents showed that product candidate, MPC-300-IV, resulted in early and sustained clinical responses.
January	The United States Food and Drug Administration agreed to a reduction of the size of ongoing Phase 3 trial in chronic heart failure of its proprietary cell-based medicine MPC-150-IM from 1,165 to approximately 600 patients.
November	Initial public offering in the United States with listing on Nasdaq Global Select Market completed.
	Mesoblast's licensee in Japan, JCR, received notification that the Japanese Government's National Health Insurance body formally set the price for the mesenchymal stem cell product TEMCELL.
October	United States Patent and Trademark Office granted a key patent covering the use of the Company's proprietary adult mesenchymal precursor cells for the formation and repair of blood vessels in ischemic tissues.

September Additional Phase 2 trial results for the treatment of chronic heart failure showed that mesenchymal precursor cell therapy had the greatest cardioprotective effect in the subset of patients with more advanced heart failure.

Mesoblast's Japanese partner, JCR, received full approval from the Japanese Ministry of Health, Labour and Welfare for TEMCELL.

July Phase 2 trial results of cell therapy product candidate for the treatment of chronic heart failure published in *Circulation Research*, the peer-reviewed journal of the American Heart Association.

Phase 2 trial results of cell therapy product candidate for the treatment of type 2 diabetes published in *Diabetes Care*, the peer-reviewed journal of the American Diabetes Association.

4.B Business Overview

We are a global leader in developing innovative cellular medicines. We have leveraged our proprietary technology platform, based on specialized cells known as mesenchymal lineage adult stem cells ("MLCs"), to establish a broad portfolio of late-stage product candidates.

Our allogeneic, "off the shelf" product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncology and hematologic conditions. We also have a promising emerging pipeline of products for follow-on indications.

Each MLC-derived product candidate has distinct technical characteristics, target indications, reimbursement strategy, commercialization potential, and partnering opportunities.

Mesenchymal Lineage Adult Stem Cells

MLCs 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 by MLCs 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. The coordinated beneficial effects of these biomolecules on damaged tissues include:

- Blood vessel function and regeneration. MLCs 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. MLCs 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, MLCs 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 MLC technology platform enables development of a broad product range based on distinct cell types derived from or that are the progeny of the earliest precursors of the mesenchymal cell lineage in adult tissues. Mesenchymal precursor cells (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. Mesenchymal stem cells (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 different functional characteristics of each cell type enables distinct product development for different targeted diseases.

Allogeneic, Off-the-Shelf, Commercially Scalable Products

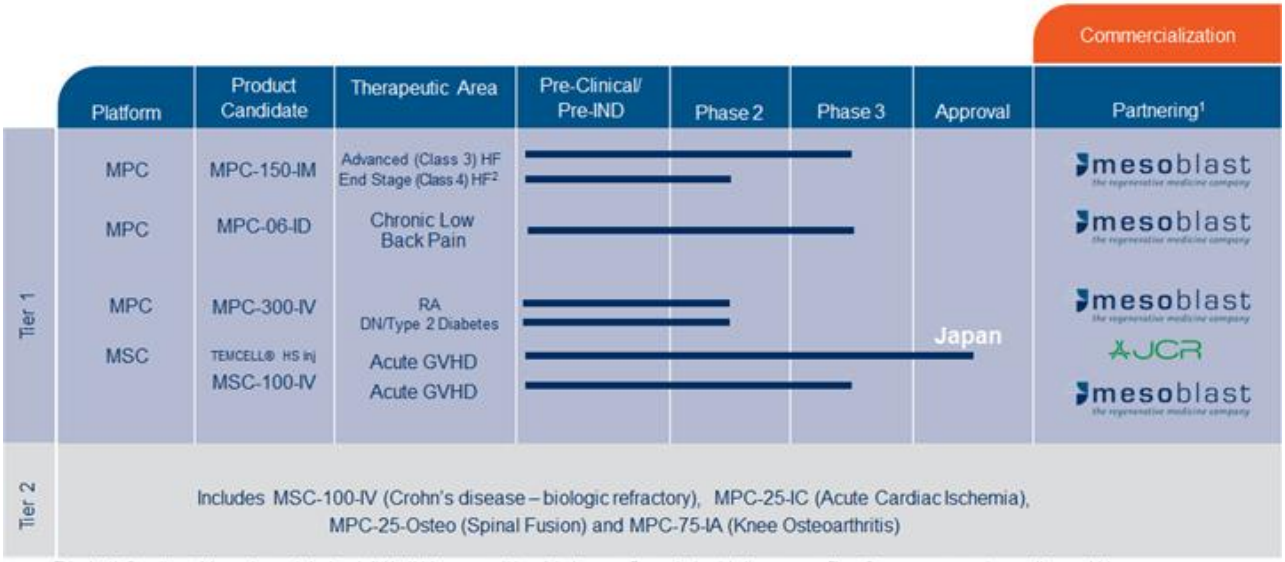
Our proprietary MLC-based products have two distinct technical properties that enable their use for allogeneic purposes, meaning cells from one donor can be expanded to treat many unrelated recipients.

Expansion: We have developed proprietary methods that enable the large scale expansion of our MLCs while maintaining their ability to produce key biomolecules associated with tissue health and repair. This allows us to produce a cellular product with consistent, well-defined therapeutic properties, batch release criteria and established potency assays, all with accompanying manufacturing economies of scale.

Immune Privilege: Unlike other categories of stem cells or mature cell lineages, MLCs are immune privileged, in that they do not express specific cell surface co-stimulatory molecules that would otherwise initiate an immune response when administered to unrelated patients.

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 are vulnerable to significant patient-to-patient variability.

Our Product Candidates



This chart is figurative and does not purports to show individual trial progress within a clinical program. For product registration purposes, Phase 3 programs may require more than one trial.
Tier 1 programs represent our lead programs where we focus the majority of our time and resources. Tier 2 programs are also in development and may advance to Tier 1 depending on the merit of newly generated data, market opportunity or partnering options.

1. On December 22, 2016, Mesoblast Ltd. entered into an equity purchase agreement with Mallinckrodt Pharmaceuticals for ~US$ 21.7m to exclusively negotiate a development and commercialization partnership for rights to GVHD and Chronic Low Back Pain outside of the Chinese and Japanese markets.
2. Clinical trial is fully funded by the National Institutes of Health (NIH).

We have prioritized our therapeutic programs into tiers based on stage of development, largest market opportunities and nearest term revenue potential. Tier 1 programs represent our lead programs where we focus the majority of our time and resources. Tier 2 programs are continually evaluated, and we may advance these programs into Tier 1 depending on merit of clinical data generated, market opportunity or collaboration opportunity. These product candidates are discussed in detail below. Additional product candidates may advance into Tier 1 and Tier 2 going forward.

We have three Tier 1 Phase 3 clinical trials actively recruiting in the United States, including MPC-150-IM for chronic and end-stage heart failure, MPC-06-ID for chronic low back pain, and MSC-100-IV for acute graft versus host disease in children. We have another Tier 1 product candidate, MPC-300-IV for immune mediated diseases, which has been evaluated in Phase 2 trials in biologic refractory rheumatoid arthritis, and also diabetic kidney disease and type 2 diabetes. Our licensee in Japan, JCR, launched the first allogeneic cell-based product in Japan in February 2016, for the treatment of acute graft versus host disease. Below, we discuss our Tier 1 programs as well as our Tier 2 programs.

Tier 1 Programs

MPC-150-IM for the Treatment of Advanced and End-Stage Chronic Heart Failure ("CHF") Due to Left Ventricular Dysfunction

Overview

MPC-150-IM is being evaluated for the treatment of advanced CHF. MPC-150-IM 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, it is believed 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.

Our 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 chronic heart failure of either ischemic or non-ischemic etiology identified the 150 million dose as the most effective for both improvement in left ventricular volumes and remodeling and in prevention of heart failure related hospitalizations or cardiac death.

Two trials of our MPC-150-IM investigational agent are ongoing: our Phase 3 trial in patients with Class II/III advanced CHF, and a Phase 2b trial in patients with end-stage CHF which is being conducted by in North America by a team of researchers within the National Institutes of Health (NIH)-funded Cardiothoracic Surgical Trials Network (CTSN).

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 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 New York Heart Association ("NYHA"), is as follows:

- Class I (mild): patients experience no 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 LV 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 LV 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 3 increasing doses (25, 75, or 150 million cells) of MPCs in patients with chronic heart failure 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 chronic heart failure 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.

More specifically:

- Using pre-specified endpoint analyses, there was a dose-related improvement in both left ventricular end-systolic volume ("LVESV") and left ventricular end-diastolic volume ("LVEDV"), with the 150 million cell dose showing the greatest effect from baseline compared to controls for LV remodeling (LVESV and LVEDV both $p<0.02$) at month 6 post treatment and functional exercise capacity for 150M dose vs. controls as measured by six minute walk test (6MTW: $p=0.062$) at month 12 post-treatment.
- An independent blind adjudication of potential HF-MACE was conducted post-hoc. Over 36 months of follow up, the 150 million cell dose was associated with a significantly greater probability of remaining free of HF-MACE events compared to the control group (0% versus 33% HF-MACE by Kaplan-Meier, $p=0.026$ by log-rank). The 25 and 75 million doses were not statistically different than controls with respect to this measure. On the basis of these results, the optimal dose for therapeutic benefit was considered to be the 150 million MPC dose.

In order to identify the most appropriate target population for the 150 million MPC dose, we evaluated whether optimal responders to MPC therapy were in the groups with more or less advanced heart failure. A further post-hoc analysis was performed in a blinded manner stratifying controls or 150 million MPC treated patients into those with a baseline LVESV of either <100 ml or >100 ml as a surrogate for significant myocardial contractile abnormality and more advanced chronic heart failure. The >100 ml LVESV threshold was chosen because it falls more than 3 standard deviations above the mean for normal LVESV. In the Phase 2 trial, 60% of patients met this criterion. A further sensitivity analysis across every decile in baseline LVESV between 70 ml and 120ml confirmed the findings seen in the stratification using a LVESV greater than 100 ml. This analysis demonstrated that:

- the therapeutic benefit of the 150 million dose on parameters of LV remodeling were markedly amplified by focusing on the target population with substantial baseline LV contractile abnormality and more advanced heart failure (LVESV greater than 100 ml);
- control patients with advanced heart failure (baseline LVESV > 100 ml) had the fastest progression of their disease over 6 months in terms of significant worsening in LVESV and LVEDV volumes, and worsening left ventricular ejection fraction ("LVEF");
- over a 6 month follow-up period, the 150 million MPC dose had a substantial cardioprotective effect on LVESV ($p<0.02$), LVEDV ($p<0.03$) and LVEF ($p<0.05$) in Class II/III patients with substantial baseline LV contractile abnormality (i.e. those with baseline LVESV > 100 ml);
- in the Phase 2 trial, all of the HF-MACE over 36 months of follow-up occurred exclusively in the controls with more advanced heart failure resulting in an annualized HF-MACE rate in these patients of 24% compared with 11% in the aggregated control group (i.e., baseline LVESV $\leq$ 100 ml or >100 ml);
- more specifically, among 18 Class II/III CHF patients with baseline LVESV > 100 ml, 5/7 (71%) control-treated versus 0/11 150 million MPC-treated patients experienced one or more HF-MACE over 36 months ($p=0.0007$); and
- therefore, the effect of the 150 million MPC dose on overall HF-MACE in the Phase 2 trials was markedly amplified in those patients with advanced heart failure and a high rate of progression. This may represent the optimal target patient population for MPC therapy in CHF patients.

Completed Pilot Phase 2a 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 left ventricular assist device ("LVAD") implantation for either bridge-to-transplant or destination therapy.

The results of this trial were presented at the American Heart Association Scientific Sessions 2013 and published in Circulation in June 2014.

No patients developed a primary safety event at the trial's 90-day primary endpoint, nor during the 12- month follow-up period. At 90 days, there were three deaths (30%) in the control group and none in the MPC group. In addition, median time to a first re-hospitalisation event in MPC-treated patients of 91 days compared with 50 days for the controls.

At the pre-specified 90 day primary endpoint analysis of the trial, 50% of MPC treated patients were able to successfully tolerate weaning off of LVAD support for at least 30 minutes compared to 20% in the control group. Over the 12 month follow-up period, eighty-five percent (85%) of MPC patients tolerated one or more temporary LVAD weans, compared to 40% of control patients. Based on these results, the posterior probability that a single injection of the 25 million low-dose of MPCs increased the likelihood of successful weaning is 93%. The duration of temporary LVAD wean, for those who tolerated it, was greater in MPC than control patients at each time point.

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. We hypothesize that a higher MPC dose may further enhance the ability to wean LVAD recipients off support, and may show a more prolonged survival benefit, which is the basis of the Phase 2b study discussed below under "Program for End-Stage CHF".

Current Status and Anticipated Milestones

Mesoblast's product candidate MPC-150-IM is in late-stage clinical development in two randomized controlled trials which target, respectively, severe and end-stage advanced CHF. Based on cumulative clinical results to date and the serious and life-threatening nature of this disease, we believe there is a pathway for accelerated entry of this product candidate into the market to provide a paradigm shift in treatment.

Patients with NYHA Class III/Class IV experience high mortality rates, recurrent hospitalizations, and incur substantial cost of care despite maximal existing therapies. We believe that under new regulatory frameworks that recognize the serious and life-threatening nature of advanced CHF, positive results from our ongoing Phase 2b/3 trials in these patients could support accelerated approval for MPC-150-IM and an opportunity to create a paradigm shift in this potential multi-billion dollar market.

MPC-150-IM is being evaluated in two ongoing randomized placebo-controlled Phase 2b/3 trials in patients with either severe or end-stage advanced CHF. The mechanism of action (MOA) by which MPC-150-IM is thought to exert its effects in these patient populations is through immunomodulation and cardiac repair. Positive clinical signals supporting a common underlying MOA have been previously published in Phase 2 trials of Mesoblast's allogeneic MPC therapy in moderate/severe and end-stage heart failure.

Program for End-Stage CHF

A Phase 2b trial of MPC-150-IM in 159 patients with end-stage heart failure and an implantable LVAD is nearly fully recruited, with top-line results for the trial's primary endpoint expected in Q1 2018. The trial is being fully funded by the NIH and conducted by a multi-center team of researchers within the NIH-funded CTSN. The trial is also supported by the National Institute of Neurological Disorders and Stroke and the Canadian Institutes for Health Research. The trial's results will be used to support the marketing approval application for the product candidate.

The trial is evaluating the effects of a single epicardial injection of MPC-150-IM into the hearts of patients with end-stage chronic heart failure. This is 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 either bridge-to-transplant or destination therapy are eligible to participate in the trial. All patients will be followed until 12 months post randomization.

The primary efficacy endpoint of the study is the number of temporary weans from LVAD tolerated over the 6 months post-randomization, indicating strengthening of the native heart muscle. Additional efficacy endpoints include patient survival, adverse events and rehospitalization rates over 12 months.

If MPC-150-IM is successful in this difficult-to-treat patient population facing high risk of hospitalization or death, data generated from this trial will be used to support a regulatory marketing application in this target population that continues to have unmet medical needs despite maximal standard of care. If data from clinical trials with our investigational agent prove successful at demonstrating improved efficacy on top of existing standard of care, we believe this may also assist us in negotiating attractive pricing and reimbursement terms.

Program for Class II/III CHF patients

We are conducting a multicenter, double-blinded, 1:1 randomized, sham-procedure-controlled Phase 3 trial of MPC-150-IM in approximately 600 Class II/III CHF patients. The trial is actively enrolling patients in the United States and Canada with NYHA Class II/III disease at high risk of repeated heart failure hospitalizations or Terminal Cardiac Event ("TCE") (cardiac death, LVAD placement, heart transplant or insertion of an artificial heart). The enrollment criteria for this trial includes a prior decompensated heart failure event (e.g., hospitalization) within the previous 9 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 chronic heart failure due to LV 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 MPC-150-IM in our previous Phase 2 trial.

More than 400 of the anticipated approximately 600 patients have been randomized to date. The trial's primary efficacy endpoint is a comparison of recurrent non-fatal HF-related major adverse cardiac events (HF-MACE) between either MPC-treated patients or sham-treated controls.

In April 2017, the trial achieved a successful pre-specified interim futility analysis of the efficacy endpoint in the first 270 patients. In addition, the independent Data Monitoring Committee formally recommended the continuation of the trial. We believe that positive results from this Phase 3 trial in advanced CHF patients would serve to confirm results with MPC-150-IM obtained in end-stage heart failure patients.

MSC-100-IV/JR-031 for the Treatment of acute Graft versus Host Disease ("aGVHD")

Overview

MSC-100-IV is our intravenously delivered product candidate for the treatment of acute steroid-refractory graft versus host disease, or SR-aGVHD, following allogeneic bone marrow transplant ("BMT"). Available data from clinical dose ranging studies identified an effective dose to be 2 x 106 MLCs/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. TEMCELL for the treatment of aGVHD is a MSC-based product candidate that our partner, JCR, has launched in Japan.

In a BMT, donor cells 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 is often fatal.

MSC-100-IV 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.

Currently there are no approved therapies for patients with acute steroid-refractory graft versus host disease ("SR-aGVHD") in the U.S., and off-label options have demonstrated mixed efficacy with high toxicity. As such, we believe there is a significant need for effective treatment with a favorable risk/benefit profile.

MSC-100-IV has been used for the treatment of aGVHD in children in the U.S., Canada and several European countries under an expanded access program, or EAP. This program enrolled more than 240 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 40% of all patients with aGVHD and are associated with the greatest risk of death, with mortality rates of up to 85%.

The 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.

Results from Expanded Access Program

From 2008 an expanded access program ("EAP"), called Protocol 275, was conducted for a group of pediatric patients with SR-aGVHD treated with MSC-100-IV. An EAP provides investigational therapy to patients outside of a clinical trial in a country that has not received marketing approval for the product candidate being evaluated. It is intended for the treatment of serious or life-threatening conditions for which there is no available alternative treatment and where there is existing evidence of safety as well as signals of efficacy in order to establish that the patient may benefit from the therapy.

In February 2016, we announced results from 241 children treated in the EAP. The results, 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 in Hawaii, demonstrated clinically meaningful responses and associated significantly increased survival in children with steroid-refractory aGVHD. Key results were:

- an overall response rate of 65% was seen at day 28 after treatment with MSC-100-IV;
- a response rate of 81% was seen when MSC-100-IV was used as front-line therapy following steroid failure;
- in patients with gastrointestinal and liver disease, who have the highest mortality risk, overall response rates were 65% and 62% respectively;
- children who achieved overall response at day 28 had significantly improved survival (82% vs 39%, log rank p-value <0.0001); and
- extending therapy beyond day 28 in the subset of children who had not achieved an overall response but had some improvement at day 28 (mixed response) resulted in significantly improved survival (72% vs 18%, log rank p-value 0.003).

Current Status and Anticipated Milestone

Japan. Our licensee, JCR, has launched its aGVHD MSC based product (TEMCELL) in Japan in February 2016. TEMCELL is the first "allogeneic" cell-based product in Japan, meaning a product containing cells from a single donor was expanded and used in many unrelated patients.

The Japanese Government's National Health Insurance ("NHI") body has formally set a price for the mesenchymal stem cell product TEMCELL® HS Inj. at ¥868,680 for 72 million cells. A four-week, multi-dose treatment course of TEMCELL for an average adult is expected to be reimbursed at ¥13,898,880, or at ¥20,848,320 if symptoms persist and additional dosing is required. We are entitled to receive royalties and other payments at pre-defined thresholds of net sales.

U.S. The FDA has acknowledged that the results from the EAP provide a substantial safety experience and likely evidence of a treatment effect. The FDA has also acknowledged that given the prior results with mesenchymal lineage stem cells in this indication, and the unmet medical needs, a randomized controlled study is neither feasible nor ethical. However, given the number of additional therapies received by many of the EAP patients (often 2-4 prior therapies), additional data in the absence of confounding additional therapies has been requested by the FDA. We expect to provide this additional data through the on-going single-arm, open-label Phase 3 study of up to 60 pediatric patients with SR-aGVHD treated with our MLC product candidate. These patients will not receive other line therapies thus allowing the treatment effect of our MLC product candidate to be clearly observed.

Supporting the notion that our MLC product candidate may be effective as first line therapy in SR-aGVHD, in a subset analysis of 28 pediatric patients recruited in Protocol 280 (a randomized, placebo controlled trial of MSC-100-IV as first-line therapy in SR-aGVHD) overall response was significantly improved in treated children. Moreover, in 32 children with SR-aGVHD within the 275 EAP protocol, where MSC-100-IV was administered as first-line therapy, a similar proportion responded as was seen in the overall EAP program.

Accordingly, we initiated an open-label Phase 3 trial of up to 60 children with enrollment expected to be completed and interim results anticipated in 2H CY2017. The pre-specified interim futility analysis of the trial's primary endpoint, conducted by the Independent Data Safety Monitoring Board, was successfully achieved in November 2016. The interim analysis showed that the predefined Bayesian futility rule used to determine the probability of the trial's success using the trial's primary endpoint of Day 28 overall response had been passed. The analysis method determined the likelihood of obtaining a statistically significant treatment effect at study completion, based on the data observed at this interim time point. The FDA has granted a Fast Track designation for the

use of MSC-100-IV to improve overall response rate in children with steroid refractory aGVHD. Fast Track designation has the potential to shorten the time to FDA approval through priority review and a streamlined rolling review process.

In December 2016, we announced that we had entered into an equity purchase agreement with Mallinckrodt Pharmaceuticals to exclusively negotiate a commercial and development partnership for the treatment or prevention of MSC-100-IV in the treatment of aGVHD. Under the terms of the agreement, Mallinckrodt will have an exclusive period of up to nine months to conclude commercial and development agreements for the two product candidates in all territories outside of Japan and China.

During the conduct of our pediatric Phase 3 trial, we expect to have discussions with the FDA regarding the trial design for a potential Phase 3 trial to support approval of this product for adults with high risk liver or gut aGVHD, the patient groups who have the highest mortality risk.

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 CLBP caused by degenerative disc disease ("DDD"). MPC-06-ID consists of a unit dose of 6 million MPCs administered with hyaluronic acid ("HA"), and is injected by syringe directly into a targeted 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 that results in chronic pain. The 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. These effects together offer the potential to strengthen the load bearing function of the disc by increasing its water content, improving disc anatomy, and improving disc stability, while also reducing inflammation and pain.

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 no treatment that prevents progression of disc degeneration, reduces pain and improves function over a sustained period of 6 to 12 months. 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, but are not disease-modifying and thus 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 US$100 billion and US$200 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 reverse, halt or slow the progression of the disease and improve physical function. MPC-06-ID is being developed to target the population of patients suffering from moderate to severe CLBP due to moderately degenerated discs. The target patient population has exhausted conservative treatment options, may have failed epidural steroid injections to alleviate pain and has no treatment option other than invasive and costly surgical interventions.

Completed Phase 2 Clinical Trial

The primary objective of our Phase 2 study 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 ("PP") 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.

In March 2017, in line with U.S. FDA guidance for the ongoing Phase 3 trial, the 24-month primary endpoint composite was additionally analyzed using an intent to treat (ITT) population. The 36-month analysis aimed to determine the proportion of patients who maintained treatment success beyond the 24-month primary evaluation.

Key 36-month trial results were:

- the primary endpoint composite over 24 months was achieved by 41% of patients who received 6 million MPCs, 35% of the 18 million MPC group, 18% of the hyaluronic acid group, and 13% of the saline group, using the pre-specified PP population analysis
    - pain responder criteria (50% pain reduction with no additional intervention at both 12 and 24 months) was achieved by 52% of the 6 million MPC group compared with 13% of the saline group ($p<0.05$)
    - functional responder criteria (15-point reduction in Oswestry disability index ("ODI") and no additional intervention at both 12 and 24 months) was achieved by 48% of the 6 million MPC group compared with 13% of the saline group ($p<0.05$)
- similar results were seen for the primary endpoint composite over 24 months using the ITT analysis, with 38% of the 6 million MPC group achieving this outcome compared with 10% of the saline group ($p<0.05$)
    - 82% of the 6 million MPC group who achieved the primary endpoint composite over 24 months maintained treatment success using this composite endpoint at 36 months
    - 86% of the 6 million MPC group who successfully met the pain responder criteria (50% pain reduction with no additional intervention at both 12 and 24 months) remained pain responders through 36 months
    - 92% of the 6 million MPC group who met the functional responder criteria (15-point reduction in ODI and no additional intervention at both 12 and 24 months) remained functional responders through 36 months
- there were no significant differences in measurements of safety between cell-treated patients and controls over 36 months

The 36-month Phase 2 trial results support the ongoing 360-patient Phase 3 trial of MPC-06-ID for CLBP by reinforcing the rationale for MPC dose selection, use of saline control, and the trial's primary endpoint composite over 24 months. If similar clinical durability is seen in the Phase 3 program, it is anticipated such data could translate into meaningful health economic benefits including increased productivity that may support attractive product reimbursement, and our ability to enter into a commercial partnership.

Current Status and Anticipated Milestones

The first of two Phase 3 clinical trials for CLBP is actively recruiting 360 patients across 30 sites 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) is an acceptable endpoint for product approval, as per guidance from the FDA. Enrollment of our ongoing Phase 3 trial is expected to be completed in Q4 CY2017.

In December 2016, we announced that we had entered into an equity purchase agreement with Mallinckrodt Pharmaceuticals to exclusively negotiate a commercial and development partnership for the treatment or prevention of moderate/severe CLBP due to disc degeneration. Under the terms of the agreement, Mallinckrodt will have an exclusive period of up to nine months to conclude commercial and development agreements for the two product candidates in all territories outside of Japan and China.

MPC-300-IV for the Treatment of Immune Mediated Diseases

The diverse and potent anti-inflammatory properties of MPCs are the foundation for their usefulness in immune-mediated diseases such as rheumatoid arthritis 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.

More specifically, MPC-300-IV was designed for intravenous delivery to treat systemic and localized conditions of excessive inflammation, whereby our MPCs can counteract inflammatory processes by down- regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of anti-inflammatory cells to involved tissues. For example, MPCs produce immunomodulatory biomolecules such as prostaglandin E2, or PGE2 and indoleamine2, 3-dioxygenase, or IDO, in response to activation by pro-inflammatory cytokines such as tumor necrosis factor-alpha, or TNF-alpha; interleukin-1, or IL-1; interleukin-6, or IL-6; interleukin-17, or IL-17. These MPC-released biomolecules act along multiple pathways, such as polarizing pro-inflammatory M1 monocytes to anti-inflammatory M2 monocytes, neutralizing harmful macrophages, and switching activated T helper cells 1 and 17, or Th1 and Th17, respectively, to Th2 cells and FOXP3 T regulatory cells.

MPC-300-IV for the Treatment of Rheumatoid Arthritis ("RA") (Biologic Refractory)

Overview

MPC-300-IV is our proprietary Phase 2 product candidate being developed for biologic-refractory rheumatoid arthritis. The product candidate is being evaluated at both 1 and 2 million MPC/kg dose(s) via intravenous infusion.

Pro-inflammatory monocytes/macrophages and activated T cells are involved in the pathogenesis of RA via activation of multiple pro-inflammatory cytokine pathways, including TNF-alpha, interleukin-6, and interleukin-17. Existing biologic therapies target any one of these cytokine pathways individually, however none target all of these pathways concomitantly. As a result, various segments of patients with RA will show moderate response to one or other of these biologic agents, but very few patients will have sustained remission due to continued expression of pro-inflammatory cytokines. In pre-clinical large animal trials, we have shown that a single intravenous injection of our proprietary allogeneic MPCs results in concomitant inhibition of TNF-alpha, IL-6 and IL-17 inflammatory pathways in the inflamed joints resulting in substantial amelioration in clinical disease. Additionally, our data show that MPCs can reduce inflammation and reverse abnormal function of blood vessels, including the coronary arteries, in a sheep model of RA. A single intravenous infusion of allogeneic MPCs significantly reduced the systemic inflammation present in a sheep model of RA, increased circulating levels of the anti-inflammatory cytokine interleukin-10, or IL-10, and reversed the abnormal endothelial dysfunction present in the coronary arteries and the digital arteries in these animals. Since patients with RA have an approximately 50% higher risk of death from cardiovascular disease than the general population, these results suggest that the anti-inflammatory effect of MPC therapy have potential to reduce cardiovascular risk associated with RA.

Market Opportunity

Major advances in the treatment of RA using biologic agents have resulted in a $19 billion global market in 2016 that is projected to grow to over $22.5 billion in 2025. There are approximately 6.0 million prevalent cases in the U.S., Japan and the five major European markets, with 2.9 million in the U.S. alone in 2016.

The disease is associated with multiple co-morbidities and psychosocial impairments, including cardiovascular disease, osteoporosis, interstitial lung disease, depression, work disability and decreased health-related quality of life. Rheumatoid arthritis is responsible for approximately 250,000 hospitalizations and 9 million physician visits per year in the U.S.

If left untreated and/or high disease activity remains, RA can lead to joint destruction, deformity, disability, decreased quality of life, and increased mortality. On average, maintenance rates for anti-TNFα therapy at 1 year is ~65% and drops to ~40% at 5 years. Switching to a second or third anti-TNFα product results in significantly lower efficacy than is seen with an anti-TNF agent in biologically naive patients. Additionally, these therapies have been associated with significant risk of opportunistic infections and malignancies. As doses are pushed in order to achieve acceptable response, such as ACR 50, ACR 70, or remission, such risks may increase with added economic burden.

RA patients who are refractory to existing biologic therapy are in need of effective new treatments and would benefit from an alternative therapeutic approach which is both safe and effective. Despite the substantial advances in RA treatment using biologic agents such as anti-TNF agents, approximately one third of patients either do not respond sufficiently or cannot tolerate these agents due to infectious or other complications. In the United States, the anti-TNF refractory population is the fastest growing branded market segment, projected to increase by 8% annually and potentially higher with the expected market entry and greater availability of anti-TNF biosimilars.

Phase 2 Trial

Mesoblast's Phase 2 trial recruited a total of 48 patients with active RA who were on a stable regimen of methotrexate and had an inadequate prior clinical response to at least one anti-Tumor Necrosis Factor (TNF) agent. Of the 48 patients, 30 (63%) had previously received 1-2 biologic agents. Patients were randomized to a single intravenous infusion of 1 million MPCs/kg (1M/kg, n=16), 2 million MPCs/kg (2M/kg, n=16) or placebo (n=16). The study was comprised of a 12 week primary study period with a 40 week follow-up for a study total duration of 52 weeks.

The primary objective of the study was to evaluate safety and tolerability of a single intravenous MPC infusion in biologic refractory RA patients through a 12 week primary endpoint. Additional objectives were to evaluate pre-specified clinical efficacy endpoints at the primary 12 week timepoint, as well as to assess the onset and time course of effect within the first 12 weeks and subsequent durability of effects and safety profile through the full 52 week study.

Pre-specified efficacy endpoints included the following: American College of Rheumatology (ACR) composite clinical response, which is an endpoint used in RA clinical trials to measure improvement in signs and symptoms of the disease in terms of 20%, 50% or 70% improvement from baseline; ACR-N which measures the mean or median magnitude of benefit using an ACR composite for a typical patient; the health assessment questionnaire-disability index (HAQ-DI), a standardized measure of functional status; and the DAS28 composite measurement of disease activity; no adjustment for multiplicity was performed as these efficacy endpoints were exploratory and the trial was not powered for efficacy.

Additionally, continuous variables ACR-N, HAQ-DI and DAS-28 were evaluated in a pre-specified manner since the use of endpoints sensitive to change provide better discriminatory power for dose-response assessment, in line with the FDA Guidance For Industry Rheumatoid Arthritis: Developing Drug Products For Treatment, May 2013.

Analyses were performed for the whole study population and for the pre-specified exploratory subgroup based on whether the subjects had previously received 1-2 or more than 2 biologic agents.

In February 2017, we announced 39-week data from this Phase 2 trial. The results showed that a single intravenous infusion of, MPC-300-IV was well tolerated and demonstrated a durable improvement in clinical symptoms, physical function, and disease activity relative to placebo over this period of follow-up.

The key trial results were:

- a single intravenous MPC infusion of either 1 million or 2 million MPC/kg resulted in durable responses through nine months (39 weeks) in the 48-patient placebo-controlled, randomized Phase 2 trial in patients who have failed one or more TNF inhibitors;
- the safety profile over 39 weeks was comparable among the placebo and both MPC treatment groups, with no cell-related serious adverse events;
- both MPC doses outperformed placebo at week 39 in each of ACR20/50/70 responses;
- both MPC doses outperformed placebo at week 39 in the proportion of patients who achieved the target of low disease activity (DAS-28<3.2); disease remission (DAS 28 <2.6) was seen at similar levels across all groups;
- use of continuous variables ACR-N, HAQ-DI and DAS-28, in line with FDA guidance for dose-finding Phase 2 trials of new RA therapies, identified the 2 million MPC/kg dose as the most effective over 39 weeks;
- while both MPC doses achieved higher median ACR-N scores compared with placebo at 39 weeks, the 2 million MPC/kg dose achieved the maximal ACR-N score earlier, at 12 weeks;
- over the entire 39 weeks, the 2 million MPC/kg MPC group had a significantly greater ACR-N Area Under the Curve (AUC) than placebo, indicating a more robust durable effect with the higher treatment dose;
- at 39 weeks, there was a dose-dependent treatment effect on mean change from baseline in function (HAQ-DI) and disease activity score (DAS-28), with the 2 million MPC/kg dose showing the greatest effect; and

- MPC treatment effects for all parameters were greatest in patients who had failed 1-2 biologic agents.

In August 2016, we released the 12 week results in this Phase 2 trial. These results showed that an intravenous infusion of allogeneic MPCs was well tolerated in biologic refractory RA patients, without serious adverse events over 12 weeks. A single intravenous MPC infusion in biologic refractory RA patients resulted in dose-related improvements in clinical symptoms, function and disease activity, with the 2 million MPCs/kg dose providing the greatest responses.

Current Status and Anticipated Milestones

Our Phase 2 trial of MPC-300-IV in biologic refractory RA continues as we evaluate safety through 52 weeks and duration of responses.

We believe the safety and efficacy results of this trial to date provide support for our MPCs to be positioned as a first-line treatment option in RA patients who have previously received a prior anti-TNF or other biologic agent.

Given the large market opportunity, we believe MPC-300-IV is well-positioned to advance through a strategic partnership into Phase 3 development for biologic refractory rheumatoid arthritis.

MPC-300-IV for the Treatment of Diabetic Complications, Including Kidney Disease

Overview

MPC-300-IV for the treatment of diabetic complications, including diabetic nephropathy, is our proprietary product candidate consisting of up to 300 million MPCs delivered intravenously.

The aberrant activation of the immune system that occurs in type 2 diabetes patients is associated with inflammation of various organs, including kidney, liver and fat tissues, resulting in resistance to the effects of insulin in the fat tissues, and poor glucose control. Inflammation in the kidneys and liver results in diabetic nephropathy and diabetes-related non-alcoholic steatohepatitis, or NASH. We are developing a high-dose product for intravenous administration to target the polyvascular complications of patients with type 2 diabetes, including diabetic nephropathy, NASH and retinopathy.

In small and large animal models of diabetes, a single intravenous injection of MPCs resulted in sustained improvement in glucose control. Additionally, in multiple small animal models of diabetic nephropathy, intravenous MPC infusions reduced inflammation in the kidneys and improved renal function and reduced albuminuria.

Market Opportunity

While all classes of current anti-diabetic agents are effective at improving glucose control, they are not effective in preventing or potentially reversing the renal complications in type 2 diabetes, which affect approximately 40 to 50% of people with diabetes. Diabetic nephropathy is the single leading cause of end-stage renal disease, accounting for nearly half of all end-stage renal disease cases in the US. The prevalence of moderate to severe diabetic nephropathy in 2013 was estimated to be approximately 1.96 million.

The current standard of care of diabetic nephropathy (rennin-angiotensin system inhibition with angiotensin converting enzyme inhibitors of angiotensin II receptor blockers) only slows the rate of progression of the disease to renal failure by 16-25%, leaving a large residual risk for end-stage renal disease. For subjects that reach end-stage renal disease the only treatment option is renal replacement (dialysis or kidney transplantation) at high cost in the US with medical costs of $100,000 for dialysis and $250,000 for kidney transplant. Furthermore, for those on dialysis the mortality rate is high with an approximately 40% fatality rate within 2 years after initiation of dialysis. To the extent MPC-300-IV can be shown to be effective in this population, additional applications would be possible for the over 20 million people in the U.S. who are estimated to have chronic kidney disease.

Phase 2 Trial

Diabetic nephropathy is thought to be caused by ongoing monocyte inflammation and endothelial dysfunction, or abnormal blood vessels, in the kidneys. Our bone marrow-derived MPCs are potent modulators of monocyte inflammation, and have been shown in preclinical studies to reduce monocyte infiltration in diabetic kidneys and to reverse endothelial dysfunction. Consequently, we are developing MPC-300-IV for intravenous delivery in the treatment of diabetic nephropathy.

This trial of MPC-300-IV was a double-blind, randomized, placebo-controlled, dose-escalating Phase 2 trial of 30 patients with type 2 diabetes and moderate to severe renal impairment, stage 3b-4 chronic kidney disease (“CKD”), who were already on a stable

regimen of the standard of care therapy for diabetic nephropathy, which consists of renin-angiotensin system inhibition with angiotensin converting enzyme inhibitors or angiotensin II receptor blockers. Patients received a single infusion of 150 million MPCs, 300 million MPCs, or saline control.

The objectives of the trial were to evaluate safety and to explore potential efficacy signals of MPC treatment on renal function. The pre-specified primary efficacy endpoint was to evaluate effects of MPC treatment relative to placebo on renal functional decline at 12 weeks, as defined by change in glomerular filtration rate ("GFR"), measured both by direct isotope scan and by serum-creatinine based estimation, and then for an additional 48 weeks of follow-up. Pre-specified secondary analyses included GFR differences between treatment and placebo groups with baseline GFR>30ml/min/1.73m2 (stage 3b CKD, accounting for 60% of enrolled patients), and treatment-related effects on the monocyte-derived cytokine interleukin-6, or IL-6, a major inflammatory marker associated with renal failure progression and adverse cardiovascular outcomes.

The primary efficacy endpoint of decline or change in GFR was in line with the 2012 joint workshop held by the United States Food and Drug Administration and the National Kidney Foundation which recommended that time to 30%-40% decline in GFR is an acceptable primary endpoint for evaluating potential benefits of new therapies for this patient population. This joint workshop recognized the significant unmet medical need and urgency to make new therapies accessible to patients who may benefit from them. This revised endpoint could make new treatments available earlier to patients with chronic renal failure by reducing trial size and duration, compared with the previously accepted composite endpoint of time to first occurrence of doubling of serum creatinine (equivalent to a 57% reduction in GFR), renal replacement or death.

In October 2016, we announced that results from our Phase 2 trial of MPC-300-IV, in patients with diabetic kidney disease have been published the peer-reviewed journal *EBioMedicine*. The paper, entitled 'Allogeneic Mesenchymal Precursor Cells (MPC) 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. Key trial results were:

- the safety profile for MPC-300-IV diabetic kidney disease treatment was similar to placebo, with no treatment-related adverse events;
- efficacy testing showed that patients receiving a single MPC infusion at either dose (150 million MPCs or 300 million MPCs) had improved renal function relative to placebo, as defined by preservation or improvement in GFR at 12 weeks;
- the rate of decline in estimated GFR at 12 weeks was significantly reduced in the group receiving a single dose of 150 million MPCs relative to the placebo group (p=0.05); and
- there was a trend toward more pronounced treatment effects relative to placebo in the pre-specified subgroup of patients with GFR>30ml/min/1.73m2 at baseline (p=0.07).

Results from the trial had previously been presented in June 2015 at the 75th annual meeting of the American Diabetes Association.

Current Status and Anticipated Milestones

The Phase 2 trial was conducted in Australia under an Australian Clinical Trial Application, or CTA. Both treatment cohorts have been followed up per protocol through 60 weeks. The positive responses we observed following a single intravenous injection of MPC-300-IV will facilitate discussions regarding adaptive Phase 2b/3 clinical trial designs with the FDA and potential strategic partner discussions.

Tier 2 Programs

MPC-25-IC for the Treatment of Acute Cardiac Ischemia

Enrollment has completed in our Phase 2 trial for MPC-25-IC for the treatment of acute myocardial infarction ("AMI"). This trial was a prospective, randomized, placebo-controlled, double blind clinical trial that will analyze the effect of intracoronary infusion of MPCs in 106 patients with a first-time acute ST-elevation myocardial infarction. The therapy was initiated directly following revascularization of the left anterior descending artery, along with standard therapies for AMI. After successful revascularization, the patients were 1:1:1 randomized to receive 12.5 or 25 million MPC or placebo via intracoronary infusion. The primary endpoint of safety was evaluated at 30 days. The secondary efficacy endpoint is defined as reduction in the left ventricular end-systolic volume at 6 months. Additional efficacy parameters from cardiac magnetic resonance and echocardiography will also be evaluated at this timepoint. Occurrence of MACE events will be evaluated over 24 months with full trial results released following this period.

MPC-25-Osteo for the Treatment of Spinal Fusion

Our Phase 2 trial for MPC-25-Osteo for the treatment of spinal fusion is completed. The study consisted of 24 patients with MPCs (implanted into intervertebral disc space) undergoing 1 or 2-level lumbar interbody fusion via posterior procedures (TLIF, PLIF). Patients were randomized to 25 million MPC dose (n=8), 75 million MPC dose (n=8) or autograft from the hip (n=8). We have had an end-of-Phase 2 meeting with the FDA, and as a result of that meeting there is a consensus regarding the scope and design of a Phase 3 program using MPC-25-Osteo for the treatment of lumbar spinal fusion.

MSC-100-IV for the Treatment of Crohn's Disease (Biologic Refractory)

A 330 patient multi-centered, double-blind, randomized, placebo-controlled Phase 3 trial for MSC-100-IV for the treatment of Crohn's Disease ("CD") is ongoing. The focus of this trial is on the safety and efficacy of MSC-100-IV in moderate to severe CD in patients who are refractory to steroid, immunosuppressant and biologic therapy. The primary endpoint is the proportion of patients experiencing disease remission within 28 days of treatment, compared to those patients receiving placebo, as defined by an absolute Crohn's Disease Activity Index score below 150. When the trial is complete, we will evaluate whether the primary endpoint of day 28 remission in biologic-refractory patients has been achieved, whether there is evidence of efficacy in high-risk groups such as those with fistulizing disease and multi-drug refractory patients, and whether maintenance dosing can result in longer duration of effect.

MPC-75-IA for the Treatment of Knee Osteoarthritis

Our double-blind, placebo-controlled, 17-patient Phase 2a trial of MPC-75-IA for prevention of radiographic and clinical features of knee osteoarthritis after traumatic injury has completed with the top-line results from this study released. Results of the Phase 2a trial have been recently published in the peer-reviewed journal Arthritis Research & Therapy. The results showed that a single intra-articular injection of Mesoblast's product candidate 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.

Complementary Technologies

In addition to establishing what we believe to be the most advanced regenerative medicine product portfolio in the industry, we have also strategically targeted the acquisition of rights to technologies that are complementary to and synergistic with our MLC platform. The aim of this activity is to maintain what we see as 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 the following.

- Additional types of MLCs, including dental pulp stem cells and periodontal stem cells, that hold promise in regenerative applications for neurological networks and in dental applications.
- Cell surface modification of MLCs using ex vivo fucosylation to improve homing characteristics to sites of inflammation.
- Cell payloading technology, which allows us to load our MLCs and other cell types with molecules or nucleotides that can either (i) enhance the natural function of our cells (e.g., increase persistence or homing and engraftment) or (ii) be delivered directly to sites of inflammation and tissue damage by our MLCs.
- Protein technologies, which are focused primarily on proteins naturally produced by our MLCs, that can be developed independently or in combination with our MLCs. For example, we are developing a product candidate based on a molecule known as stromal cell derived factor 1, or SDF-1, that has shown various tissue regeneration capabilities in preclinical studies. We have a proprietary variant of SDF-1 that has been engineered to be resistant to enzymatic cleavage and that has a longer half-life in vivo compared to the native molecule.
- Gene targeting technologies, that allow us to target various helpful or harmful genes related to a given disease indication.

MLCs modified using our proprietary cell targeting technology, called ex vivo fucosylation, have successfully induced durable reversal of Type 1 diabetes in a preclinical study. The study results were published in the peer reviewed journal *Stem Cells* in 2015. The results showed that the cell targeting technology increased by three-fold the numbers of MLCs reaching the inflamed pancreas in autoimmune diabetic mice following intravenous infusion, compared with unmodified MLCs. This resulted in a markedly increased number of mice who reverted to having normal blood glucose, and in durable reversal of Type 1 diabetes. We have conducted a placebo-controlled, randomized, dose-escalating Phase 2 clinical trial of our product candidate MPC-300-IV in patients with Type 2 diabetes, the results of which were published in the peer-reviewed journal *Diabetes Care* in 2015. By enhancing targeting of the cells to the inflamed pancreas, we believe the ex vivo fucosylation technology has the potential to further augment the glucose lowering properties of MPC-300-IV, and to extend its use to patients with Type 1 diabetes.

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 conducted in Lonza's Singapore facility, and products will be cryopreserved, then shipped to Lonza or other 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 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 settle on a new network of distributors in various regions.

Our product candidates are currently 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 MSC-100-IV for aGVHD lead us to believe that 2D manufacturing will provide commercial cost of goods for this product candidate if fully approved. We also believe that 2D manufacturing is 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 manufacturing processes using three-dimensional, or 3D, bioreactors with greater capacity to improve efficiency and yields, with resulting lower-cost of goods. We expect to evaluate products produced in 3D bioreactors in later stages of our Phase 3 clinical trials, which will 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 have met stringent criteria set by international regulatory agencies, including the U.S. 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 MLC cell-based technologies and other proprietary regenerative product candidates and technologies, as well as for elements of our manufacturing processes, with approximately 800 patents and patent applications across 69 patent families as of August 2017.

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 MLC 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 MLCs are those which are directed to our Tier 1 product candidates: CLBP, CHF, aGVHD and chronic inflammatory conditions such as RA and DKD. We also have issued and pending patents covering our Tier 2 and pipeline indications, including inflammatory bowel disease (e.g., Crohn's disease), neurologic diseases, eye diseases and orthopedic diseases.

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 2017, our patent portfolio includes the following patents and patent applications in the following major jurisdictions: 77 granted U.S. patents and 52 pending U.S. patent applications; 43 granted Japanese patents and 33 pending Japanese patent applications; 20 granted Chinese patents and 18 pending Chinese patent applications; 27 granted European patents and 42 pending European patent applications; and 49 granted Australian patents and 23 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

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, or the 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, 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.

The Japanese Pharmaceuticals and Medical Devices Agency granted JR-031 orphan drug status in December 2013, and, as a result, it underwent a priority review. JCR filed for approval in September 2014 and received full approval in September 2015 for TEMCELL. JCR has expanded its manufacturing facility to support commercial launch. JR-031 is the first culture-expanded allogeneic stem cell product to be approved in Japan.

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 US$2.5 million in the aggregate when JCR reaches certain development and 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.

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 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 US$2.5 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 mesenchymal precursor cells and methods of isolating, culturing and expanding mesenchymal precursor cells and their use in any therapeutic area. We also acquired all related materials, information and know-how.

Case Western Reserve University—Mesenchymal Stem Cell Intellectual Property

In October 2013, our wholly owned subsidiary, Mesoblast International Sàrl, acquired certain MSC-based assets from Osiris including a technology transfer and license agreement between Osiris and Case Western Reserve University, or CWRU. Pursuant to the technology transfer and license agreement, or CWRU Agreement, we (i) were assigned certain patent rights relating to MSCs, or CWRU Assigned Patents, and (ii) obtained an exclusive, worldwide, sublicensable license to (A) information and know-how relating to MSCs, or CWRU Technology, and (B) certain patents relating to (x) MSCs, or CWRU Licensed Patents, and (y) the CWRU Assigned Patents, to the extent the CWRU Assigned Patents are not owned by us (collectively, with the CWRU Technology and CRWU Licensed Patents, the CWRU Licensed Technology and Patents).

Pursuant to the CWRU License, we acquired sole and exclusive worldwide sublicensable rights to more than ten U.S. patents or patent applications (including any divisions, continuations, continuations-in-part, reissues, reexaminations or extensions thereof along with all foreign equivalents) and related technologies. These patents and technologies generally relate to isolated human mesenchymal stem cells, methods for isolating, purifying, and culturally expanding human mesenchymal stem cells without having them differentiate, and characterization of and uses of mesenchymal stem cells including related research reagents, diagnostics and therapeutic uses for such cells and other related materials, methods and subject matter.

CWRU retained a right to use the CWRU Licensed Technology and Patents for nonclinical research, testing or educational purposes, including research funded by a commercial entity unless the commercial entity obtains a license or ownership of the research results. Under the CWRU Agreement, we are obligated to pay single-digit royalties on net sales of product covered by the CWRU Licensed Patents and a double-digit percentage of royalties received from a sublicensee of the CWRU Licensed Patents. Additionally, we are obligated to pay single-digit royalties on products covered by certain of the CWRU Assigned Patents. The royalties that we are obligated to pay to CWRU on sales of products are not due for an initial period of sales of each such product, and are subject to a reduction in the event we have to pay royalties to a third party for the sale of those products. The royalties that we owe under the CWRU License on sales of products will also be reduced for costs arising from an infringement suit against us by a third party based on sales of covered products and for costs arising from any suit we file against a third party to protect any intellectual property right granted under the CWRU Agreement. Our payment obligations under the CWRU Agreement are subject to a minimum annual payment.

Either we or CWRU may initiate a suit based on the infringement of the CWRU Licensed Technology and Patents. In the event CWRU notifies us that a third party desires to obtain a sublicense to the CWRU Licensed Technology and Patents in a field that we are not practicing, we are obligated to negotiate in good faith a sublicense with the third party subject to certain limitations that protect our commercial interests.

The CWRU Agreement continues until at least expiration of all of the patents within the CWRU Licensed Technology and Patents, unless the CWRU Agreement is terminated at an earlier time. The last patent in this portfolio expires in July 2020. We have a right to terminate the CWRU License upon advance written notice to CWRU. CWRU has a more limited right to terminate the CWRU License that includes a right to terminate the CWRU License in the event we have materially breached the CWRU License and have not cured the breach within a specified time period.

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 MSC-100-IV 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 US$50 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 US$750 million. These royalty payments will cease after the earlier of a ten year commercial sales period and the first sale of a competing product.

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.

We believe that 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.

U.S. 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 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 Biologics License Application ("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 or 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;
- 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. ;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced 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 the nonclinical 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 subject to 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 investigators, generally physicians 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 of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, 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.

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. However, complexities associated with the larger, and often more complex, structure of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product.

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 ("EEA") 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 ("MAA"). 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.

Japanese Regulation

In Japan, the Pharmaceuticals and Medical Device Agency ("PDMA"), a division of the Ministry of Health, Labour and Welfare ("MHLW"), regulates the development and commercialization of medical therapies. Recently, Japan's parliament enacted new legislation to promote the safe and accelerated development of treatments using stem cells.

The Pharmaceuticals, Medical Devices and Other Therapeutic Products ("PMD") Act, took effect on November 25, 2014 in Japan. The PMD Act established a framework for expedited approval in Japan for certain regenerative medical products. We intend to

seek expedited conditional approvals in Japan for our cell therapy product candidates by capitalizing on our clinical data generated to date, our strong intellectual property, and our manufacturing know how.

Key takeaways of the PMD Act for us are:

- Conditional product approvals may be based on existing Phase 2 trial results demonstrating probable efficacy and safety with bridging studies in Japanese patients;
- Conditional approvals will allow sales of each product candidate for up to 7 years;
- Conditionally approved products will be covered by health insurance;
- Conditional approvals will cover allogeneic cell therapy product candidates manufactured under GMP outside of Japan; and
- Full approval is expected to require further confirmation of safety and efficacy in a larger population.
- The PMD Act may enable us to make our cell therapy product candidates available sooner to patients with unmet medical needs, and to achieve nearer term revenues in Japan ahead of other major jurisdictions.

For other countries outside of the EU and Japan, 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. 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. In addition, beginning in 2013, a similar federal requirement began requiring manufacturers to track and report to the federal government certain payments and other transfers of value made to physicians and other healthcare professionals and teaching hospitals and 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 the United States as reporting is required also for payments made by affiliated entities in many cases to US covered persons. This requires extensive administration and systems. The federal government began disclosing the reported information on a publicly available website in 2014. These laws may affect our 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 comply with these laws, we could be subject to the penalty provisions 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, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Employees

As of June 30, 2017, we had 75 employees, 44 of whom are based in the United States, 22 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 108 and 115 employees as of June 30, 2016 and 2015, respectively. We have no collective bargaining agreements with our employees. We have not experienced any work stoppages to date and consider our relations with our employees to be good.

Facilities

See "Item 4.B Business Overview – Manufacturing and Supply Chain" and "Item 4.D – Property, Plants and Equipment".

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.

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, 2017. 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$786,000 per year for this lease, which expires in April 2020. We also lease approximately 15,600 square feet in New York City, where significant development and commercial activities are conducted. We pay US$1,015,000 per year for this lease. We also lease laboratory and office space in Singapore. We pay approximately S$334,000 per year for this lease, which expires in December 2017. We also lease laboratory and office space in Texas and pay approximately US$209,000 per year for this lease. 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.

Overview

We are a global leader in developing innovative cellular medicines. We have leveraged our proprietary technology platform based on specialized cells known as MLCs, to establish a broad portfolio of late-stage product candidates.

Our allogenic "off-the-shelf" product candidates target advanced stages of diseases with high, unmet medical needs including cardiovascular conditions, immunologic and inflammatory conditions, orthopedic disorders, and oncology and hematology conditions. We also have a promising emerging pipeline of products for follow-on indications.

Each MLC-derived product candidate has distinct technical characteristics, target indications, reimbursement strategy, commercialization potential, and partnering opportunities.

We have incurred net losses during most of our fiscal periods since our inception. For the year ended June 30, 2017, we had an accumulated deficit of $344.9 million. Our net loss for the year ended June 30, 2017 was $76.8 million.

Financial Overview

We have incurred significant losses since our inception. 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 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.

Over the short term (12 to 24 months) if we are able to successfully partner one or more of our products we would expect our research and development expenditure to decrease. 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. As described in "Item 18 Financial Statements – Note 1(ii)", a fully discretionary equity facility remains for up to A$120 million/US$90 million over 24 months to provide additional funds as required. 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 "Item 18. Financial Statements – Note 1(ii)."

Commercialization and Milestone Revenue. Commercialization and milestone revenue relates to up-front, royalty and milestone payments recognized under development and commercialization agreements.

In the year ended June 30, 2011, we received up-front payments of $130.0 million under a development and commercialization agreement ("DCA"), with Cephalon, Inc., now a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd (collectively

"Teva"), which allowed for Teva to obtain world-wide rights to commercialize our mesenchymal precursor cell (MPC) technology platform for specific products in our cardiovascular portfolio. In June 2016, Teva exercised a contractual right under the DCA to end the joint development of the lead asset in our cardiovascular portfolio, product candidate MPC-150-IM, and we regained full world-wide rights on this product candidate.

Revenues from such non-refundable, up-front payments are initially reported as deferred revenues on the consolidated balance sheet and are recognized in revenue as earned over the estimated development period. As the joint development of product candidate MPC-150-IM was ended in June 2016, we recognized in revenue the remaining full amount of deferred revenues during June 2016. There are no further performance obligations required of us in relation to this DCA. Prior to June 2016, management could not readily estimate the costs required to complete the development program pursuant to the DCA and concluded that the revenue was earned over the estimated development period of MPC-150-IM. Therefore, during the period from the initial recognition date until June 2016, revenues from the up-front payments received were recognized on a straight line basis over the estimated development period of this product candidate.

In the year ended June 30, 2017, we recognized $0.5 million in milestone revenue upon our licensee, JCR, achieving a sales milestone on cumulative net sales of TEMCELL® Hs. Inj., a registered trademark of JCR Pharmaceuticals Co., Ltd ("TEMCELL"), in Japan. This amount was recorded in revenue as there are no further performance obligations required in regards to this item. In the year ended June 30, 2016, we recognized $3.5 million in milestone revenue from JCR Pharmaceuticals Co. Ltd. ("JCR") for the receipt of full regulatory approval of TEMCELL which was a milestone under our agreement with JCR. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

We commenced earning royalty income on sales of TEMCELL by our licensee JCR after the product's launch in Japan on February 24, 2016.

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

Management and Administration. Management and administration expenses consist primarily of salaries and related costs 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 developmental timelines, probability of success, market penetration, market population, 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 $0.1 million and a net remeasurement gain of $28.1 million for the years ended June 30, 2017 and 2016, respectively.

Other Operating Income and Expenses. Other operating income and expenses primarily comprise tax incentives and foreign exchange gains and losses.

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 grant 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. The commercialization revenue is not subject to inclusion in the determination of the annual aggregate turnover measure. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending. For the years ended June 30, 2017 and 2016, the rate of the refundable tax offset is 43.5% and 45%, respectively. We recognized income of $1.5 million and $3.8 million, respectively, from the Research and Development Tax Incentive program for the years ended June 30, 2017 and 2016.

Foreign exchange gains and losses relate to unrealized foreign exchange gains and losses on our U.S. dollar deposits plus realized gains and losses on any foreign currency payments to our suppliers due to movements in exchange rates. We recognized $Nil foreign exchange losses in the year ended June 30, 2017 and a foreign exchange loss of $1.1 million in the year ended June 30, 2016.

Results of Operations

Comparison of Our Results for the Year ended June 30, 2017 with the Year ended June 30, 2016

The following table summarizes our results of operations for the years ended June 30, 2017 and 2016, together with the changes in those items in dollars and as a percentage.

(in thousands except per share information)	Year ended June 30, 2017	2016	$ Change	% Change
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	$ 1,444	$ 37,969	(36,525)	(96%)
Milestone revenue	500	3,500	(3,000)	(86%)
Interest revenue	468	1,079	(611)	(57%)
Total revenue	**2,412**	**42,548**	**(40,136)**	**(94%)**
Research & development	(58,914)	(50,013)	(8,901)	18%
Manufacturing commercialization	(12,065)	(29,763)	17,698	(59%)
Management and administration	(23,007)	(22,500)	(507)	2%
Fair value remeasurement of contingent consideration	(130)	28,112	(28,242)	NM
Impairment of intangible assets	—	(61,919)	61,919	NM
Other operating income and expenses	1,489	2,714	(1,225)	(45%)
Loss before income tax	**(90,215)**	**(90,821)**	**606**	**(1%)**
Income tax benefit/(expense)	13,400	86,694	(73,294)	(85%)
Loss attributable to the owners of Mesoblast Limited	**$ (76,815)**	**$ (4,127)**	**(72,688)**	**NM**
Losses per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**% Change**
Basic - losses per share	(19.43)	(1.14)	(18.29)	NM
Diluted - losses per share	(19.43)	(1.14)	(18.29)	NM

* NM = not meaningful.

Revenue

Revenues were $2.4 million for the year ended June 30, 2017, compared with $42.5 million for the year ended June 30, 2016, a decrease of $40.1 million. The following table shows the movement within revenue for the years ended June 30, 2017 and 2016, together with the changes in those items.

(in thousands)	Year ended June 30, 2017	2016	$ Change	% Change
Revenue:				
Commercialization revenue	$ 1,444	$ 37,969	(36,525)	(96%)
Milestone revenue	500	3,500	(3,000)	(86%)
Interest revenue	468	1,079	(611)	(57%)
Revenue	**$ 2,412**	**$ 42,548**	**(40,136)**	**(94%)**

Commercialization revenues were $1.4 million in the year ended June 30, 2017, a decrease of $36.5 million as compared with $38.0 million in the year ended June 30, 2016. This $36.5 million decrease in the year ended June 30, 2017 is due to the recognition of $37.5 million of revenue for the year ended June 30, 2016, being the recognition of the remaining unamortized portion of the initial up-front payments of $130.0 million received under the DCA with Teva over our initial estimated development program term, compared with $Nil in the year ended June 30, 2017 as we had fully recognized the remaining deferred revenue amounts relating to the $130 million up-front payment in June 2016, when we regained full world-wide rights from Teva on our product candidate MPC-150-IM. This decrease of commercialization revenue in the year ended June 30, 2017 was offset by an increase of $1.0 million relating to royalty income earned on sales of TEMCELL in Japan since the launch of the product on February 24, 2016 by our licensee JCR, with $1.4 million of royalty revenue recognized in the year ended June 30, 2017, compared with $0.4 million of royalty revenue recognized in the year ended June 30, 2016.

Milestone revenue was $0.5 million in the year ended June 30, 2017, a decrease of $3.0 million as compared with $3.5 million in the year ended June 30, 2016. The difference of $3.0 million is due to the recognition of $3.5 million in milestone revenue in the year ended June 30, 2016 upon our licensee, JCR, receiving full regulatory approval of MSC product TEMCELL in Japan, which is a milestone under our agreement with JCR. In the year ended June 30, 2017, we recognized $0.5 million in milestone revenue upon our licensee, JCR, reaching a cumulative net sales milestone for sales of TEMCELL in Japan.

The $0.6 million decrease in interest revenue from the year ended June 30, 2017 compared with the year ended June 30, 2016 was primarily driven by us retaining higher cash reserves in the year ended June 30, 2016, when compared with the year ended June 30, 2017. The decrease was also driven by us retaining a higher proportion of cash reserves in US$ instead of A$ in the year ended June 30, 2017, when compared with the year ended June 30, 2016. This change in cash reserve holdings decreased revenue as yield on US$ cash deposits are lower than yields on A$ cash deposits. We increased the proportion of cash reserves held in US$ to reduce currency risk. Currency risk is minimized by ensuring the proportion of cash reserves held in each currency matches the expected rate of spend of each currency.

Research and development

Research and development expenses were $58.9 million for the year ended June 30, 2017, compared with $50.0 million for the year ended June 30, 2016, an increase of $8.9 million. The $8.9 million net increase in research and development expenses primarily reflects an increase in expenditures on our clinical program for MPC-150-IM, which were partially offset by a reduction in product support costs as management reduced costs in line with our corporate strategy.

(in thousands)	Year ended June 30, 2017	2016	$ Change	% Change
Research and development:				
Third party costs	$ 37,249	$ 26,189	11,060	42%
Product support costs	17,122	20,643	(3,521)	(17%)
Intellectual property support costs	3,208	2,737	471	17%
Amortization of current marketed products	1,335	444	891	201%
Research and development	**$ 58,914**	**$ 50,013**	**8,901**	**18%**

Third party costs, which consist of all external expenditure on our research and development programs, increased by $11.0 million in the year ended June 30, 2017 compared with the year ended June 30, 2016.

Within this $11.0 million increase, there was a $11.6 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, 2017, compared with the year ended June 30, 2016, primarily due to the increase in clinical program costs for MPC-150-IM (CHF) as we regained full world-wide rights from Teva on this product candidate in the month of June 2016 and consequently we were responsible for all research and development expenditure incurred on this product candidate in the year ended June 30, 2017 whereas Teva was responsible for the majority of research and development expenses in the year ended June 30, 2016. In the year ended June 30, 2017 we also incurred costs on our MPC-06-ID (CLBP), MSC-100-IV (aGVHD) and MPC-300-IV (inflammatory conditions) Tier 1 products. The increase in Tier 1 third party costs were offset by a $0.6 million decrease in third party costs for our Tier 2 and pipeline products for the year ended June 30, 2017, compared with the year ended June 30, 2016 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 $3.5 million for the year ended June 30, 2017, compared with the year ended June 30, 2016. In the year ended June 30, 2017, operational streamlining initiatives from the June 2016 strategic review were maintained resulting in full time equivalents reducing by 26.1 (35%) from 74.5 for the year ended June 30, 2016 to 48.4 for the year ended June 30, 2017. This led to cost savings of $4.0 million in salaries and associated costs and $0.5 million in travel expenses, for the year ended June 30, 2017 compared with the year ended June 30, 2016. The cost savings of $4.5 million in the year ended June 30, 2017 were offset by an increase of $0.7 million in share based payment expenses and an increase of $0.3 million in consultancy fees primarily due to an increase in the associated clinical program costs for CHF in the year ended June 30, 2017, compared with the year ended June 30, 2016.

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 risen by $0.5 million in the year ended June 30, 2017 compared with the year ended June 30, 2016 due to increased activities across our entire patent portfolio.

Amortization of current marketed products increased by $0.9 million for the year ended June 30, 2017, compared with the year ended June 30, 2016 due to the TEMCELL asset becoming available for use in Japan since the launch of the product in February 2016.

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 $17.7 million from the year ended June 30, 2016 compared with the year ended June 30, 2017. The decrease was primarily due to a reduction in the number of production runs completed in the year ended June 30, 2017 compared with the year ended June 30, 2016 due to the clinical supply demands for all ongoing trials being met and a tax related credit for MSC-based product expenditure incurred in prior years.

(in thousands)	Year ended June 30, 2017	2016	$ Change	% Change
Manufacturing commercialization:				
MSC platform technology	$ (285)	$ 17,993	(18,278)	(102%)
MPC platform technology	10,058	8,235	1,823	22%
Manufacturing support costs	2,292	3,535	(1,243)	(35%)
Manufacturing commercialization	**$ 12,065**	**$ 29,763**	**(17,698)**	**(59%)**

The MSC-based manufacturing commercialization expenses decreased by $18.3 million in the year ended June 30, 2017 compared with the year ended June 30, 2016. $17.1 million of this decrease was a result of no MSC-based production being undertaken in the year ended June 30, 2017 whereas 81% of production runs in the year ended June 30, 2016 were for MSC-based clinical supply. The remaining decrease of $1.2 million relates to a Goods and Services-Tax (“GST”) credit received in the year ended June 30, 2017 for MSC-based product expenditure incurred in prior years.

The MPC-based manufacturing commercialization expenses increased by $1.8 million in the year ended June 30, 2017 compared with the year ended June 30, 2016. There was a $4.1 million increase as a result of purchases of materials for future production runs and 100% of the production runs being for MPC-based clinical supply in the year ended June 30, 2017 whereas 19% of production was for MPC-based clinical supply in the year ended June 30, 2016. This was offset by a $2.3 million decrease due to a reduction in process development activities in year ended June 30, 2017 compared with the year ended June 30, 2016.

Manufacturing support expenses, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, decreased by $1.2 million from $3.5 million for the year ended June 30, 2016 to $2.3 million for the year ended June 30, 2017 as a result of operational streamlining and management’s cost containment efforts. Full time equivalents decreased by 2.9 (27%) from 10.8 for the year ended June 30, 2016 to 7.9 for the year ended June 30, 2017 resulting in cost savings of $0.4 million in salaries and $0.3 million in share based payments. Management’s cost reduction efforts also resulted in a decrease of $0.5 million across consulting and travel expenditure.

Management and administration

Management and administration expenses were $23.0 million for the year ended June 30, 2017, compared with $22.5 million for the year ended June 30, 2016, an increase of $0.5 million. This increase was primarily due to an increase in labor and associated expenses and legal and professional fees offset by a reduction in corporate overheads.

(in thousands)	Year ended June 30, 2017	2016	$ Change	% Change
Management and administration:				
Labor and associated expenses	$ 10,678	$ 9,295	1,383	15%
Corporate overheads	8,689	10,274	(1,585)	(15%)
Legal and professional fees	3,640	2,931	709	24%
Management and administration	**$ 23,007**	**$ 22,500**	**507**	**2%**

Labor and associated expenses increased by $1.4 million from $9.3 million for the year ended June 30, 2016 to $10.7 million for the year ended June 30, 2017. In the year ended June 30, 2017, operational streamlining initiatives from the June 2016 strategic review were maintained resulting in full time equivalents reducing by 2.3 (8%) from 27.2 for the year ended June 30, 2016 to 24.9 for the year ended June 30, 2017. This led to cost savings of $0.4 million in salaries and associated benefits, $0.2 million in consultancy expenses and $0.1 million in directors’ fees for the year ended June 30, 2017 compared with the year ended June 30, 2016. This

decrease was offset by an increase of $0.5 million in short term incentives and an increase of $1.4 million in share based payments in the year ended June 30, 2017, compared with the year ended June 30, 2016. Labor and associated expenses also experienced unfavorable exchange rate fluctuations of $0.2 million in the year ended June 30, 2017 compared with the year ended June 30, 2016, as the A$ 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 $1.6 million from $10.3 million for the year ended June 30, 2016 to $8.7 million for the year ended June 30, 2017 as operational streamlining from the strategic review in June 2016 enabled us to reduce rent, accommodation costs, travel expenses and other staff associated costs.

Legal and professional fees increased by $0.7 million from $2.9 million for the year ended June 30, 2016 to $3.6 million for the year ended June 30, 2017 primarily due to Sarbanes Oxley Act implementation activities.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration was a $0.1 million loss for the year ended June 30, 2017 compared with a $28.1 million gain for the year ended June 30, 2016, a decrease of $28.2 million. 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.

Within the $28.1 million gain for the year ended June 30, 2016, we recognized a gain of $34.5 million due to a reduction in contingent consideration expected to be paid to Osiris on the MSC-assets due to a greater certainty over the commencement of the earn out period. This change in assumption results in a reduction in the valuation of contingent consideration as an earlier earn out period results in royalties being applicable to sales in years that are prior to peak year sales. The remaining net loss of $6.4 million was recognized during the year ended June 30, 2016 as a result of changes to the key assumptions of contingent consideration valuation such as developmental timelines, market population, market penetration, product pricing 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.

Impairment of intangible assets

Impairment of intangible assets were $61.9 million for the year ended June 30, 2016, compared with $Nil for the year ended June 30, 2017. As a consequence of the June 2016 strategic review we recognized a $61.9 million non-cash impairment charge in the year ended June 30, 2016 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 of June 30, 2016 we had completed the enrollment of Phase IIa MPC-MICRO-IO clinical trial and we were in a Phase III MPC-CBE clinical trial. We had suspended further patient enrollment of both programs as we prioritized the funding of our Tier 1 product candidates. Existing and future cash resources will be primarily directed to the delivery of Tier 1 product candidates for the foreseeable future and therefore we are unable to ascertain when MPC-MICRO-IO and MPC-CBE patient enrollment will be restarted. Accordingly, impairment losses for the full carrying amounts of the intangible assets relating to product candidates MPC-MICRO-IO and MPC-CBE were recognized in line with our accounting policy.

These product candidates will remain technically viable and available to consider for future resource allocation and we will continue to seek potential partners for them. The decision to impair the assets was required given resources have not been allocated to continue the development and commercialization efforts of these assets for the foreseeable future.

This accounting charge for the year ended June 30, 2016 was non-cash and does not impact our liquidity or cash flows from our operating activities. There were no impairment losses recognized for the year ended June 30, 2017.

Other operating income and expenses

Other operating income and expenses were $1.5 million for the year ended June 30, 2017, compared with $2.7 million for the year ended June 30, 2016, a decrease of $1.2 million. The following table shows movements within other operating income and expenses for the years ended June 30, 2017 and 2016, together with the changes in those items:

(in thousands)	Year ended June 30, 2017	2016	$ Change	% Change
Other operating income and expenses:				
Research and development tax incentive income	$ 1,532	$ 3,840	(2,308)	(60%)
Foreign exchange (losses)/gains (net)	(43)	(1,126)	1,083	(96%)
Other operating income and expenses	**$ 1,489**	**$ 2,714**	**(1,225)**	**(45%)**

Research and development tax incentive income decreased by $2.3 million from $3.8 million for the year ended June 30, 2016 to $1.5 million for the year ended June 30, 2017 due to a reduction in expenditure that is eligible for the Australian tax incentive. 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 claim and our on-going eligibility to claim the research and development tax incentive in Australia.

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.

Of the $3.8 million research and development tax incentive recorded in other income for the year ended June 30, 2016, $1.1 million 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, 2015.

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, 2016 we recognized a foreign exchange loss of $1.1 million, primarily relating to depreciation recognized on US$ deposits held in Mesoblast Limited.

Loss after income tax

(in thousands)	Year ended June 30, 2017	2016	$ Change	% Change
Loss before income tax	$ (90,215)	$ (90,821)	606	(1%)
Income tax benefit/(expense)	13,400	86,694	(73,294)	(85%)
Loss after income tax	**$ (76,815)**	**$ (4,127)**	**(72,688)**	**NM**

Loss before income tax was $90.2 million for the year ended June 30, 2017 compared with $90.8 million for the year ended June 30, 2016, a decrease in the loss of $0.6 million. This decrease is the net effect of the changes in revenues and expenses which have been fully discussed above.

Non-cash income tax benefits of $13.4 million and $86.7 million were recognized in the years ended June 30, 2017 and 2016, in relation to the net of deferred tax assets and liabilities recognized on the balance sheet during these periods, respectively.

Following our strategic review in June 2016 and the resulting operational streamlining, we recognized deferred tax assets for operating tax losses and deductible temporary differences in the jurisdictions where there are offsetting taxable temporary differences (deferred tax liabilities). Prior to this strategic review, we were in the process of consolidating certain intellectual property assets and consequently taxable temporary differences were not available to offset deferred tax assets in the same jurisdiction.

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.

As of June 30, 2017 and 2016, our cumulative operating losses have a total potential tax benefit of $113.1 million and $84.7 million at local tax rates (excluding other temporary differences), respectively, which may be available for use once we are in a taxable profit position. These losses were incurred in different jurisdictions and can only be offset against profits earned in the relevant jurisdiction. Further, 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.

Comparison of Our Results for the Year ended June 30, 2016 with the Year ended June 30, 2015

The following table summarizes our results of operations for the year ended June 30, 2016 and 2015, together with the changes in those items in dollars and as a percentage.

(in thousands except per share information)	Year ended June 30, 2016	2015	$ Change	% Change
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	$ 37,969	$ 15,004	22,965	153%
Milestone revenue	3,500	2,000	1,500	75%
Interest revenue	1,079	2,757	(1,678)	(61%)
Total revenue	**42,548**	**19,761**	**22,787**	**115%**
Research & development	(50,013)	(62,649)	12,636	(20%)
Manufacturing commercialization	(29,763)	(23,783)	(5,980)	25%
Management and administration	(22,500)	(29,540)	7,040	(24%)
Fair value remeasurement of contingent consideration	28,112	(15,336)	43,448	NM
Impairment of intangible assets	(61,919)	—	(61,919)	NM
Other operating income and expenses	2,714	15,303	(12,589)	(82%)
Loss before income tax	**(90,821)**	**(96,244)**	**5,423**	**(6%)**
Income tax benefit/(expense)	86,694	—	86,694	NM
Loss attributable to the owners of Mesoblast Limited	**$ (4,127)**	**$ (96,244)**	**92,117**	**(96%)**
Losses per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**% Change**
Basic - losses per share	(1.14)	(29.99)	28.85	(96%)
Diluted - losses per share	(1.14)	(29.99)	28.85	(96%)

* NM = not meaningful.

Revenue

Revenues were $42.5 million for the year ended June 30, 2016, compared with $19.8 million for the year ended June 30, 2015, an increase of $22.7 million. The following table shows the movement within revenue for the year ended June 30, 2016 and 2015, together with the changes in those items.

(in thousands)	Year ended June 30, 2016	2015	$ Change	% Change
Revenue:				
Commercialization revenue	$ 37,969	$ 15,004	22,965	153%
Milestone revenue	3,500	2,000	1,500	75%
Interest revenue	1,079	2,757	(1,678)	(61%)
Revenue	**$ 42,548**	**$ 19,761**	**22,787**	**115%**

Commercialization revenues were $38.0 million in the year ended June 30, 2016, an increase of $23.0 million as compared with $15.0 million in the year ended June 30, 2015. This increase in the year ended June 30, 2016 relates primarily to the recognition in revenues of $22.6 million of the remaining full deferred revenue amounts relating to the up-front payments of $130.0 million received in the year ended June 30, 2011 under the DCA with Teva as we regained full world-wide rights on our product candidate MPC-150-IM in the month of June 2016. The recognition of commercialization revenue relating to the deferred revenue amounts in the years

ended June 30, 2016 and 2015 had no impact to cash flows as the cash receipt pertaining to these deferred revenues recognized was received in the year ended June 30, 2011. There are no further performance obligations required of us in relation to this product candidate under the DCA. Within the increase of commercialization revenue in the year ended June 30, 2016 was an increase of $0.4 million relating to royalty income earned on sales of TEMCELL® HS Inj. in Japan since the launch of the product on February 24, 2016 by our licensee JCR, compared with $Nil for the year ended June 30, 2015.

We recognized $3.5 million in milestone revenue in the year ended June 30, 2016 upon our licensee, JCR, receiving full regulatory approval of MSC product TEMCELL® HS Inj. in Japan, which is a milestone under our agreement with JCR. In the year ended June 30, 2015 we recognized milestone revenue of $2.0 million as JCR filed for marketing approval for TEMCELL® HS Inj. in Japan which constitutes a milestone under our agreement with JCR.

The $1.7 million decrease in interest revenue from the year ended June 30, 2016 compared with June 30, 2015 was primarily driven by us retaining a higher proportion of cash reserves in US$ instead of A$ in the year ended June 30, 2016, when compared with the year ended June 30, 2015. This change in cash reserve holdings decreased revenue as yields on US$ cash deposits are lower than yields on A$ cash deposits. We increased the proportion of cash reserves held in US$ to reduce currency risk. Currency risk is minimized by ensuring the proportion of cash reserves held in each currency matches the expected rate of spend of each currency.

Research and development

Research and development expenses were $50.0 million for the year ended June 30, 2016, compared with $62.6 million for the year ended June 30, 2015, a decrease of $12.6 million. The $12.6 million net decrease in research and development expenses reflects a reduction in expenditures of our Tier 2 products and product support costs.

(in thousands)	Year ended June 30, 2016	2015	$ Change	% Change
Research and development:				
Third party costs	$ 26,189	$ 30,612	(4,423)	(14%)
Product support costs	20,643	29,361	(8,718)	(30%)
Intellectual property support costs	2,737	2,676	61	2%
Amortization of current marketed products	444	—	444	NM
Research and development	**$ 50,013**	**$ 62,649**	**(12,636)**	**(20%)**

Third party costs, which consist of all external expenditure on our research and development programs, decreased by $4.4 million in the year ended June 30, 2016 compared with the year ended June 30, 2015.

Within this $4.4 million decrease, there was a $1.0 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, 2016 compared with the year ended June 30, 2015. In the year ended June 30, 2016 we incurred costs on our MPC-06-ID, MSC-100-IV, and MPC-150-IM Tier 1 products as well as our MPC-300-IV Tier 1 product which was promoted from Tier 2 to Tier 1 on June 30, 2015. This increase in Tier 1 costs was offset by a $5.0 million decrease in third party costs for our Tier 2 and pipeline products for the year ended June 30, 2016, compared with the year ended June 30, 2015. The $5.4 million decrease in third party costs for our Tier 2 and pipeline products was primarily due to a $1.8 million decrease in costs on our MPC-300-IV product for the treatment of biologic refractory rheumatoid arthritis as the phase 2 trial incurred costs in the year ended June 30, 2015 and was promoted to Tier 1 on June 30, 2015 and a $1.5 million decrease in costs on our MPC-300-IV product for the treatment of diabetic complications, including type 2 diabetes and kidney disease as the phase 2 trials incurred costs in the year ended June 30, 2015 before completing enrollment in June 2015. Tier 1 programs were also prioritized ahead of Tier 2 clinical trials and pipeline activities in the year ended June 30, 2016.

Product support costs, which consist primarily of salaries and related overhead expenses for personnel in research and development functions, have decreased by $8.7 million for the year ended June 30, 2016 compared with the year ended June 30, 2015. A cost saving of $4.3 million was realized in salaries and $1.5 million was realized in share based payments primarily due to the elimination of vacant positions. In the year ended June 30, 2016, full time equivalents decreased by 8.1 from 82.6 for the year ended June 30, 2015 to 74.5 for the year ended June 30, 2016. Additionally, consultancy expenses, travel and recruitment expenses decreased by $2.0 million, $0.8 million and $0.1 million, respectively, for the year ended June 30, 2016 compared with the year ended June 30, 2015 due to management's cost reduction efforts.

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 increased by $0.1 million in

the year ended June 30, 2016 compared with the year ended June 30, 2015 due to a one off catch up of patent attorney costs relating to the prior year.

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 $6.0 million from $23.8 million for the year ended June 30, 2015 to $29.8 million for the year ended June 30, 2016. This increase was primarily due to a 55% growth in the number of production runs completed in the year ended June 30, 2016 compared with the year ended June 30, 2015 in order to meet the clinical supply demands of our Tier 1 products.

(in thousands)	Year ended June 30, 2016	2015	$ Change	% Change
Manufacturing commercialization:				
MSC platform technology	$ 17,993	$ 11,388	6,605	58%
MPC platform technology	8,235	8,855	(620)	(7%)
Manufacturing support costs	3,535	3,540	(5)	(0%)
Manufacturing commercialization	**$ 29,763**	**$ 23,783**	**5,980**	**25%**

The MSC-based manufacturing commercialization expenses increased by $6.6 million in the year ended June 30, 2016 compared with the year ended June 30, 2015 as 81% of the production runs in the year ended June 30, 2016 were for MSC-based clinical supply whereas 55% of production was for MSC-based process development activities and clinical supply in the year ended June 30, 2015.

The MPC-based manufacturing commercialization expenses decreased by $0.6 million in the year ended June 30, 2016 compared with the year ended June 30, 2015 as 19% of the production runs in the year ended June 30, 2016 were for MPC-based production whereas 45% of production was for MPC-based clinical supply in the year ended June 30, 2015. The balance of expenditure incurred in both the years ended June 30, 2016 and 2015 was for process development activities.

Manufacturing support expenses, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, for the year ended June 30, 2016 compared with the year ended June 30, 2015 were relatively consistent decreasing less than 1%. There was an overall net decrease in manufacturing support expenses due to a reduction in the valuation of share based payments resulting from changes in the key assumptions such as the share price and risk free rate. This decrease was offset by a minimal increase in labor and associated costs and consultancy expenses. Within this increase, there was an increase in full time equivalents of 1.1 from 9.7 for the year ended June 30, 2015 to 10.8 for the year ended June 30, 2016.

Management and administration

Management and administration expenses were $22.5 million for the year ended June 30, 2016, compared with $29.5 million for the year ended June 30, 2015, a decrease of $7.0 million. This decrease was primarily due to lower share based payment expenses because of lower valuations, a savings in labor and associated costs, a reduction in legal and professional advisor activities and favorable exchange rate fluctuations as the US$ strengthened against the A$ given that the majority of management and administration expenses are incurred in A$ by our headquarter office located in Australia.

(in thousands)	Year ended June 30, 2016	2015	$ Change	% Change
Management and administration:				
Labor and associated expenses	$ 9,295	$ 14,309	(5,014)	(35%)
Corporate overheads	10,274	9,707	567	6%
Legal and professional fees	2,931	5,524	(2,593)	(47%)
Management and administration	**$ 22,500**	**$ 29,540**	**(7,040)**	**(24%)**

Labor and associated expenses decreased by $5.0 million from $14.3 million for the year ended June 30, 2015 to $9.3 million for the year ended June 30, 2016. Within this $5.0 million decrease is a decrease in share based payment expenses of $2.1 million due to a reduction in the valuation of equity settled share based payments resulting from changes in the key assumptions such as the share price and risk free rate. There was an increase in full time equivalents of 0.5 from 26.7 for the year ended June 30, 2015 to 27.2 for the year ended June 30, 2016, however overall there was a savings in labor and associated costs of $1.1 million during the year ended June 30, 2016. Labor and associated expenses also benefited by $0.7 million from exchange rate fluctuations as described above,

consultancy and recruitment expenses decreased $1.1 million due to management's cost reduction efforts and other associated expenses decreased $0.1 million.

Corporate overhead expenses increased by $0.6 million for the year ended June 30, 2016 compared with the year ended June 30, 2015. This $0.6 million increase was due to one off costs related to office space and increase in non-cash depreciation charges.

Legal and professional fees decreased by $2.6 million from $5.5 million for the year ended June 30, 2015 to $2.9 million for the year ended June 30, 2016 due to reductions on legal, taxation and accounting compliance advice associated with the intellectual property management program and reductions on audit and legal fees associated with the "United States Initial Public Offering" readiness incurred in the year ended June 30, 2015. We also benefited from exchange rate fluctuations as indicated above.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration was a $28.1 million gain for the year ended June 30, 2016 compared with a $15.3 million loss for the year ended June 30, 2015, an increase of $43.4 million. Within the $28.1 million gain for the year ended June 30, 2016, we recognized a gain of $34.5 million due to a reduction in contingent consideration expected to be paid to Osiris on the MSC-assets due to a greater certainty over the commencement of the earn out period. This change in assumption results in a reduction in the valuation of contingent consideration as an earlier earn out period results in royalties being applicable to sales in years that are prior to peak year sales. The remaining loss of $6.4 million was recognized during the year ended June 30, 2016 as a net result of changes to the key assumptions of contingent consideration valuation such as developmental timelines, market population, market penetration, 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 $15.3 million loss for the year ended June 30, 2015 was due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This loss was as a result of changes to the key assumptions of the contingent consideration valuation such as product pricing, market population, the value of payments for contractual commitments 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 the profits generated.

Impairment of intangible assets

Impairment of intangible assets were $61.9 million for the year ended June 30, 2016, compared with $Nil for the year ended June 30, 2015. As a consequence of the June 2016 strategic review we recognized a $61.9 million non-cash impairment charge in the year ended June 30, 2016 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 of June 30, 2016 we completed the enrollment of Phase IIa MPC-MICRO-IO clinical trial and we were in a Phase III MPC-CBE clinical trial. We suspended further patient enrollment of both programs as we prioritize the funding of our Tier 1 product candidates. Existing and future cash resources will be primarily directed to the delivery of Tier 1 product candidates for the foreseeable future and therefore we are unable to ascertain when MPC-MICRO-IO and MPC-CBE patient enrollment will be restarted. Accordingly, impairment losses for the full carrying amounts of the intangible assets relating to product candidates MPC-MICRO-IO and MPC-CBE were recognized in line with our accounting policy.

These product candidates will remain technically viable and available to consider for future resource allocation and we will continue to seek potential partners for them. The decision to impair the assets was required given resources have not been allocated to continue the development and commercialization efforts of these assets for the foreseeable future.

This accounting charge for the year ended June 30, 2016 was non-cash and does not impact our liquidity or cash flows from our operating activities. There were no impairment losses recognized for the year ended June 30, 2015.

Other operating income and expenses

Other operating income and expenses were $2.7 million for the year ended June 30, 2016, compared with $15.3 million for the year ended June 30, 2015, a decrease of $12.6 million. The following table shows movements within other operating income and expenses for the year ended June 30, 2016 and 2015, together with the changes in those items:

(in thousands)	Year ended June 30, 2016	2015	$ Change	% Change
Other operating income and expenses:				
Research and development tax incentive income	$ 3,840	$ 4,418	(578)	(13%)
Foreign exchange (losses)/gains (net)	(1,126)	10,478	(11,604)	(111%)
Other revenue	—	407	(407)	(100%)
Other operating income and expenses	**$ 2,714**	**$ 15,303**	**(12,589)**	**(82%)**

Research and development tax incentive income decreased by $0.6 million from $4.4 million for the year ended June 30, 2015 to $3.8 million for the year ended June 30, 2016. 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 claim and our on-going eligibility to claim the research and development tax incentive in Australia.

Of the $3.8 million research and development tax incentive recorded in other income for the year ended June 30, 2016, $1.1 million relates to a change in the original estimate of the research and development tax incentive income we estimated we would receive from the Australian government for the year ended June 30, 2015.

Of the $4.4 million research and development tax incentive recorded in other income for the year ended June 30, 2015, $0.5 million 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, 2014.

For the year ended June 30, 2015, we recognized a net foreign exchange gain of $10.5 million due to movements in exchange rates as the US$ appreciated against the A$. Within Mesoblast Limited (exclusive of its consolidated subsidiaries), we held certain cash and term deposit balances in US$, resulting in foreign exchange gains on the revaluation of foreign currency denominated monetary assets and liabilities into our functional currency of A$.

In July 2015, we transferred the majority of US$ deposits to a wholly owned subsidiary of Mesoblast Limited that has a US$ functional currency. We are subject to foreign exchange gains and losses on foreign currency cash balances, creditors and debtors. In the year ended June 30, 2016 we recognized a foreign exchange loss of $1.1 million, primarily relating to depreciation recognized on US$ deposits held in Mesoblast Limited.

Other revenue decreased by $0.4 million as we recognized a one-off insurance recovery in the year ended June 30, 2015.

Loss after income tax

(in thousands)	Year ended June 30, 2016	2015	$ Change	% Change
Loss before income tax	$ (90,821)	$ (96,244)	5,423	(6%)
Income tax benefit/(expense)	86,694	—	86,694	NM
Loss after income tax	**$ (4,127)**	**$ (96,244)**	**92,117**	**(96%)**

Loss before income tax was $90.8 million for the year ended June 30, 2016 compared with $96.2 million for the year ended June 30, 2015, a decrease in the loss of $5.4 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 $86.7 million was recognized in the year ended June 30, 2016 compared with $Nil for the year ended June 30, 2015.

In the three month period ended March 31, 2016 a deferred tax asset of $4.2 million was recorded following our conclusion to retain existing intellectual property assets in the jurisdiction that the intellectual property assets were expected to be consolidated. The

deferred tax asset was increased by a further $0.7 million in the three months ended June 30, 2016 for operating tax losses attributable to that period.

Historically we have had a plan to consolidate certain intellectual property assets and consequently taxable temporary differences have not been available to offset deferred tax assets in the same jurisdiction. However, following the June 2016 strategic review and the resulting operational streamlining we are no longer actively pursuing the consolidation of these intellectual property assets. As a result we recognized $60.0 million of deferred tax assets for operating tax losses and deductible temporary differences in the jurisdictions where there are offsetting taxable temporary differences (deferred 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.

We also recognized an income tax benefit of $21.8 million due to a reversal of deferred tax liabilities recognized on intellectual property assets. This reversal was triggered by a non-cash impairment charge on intellectual property assets during the year ended June 30, 2016 relating to our product candidates, MPC-MICRO-IO for the treatment of age-related macular degeneration and MPC-CBE for use in BMT, consisting of hematopoietic stem cells expanded ex vivo by incubation with MPCs, administered intravenously.

As of June 30, 2016 and 2015, our cumulative operating losses have a total potential tax benefit of $84.7 million and $69.9 million at local tax rates (excluding other temporary differences), respectively, which may be available for use once we are in a taxable profit position. These losses were incurred in different jurisdictions and can only be offset against profits earned in the relevant jurisdiction. Further, 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.

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 21”.

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).”

Interest rate risk

We are not exposed to typical interest rate risk, which is the impact of interest rates on the cost of servicing and repaying debt. Our exposure to interest rate risk arises through movements in regards to 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 spreading the maturity date of our deposits across various periods. Our strategy of entering into new deposits as old deposits mature and reinvesting surplus funds ensures that we spread the timing of new deposits which assists us to achieve the average interest rates available in the market throughout the year. We also ensure that sufficient funds are available, in at-call accounts, to meet our working capital requirements.

Foreign currency exchange risk

We have foreign currency amounts owing primarily in our Australian parent entity, whose functional currency is the A$, 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.

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

Revenues comprise the fair value of the consideration received or receivable.

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.

Cephalon arrangement

In December 2010, we entered into a development and commercialization agreement (“DCA”), with Cephalon, Inc., now a wholly-owned subsidiary of Teva, which allowed for Teva to obtain world-wide rights to commercialize specific products based on our proprietary adult stem cell technology platform. As part of the DCA, we received $130.0 million as a non-refundable up-front payment. In the month of June 2016, Teva exercised a contractual right under the DCA to end the joint development of the lead asset in our cardiovascular portfolio, product candidate MPC-150-IM, and we regained full world-wide rights on this product candidate.

As the joint development of product candidate MPC-150-IM was ended in June 2016, we brought the remaining full amounts of deferred revenues to account, resulting in a total of $37.5 million of commercialization revenue recognized during the year ended June 30, 2016. The recognition of commercialization revenue relating to the deferred revenue amounts in the year ended June 30, 2016 had no impact to cash flows as the cash receipt pertaining to these deferred revenues recognized was received in the year ended June 30, 2011. There are no further performance obligations required of us in relation to this product candidate.

For the year ended June 30, 2015 we recognized $15.0 million of revenue, being the amortization of the initial payment over the estimated development program term. During the period from the initial recognition date until June 2016, the revenue was being recognized on a straight line basis over the estimated development period of product candidate, MPC-150-IM and had no impact to cash flows as the cash receipt pertaining to this revenue recognized was received in the year ended June 30, 2011. Our accounting policy requires us to review the estimated development program term on a quarterly basis.

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, 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. Royalty revenue is recognized upon the sale of the related products provided we have no remaining performance obligations under the arrangement.

In the year ended June 30, 2017, we recognized $1.4 million, in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan since the launch of the product on February 24, 2016, by our licensee JCR, compared with $0.4 million for the year ended June 30, 2016. 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, 2017, we recognized $0.5 million in milestone revenue upon our licensee, JCR, reaching a cumulative net sales milestone for sales of TEMCELL in Japan. In the year ended June 30, 2016, we recognized $3.5 million in milestone revenue from JCR for the receipt of full regulatory approval of TEMCELL in Japan, which is a milestone under our agreement with JCR. These amounts were recorded in revenue as there are no further performance obligations required in regards to these milestones.

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 45% for periods prior to June 30, 2016 and an expected rate of 43.5% for periods from July 1, 2016. We have assessed our research and development activities and expenditure to determine which of these spending 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.

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 assets from Osiris 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. We test for impairment annually in the fourth quarter. 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 annual report 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 prioritize the funding of our Tier 1 product candidates. The remaining carrying amount of in-process research and development as at June 30, 2017 and June 30, 2016 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 the fourth quarter of each year in accordance with IAS 36 Impairment of Assets which requires testing annually, or whenever there is an indication that an asset may be impaired. There was no impairment charge recognized during the year ended June 30, 2017.

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 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 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.

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 Impairment of Assets 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 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 and therefore no impairment charge was recognized during the year ended June 30, 2017.

As a consequence of the June 2016 strategic review we recognized non-cash impairment charges of $61.9 million in the year ended June 30, 2016 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 of June 30, 2016 we had completed the Phase IIa MPC-MICRO-IO clinical trial and MPC-CBE was in a Phase III clinical trial. In June 2016, we suspended further patient enrollment of both programs as we prioritized the funding of our Tier 1 product candidates. Existing and future cash resources will be deployed on delivery of Tier 1 product candidates for the foreseeable future and therefore we are unable to ascertain when MPC-MICRO-IO and MPC-CBE patient enrollment will be restarted. Accordingly impairment losses for the full carrying amounts of the intangible assets relating to product candidates MPC-MICRO-IO and MPC-CBE were recognized in June 2016 in line with our accounting policy. These product candidates will remain technically viable and available to consider for future resource allocation and on this basis we have not abandoned the programs. The decision to impair the assets was required given resources have not been allocated to continue the development and commercialization efforts of these assets for the foreseeable future. This accounting charge was non-cash and has not impacted our liquidity or cash flows from our operating activities.

Excluding the abovementioned impairment charges, the recoverable amount of our cash generating unit, including goodwill and in-process research and development, exceeded the carrying amounts in the impairment testing completed 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, 2017 and June 30, 2016, 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 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, and trading and available-for-sale 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, 2017 and June 30, 2016.

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, 2017 and June 30, 2016. 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) Description	Fair value as of June 30, 2017	2016	Valuation technique	Unobservable inputs[1]	Range of inputs (weighted average) for the year ended June 30, 2017	2016	Relationship of unobservable inputs to fair value
Contingent consideration provision	63,595	63,716	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Year ended June 30, 2017: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%. Year ended June 30, 2016: A change in the discount rate by 0.5% would increase/decrease the fair value by 2%.
				Expected unit revenues	n/a	n/a	Year ended June 30, 2017: A 10% increase in the price assumptions adopted would increase the fair value by 5%. Year ended June 30, 2016: A 10% increase in the price assumptions adopted would increase the fair value by 6%.

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

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, 2017.

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

No significant changes occurred within our state of affairs during the year ended June 30, 2017.

Likely Developments and Expected Results of Operations

Our continued progress in clinical developments brings our leading Tier 1 product candidates closer to potential approval, with upcoming significant milestones expected in the coming financial year. With control of our valuable CHF product candidate, the Company can refine the clinical pathway to global commercialization for this asset. We believe we have enhanced opportunities for partnering based on cumulative Phase 2/3 clinical results.

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, 2017, we had an accumulated deficit of $344.9 million. We had cash and cash equivalents of $45.8 million as of June 30, 2017 and incurred net cash outflows from operations of $95.5 million for the year then ended. In August 2017, we announced a fully underwritten entitlement offer to existing eligible shareholders (on a 1 for 12 basis) in Australia and New Zealand and institutional shareholders in certain other countries in private placements. US$38.2 million of net proceeds from the entitlement offer is expected to be received and recognized in cash and cash equivalents in September 2017.

We have committed to partner one or more of our four Tier 1 product candidates resulting in a non-dilutive funding for operations. This may include MSC-100-IV for steroid-refractory graft versus host disease (“GVHD”) and MPC-06-ID for CLBP, in relation to which we have entered into an agreement with Mallinckrodt in order to exclusively negotiate a commercial and development partnership. We are also continuing to work on various cost containment and deferment strategies, including the reprioritization of projects. A fully discretionary equity facility remains for up to A$120.0 million / US$90.0 million over 24 months to provide additional funds as required. We may also consider issuing new capital to fund future operational requirements.

There is uncertainty related to our ability to partner programs and raise capital at terms to meet our requirements. Additionally, there is uncertainty related to our ability to sustainably implement further cost reductions and defer programs on a timely basis while achieving expected outcomes.

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 entering into an arrangement with a third party partner on one or more of our four Tier 1 product candidates that would result in non-dilutive funding and/or raising further capital, together with various cost containment and deferment strategies being completed including the reprioritization of certain projects.

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 ("PCAOB") 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(ii)).

Cash flows

(in thousands)	Year ended June 30, 2017	2016	2015
Cash Flow Data:			
Net cash (outflows) in operating activities	(95,471)	(87,996)	(101,036)
Net cash inflows/(outflows) in investing activities	142	(1,727)	(5,064)
Net cash inflows in financing activities	60,005	62,066	45,852
Net (decrease) in cash and cash equivalents	**(35,324)**	**(27,657)**	**(60,248)**

Comparison of Cash flows for the Year ended June 30, 2017 with the Year ended June 30, 2016

Net cash outflows in operating activities

Net cash outflows for operating activities were $95.5 million for the year ended June 30, 2017, compared with $88.0 million for the year ended June 30, 2016, an increase of $7.5 million. The increase of $7.5 million is due to a reduction in cash inflows of $4.1 million and an increase in cash outflows of $3.4 million in the year ended June 30, 2017 compared with the year ended June 30, 2016.

The $4.1 million reduction of inflows comprised: inflows from milestone payments received decreased by $3.0 million after our licensee, JCR, reached a cumulative net sales milestone for sales of TEMCELL in Japan, during the year ended June 30, 2017 where our licensee, JCR, reached a milestone for receiving full regulatory approval of MSC product TEMCELL in Japan during the year ended June 30, 2016; interest receipts reduced by $0.6 million as our cash reserves in the year ended June 30, 2017 have decreased when compared with the year ended June 30, 2016; inflows decreased by $1.7 million as receipts for the research and development tax incentive were lower during the year ended June 30, 2017 when compared with the year ended June 30, 2016; these decreases in inflows were offset by an increase of $1.2 million in receipts from royalty income earned on sales of TEMCELL in Japan during the year ended June 30, 2017.

Outflows increased by $3.4 million due to fully absorbing the incremental clinical program costs for MPC-150-IM (CHF) during the year ended June 30, 2017 as we were responsible for all research and development expenditure incurred on this product candidate in the year ended June 30, 2017 whereas Teva was responsible for the majority of research and development expenses in the year ended June 30, 2016. These increases in outflows were offset by cost savings due to operational streamlining efforts that reduced full time equivalents and associated labor costs as well as a decrease in payments to suppliers in relation to manufacturing and commercialization costs.

Net cash inflows in investing activities

Net cash inflows for investing activities were $0.2 million for the year ended June 30, 2017, compared with cash outflows of $1.7 million for the year ended June 30, 2016, a decrease of $1.9 million. The $1.9 million decrease in cash outflows was comprised of: a $0.8 million reduction in payments for investments in the year ended June 30, 2017; a decrease of $0.2 million for payments for licenses in the year ended June 30, 2017; a decrease of $0.4 million related to lower payments for fixed assets, such as plant and equipment, in the year ended June 30, 2017; and cash outflows were further decreased with an increase in cash inflows of $0.5 million for rental deposits received as proceeds 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 $60.0 million for the year ended June 30, 2017, compared with cash inflows for financing activities of $62.1 million for the year ended June 30, 2016, a decrease of $2.1 million. The net cash inflows in the year ended June 30, 2017 include a $21.6 million receipt of net proceeds from Mallinckrodt Pharmaceuticals on January 6, 2017, in a private placement, and a $38.5 million receipt of net proceeds from an institutional private placement on March 27, 2017. In the year

ended June 30, 2016, we received net proceeds of $61.8 million from our initial public offering ("IPO") of the Company's ordinary shares on Nasdaq. Additionally, there was $0.1 million in receipts from employee share option exercises and $0.2 million of payments for other associated capital raising costs in the year ended June 30, 2017.

Comparison of Cash flows for the Year ended June 30, 2016 with the Year ended June 30, 2015

Net cash outflows in operating activities

Net cash outflows for operating activities were $88.0 million for the year ended June 30, 2016, compared with $101.0 million for the year ended June 30, 2015, a decrease of $13.0 million. The decrease of $13.0 million was due to a decrease in cash outflows of $13.7 million net by a decrease in cash inflows of $0.7 million in the year ended June 30, 2016 compared to the year ended June 30, 2015.

The $13.7 million reduction in cash outflows comprised: $9.5 million due to a decrease in payments to suppliers in relation to research and development costs, primarily for our Tier 2 products, and a decrease in management and administration costs as well as payments to employees as a result of management's ongoing cost reduction efforts in the year ended June 30, 2016; $4.1 million due to payments to Osiris related to fair value in excess of amounts originally recorded for contingent consideration subsequent to the business combination measurement period in the year ended June 30, 2015; and outflows for income tax paid decreased by $0.1 million the year ended June 30, 2016.

The $0.7 million reduction in cash inflows comprised: interest receipts decreased by $1.9 million as we held a higher proportion of cash reserves in US$ compared with A$ in the year ended June 30, 2016, when compared with the year ended June 30, 2015; inflows decreased by $0.4 million as we received a one-off insurance recovery in the year ended June 30, 2015; these decreases in inflows were offset by an increase in milestone payments received of $1.5 million after our licensee, JCR, received full regulatory approval of MSC product TEMCELL in Japan, during the year ended June 30, 2016; and an increase of inflows from commercialization payments received by $0.1 million for royalty income earned on sales of TEMCELL in Japan during the year ended June 30, 2016.

Net cash outflows in investing activities

Net cash outflows for investing activities were $1.7 million for the year ended June 30, 2016, compared with $5.1 million for the year ended June 30, 2015, a decrease of $3.4 million. The $3.4 million decrease in cash outflows was comprised of: $2.1 million due to a reduction in payments for business combinations in the year ended June 30, 2016; $1.5 million due to lower payments for fixed assets, such as plant and equipment for our clinical trials as well as office and computer equipment for our staff in the year ended June 30, 2016; $0.8 million due to a reduction in payments for financial derivatives; these decreases in cash outflows were offset by an increase in outflows of $0.8 million for payments for investments in the year ended June 30, 2016 and a reduction of cash inflows by $0.2 million as rental deposits paid as security for the sublease agreement for our New York offices were received in the year ended June 30, 2015.

Net cash inflows in financing activities

Net cash inflows from financing activities were $62.1 million for the year ended June 30, 2016, compared with $45.9 million for the year ended June 30, 2015, an increase of $16.2 million. This increase primarily relates to a $68.3 million receipt of gross proceeds from our initial public offering ("IPO") of the Company's ordinary shares on Nasdaq in November 2015 which was offset by a $6.5 million payment for share issue costs in the year ended June 30, 2016, compared with a $45.0 million receipt of gross proceeds from Celgene Corporation in a private placement which was offset by a $0.4 million payment for share issue costs in the year ended June 30, 2015. This increase in inflows from net proceeds from share issues was offset by a $1.0 million decrease in receipts from employee share option exercises.

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.

Over the short term (12 to 24 months) if we are able to successfully partner one or more of our products we would expect our research and development expenditure to decrease. 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.

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 debt or additional 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 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.

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 an application for regulatory approval of our product candidates. Health regulators have increased their focus on product safety. In addition regulators have also increased their attention 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

Lease commitment – as lessee:

We lease various offices under non-cancellable operating leases expiring within 1 to 5 years. The leases have varying terms, escalation clauses and renewal rights. On renewal, the terms of the leases are renegotiated. Excess office space is sub-let to a third party also under a non-cancellable operating lease.

(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	5,574	1,733	2,954	887	—
Total commitments	5,574	1,733	2,954	887	—

Lease commitments include amounts in A$ and Singapore dollars which have been translated to US$ as of June 30, 2017 using foreign exchange rates published by the Reserve Bank of Australia.

Lease commitment – as lessor:

Future minimum lease payments expected to be received in relation to a non-cancellable sub-lease of operating leases are set out below:

(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	390	161	229	—	—
Total commitment	390	161	229	—	—

Sub-lease commitment includes amounts in A$ which have been translated to US$ as of June 30, 2017 using foreign exchange rate published by the Reserve Bank of Australia.

In addition to the obligations in the table above, as of June 30, 2017 we also had the following significant contractual obligations described below.

Contingent liabilities

We will be required to make a milestone payment to Central Adelaide Local Health Network Incorporated, or CALHNI, of $0.25 million on completion of each Phase 3 (human) clinical trial and $0.35 million on each FDA marketing approval for products in the orthopedic field. We will pay CALHNI a commercial arm's length royalty based on net sales by us of licensed products in the orthopedic field each quarter.

We may also be required to pay consideration to CALHNI upon successful completion of subsequent clinical milestones in fields other than orthopedic.

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. As of June 30, 2017 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, 2017.

Item 6. Directors, Senior Management and Employees

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

Our board of directors ("the Board") presents the 2016/17 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, 2017.

The Board is committed to the principle that KMP remuneration be closely tied to our financial and operational performance.

Key Remuneration Considerations for the financial year end June 30, 2017

Our corporate focus throughout this year was on delivering operational streamlining activities to enable significant absorption of the incremental costs of the MPC-150-IM program in advanced chronic heart failure (CHF) while still delivering critical milestones on our Tier 1 programs. One of the key operational streamlining activities undertaken was a staff restructure undertaken in July 2016. This restructure led to headcount reducing from 108 employees at June 30, 2016 to 75 employees at June 30, 2017. This smaller workforce maintained momentum throughout the year and delivered significant results in our Tier 1 programs including successful interim futility analyses for our GVHD and CHF programs. For the financial year ended June 30, 2017, the Board assessed our overall Group performance as meeting 70% of objectives.

The previous financial year ended June 30, 2016 was a challenging one. Our team had achieved several significant operational goals, while overall performance on our KPIs was assessed as achieving 60% of targets. As the board of directors ("the Board")

reflected on performance for the year and the circumstances in the company at the time, they determined that performance had not met a sufficient threshold for an STI payment to executives. As a result, no executives received an STI payment for performance relating to the financial year ended June 30, 2016.

Our executives started this financial year facing clear performance imperatives: maintain patient recruitment and regulatory timelines on all Tier 1 programs, successfully bring the heart-failure program in house, identify partners committed to product commercialization, and continue research and technology transfer activities for commercial manufacturing among other goals – all while managing in a manner to allow us to spend as little cash as possible. To incentivize around these objectives in a cash-constrained environment the Board moved beyond our STI program to look at how our LTI program could be leveraged for greater impact. Under the previous structure, executive LTI grants were issued with a price premium performance hurdle and vested in three tranches over three years subject to continued service.

A new vesting framework was introduced in which we tailored individual executive LTI grants to vest with the achievement of significant objectives relevant to each executive's role. Collectively these milestones are expected to generate return in the interests of shareholders over the longer term, resulting in an even stronger alignment between executive rewards and shareholder returns. Upon the Board's determination that a milestone has been achieved, the options relevant to that milestone will be designated as having vested. For the introductory grant under this new framework executive LTI grants were increased to maintain performance-based remuneration after a year in which executives did not receive an STI payment.

At the Board level, a reduced fee structure took effect from July 1, 2016 in which the Board Chair fee was reduced and all committee fees were suspended. This fee structure was adopted to conserve cash, with consideration of the Group's lower market capitalization at June 30, 2016, and remains in effect.

6.A Directors and Senior Management

Mesoblast is a development stage biotechnology company with headquarters and operations in Australia and significant clinical trial and manufacturing operations in the United States and Singapore. Our principal activity is the research and development of our Mesenchymal Lineage Adult Stem Cell (MLC) technology platform characterized by distinct properties which enable allogeneic or "off-the-shelf" use. Given our business activity and current development stage, we generate losses each year and are net users of cash.

We operate at the forefront of a highly specialized industry in which our people are the key to developing our proprietary adult stem cell technologies. As we seek to attract and retain established leaders and emerging experts in an innovative field, our remuneration framework is designed to be competitive worldwide and in particular within the United States life sciences industry – where the majority of our employees are based. This remuneration framework also allows us to meet both the expectations of our global shareholder base and the Australian regulatory framework by which Mesoblast is governed.

Board of Directors

Brian Jamieson, FCA

Chairman of the Board of Directors

Experience and expertise

Mr. Jamieson has served on our board of directors as Chairman since 2007. He was Chief Executive of Minter Ellison Melbourne and a partner of the Minter Ellison Revenue Group from 2002 to 2005. He retired as Chief Executive of Minter Ellison Melbourne on December 31, 2005. Prior to joining Minter Ellison, Mr. Jamieson was Chief Executive Officer at KPMG Australia from 1998 to 2000, Managing Partner of KPMG Melbourne and Southern Regions from 1993 to 1998 and Chairman of KPMG Melbourne from 2001 to 2002. He was also a KPMG Board Member in Australia, and a member of the USA Management Committee. Mr. Jamieson is Chairman of Sigma Pharmaceuticals Limited and a Non-Executive Director of the Tatts Group Limited. He is also a Director and Treasurer of the Bionics Institute. He is a fellow of the Institute of Chartered Accountants in Australia. With his over 40 years of experience in providing advice and audit services to a diverse range of public and large private companies, together with his service as a chairman and director at other companies, Mr. Jamieson provides leadership, global management, accounting and regulatory expertise.

Other current directorships of listed public companies
Chairman, Sigma Pharmaceuticals Ltd (since 2005)
Non-executive Director, Tatts Group Ltd (since 2005)

Former directorships of listed public companies within the last 3 years
Non-executive Director, Tigers Realm Coal Ltd (2011 – 2014)
Non-executive Director, OZ Minerals Ltd (2004 – 2015)

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 a Non-Executive Lead Independent Director of Shire PLC, has been a Non-Executive Director of 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, Mr. Burns was appointed a trustee of the Institute of Cancer Research, London, UK, and in 2016 a Governor of The Wellcome Trust in London. 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
Non-executive Director, Shire Plc. (since 2010)

Former directorships of listed public companies within the last 3 years
Chairman, Biotie Therapies Corp. (2014 – 2016)
Director, Roche Holdings AG (2010 – 2014)
Director, Chugai Pharmaceuticals Co. (2002 – 2014)

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, Atcor Medical Holdings Ltd, Fisher & Paykel Healthcare Ltd and NIB Health Funds Ltd. 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, Atcor Medical Holdings Ltd (since 2004)
Non-executive Director, Fisher & Paykel Healthcare (since 2013)
Non-executive Director, NIB Holding 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

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 Chairman from the date of our Australian IPO in 2004 until 2007, Chair of the Audit and Risk Committee as well as a member of our Nomination and Remuneration Committee. 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. 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

Ben-Zion Weiner, BSc, MSc, PhD

Non-Executive Member of the Board of Directors

Experience and expertise

Dr. Weiner has served on our board of directors since 2012. In a 37-year career at Teva Pharmaceutical Industries Ltd, he held various senior research and development positions, including Senior Vice President of Global Research and Development. Dr Weiner twice received the Rothschild Prize for industrial innovation - for the development of Copaxone for the treatment of multiple sclerosis, and alpha D3 for kidney and bone disorders. He is on the Board of Directors at Novaremed Ltd., the scientific advisory board at E-QURE Corp. and Breed IT, Corp. and has served on the Board of Directors at Geffen Biomed Investments Ltd (2010-2013), XTL Biopharmaceuticals Limited (2012-2013) and Breed IT, Corp (2014). His extensive experience in the pharmaceutical industry and pharmaceutical companies provides pharmaceutical development, industry, scientific and management expertise.

Other current directorships of listed public companies
None

Former directorships of listed public companies within the last 3 years
Director, BreedIT (2014)

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

Paul Hodgkinson, MA (Hons) FCA

Chief Financial Officer

Mr. Hodgkinson has served as our Chief Financial Officer ("CFO") since June 2014. He has 16 years of international pharmaceutical experience in the areas of finance, strategic planning, business development and licensing, manufacturing and supply chain, and procurement. From 2011 through 2014, Mr. Hodgkinson served as the Country Chief Financial Officer for the Novartis Australia and New Zealand, or ANZ, group of companies and divisions, which was comprised of Alcon, Sandoz, and the Novartis Vaccines and Diagnostics, Consumer Health, Animal Health, and Pharmaceuticals divisions. From 1998 to 2006, Mr. Hodgkinson held a number of leadership roles with AstraZeneca in the United Kingdom, including Global Licensing Finance Director, before serving as CFO for AstraZeneca Australia from 2006 through 2011. Mr. Hodgkinson is a member of the Institute of Chartered Accountants in Australia, is a Fellow of the Institute of Chartered Accountants of England and Wales and holds a Master's degree in engineering from Cambridge University. He has also undertaken executive leadership programs at the Harvard Business School and INSEAD.

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.

Donna Skerrett, MD

Chief Medical Officer

Dr. Skerrett has served as our Chief Medical Officer since 2011, and she previously held roles at Mesoblast in Clinical and Regulatory Affairs since 2004. Dr. Skerrett has 20 years of combined experience in transfusion medicine, cellular therapy, and transplantation. Prior to joining Mesoblast, Dr. Skerrett was Director of Transfusion Medicine and Cellular Therapy at Weill Cornell Medical Center in New York from 2004 to 2011, and she served as Associate Director of Transfusion Medicine and Director of Stem Cell Facilities at Columbia University's New York-Presbyterian Hospital from 1999 to 2004. She has been an advisor to the New York State Department of Health on the Progenitor Cell Committee since 1989 and has been Chair of the Governor's Council on Blood and Transfusion Services since 2007, and serves on the Executive Committee of the Alliance for Regenerative Medicine.

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.

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.

Key Management Personnel

Mesoblast has developed into a late stage biopharmaceutical company with three programs in active Phase 3 clinical studies to treat serious and life-threatening illnesses. Throughout this evolution the CEO and our board of directors have set the strategy and direction of our company. With 75 employees globally, our company has a flat structure with 13 employees directly reporting to the CEO, 8 of whom form the executive management team.

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 the CEO, the Chief Financial Officer (CFO), Paul Hodgkinson, should also be designated as key management personnel.

In summary, our key management personnel for the financial year ended June 30, 2017 are listed in table below:

Name	Position	Change from last year
Non-executive directors		
Brian Jamieson	Chair, board of directors Member, Nomination and Remuneration Committee Member, Audit and Risk Committee	No change
William Burns	Vice Chair Member, Science and Technology Committee	Transitioned from Non-executive Director to Vice Chair, effective September 1, 2016
Donal O’Dwyer	Non-executive Director Chair, Nomination and Remuneration Committee Member, Audit and Risk Committee	No change
Eric Rose	Non-executive Director Chair, Science and Technology Committee	No change
Michael Spooner	Non-executive Director Chair, Audit and Risk Committee Member, Nomination and Remuneration Committee	No change
Ben-Zion Weiner	Non-executive Director Member, Science and Technology Committee	No change
Executive director		
Silviu Itescu	Chief Executive Officer Executive Director	No change
Other executive KMP		
Paul Hodgkinson	Chief Financial Officer	No change

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
William Burns	28,000	80,000
Silviu Itescu	68,244,642	—
Brian Jamieson	625,000	—
Donal O'Dwyer	875,730	255,912
Eric Rose	—	80,000
Michael Spooner	1,050,000	—
Ben-Zion Weiner	40,000	80,000

Meeting of Directors

The number of meetings our board of directors (including committee meetings of directors) held during the year ended June 30, 2017 and the number of meetings attended by each director were:

	Board of Directors		Audit and Risk Committee		Nomination and Remuneration Committee		Science and Technology Committee	
Director	A*	B*	A	B	A	B	A	B
William Burns	14	10	—	—	—	—	1	1
Silviu Itescu	14	14	—	—	—	—	1	1
Brian Jamieson	14	14	5	5	4	4	—	—
Donal O'Dwyer	14	13	5	5	4	4	—	—
Eric Rose	14	13	—	—	—	—	1	1
Michael Spooner	14	13	5	5	4	4	—	—
Ben-Zion Weiner	14	12	—	—	—	—	1	1

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

* = This includes both in-person scheduled meetings as well teleconference meetings organized on an ad-hoc basis. There were a total of 11 scheduled meetings for the year. Each director attended every in-person, scheduled meeting.

— = 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

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 (see below).

Use of Remuneration Consultants

During the financial year ended June 30, 2017, the Nomination and Remuneration Committee engaged KPMG to provide the following remuneration advice to assist the Board in decision making:

- review of the Remuneration Report for the financial year ended June 30, 2016; and
- disclosure advice for KMP.

The advice provided by KPMG does not constitute a 'remuneration recommendation' as defined in section 9B of the Corporations Act as it relates to the provision of information and/or advice on the taxation, legal or accounting implications of specific elements of the remuneration framework.

Non-Executive Director Remuneration

Our aim is to establish a board of directors comprised of global expertise in the biopharmaceutical industry and capital markets. We have six NEDs, three based in Australia, one in the United States, one in Switzerland and one in Israel. 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 2013 Annual General Meeting, not to exceed a maximum fee pool of A$1,250,000. A board and committee fee structure was adopted on November 1, 2013 based on advice provided by Towers Watson in October 2012 with reference to companies of comparable size and complexity.

In consideration of our lower market capitalization at June 30, 2016, and with a goal of conserving cash, NEDs proposed that a reduced fee structure take effect from July 1, 2016. Under this revised fee structure the Board Chair fee is reduced to A$250,000 per annum and committee fees are suspended for all other NEDs. This fee structure remains in place.

	From July 1, 2016 to June 30, 2017			
Position	Board of Directors	Audit and Risk Committee	Nomination and Remuneration Committee	Science and Technology Committee
Chair	A$250,000	—	—	—
Vice Chair*	A$175,000	—	—	—
Member	A$128,250	—	—	—

* William Burns transitioned from Non-executive Director to Vice Chair, effective September 1, 2016

The Mesoblast Constitution allows the Board to approve a Special Exertion payment to NEDs who perform duties in excess of their expected role. Effective January 1, 2016, the Board approved payment of a special exertion fee to Eric Rose of US$ 12,500 per month in recognition of a significantly higher level of involvement in our company. Initially approved through June 30, 2016, the Board approved extending this fee through December 31, 2016. For the purposes of the Corporations Act, this payment is made as part of Dr. Rose's director's remuneration. The Board considers the payment reasonable given Mesoblast's circumstances (i.e. the nature of the industry that Mesoblast operates in, and nature and position of Mesoblast within the industry) and the director's circumstances (i.e. the position and responsibilities of the director).

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.

Performance Review

The Board conducts periodic performance reviews of the Board and its operations as a whole. The last review was conducted during the financial year ended June 30, 2016. 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. Our next review is scheduled to be finalized by November 2017 with a similar scope of topics as previously covered.

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.

Mesoblast applies the following market and performance-based remuneration framework for all employees. This provides cohesion across our global team through shared objectives and consistent communication. Our application of this framework for our KMP in the financial year ended June 30, 2017 is detailed in a subsequent section labelled 'Executive Remuneration – Outcomes'.

		Performance-based Remuneration	
	Fixed Pay	**Short-term Incentives**	**Long-term Incentives**
Description	Set according to each role's responsibilities, 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 individual performance against annual corporate and individual key performance indicators (KPIs). Executive KPIs are typically milestone related as befitting a development stage 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. Only available to select roles.
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 Group 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.	Individual outcomes are reviewed and approved first by the Nomination & Remuneration Committee and then the Board.	
Delivered as	Cash.	Cash.	Mesoblast equity with vesting conditions that vary according to role.

KMP Target Remuneration Mix

The CEO and CFO are designated as KMP due to the particular nature of their roles in planning, directing and controlling the activities of our company. Their target remuneration mix is as follows:

	Fixed Remuneration %		At-Risk STI %		At-Risk LTI %	
Name	**2017**	**2016**	**2017**	**2016**	**2017**	**2016**
Silviu Itescu	50	50	50	50	—	—
Paul Hodgkinson	40	40	20	20	40	40

The Board has customized the CEO's remuneration mix in comparison with other executive KMP in recognition that he continues to be Mesoblast's single largest shareholder. The Board believes the CEO has sufficient exposure to our company's share performance to align his interests in value creation, and he therefore does not currently participate in the LTI. The Board reviews the CEO's remuneration package annually, including the remuneration mix.

The Nomination and Remuneration Committee retained KPMG to conduct a benchmarking study on CEO remuneration in July 2015. The findings of this exercise show the CEO's total remuneration package is positioned below the 25th percentile of the comparator group based on the exchange rate at that time. The comparator group included other pre-revenue biopharmaceutical companies in the US with comparable expenditure levels with regard to market capitalization.

The CFO's remuneration mix is a more typical executive remuneration package, reflecting a significant emphasis on LTI as befitting a company in the development stage when conserving cash is a priority.

Performance-Based Remuneration

Short-Term Incentives (STIs)

To align the organization around key shorter-term objectives that drive long-term shareholder value, our Board sets annual key performance indicators ("KPI") for the CEO which also serve as our company's objectives. 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.

The Board approved KPIs for the CEO in the following performance categories for the financial year ended June 30, 2017. The Board assessed the CEO's performance on these KPIs for the financial year ended June 30, 2017 as achieving 75% of his target STI. The CFO was assessed as achieving 70% of his target STI. The Board's assessment rationale is summarized below with details provided in the section "Important Corporate Developments – Fiscal year 2017 to date" in "Item 4.A History and Development of Mesoblast".

KPI	Percentage	Achievement	Justification
Product management of Tier 1 and Tier 2 studies - each with individual enrolment, partnering and regulatory targets	50	Partially achieved	Successful interim analyses and progress with patient enrollment. Equity purchase agreement with Mallinckrodt.
Manufacturing achievements • Advances in technology transfer • Progress with commercial manufacturing capabilities	10	Substantially achieved	Progress with three-dimensional bioreactors
Strategy, Financial and Risk Management • company performance versus budget • development of strategic and capital market initiatives	35	Substantially achieved	Raise capital and control expenditure
Organizational development	5	Achieved	Reduced headcount from 108 to 75

The following table outlines a summary of the 2017 Short-Term Incentive Plan:

What is the 2017 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 2017 STI grant paid to eligible employees?	The STI amount will be paid, in the three month period ended September 30, 2017, to each participant who satisfies applicable performance measures, following assessment of performance against the applicable measures for the financial year ended June 30, 2017.
Who participates in the 2017 STI?	All employees hired on or before March 31, 2017, including the CEO and CFO, are eligible for consideration. Employees hired during the year are recognized on a pro-rata basis.
Why does our board of directors consider the 2017 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 2017 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 our CEO's KPIs. This assessment will adjust how much of our bonus pool is eligible for allocation. For the financial year ended June 30, 2017, the Board assessed our overall Company performance as meeting 70% 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).

In designing a LTI mechanism that is appropriate to our global team where 59% 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.

As a development stage company, the achievement of significant milestones are key drivers in helping us get to major objectives such as product approval. For the financial year ended June 30, 2017 the Board introduced a milestone vesting framework for executive LTI grants. We believe this approach is appropriate at this time. In this structure, we tailor individual LTI grants to vest with the achievement of objectives relevant to each executive's role at an exercise price per share that is equal to the fair market value at grant date. Upon the Board's determination that the milestone has been achieved, the options are designated as vested. We have

adopted this approach to strengthen the link between our executive LTI rewards and achievements which we expect to generate shareholder returns.

LTI allocations are determined with consideration to the nature of the role within our organization, market value of LTI allocations 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 number of options reflecting the Board's assessment that this grant size will deliver the desired value to the participants over time.

In determining executive LTI allocations for the financial year ended June 30, 2017, the executive remuneration outcome of the previous financial year was considered. For the financial year ended June 30, 2016, the Board determined that while the Group had achieved significant operational outcomes, when assessed in the context of our cash position at that time, performance had not met a sufficient threshold for an STI payment to executives. As a result, no executives received an STI payment for the financial year ended June 30, 2016. In recognition of the significant performance expectations on the executive team, the Board introduced the milestone vesting framework and enhanced the number of options granted to achieve the desired remuneration mix for the financial year ended June 30, 2017.

Outside this executive milestone framework we issue traditional LTIs to select other participants at a 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 in which allows us to attract and retain the people we need. We believe this approach is appropriate at this stage and that applying additional performance hurdles to our traditional 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.
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?	In the financial year ended June 30, 2017, executive LTI grants were issued with an exercise price per share that was equal to the fair market value at grant date and vest with the achievement of milestones relevant to each executive's role. Typically each executive has two or three milestones, 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, completing an interim analysis, submitting a regulatory filing. Traditional options granted to other participants 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 Group 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 milestones 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 milestones, to the satisfaction of the Board, for the Options to vest. The value of the remuneration fluctuates with our share price. 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. In the financial year ended June 30, 2017 executive LTI grants were increased to maintain performance-based remuneration after a year in which executives did not receive an STI payment.
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 has authority to designate that options have vested when the related milestone has been met. For other participants, 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.

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 (Paul Hodgkinson)	An ongoing employment agreement until notice is given by either party.	6 months	6 months base salary

On termination of employment, key management personnel are entitled to receive their statutory entitlements of accrued annual and long service leave, together with any superannuation benefits.

There is no entitlement to a termination payment in the event of resignation 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 two to six months.

Executive Remuneration – Outcomes

Relationship between performance and executive KMP remuneration

Mesoblast is specializing in the development of biologic products for the broad field of regenerative medicine based on its proprietary cell-based technologies. 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 do they 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. Annually the Board prioritizes the milestones for the coming year as outlined in the discussion on STIs. These milestones form the CEO's KPIs which establish the basis for all STI payments.

As of June 30, 2017 we have cash and cash equivalents of US$45.8 million. During the year Mesoblast entered into an equity purchase agreement with Mallinckrodt Pharmaceuticals in which 20.04 million new shares were issued raising US$21.7 million in December 2016, we successfully completed a fully underwritten institutional placement of 26.25 million new shares raising US$40 million in March 2017. Subsequent to the year ended June 30, 2017 we announced a fully underwritten entitlement offer to existing eligible shareholders (on a 1 for 12 basis) in Australia and New Zealand and institutional shareholders in certain other countries in private placements. US$38.2 million of net proceeds from the entitlement offer is expected to be received and recognized in cash and cash equivalents in September 2017. Under our agreement with JCR, we receive royalties and other payments at predefined thresholds of cumulative net sales of TEMCELL® HS. Inj., a registered product of JCR Pharmaceuticals Co Ltd launched, for the treatment of acute graft versus host disease in children and adults in Japan. The funding framework detailed above has enabled us to fund clinical programs towards well-defined milestones. To date we have not utilized any debt financing and our sources of funding for the programs have predominantly been through capital raisings from institutional and sophisticated investors, the signing of a collaboration with Teva, the execution of share placement agreements with Celgene Corporation and Mallinckrodt Pharmaceuticals, an initial public offering on the NASDAQ and to a lesser extent milestone receipts and royalties, government grants and research and development tax credits.

The table and chart below detail Company performance on a market capitalization basis, against executive key management personnel short-term at-risk compensation:

	2017	2016	2015	2014	2013
Share price (ASX:MSB)					
– closing at June 30	A$2.08	A$1.08	A$3.76	A$4.47	A$5.30
– high for the year	A$3.44	A$4.06	A$5.88	A$6.8	A$7.49
– low for the year	A$1.03	A$1.01	A$3.17	A$4.18	A$4.22
– share price volatility (annual)	52%	60%	46%	36%	39%
Market capitalization at June 30 (in millions)	A$891	A$412	A$1,267	A$1,438	A$1,677
– increase/(decrease) – in $ millions	A$479	(A$855)	(A$170)	(A$240)	(A$93)
– increase/(decrease) – as %	116%	(67%)	(12%)	(14%)	(5%)
Short-term incentives – % of target paid to CEO	75%	—	90%	87.5%	85%
Short-term incentives – as % of base salary paid to CEO	75%	—	90%	87.5%	85%
Short-term incentives – % of target paid to CFO	70%	—	100%	n/a	n/a
Short-term incentives – as % of base salary paid to CFO	35%	—	50%	n/a	n/a

KMP Remuneration Details

Details of the remuneration of our key management personnel for the year ended June 30, 2017 are set out below (amounts are presented in Australian dollar):

2017		Short-term benefits					Post-employment benefits	Long-term benefits	Share-based payments	Other	
Name	Currency	Salary & fees $	Cash Bonus(1) $	Annual Leave $	Non-monetary benefits $	Other $	Super-annuation $	Long service leave $	Options $	Termi-nation benefits $	Total $
Silviu Itescu (CEO)	A$	1,010,000	757,500	46,610	—	—	19,616	16,880	—	—	1,850,606
Paul Hodgkinson (CFO)	A$	439,143	148,750	5,721	—	—	30,416	6,641	676,692	—	1,307,363
William Burns	A$	167,208	—	—	—	—	—	—	18,448	—	185,656
Brian Jamieson	A$	250,000	—	—	—	—	19,616	—	—	—	269,616
Donal O'Dwyer	A$	128,250	—	—	—	—	12,184	—	—	—	140,434
Michael Spooner	A$	128,250	—	—	—	—	12,184	—	—	—	140,434
Ben-Zion Weiner	A$	128,250	—	—	—	—	—	—	18,448	—	146,698
Eric Rose	A$	227,222	—	—	—	—	—	—	18,448	—	245,670
Total directors and executive KMP	**A$**	**2,478,323**	**906,250**	**52,331**	—	—	**94,016**	**23,521**	**732,036**	—	**4,286,477**
Total directors and executive KMP(2)	**US$**	**1,869,399**	**683,584**	**39,473**	**—**	**—**	**70,915**	**17,742**	**552,174**	**—**	**3,233,287**

(1) STI bonus payable for performance in the year ended June 30, 2017, not paid as at June 30, 2017.
(2) The US$ results has been translated at the average weighted exchange rate of 0.7543 for the year ended June 30, 2017.

Details of the remuneration of our key management personnel for the year ended June 30, 2016 are set out below (amounts are presented in Australian dollar):

2016		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 $	Termi-nation benefits $	Total $
Silviu Itescu (CEO)	A$	1,010,000	—	81,546	—	—	19,308	24,028	—	—	1,134,882
Paul Hodgkinson (CFO)	A$	433,057	—	17,168	—	—	30,108	3,063	12,850	—	496,246
William Burns	A$	138,250	—	—	—	—	—	—	42,737	—	180,987
Brian Jamieson	A$	328,320	—	—	—	—	19,308	—	—	—	347,628
Donal O'Dwyer	A$	160,750	—	—	—	—	15,271	—	—	—	176,021
Michael Spooner	A$	163,250	—	—	—	—	15,509	—	—	—	178,759
Ben-Zion Weiner	A$	138,250	—	—	—	—	—	—	42,737	—	180,987
Eric Rose	A$	250,531	—	—	—	—	—	—	42,737	—	293,268
Total directors and executive KMP	**A$**	**2,622,408**	**—**	**98,714**	**—**	**—**	**99,504**	**27,091**	**141,061**	**—**	**2,988,778**
Total directors and executive KMP(1)	**US$**	**1,908,062**	**—**	**71,823**	**—**	**—**	**72,398**	**19,710**	**102,635**	**—**	**2,174,628**

(1) The US$ results has been translated at the average weighted exchange rate of 0.7276 for the year ended June 30, 2016.

Relative proportions of fixed versus variable remuneration expenses

For the year ended June 30, 2017 and 2016, the following table shows the relative proportions of remuneration 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	2017 %	2016 %	2017 %	2016 %	2017 %	2016 %
Silviu Itescu (CEO)	59	100	41	—	—	—
Paul Hodgkinson (CFO)	37	97	11	—	52	3

Performance-Based Remuneration

The proportion of at-risk performance remuneration 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, 2017			
Silviu Itescu	1,010,000	75	25
Paul Hodgkinson	212,500	70	30
For the year ended June 30, 2016			
Silviu Itescu (for the year ended June 30, 2016)	1,010,000	—	100
Paul Hodgkinson (for the year ended June 30, 2016)	212,500	—	100

Share Based Compensation

Share options granted to key management personnel in the year ended June 30, 2017, were 450,000 share options granted to Mr. Hodgkinson. There were no other grants made to key management personnel, including to our directors, in the year ended June 30, 2017. There has been no modification to any terms and conditions of share-based payment transactions during the year ended June 30, 2017.

Share options granted to key management personnel in the year ended June 30, 2016 were 400,000 share options granted to Mr. Hodgkinson. There were no other grants made to key management personnel, including to our directors, in the year ended June 30, 2016. There was no modification to any terms and conditions of share-based payment transactions during the year ended June 30, 2016.

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, 2017 and June 30, 2016 are set out in the tables below:

Remuneration Values

The following table provides the remuneration values:

	Remuneration consisting of options or loan-funded(1)	Values of options or loan-funded granted(2)	Value of options or loan-funded exercised(3)	Value of options or loan-funded lapsed(4)
For the year ended June 30, 2017				
William Burns	9.9%	—	—	—
Eric Rose	7.5%	—	—	—
Ben-Zion Weiner	12.6%	—	—	—
Donal O'Dwyer	—	—	A$689,028	—
Paul Hodgkinson	51.8%	A$605,025	—	—
For the year ended June 30, 2016				
William Burns	—	—	—	—
Eric Rose	14.6%	—	—	—
Ben-Zion Weiner	23.6%	—	—	—
Donal O'Dwyer	—	—	A$1,079,474	—
Paul Hodgkinson	2.6%	A$492,000	—	—

(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 Payments*.

(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 Payments*. 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, but valued as if the performance condition had been met.

Reconciliation of Options held by KMP

The following table shows a reconciliation of options held by each KMP from the beginning to the year ended June 30, 2017:

		Balance at the start of the year	Granted during the year	Vested		Exercised	Forfeited		Balance at the end of the year		
Name	Year granted	Number	Number	Number	%	Number	Number	%	Vested and exercisable	Vested and unexercisable	Unvested
Silviu Itescu	—	—	—	—	—	—	—	—	—	—	—
William Burns	2015	80,000	—	53,334	67	—	—	—	53,334	—	26,666
Brian Jamieson	—	—	—	—	—	—	—	—	—	—	—
Donal O'Dwyer	2011	511,824	—	—	—	(255,912)	—	—	255,912	—	—
Michael Spooner	—	—	—	—	—	—	—	—		—	—
Ben-Zion Weiner	2015	80,000	—	53,334	67	—	—	—	53,334	—	26,666
Eric Rose	2015	80,000	—	53,334	67	—	—	—	53,334	—	26,666
Paul Hodgkinson	2017	—	450,000	150,000	33	—	—	—	150,000	—	300,000
Paul Hodgkinson	2016	400,000	—	133,334	33	—	—	—	133,334	—	266,666
Paul Hodgkinson	2015	450,000	—	450,000	100	—	—	—	300,000	150,000	—

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 %
13/01/2017(1)	one third - 31/03/2017 one third - 31/08/2017 one third - 30/09/2017	12/01/2024	A$1.67	A$1.34	33
27/04/2016	one third - 07/03/2017 one third - 07/03/2018 one third - 07/03/2019	06/03/2023	A$2.82	A$1.05	33
10/07/2015	one third - 02/07/2016 one third - 02/07/2017 one third - 02/07/2018	30/06/2022	A$4.22	A$1.40	33
25/03/2015(2)	25/03/2015	23/07/2019	A$4.71	A$0.92	100
25/11/2014	one third - 25/11/2015 one third - 25/11/2016 one third - 25/11/2017	24/11/2019	A$4.02	A$1.30	67

(1) These options vest on the achievement of milestones relevant to the KMPs role. The milestones of this grant relate to capital raising, compliance and partnering. The Board has authority to designate that options have vested when the related milestones are met.

(2) These options have vested and were initially held in escrow. As of June 30, 2017, 67% of the options have reached the end of the escrow period and are exercisable. 33% of the options have not reached the end of the escrow period, and therefore they may not be exercised until the escrow period concludes.

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, 2017					
Donal O'Dwyer (for the year ended June 30, 2017)	255,912	255,912	April 26, 2017	A$3.28	US$0.444
For the year ended June 30, 2016					
Donal O'Dwyer (for the year ended June 30, 2016)	287,903	287,903	July 6, 2015	A$3.81	US$0.046

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, 2017, to our key management personnel and our next 4 highest remunerated officers that are not also designated as key management personnel.

Name	Issue Date	Exercise Price	Number of shares, under option
KMP			
Silviu Itescu	—	—	—
Paul Hodgkinson	January 13, 2017	A$1.67	450,000
Other than KMP			
Kenneth Borow(1)	December 6, 2016	A$1.21	750,000
Peter Howard(1)	October 31, 2016	A$2.82	200,000
Peter Howard(1)	December 6, 2016	A$1.21	600,000
Michael Schuster(1)	December 6, 2016	A$1.21	550,000
Donna Skerrett(1)	December 6, 2016	A$1.21	425,000

(1) Four most highly remunerated officers that are not also designated as key management personnel.

Shareholdings

The table below shows a reconciliation of ordinary shares held by each KMP from the beginning to the end of the 2017 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	68,244,642	—	—	68,244,642
William Burns	28,000	—	—	28,000
Brian Jamieson	625,000	—	—	625,000
Donal O'Dwyer	619,818	255,912	—	875,730
Michael Spooner(1)	1,081,335	—	—	1,081,335
Ben-Zion Weiner	40,000	—	—	40,000
Eric Rose	—	—	—	—
Paul Hodgkinson	—	—	—	—

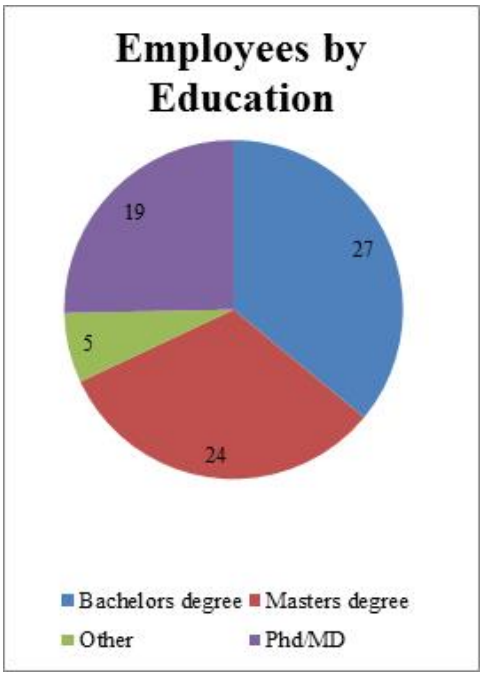
(1) Of this balance, Mr. Spooner has a relevant interest of 1,050,000 ordinary shares.

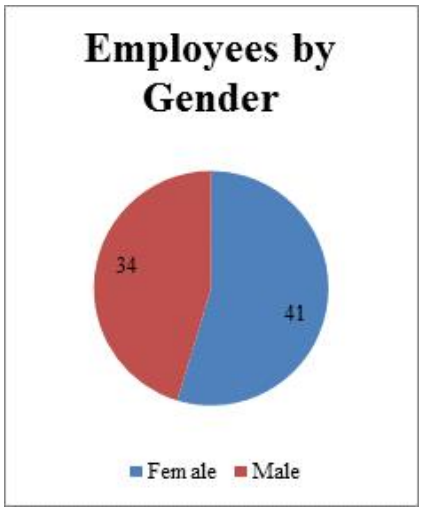
Voting and comments made at our company's 2016 Annual General Meeting ("AGM")

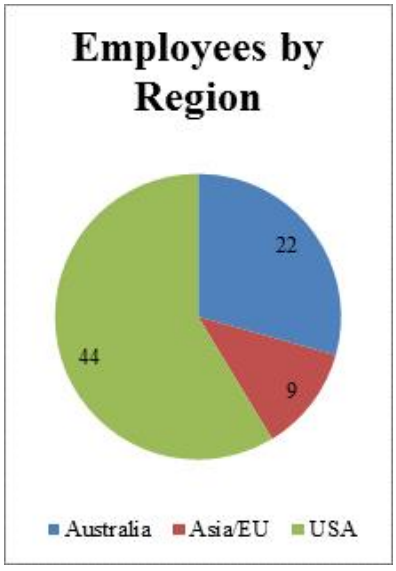
We received 99.3% of the votes cast in person or by proxy on a poll in favor of adopting the 2015/2016 remuneration report, and the same resolution was passed on a show of hands at the meeting.

Employee Profile

As of June 30, 2017, we had 75 (2016: 108) employees globally:





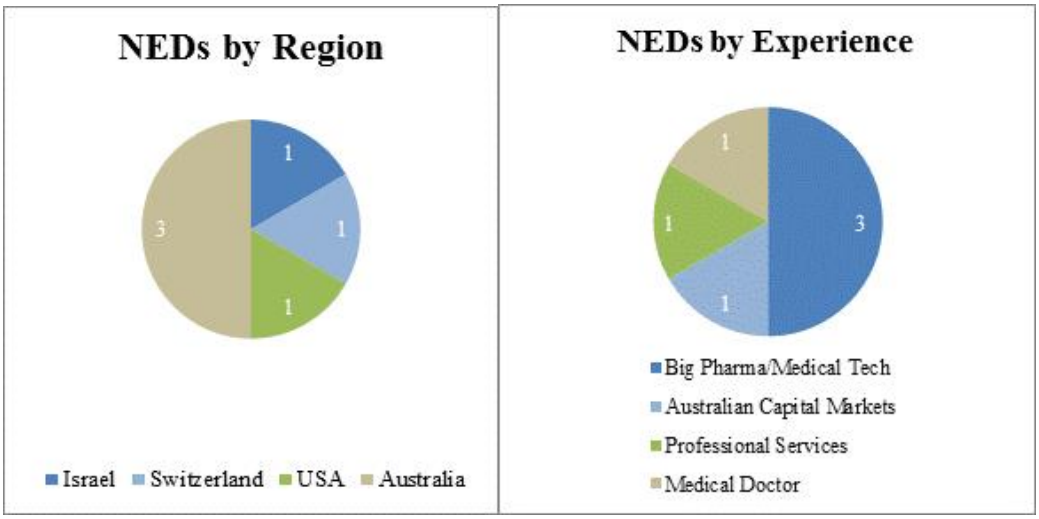


44 (or 59%) of our employees are based in the United States where our operational activities are concentrated. Australia consists primarily of corporate headquarter activities with 22 (or 29%) employees, including the CEO and other executive team members.

Of the remaining employees, 8 (or 11%) are located in Singapore where our research and technology transfer activities are performed and 1 is in Switzerland.

Non-Executive Director Profile

As at June 30, 2017, 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:

Issue date	Exercise price of options	Expiry date of options	Number of shares under option
9/07/2012	A$6.69	8/07/2018	100,000
24/05/2013	A$6.36	23/05/2018	325,000
3/09/2013	A$5.92	9/02/2018	1,465,000
4/09/2013	A$6.28	27/08/2018	125,000
24/02/2014	A$6.38	31/12/2018	650,000
25/08/2014	A$4.67	24/08/2019	75,000
5/09/2014	A$4.71	30/06/2019	1,545,000
9/10/2014	A$4.54	8/10/2019	60,000
25/11/2014	A$4.02	24/11/2019	240,000
12/12/2014	A$4.51	31/10/2019	50,000
25/03/2015	A$5.00	30/06/2018	650,000
25/03/2015	A$5.00	25/01/2018	235,000
25/03/2015	A$5.00	20/01/2019	135,000
25/03/2015	A$5.00	25/01/2019	300,000
25/03/2015	A$5.00	25/01/2018	165,000
25/03/2015	A$5.00	25/01/2019	200,000
25/03/2015	A$4.71	23/07/2019	300,000
25/03/2015	A$4.71	30/06/2019	400,000
25/03/2015	A$4.46	30/06/2019	600,000
25/03/2015	A$4.71	23/07/2019	150,000
12/05/2015	A$4.30	16/02/2020	200,000
10/07/2015	A$4.22	30/06/2022	2,620,000
26/08/2015	A$4.07	16/08/2022	91,667
27/04/2016	A$2.82	6/03/2023	3,621,667
27/04/2016	A$2.76	17/04/2023	200,000
30/06/2016	A$2.22	6/10/2019	1,500,000
31/10/2016	A$2.82	6/03/2023	200,000
06/12/2016	A$1.33	5/12/2023	2,045,000
06/12/2016	A$1.21	5/12/2023	4,400,000
13/01/2017	A$1.67	12/01/2024	450,000
28/06/2017	A$2.23	27/06/2024	300,000
Sub-total			**23,398,334**
07/07/2010	US$0.305	26/10/2018	154,064
07/07/2010	US$0.340	26/10/2019	447,848
Sub-total			**601,912**
Grand Total			**24,000,246**

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
27/04/2016	16,667	A$2.82	—
07/12/2010	255,912	US$0.444	—
Total	**272,579**		—

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, 2017 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/ Brian Jamieson	/s/ Silviu Itescu
Brian Jamieson	Silviu Itescu
Chairman	Chief Executive Officer

Dated: August 30, 2017

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. At every annual general meeting, one-third of the previously elected directors or, if their number is not a multiple of three then the number nearest to but not exceeding one-third, must retire from office and are eligible for re-election. The directors who retire in this manner are required to be the directors or director longest in office since last being elected. Additionally, 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. O'Dwyer and Weiner will expire at the annual shareholders' meeting in 2017.

Name	First election at AGM	Last election at AGM	End of current term
Brian Jamieson	2007	2015	2018
William Burns	2014	2016	2019
Donal O'Dwyer	2004	2014	2017
Eric Rose	2013	2016	2019
Michael Spooner	2004	2015	2018
Ben-Zion Weiner	2012	2014	2017

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.

None of our directors 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, an Audit and Risk Management Committee and a Science and Technology 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. Jamieson, 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. Jamieson, O'Dwyer and Spooner (Chairman), 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.

Science and Technology Committee. The members of the Science and Technology Committee are Messrs. Itescu, Rose (Chairman), Burns and Weiner. The Science and Technology Committee is a committee of our board of directors, and is primarily responsible for making recommendations to our board of directors pertaining to our strategic direction and investment in research and development and technology, by:

- identifying areas and activities that are critical to the success of our regenerative medicine discovery, development and licensing efforts;
- evaluating the effectiveness of our regenerative medicine development and licensing strategies and operations;
- keeping our board of directors apprised of this evaluation process and findings;
- making appropriate recommendations to our board of directors on modifications of strategies and operations; and
- identifying additional areas of focus as appropriate.

6.D Employees

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, 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**

As of June 30, 2016	Research & Development	Commercial	Manufacturing	Corporate	Total
USA	49	1	9	12	71
Australia	11	1	—	15	27
Singapore	6	—	2	1	9
Switzerland	—	—	—	1	1
Total	**66**	**2**	**11**	**29**	**108**

As of June 30, 2015	Research & Development	Commercial	Manufacturing	Corporate	Total
USA	60	—	9	11	80
Australia	9	2	—	15	26
Singapore	6	—	1	1	8
Switzerland	—	—	—	1	1
Total	**75**	**2**	**10**	**28**	**115**

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 following table sets forth information regarding the beneficial ownership of our ordinary shares based on 428,221,398 ordinary shares outstanding at June 30, 2017 by each of our directors and key management personnel.

We have determined beneficial ownership in accordance with the rules of the SEC and 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, 2017. Ordinary shares subject to options currently exercisable or exercisable within 60 days of June 30, 2017 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, but are not deemed outstanding for computing the percentage of any other person.

Based upon information known to us, as of June 30, 2017 we had 17 shareholders in the United States. These shareholders held an aggregate of 54,084,938 of our ordinary shares, or approximately 13% of our outstanding ordinary shares.

Unless otherwise indicated, to our knowledge each shareholder possesses sole voting and investment power over the ordinary shares listed subject to community property laws, where applicable. 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)	68,244,642	15.9%
William Burns(2)	81,334	*
Brian Jamieson(3)	625,000	*
Paul Hodgkinson(4)	583,334	*
Eric Rose(5)	53,334	*
Donal O'Dwyer(6)	1,131,642	*
Ben-Zion Weiner(7)	93,334	*
Michael Spooner	1,050,000	*
All directors and key management personnel as a group (8 persons)	**71,862,620**	**16.8%**

* Less than 1% of the outstanding ordinary shares.

(1) Includes (a) 67,756,838 ordinary shares owned by Dr. Itescu and (b) 487,804 ordinary shares owned by Josaka Investments Pty Ltd, the trustee of Dr. Itescu's self-managed superannuation fund.

(2) Includes (a) 28,000 ordinary shares owned by Mr. Burns, (b) 53,334 ordinary shares subject to options exercisable at a price of A$4.02 per share until November 24, 2019.

(3) Includes (a) 150,000 ordinary shares owned by Mr. Jamieson, (b) 475,000 ordinary shares owned by Mr. Jamieson through Timaru Close Pty Ltd.

(4) Includes 583,334 ordinary shares subject to options of which; 300,000 are exercisable at a price of A$4.71 per share until July 23, 2019; 66,667 are exercisable at a price of A$4.22 per share until June 20, 2022; 66,667 are exercisable at a price of A$2.82 per share until March 6, 2023; and 150,000 are exercisable at a price of A$1.67 per share until January 12, 2024.

(5) Includes 53,334 ordinary shares subject to options exercisable at a price of A$4.02 per share until November 25, 2019.

(6) Includes (a) 555,912 ordinary shares owned by Mr. O'Dwyer, (b) 319,818 ordinary shares owned by Dundrum Investments Ltd. as trustee for The O'Dwyer Family Trust, and (c) 255,912 ordinary shares subject to options of which 127,956 are exercisable at a price of US$0.31 per share until October 26, 2018 and 127,956 are exercisable at a price of US$0.34 per share until October 26, 2019. Mr. O'Dwyer and his spouse are the sole shareholders of Dundrum Investments Ltd.

(7) Includes (a) 40,000 ordinary shares owned by Dr. Weiner, (b) 53,334 ordinary shares subject to options exercisable at a price of A$4.02 per share until November 24, 2019.

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 428,221,398 ordinary shares outstanding at June 30, 2017 by each person known by us to be the beneficial owner of more than 5% of our ordinary shares.

	Ordinary Shares beneficially owned	
Name	**Number**	**%**
5% or Greater Shareholders:		
Silviu Itescu(1)	68,244,642	15.9%
Cephalon, Inc.(2)	55,785,806	13.0%
M&G Investment Group(3)	54,026,630	12.6%
Capital Research Global Investors(4)	30,364,000	7.1%
Thorney Holdings(5)	24,696,000	5.8%

(1) Includes (a) 67,756,838 ordinary shares owned by Dr. Itescu and (b) 487,804 ordinary shares owned by Josaka Investments Pty Ltd, the trustee of Dr. Itescu's self-managed superannuation fund.

(2) The address for Cephalon Inc. is 41 Moores Road, Frazer, PA 19355.

(3) 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 Laurence Pountney Hill, London 4C4R 0HH, United Kingdom.

(4) 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, Los Angeles, California, 90071.

(5) 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).

- The Capital Group Companies, Inc. reported on March 24, 2015 that, after acquiring 4,021,588 ordinary shares between January 31, 2014 and March 23, 2015, in total it held 25,488,187 ordinary shares, or 7.9% of the total voting power as of that date. It 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.

- Thorney Opportunities Ltd reported on April 17, 2015 that, after acquiring 821,593 ordinary shares between April 14, 2014 to April 13, 2015, in total it held 18,851,000 ordinary shares, or 5.81% of the total voting power as of that date. It 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.

- M&G Investment Group reported on November 25, 2015 that, after acquiring 14,625,593 ordinary shares (including 1,497,235 ADSs, each representing 5 ordinary shares acquired in the November 13, 2015 Nasdaq IPO) between February 21, 2012 and November 25, 2015, in total it held 46,643,788 ordinary shares, or 12.3% of the total voting power as of that date. It reported on March 30, 2017 that it acquired 7,196,982 ordinary shares between November 26, 2015 and March 30, 2017, and that 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.

7.B Related Party Transactions

The Company has not entered into any related party transactions during the years ended June 30, 2017 and 2016 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.”

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

In August 2017, the Group announced a fully underwritten entitlement offer to existing eligible shareholders (on a 1 for 12 basis) in Australia and New Zealand and institutional shareholders in certain other countries in private placements. US$38.2 million of net proceeds from the entitlement offer is expected to be received and recognized in cash and cash equivalents in September 2017.

There were no other events that have arisen subsequent to June 30, 2017 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 shares have been listed in Australia on the Australian Securities Exchange (ASX) since December 2004.

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 JPMorgan 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".

The NASDAQ Global Select Market

Since November 2015, our ordinary shares in the form of ADSs have been trading on the Nasdaq Global Select Market under the symbol "MESO." The following table sets forth the high and low market prices for our ADSs reported on Nasdaq for the periods indicated in U.S. dollars.

Period	US$ High	US$ Low
Annual:		
Fiscal year ended		
June 30, 2016	15.56	3.50
June 30, 2017	12.50	3.90
Quarterly:		
Fiscal year ended June 30, 2016		
Second quarter ended December 31, 2015	8.46	4.50
Third quarter ended March 31, 2016	10.89	4.26
Fourth quarter ended June 30, 2016	9.79	3.50
Fiscal year ended June 30, 2017		
First quarter ended September 30, 2016	6.57	3.90
Second quarter ended December 31, 2016	5.90	4.01
Third quarter ended March 31, 2017	9.78	5.28
Fourth quarter ended June 30, 2017	12.50	7.55
Most recent six months:		
Month ended February 28, 2017	6.59	5.39
Month ended March 31, 2017	9.78	6.43
Month ended April 30, 2017	12.50	8.84
Month ended May 31, 2017	12.02	7.60
Month ended June 30, 2017	9.64	7.55
Month ended July 31, 2017	8.55	6.85

The Australian Securities Exchange

Since December 2004, our ordinary shares have been listed in Australia on the ASX trading under the symbol "MSB". The following table sets forth the high and low market prices for our ordinary shares reported on the ASX for the periods indicated in Australian dollars.

Period	A$ High	A$ Low
Annual:		
Fiscal year ended		
June 30, 2013	7.49	4.22
June 30, 2014	6.80	4.18
June 30, 2015	5.88	3.17
June 30, 2016	4.06	1.01
June 30, 2017	3.44	1.03
Quarterly:		
Fiscal year ended June 30, 2016		
First quarter ended September 30, 2015	4.06	2.91
Second quarter ended December 31, 2015	3.50	1.35
Third quarter ended March 31, 2016	3.03	1.14
Fourth quarter ended June 30, 2016	2.70	1.01
Fiscal year ended June 30, 2017		
First quarter ended September 30, 2016	1.93	1.03
Second quarter ended December 31, 2016	1.55	1.07
Third quarter ended March 31, 2017	2.50	1.43
Fourth quarter ended June 30, 2017	3.44	1.93
Most recent six months:		
Month ended February 28, 2017	1.71	1.43
Month ended March 31, 2017	2.50	1.63
Month ended April 30, 2017	3.44	2.28
Month ended May 31, 2017	3.23	1.96
Month ended June 30, 2017	2.25	1.93
Month ended July 31, 2017	2.36	1.72

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 is a resolution 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 any contract or arrangement in which the director has any direct or indirect material personal interest or any lesser 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, a director is liable to us for any profits derived with regard to any matter in which the director has a material interest unless the director:

- declares the director's interest in the matter as soon as practicable after the relevant facts come to the director's knowledge; and
- does not contravene our Constitution or the Corporations Act in relation to the matter.

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 incur liens on or grant a security interest in any of our property or business or any uncalled portion of any partly paid shares, and may issue debentures or give any other security for any of our debts, liabilities or obligations or of any other person, in each case, in the manner and on terms it deems fit.

Election, Removal and Retirement of Directors

We may appoint or remove any director by resolution passed in the 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. At every annual general meeting, one-third of the previously elected directors or, if their number is not a multiple of three then the number nearest to but not exceeding one-third, must retire from office and are eligible for re-election. Additionally, 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, no person is eligible to be elected as a director unless a notice of the director's candidature is given to us at least 35 business days (30 business days for a meeting shareholders have requested directors to call) before the meeting. This restriction does not apply to a retiring director or to the election of a director previously appointed by the directors during the year.

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 preferred, deferred or other special rights, whether in relation to dividends, voting, return of share capital, payment of calls 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. All unclaimed dividends may be invested or otherwise made use of by our board of directors for our benefit until claimed or otherwise disposed of in accordance with our Constitution.

Voting Rights

Under 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. 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; any shareholder or shareholders representing at least 5% of the votes that may be cast on the resolution on a poll; or any shareholder or shareholders holding our shares conferring a right to vote at the meeting on which an aggregate sum has been paid up equal to not less than 5% of the total sum paid up on all the shares conferring that right. 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 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) at the meeting.

Pursuant to our Constitution, each shareholder entitled to attend and vote at a meeting may attend and vote in person or by proxy or attorney and by representative. Shareholders may not vote electronically. Under Australian law, shareholders of a public listed company are not permitted to approve corporate matters by written consent. Our Constitution does not 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, prior to our liquidation, our shareholders are entitled to participate in our profits only by payment of dividends. Our board of directors may from time to time determine to pay dividends to the shareholders; however, no dividend is payable except in accordance with the thresholds set out in the Corporations Act.

Rights to Share in the Surplus in the Event of Liquidation

Our Constitution provides for the right of shareholders to participate in a surplus in the event of our liquidation.

Redemption Provisions

There are no redemption provisions in our Constitution in relation to ordinary shares. Under our Constitution and subject to the Corporations Act, any preference shares may be issued on the terms that they are, or may at our option or at the option of the holder be, liable to be redeemed.

Sinking Fund Provisions

Our Constitution allows our directors to, at their discretion, set aside any sums they think proper out of our profits as reserves, which may be applied for any proper purpose.

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.

Quorum for General Meetings of Shareholders

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 five shareholders constitutes a quorum, or if we have less than five shareholders, then the shareholders present at a meeting constitute a quorum. If a quorum is not present within 15 minutes after the time appointed for the meeting, the meeting must be either dissolved if it was summoned 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 15 minutes after the time appointed for the meeting.

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. 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 issue shares and grant options or warrants on any terms, with preferred, deferred or other special rights and restrictions 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 consolidate or divide our share capital into a smaller or larger number by resolution, 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.

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%, 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;
- 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;
- has 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

- has 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 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 under a takeover bid and the acquisition occurs during the bid period;
- when shareholders of Mesoblast approve an acquisition that would otherwise breach the prohibition, by resolution passed at general meeting;
- 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;
- as a result of a rights issue;
- as a result of dividend reinvestment schemes;
- as a result of certain underwriting arrangements;
- through operation of law;
- an acquisition that arises through the acquisition of a relevant interest in another company listed on the ASX, certain other Australian financial markets or a foreign stock exchange approved in writing by ASIC;
- arising from an auction of forfeited shares; or
- 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 canceling 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.

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

We have not entered into any new material contracts since our final prospectus that was filed with the SEC on November 12, 2015. See "Item 19. Exhibits."

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 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 total assets of A$252 million or more (or A$1,094 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 and acquiring a direct interest in land owning entities Australia (generally 10%). 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 holding 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, government entities of that government.

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 total assets of A$252 million or more (or A$1,094 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 exceeds 40% at any time, we would be considered a foreign person under the Takeovers Act. In such event, we would be required to obtain the approval of the Australian Treasurer for our company, together with our associates, to acquire (i) more than 20% of an Australian company or business with assets totalling over A$252 million; 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 would also be included determining the foreign ownership of any Australian company or business in which it 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 a non-resident's right to hold or vote our securities.

Australian law requires the transfer of shares in our company to be made in writing or electronically through the Clearing House Electronic Subregister System. No stamp duty will be payable in Australia on the transfer of ADSs.

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.

Material U.S. Federal Income Tax Considerations to U.S. Holders

The following summary describes the 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 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 our equity; 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 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 a maximum rate of 20% 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 reduced income tax rate 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.

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 its option, to claim either a credit against its U.S. federal income tax liability or a deduction in computing its 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 percentage 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 is 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, 2017. 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 a 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 its 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 the U.S. holder receives an annual information statement from us setting forth its 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 28%, 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 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 not intended to constitute a complete analysis of all tax considerations applicable to an investment in our ordinary shares or ADSs. You should consult with your own tax advisor concerning the tax consequences to you in your particular situation.

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 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
$0.04 (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, 2017. “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, 2017.

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, 2017 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, 2017.

Our independent registered public accounting firm, PricewaterhouseCoopers (“PwC”), has issued an audit report with respect to the effectiveness of our internal control over financial reporting as of June 30, 2017, as stated in their report which appears in Item 18 *Financial Statements*.

Previously Identified Material Weaknesses in Internal Control Over Financial Reporting

We previously identified and disclosed in Form 20-F for the period ended June 30, 2016, a material weakness in our internal control over financial reporting relating to us not having designed and implemented controls to maintain appropriate segregation of duties in our manual and computer based business processes which could have a pervasive impact over the preparation of the financial statements.

Remediation Efforts to Address the Previously Disclosed Material Weaknesses

Our management, with oversight from our Audit Committee, has implemented the following remediation steps to address the previously disclosed material weaknesses and to improve our internal control over financial reporting:

- Segregated duties and introduced periodic monitoring of potential segregation of duties conflicts within key financial reporting processes; and
- Implemented additional internal monitoring activities, including enhancing the analytical procedures related to journal entries and balance sheet reconciliations, to add depth to our review process and improve our segregation of duties.

As noted above, our management conducted an assessment of the effectiveness of our internal control over financial reporting as of June 30, 2017 and has concluded that its internal control over financial reporting was effective as of June 30, 2017. Accordingly, we concluded the previously reported material weakness has been remediated as of June 30, 2017.

Changes in Internal Control over Financial Reporting

Other than the remediation of the previously disclosed material weakness discussed above, 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 Brian Jamieson and Michael Spooner each possess specific accounting and financial management expertise and that each is an Audit Committee Financial Expert as defined by the SEC. The Board of Directors has also determined that Donal O'Dwyer, a member of the Audit and Risk Management Committee, has sufficient experience and ability in finance and compliance matters to enable him to adequately discharge his 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 during the year ended June 30, 2017 and 2016.

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, 2017. 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 Board of Directors and shareholders of Mesoblast Limited:

In our opinion, the accompanying consolidated balance sheets and the related consolidated income statements, consolidated statements of comprehensive income, consolidated statements of changes in equity and consolidated statements of cash flows present fairly, in all material respects, the financial position of Mesoblast Limited and its subsidiaries at June 30, 2017 and June 30, 2016, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2017 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of June 30, 2017, based on criteria established in *Internal Control - Integrated Framework 2013* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these 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 these financial statements and on the Company's internal control over financial reporting based on our audits (which was an integrated audit for the year ended June 30, 2017). We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. 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.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations 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. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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, 2017

Index to Financial Statements

(in U.S. dollars, in thousands, except per share amount)	Note	Year Ended June 30, 2017	2016	2015
Revenue	3	2,412	42,548	19,761
Research & development		(58,914)	(50,013)	(62,649)
Manufacturing commercialization		(12,065)	(29,763)	(23,783)
Management and administration		(23,007)	(22,500)	(29,540)
Fair value remeasurement of contingent consideration	3	(130)	28,112	(15,336)
Impairment of intangible assets	3	—	(61,919)	—
Other operating income and expenses	3	1,489	2,714	15,303
Loss before income tax	3	**(90,215)**	**(90,821)**	**(96,244)**
Income tax benefit/(expense)	4	13,400	86,694	—
Loss attributable to the owners of Mesoblast Limited		**(76,815)**	**(4,127)**	**(96,244)**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:		**Cents**	**Cents**	**Cents**
Basic - losses per share		(19.43)	(1.14)	(29.99)
Diluted - losses per share		(19.43)	(1.14)	(29.99)

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, 2017	2016	2015
Loss for the year		**(76,815)**	**(4,127)**	**(96,244)**
Other comprehensive (loss)/income				
Items that may be reclassified to profit and loss				
Changes in the fair value of available-for-sale financial assets	7(b)	31	(334)	—
Exchange differences on translation of foreign operations	7(b)	316	(705)	(25,783)
Other comprehensive (loss)/income for the period, net of tax		**347**	**(1,039)**	**(25,783)**
Total comprehensive loss attributable to the owners of Mesoblast Limited		**(76,468)**	**(5,166)**	**(122,027)**

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	Total
Balance as of July 1, 2014		**662,722**	**55,754**	**—**	**(12,201)**	**(167,716)**	**538,559**
Loss for the year		—	—	—	—	(96,244)	(96,244)
Other comprehensive loss		—	—	—	(25,783)	—	(25,783)
Total comprehensive loss for the period		**—**	**—**	**—**	**(25,783)**	**(96,244)**	**(122,027)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		45,873	—	—	—	—	45,873
	7(a)	**45,873**	**—**	**—**	**—**	**—**	**45,873**
Transfer exercised options		596	(596)	—	—	—	—
Fair value of share-based payments	17	—	6,976	—	—	—	6,976
Reclassification of modified options to liability		—	(1,394)	—	—	—	(1,394)
		596	**4,986**	**—**	**—**	**—**	**5,582**
Balance as of June 30, 2015		**709,191**	**60,740**	**—**	**(37,984)**	**(263,960)**	**467,987**
Balance as of July 1, 2015		**709,191**	**60,740**	**—**	**(37,984)**	**(263,960)**	**467,987**
Loss for the period		—	—	—	—	(4,127)	(4,127)
Other comprehensive income		—	—	(334)	(705)	—	(1,039)
Total comprehensive profit/(loss) for the period		**—**	**—**	**(334)**	**(705)**	**(4,127)**	**(5,166)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		60,947	—	—	—	—	60,947
	7(a)	**60,947**	**—**	**—**	**—**	**—**	**60,947**
Transfer exercised options		134	(134)	—	—	—	—
Fair value of share-based payments	17	—	3,149	—	—	—	3,149
Reclassification of modified options to liability		—	1,244	—	—	—	1,244
		134	**4,259**	**—**	**—**	**—**	**4,393**
Balance as of June 30, 2016		**770,272**	**64,999**	**(334)**	**(38,689)**	**(268,087)**	**528,161**
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		—	—	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
	7(a)	**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		**830,425**	**69,919**	**(303)**	**(38,373)**	**(344,902)**	**516,766**

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, 2017	2016
Assets			
Current Assets			
Cash & cash equivalents	5(a)	45,761	80,937
Trade & other receivables	5(b)	3,743	4,054
Prepayments	5(b)	14,105	3,832
Total Current Assets		**63,609**	**88,823**
Non-Current Assets			
Property, plant and equipment	6(a)	1,814	3,063
Available-for-sale financial assets	5(c)	1,997	1,966
Other non-current assets	5(d)	1,916	2,343
Intangible assets	6(b)	586,350	587,823
Total Non-Current Assets		**592,077**	**595,195**
Total Assets		**655,686**	**684,018**
Liabilities			
Current Liabilities			
Trade and other payables	5(e)	21,805	27,155
Provisions	6(d)	14,865	2,260
Total Current Liabilities		**36,670**	**29,415**
Non-Current Liabilities			
Deferred tax liability	6(e)	49,293	62,693
Provisions	6(d)	52,957	63,749
Total Non-Current Liabilities		**102,250**	**126,442**
Total Liabilities		**138,920**	**155,857**
Net Assets		**516,766**	**528,161**
Equity			
Issued Capital	7(a)	830,425	770,272
Reserves	7(b)	31,243	25,976
(Accumulated losses)/retained earnings		(344,902)	(268,087)
Total Equity		**516,766**	**528,161**

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, 2017	2016	2015
Cash flows from operating activities				
Commercialization revenue received		1,332	99	—
Milestone revenue received		500	3,500	2,000
Research and development tax incentive received		2,813	4,466	4,456
Payments to suppliers and employees (inclusive of goods and services tax)		(100,598)	(97,190)	(106,760)
Payments for fair value adjustments to contingent consideration subsequent to the business combination measurement period		—	—	(4,112)
Interest received		483	1,129	3,043
Other income received		—	—	405
Income taxes (paid)/refunded		(1)	—	(68)
Net cash (outflows) in operating activities	8(b)	**(95,471)**	**(87,996)**	**(101,036)**
Cash flows from investing activities				
Payments for financial derivatives		—	—	(851)
Payments for business combination		—	—	(2,086)
Payments for investments		—	(805)	—
Payments for licenses		—	(200)	(195)
Investment in fixed assets		(311)	(722)	(2,204)
Rental deposits received		453	—	272
Net cash inflows/(outflows) in investing activities		**142**	**(1,727)**	**(5,064)**
Cash flows from financing activities				
Proceeds from issue of shares		61,932	68,549	46,291
Payments for share issue costs	7(a)	(1,927)	(6,483)	(439)
Net cash inflows by financing activities		**60,005**	**62,066**	**45,852**
Net (decrease)/increase in cash and cash equivalents		(35,324)	(27,657)	(60,248)
Cash and cash equivalents at beginning of period		80,937	110,701	185,003
FX gains/(losses) on the translation of foreign bank accounts		148	(2,107)	(14,054)
Cash and cash equivalents at end of period	8(a)	**45,761**	**80,937**	**110,701**

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. Significant changes in the current reporting period

(i) Significant events

The financial position and performance of the Group was not affected by any significant changes in the year ended June 30, 2017.

(ii) Going concern

For the financial years ended June 30, 2017, 2016 and 2015, the Group has incurred a total comprehensive loss after income tax of $76.5 million, $5.2 million and $122.0 million, respectively, and net cash outflows from operations of $95.5 million, $88.0 million and $101.0 million, respectively. As of June 30, 2017 the Group held total cash and cash equivalents of $45.8 million. In August 2017, the Group announced a fully underwritten entitlement offer to existing eligible shareholders (on a 1 for 12 basis) in Australia and New Zealand and institutional shareholders in certain other countries in private placements. US$38.2 million of net proceeds from the entitlement offer is expected to be received and recognized in cash and cash equivalents in September 2017.

The Group has committed to partner one or more of its four Tier 1 product candidates resulting in non-dilutive funding for operations. This may include MSC-100-IV for steroid-refractory graft versus host disease ("GVHD") and MPC-06-ID for chronic low back pain, in relation to which the Group has entered into an agreement with Mallinckrodt Pharmaceuticals ("Mallinckrodt") in order to exclusively negotiate a commercial and development partnership. The Group is also continuing to work on various cost containment and deferment strategies, including the reprioritization of projects. A fully discretionary equity facility remains for up to A$120 million/US$90 million over 24 months to provide additional funds as required. The Group may also consider issuing new capital to fund future operational requirements.

There is uncertainty related to the Group's ability to partner programs and raise capital at terms to meet the Group's requirements. Additionally, there is uncertainty related to the Group's ability to sustainably implement further cost reductions and defer programs on a timely basis while achieving expected outcomes.

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 entering into an arrangement with a third party partner on one or more of its four Tier 1 product candidates that would result in non-dilutive funding and/or raising further capital, together with various cost containment and deferment strategies being completed including the reprioritization of certain projects.

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.

2. 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.

3. Loss before income tax

(in U.S. dollars, in thousands)	Note	Year Ended June 30, 2017	2016	2015
Revenue				
Commercialization revenue		1,444	37,969	15,004
Milestone Revenue		500	3,500	2,000
Interest Revenue		468	1,079	2,757
Total Revenue		**2,412**	**42,548**	**19,761**
Clinical trial research & development		**(38,141)**	**(30,270)**	**(33,877)**
Manufacturing production & development		**(8,313)**	**(21,506)**	**(16,965)**
Employee benefits				
Salaries and employee benefits		(20,039)	(24,350)	(30,945)
Defined contribution superannuation expenses		(362)	(362)	(441)
Equity settled share-based payment transactions[1]		(5,276)	(3,389)	(6,976)
Total Employee benefits		**(25,677)**	**(28,101)**	**(38,362)**
Depreciation and amortization of non-current assets				
Plant and equipment depreciation		(1,578)	(1,625)	(1,474)
Intellectual property amortization		(1,479)	(567)	(127)
Total Depreciation and amortization of non-current assets		**(3,057)**	**(2,192)**	**(1,601)**
Other Management & administration expenses				
Overheads & administration		(8,128)	(10,361)	(10,587)
Consultancy		(3,329)	(3,396)	(5,857)
Legal, patent and other professional fees		(4,452)	(3,888)	(6,294)
Intellectual property expenses (excluding the amount amortized above)		(2,889)	(2,562)	(2,429)
Total Other Management & administration expenses		**(18,798)**	**(20,207)**	**(25,167)**
Fair value remeasurement of contingent consideration				
Remeasurement of contingent consideration	5(f)(iii)	(130)	28,112	(15,336)
Total Fair value remeasurement of contingent consideration		**(130)**	**28,112**	**(15,336)**
Other operating income and expenses				
Research & development tax incentive[2]		1,532	3,840	4,418
Foreign exchange gains/(losses)		(43)	(1,126)	10,478
Other revenue		—	—	407
Total Other operating income and expenses		**1,489**	**2,714**	**15,303**
Impairment of intangible assets				
Impairment of in-process research and development acquired	6(b)	—	(61,919)	—
Total Impairment of intangible assets		—	**(61,919)**	—
Total loss before income tax		**(90,215)**	**(90,821)**	**(96,244)**

(1) Share-based payment transactions

For the year ended June 30, 2017, 2016 and 2015, share-based payment transactions have been reflected in the Consolidated Statement of Comprehensive Income functional expense categories as follows:

(in U.S. dollars)	Year Ended June 30, 2017	2016	2015
Research and development	2,837,231	2,461,110	3,022,572
Manufacturing and commercialization	420,762	681,355	717,912
Management and administration	2,017,172	246,197	3,235,490
	5,275,165	**3,388,662**	**6,975,974**

(2) Research and development tax incentive

The Group's research and development activities are eligible under an Australian Government tax incentive for eligible expenditures from July 1, 2011. Management has assessed these activities and expenditures to determine which are likely to be eligible under the incentive scheme. At each period end management estimates the refundable tax offset available to the Group based on available information at the time. The Group uses the assistance of independent 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 year ended June 30, 2017, 2016 and 2015, the Group has recognized income of $1.5 million, $3.8 million and $4.4 million, respectively.

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.

Of the $3.8 million research and development tax incentive recorded in other income for the year ended June 30, 2016, $1.1 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, 2015.

Of the $4.4 million research and development tax incentive recorded in other income for the year ended June 30, 2015, $0.5 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, 2014.

4. Income tax benefit/(expense)

(in U.S. dollars, in thousands)	Year Ended June 30, 2017	2016	2015
(a) Reconciliation of income tax to prima facie tax payable			
Loss from continuing operations before income tax	(90,215)	(90,821)	(96,244)
Tax benefit at the Australian tax rate of 30% (2016: 30%)	(27,065)	(27,246)	(28,872)
Tax effect of amounts which are not deductible/(exempt) in calculating taxable income:			
Share-based payments expense	1,488	884	2,048
Research and development tax concessions	2,442	699	1,343
Contingent consideration	39	(11,221)	4,439
Other sundry items	497	(1,873)	1,298
Current year tax expense/(benefit)	**(22,599)**	**(38,757)**	**(19,744)**
Adjustments for current tax of prior periods	(5,870)	(2,224)	3,633
Differences in overseas tax rates	7,797	9,192	11,528
Tax benefit not recognized	7,272	5,851	4,583
Previously unrecognized tax losses now recouped to reduce deferred tax expense/(benefit)	—	(60,756)	—
Alternative minimum tax charge (USA)	—	—	—
USA City and State tax benefit/(charge)	—	—	(323)
USA City and State tax benefit — not recognized	—	—	323
Income tax expense/(benefit) attributable to loss before income tax	**(13,400)**	**(86,694)**	**—**

(in U.S. dollars, in thousands)	Year Ended June 30, 2017	2016	2015
(b) Income tax expense/(benefit)			
Current tax			
Current tax	—	—	—
Total current tax expense/(benefit)	—	—	—
Deferred tax			
(Increase)/decrease in deferred tax assets	(13,204)	(65,022)	—
Increase/(decrease) in deferred tax liabilities	(196)	(21,672)	—
Total deferred tax expense/(benefit)	**(13,400)**	**(86,694)**	—
Income tax expense/(benefit)	**(13,400)**	**(86,694)**	—

Deferred tax assets have been brought to account only to the extent that it is foreseeable that they are recoverable against future tax liabilities.

Following the Group's strategic review in June 2016 and the resulting operational streamlining, the Group recognized deferred tax assets for operating tax losses and deductible temporary differences in the jurisdictions where there are offsetting taxable temporary differences (deferred tax liabilities). Prior to this strategic review, the Group was in the process of consolidating certain intellectual property assets and consequently taxable temporary differences were not available to offset deferred tax assets in the same jurisdiction.

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 U.S. dollars, in thousands)	Year Ended June 30, 2017	2016	2015
(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)	(764)	(148)	(137)
Deferred tax recorded in equity (if brought to account)	960	808	516
	196	**660**	**379**

(in U.S. dollars, in thousands)	Year Ended June 30, 2017	2016	2015
(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, 2017	2016	2015
(e) Deferred tax assets not brought to account			
Unused tax losses			
Potential tax benefit at local tax rates	34,896	27,060	69,929
Other temporary differences			
Potential tax benefit at local tax rates	3,908	3,432	16,507
	38,804	**30,492**	**86,436**

As of June 30, 2017, 2016 and 2015, the Group has deferred tax assets not brought to account of $38.8 million, $30.5 million and $86.4 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, 2017					
Cash & cash equivalents	5(a)	—	—	45,761	45,761
Trade & other receivables	5(b)	—	—	3,743	3,743
Available-for-sale financial asset	5(c)	1,997	—	—	1,997
Other non-current assets	5(d)	—	—	1,916	1,916
		1,997	**—**	**51,420**	**53,417**
As of June 30, 2016					
Cash & cash equivalents	5(a)	—	—	80,937	80,937
Trade & other receivables	5(b)	—	—	4,054	4,054
Available-for-sale financial asset	5(c)	1,966	—	—	1,966
Other non-current assets	5(d)	—	—	2,343	2,343
		1,966	**—**	**87,334**	**89,300**

(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, 2017					
Trade and other payables	5(e)	—	—	21,805	21,805
Contingent considerations	5(f)	—	63,595	—	63,595
		—	**63,595**	**21,805**	**85,400**
As of June 30, 2016					
Trade and other payables	5(e)	—	—	27,155	27,155
Contingent considerations	5(f)	—	63,716	—	63,716
		—	**63,716**	**27,155**	**90,871**

(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)	As of June 30, 2017	2016
Cash at bank	7,722	21,860
Deposits at call(1)	38,039	59,077
	45,761	**80,937**

(1) As of June 30, 2017 and June 30, 2016, interest-bearing deposits at call include amounts of $0.5 million and $4.6 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

(in U.S. dollars, in thousands)	As of June 30, 2017	2016
Income tax and tax incentives recoverable	1,631	2,818
Other receivables	698	13
Trade debtors	474	460
Foreign withholding tax recoverable	471	471
Security deposit	250	—
Sundry debtors	120	242
Other recoverable taxes (Goods and services tax and value-added tax)	87	24
Interest receivables	12	26
Trade and other receivables	**3,743**	**4,054**

(in U.S. dollars, in thousands)	As of June 30, 2017	2016
Clinical trial research and development expenditure	13,571	2,684
Other	340	510
Prepaid insurance and subscriptions	194	638
Prepayments	**14,105**	**3,832**

(i) Classification as trade and other receivables

Interest receivables are amounts due at maturity of term deposits. All trade and other receivable balances are within their due dates and none are considered to be impaired as of June 30, 2017 and June 30, 2016.

(ii) Other receivables

These amounts generally arise from transactions outside the usual operating activities of the Group.

(iii) 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.

(iv) 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(b) and (c).

c. Available-for-sale financial assets

Available-for-sale financial assets include the following classes of financial assets:

(in U.S. dollars, in thousands)	As of June 30, 2017	2016
Unlisted securities:		
Equity securities	1,997	1,966
	1,997	**1,966**

(i) Classification of financial assets as available-for-sale

Investments are designated as available-for-sale financial assets if they do not have fixed maturities and fixed or determinable payments, and management intends to hold them for the medium to long-term. Financial assets that are not classified into any of the other categories (at FVPL, loans and receivables or held-to-maturity investments) are also included in the available-for-sale category.

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 available-for-sale financial assets

A security is considered to be impaired if there has been a significant or prolonged decline in the fair value below its cost. See Note 21(m)(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, 2017 and 2016, the Group recognized a gain of $Nil in statement of comprehensive income and a loss of $0.3 million for change in fair value of the available-for-sale financial assets. For the year June 30, 2015 there were no gains or losses recognized in 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(f). None of the available-for-sale financial assets are either past due or impaired.

All available-for-sale financial assets are denominated in USD.

d. Other non-current assets

(in U.S. dollars, in thousands)	As of June 30, 2017	2016
Bank Guarantee	738	713
Letter of Credit	1,178	1,630
	1,916	**2,343**

(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.

(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)	As of June 30, 2017	2016
Trade payables and other payables	21,805	27,155
	21,805	**27,155**

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. 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, 2017 and June 30, 2016 on a recurring basis, categorized by level according to the significance of the inputs used in making the measurements:

As of June 30, 2017 (in U.S. dollars, in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Available-for-sale financial assets:					
Equity securities - biotech sector	5(c)	—	—	1,997	1,997
Total Financial Assets		**—**	**—**	**1,997**	**1,997**
Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	6(d)	—	—	63,595	63,595
Total Financial Liabilities		**—**	**—**	**63,595**	**63,595**

As of June 30, 2016 (in U.S. dollars, in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial Assets					
Available-for-sale financial assets:					
Equity securities - biotech sector	5(c)	—	—	1,966	1,966
Total Financial Assets		**—**	**—**	**1,966**	**1,966**
Financial Liabilities					
Financial liabilities at fair value through profit or loss:					
Contingent consideration	6(d)	—	—	63,716	63,716
Total Financial Liabilities		**—**	**—**	**63,716**	**63,716**

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 available-for-sale securities) 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, 2017 and June 30, 2016:

(in U.S. dollars, in thousands)	Contingent consideration provision
Opening balance - July 1, 2015	91,890
Amount used during the year	(62)
Charged/(credited) to consolidated income statement:	
Remeasurement(1)	(28,112)
Closing balance - June 30, 2016	**63,716**
Opening balance - July 1, 2016	63,716
Amount used during the year	(251)
Charged/(credited) to consolidated income statement:	
Remeasurement(2)	130
Closing balance - June 30, 2017	**63,595**

(1) The remeasurement gain of $28.1 million recognized in the year ended June 30, 2016 includes a gain of $34.5 million relating to a reduction in contingent consideration expected to be paid to Osiris Therapeutics, Inc. (“Osiris”) on the MSC-assets due to a greater certainty over the commencement of the earn out period. This change in assumption results in a reduction in the valuation of contingent consideration as an earlier earn out period results in royalties being applicable to sales in years that are prior to peak year sales. The remaining loss of $6.4 million was recognized during the year ended June 30, 2016 as a net result of changes to the key assumptions of contingent consideration valuation such as developmental timelines, market population, market penetration, product pricing 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, 2017 a loss of $0.1 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 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.

(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) Description	Fair value as of June 30, 2017	Fair value as of June 30, 2016	Valuation technique	Unobservable inputs[1]	Range of inputs (weighted average) for the year ended June 30, 2017	Range of inputs (weighted average) for the year ended June 30, 2016	Relationship of unobservable inputs to fair value
Contingent consideration provision	63,595	63,716	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Year ended June 30, 2017: A change in the discount rate by 0.5% would increase/decrease the fair value by 1%. Year ended June 30, 2016: A change in the discount rate by 0.5% would increase/decrease the fair value by 2%.
				Expected unit revenues	n/a	n/a	Year ended June 30, 2017: A 10% increase/decrease in the price assumptions adopted would increase the fair value by 5%. Year ended June 30, 2016: A 10% increase/decrease in the price assumptions adopted would increase the fair value by 6%.

(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 year ended 2017 , 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 result of changes to key assumptions such as periods applicable to royalty payments, developmental timelines, probability of success, market population, market penetration, 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 fair value of contingent consideration (in U.S. dollars, in thousands)	As of June 30, 2017	As of June 30, 2016
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets	34,501	30,327
Fair value of royalty payments from commercialization of the intellectual property acquired	29,094	33,389
	63,595	**63,716**

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.

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, 2016				
Opening net book amount	2,646	825	927	4,398
Additions	189	4	127	320
Exchange differences	(26)	15	(19)	(30)
Depreciation charge	(1,057)	(138)	(430)	(1,625)
Closing net book value	**1,752**	**706**	**605**	**3,063**
As of June 30, 2016				
Cost	4,118	1,276	2,752	8,146
Accumulated depreciation	(2,366)	(570)	(2,147)	(5,083)
Net book value	**1,752**	**706**	**605**	**3,063**
Year Ended June 30, 2017				
Opening net book amount	1,752	706	605	3,063
Additions	17	—	296	313
Exchange differences	31	(25)	13	19
Disposals	—	—	(3)	(3)
Depreciation charge	(1,049)	(134)	(395)	(1,578)
Closing net book value	**751**	**547**	**516**	**1,814**
As of June 30, 2017				
Cost	4,139	1,255	3,105	8,499
Accumulated depreciation	(3,388)	(708)	(2,589)	(6,685)
Net book value	**751**	**547**	**516**	**1,814**

(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 10 – 15 years
- Office furniture and equipment 5 – 10 years
- Computer hardware and software 3 – 4 years

See Note 21(o) 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, 2016					
Opening net book value	134,453	2,091	513,697	—	650,241
Additions	—	75	—	—	75
Reclassifications(1)	—	—	(23,999)	23,999	—
Exchange differences	—	(7)	—	—	(7)
Amortization charge	—	(123)	—	(444)	(567)
Impairment charge(2)	—	—	(61,919)	—	(61,919)
Closing net book value	**134,453**	**2,036**	**427,779**	**23,555**	**587,823**
As of June 30, 2016					
Cost	134,453	2,769	489,698	23,999	650,919
Accumulated amortization	—	(733)	—	(444)	(1,177)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**2,036**	**427,779**	**23,555**	**587,823**
Year Ended June 30, 2017					
Opening net book value	134,453	2,036	427,779	23,555	587,823
Exchange differences	—	6	—	—	6
Amortization charge	—	(144)	—	(1,335)	(1,479)
Closing net book value	**134,453**	**1,898**	**427,779**	**22,220**	**586,350**
As of June 30, 2017					
Cost	134,453	2,770	489,698	23,999	650,920
Accumulated amortization	—	(872)	—	(1,779)	(2,651)
Accumulated impairment	—	—	(61,919)	—	(61,919)
Net book amount	**134,453**	**1,898**	**427,779**	**22,220**	**586,350**

(1) The Group reclassified $24.0 million from in-process research and development ("IPRD") acquired to current marketed products upon TEMCELL® Hs. Inj. ("TEMCELL"), a registered trademark of JCR Pharmaceuticals Co., Ltd. ("JCR"), becoming available for use in Japan.

IPRD that was acquired as part of a business acquisition is not amortized as it is considered to be incomplete and cannot be used in its current form and therefore has an indefinite life. IPRD is tested for impairment annually, or when events or circumstances present an indication of impairment. IPRD 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, when the asset becomes available for use, 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.

(2) The Group recognized $61.9 million non-cash impairment charge during the year ended June 30, 2016 relating to the 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 of June 30, 2016 the Group completed the Phase IIa MPC-MICRO-IO clinical trial and MPC-CBE was in a Phase III clinical trial. In June 2016, further patient enrollment of both programs was suspended as the Group prioritized the funding of the Tier 1 product candidates. Existing and future cash resources will be deployed on delivery of Tier 1 product candidates for the foreseeable future and therefore the Group is unable to ascertain when MPC-

MICRO-IO and MPC-CBE patient enrollment will be restarted. Accordingly impairment losses for the full carrying amounts of the intangible assets relating to product candidates MPC-MICRO-IO and MPC-CBE were recognized in line with the Group's accounting policy. These product candidates will remain technically viable and available to consider for future resource allocation and on this basis we have not abandoned the programs. The decision to impair the assets was required given resources have not been allocated to continue the development and commercialization efforts of these assets for the foreseeable future. See Note 21(j) and Note 2 for the accounting policy on impairment of intangible assets and segment information, respectively.

(i) Carrying value of in-process research and development acquired by product

	As of June 30,	
(in U.S. dollars, in thousands)	**2017**	**2016**
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 21(p) for the other accounting policies relevant to intangible assets and Note 21(j) 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 21(j). 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.

(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 21(p)(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.

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, 2017 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 indicators:

- discounted expected future cash flows of programs;
- the scientific results and progress of the trials since acquisition;

- the valuation of the Group that was applicable to the January 6, 2017 equity placement undertaken with Mallinckrodt Pharmaceuticals (NYSE: MNK) through issuing of the Group's securities on the ASX;
- the valuation of the Group that was applicable to the March 31, 2017 equity placement undertaken with institutional investors through issuing of the Group's securities on the ASX;
- the valuation of the Group's assets from an independent valuation as of June 30, 2017; and
- the market capitalization of the Group on the ASX (ASX:MSB) on the impairment testing date of June 30, 2017.

Costs of disposal were assumed to be immaterial.

Discounted cash-flows used a real pre-tax discount rate range of 14.4% to 19.3%, and include estimated real cash inflows and outflows for each program through to patent expiry, at which point a terminal value is assigned to the program.

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, 2017 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. Deferred revenue

	As of June 30,	
(in U.S. dollars, in thousands)	**2017**	**2016**
Opening Balance	—	37,509
Amount recognized as revenue in the year(1)	—	(37,509)
Closing balance	—	—
- To be recognized in the next twelve months (current deferred revenue)	—	—
- To be recognized in the next twelve months (non-current deferred revenue)	—	—
Closing balance	—	—

(1) Please refer to Note 21(e)(i) for the Group's accounting policy relating to revenue recognition.

d. Provisions

(in U.S. dollars, in thousands)	As of June 30, 2017 Current	Non-current	Total	As of June 30, 2016 Current	Non-current	Total
Contingent consideration	11,054	52,541	63,595	241	63,475	63,716
Employee benefits	3,811	416	4,227	2,019	274	2,293
	14,865	**52,957**	**67,822**	**2,260**	**63,749**	**66,009**

(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(f)(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, 2017 and 2016, the entire amount of the accrual was $0.7 million and $0.6 million respectively, and is presented as current, since the Group does not have an unconditional right to defer settlement for any of these obligations. However, based on past experience, the Group expects all employees to take the full amount of the accrued leave or require payment within the next 12 months.

(ii) Movements

The contingent consideration provision relates to the Group's liability for certain milestones and royalty achievements. Refer to Note 5(f)(iii) for movements in contingent consideration for the years ended June 30, 2017 and 2016.

e. Deferred tax balances

(i) Deferred tax balances

(in U.S. dollars, in thousands)	As of June 30, 2017	2016
Deferred tax assets		
The balance comprises temporary differences attributable to:		
Tax losses	74,660	57,650
Other temporary differences	3,566	7,372
Total deferred tax assets	**78,226**	**65,022**
Deferred tax liabilities		
The balance comprises temporary differences attributable to:		
Intangible assets	127,519	127,715
Total deferred tax liabilities	**127,519**	**127,715**
Net deferred tax liabilities	**49,293**	**62,693**
Deferred tax assets expected to be settled within 12 months	—	—
Deferred tax assets expected to be settled after 12 months	78,226	65,022
Deferred tax liabilities expected to be settled within 12 months	147	—
Deferred tax liabilities expected to be settled after 12 months	127,372	127,715

(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, 2015	**—**	**—**	**149,387**	**149,387**
Charged/(credited) to:				
- profit or loss(2)	(57,650)	(7,372)	(21,672)	(86,694)
As of June 30, 2016	**(57,650)**	**(7,372)**	**127,715**	**62,693**
Charged/(credited) to:				
- profit or loss(2)	(17,010)	3,806	(196)	(13,400)
As of June 30, 2017	**(74,660)**	**(3,566)**	**127,519**	**49,293**

(1) Deferred tax assets are netted against deferred tax liabilities.

(2) The total amount recognized in income tax benefit for the year ended June 30, 2017 was $13.4 million and $86.7 million for the year ended June 30, 2016. Refer to Note 4(b).

7. Equity

a. Contributed equity

(i) Share capital

	As of June 30,					
	2017	2016	2015	2017	2016	2015
	Shares No.			(U.S. dollars, in thousands)		
Contributed equity						
(i) Share capital						
Ordinary shares	428,221,398	381,373,137	336,997,729	830,425	770,272	709,191
Less: Treasury Shares	(3,500,000)	(3,500,000)	(3,500,000)	—	—	—
Total Contributed Equity	**424,721,398**	**377,873,137**	**333,497,729**	**830,425**	**770,272**	**709,191**

(ii) Movements in ordinary share capital

	As of June 30,					
	2017	2016	2015	2017	2016	2015
	Shares No.			(U.S. dollars, in thousands)		
Opening balance	381,373,137	336,997,729	321,640,094	770,272	709,191	662,722
Issues of ordinary shares during the period						
Exercise of share options(1)	272,579	422,903	1,043,798	149	268	1,312
Share issue for Nasdaq IPO	—	42,675,295	—	—	68,280	—
Consideration for available-for-sale financial assets	—	1,277,210	—	—	1,495	—
Share based compensation for services rendered	280,911	—	—	240	—	—
Placement of shares under LFSP(2)	—	—	2,000,000	—	—	—
Placement of shares under a share placement agreement(3)	46,294,771	—	15,298,837	61,710	—	45,000
Share buy-back of LFSP(2)	—	—	(2,985,000)	—	—	—
Transaction costs arising on share issue(4)				(1,959)	(9,096)	(439)
	46,848,261	44,375,408	15,357,635	60,140	60,947	45,873
Share options reserve transferred to equity on exercise of options				13	134	596
Ending balance	**428,221,398**	**381,373,137**	**336,997,729**	**830,425**	**770,272**	**709,191**

(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) Shares are issued to employees and consultants in accordance with the Mesoblast Australian Loan Funded Share Plan ("LFSP"). Initially these shares are issued and held in trust. Therefore there is no dollar movement recorded in ordinary share capital at this time. If the shares are purchased in accordance with the conditions of the LFSP a dollar movement will be recorded at that date.

(3) In the year ended June 30, 2017, 20,044,771 shares were issued to Mallinckrodt (NYSE:MNK) on January 6, 2017 under a placement agreement pursuant to which Mallinckrodt purchased Mesoblast Limited securities and received a period of up to nine months to exclusively negotiate a commercial and development partnership for two of Mesoblast's Tier 1 product candidates and 26,250,000 shares were issued on March 31, 2017 under an institutional private placement agreement. In the year ended June 30, 2015, 15,298,837 shares were issued to Celgene Corporation (Nasdaq:CELG) under a placement agreement pursuant to which Celgene purchased Mesoblast Limited securities.

(4) Payments for share issue costs in the year ended June 30, 2017 were $1.9 million. Payments for share issue costs in the year ended June 30, 2016 were $6.5 million with $2.8 million paid in prior periods offset by $0.2 million of non-cash items recognized as transaction costs on the balance sheet in association with the Nasdaq IPO equity raising.

(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.

(iii) Ordinary shares

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 of June 30, 2017	2016
Share-based payments reserve	69,919	64,999
Investment Revaluation Reserve	(303)	(334)
Foreign currency translation reserve	(38,373)	(38,689)
	31,243	**25,976**

(ii) Reconciliation of reserves

(in U.S. dollars, in thousands)	As of June 30,	
Share-based payments reserve	**2017**	**2016**
Opening balance	64,999	60,740
Transfer to ordinary shares on exercise of options	(13)	(134)
Share option expense for the year	5,036	3,149
Reclassification of modified options to/(from) liability	(103)	1,244
Closing Balance	**69,919**	**64,999**
Investment Revaluation Reserve		
Opening balance	(334)	—
Changes in the fair value of available-for-sale financial assets	31	(334)
Closing Balance	**(303)**	**(334)**
Foreign currency translation reserve		
Opening balance	(38,689)	(37,984)
Currency gain/(loss) on translation of foreign operations net assets	316	(705)
Closing Balance	**(38,373)**	**(38,689)**

(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)	As of June 30,		
(a) Reconciliation of cash and cash equivalents	**2017**	**2016**	**2015**
Cash at bank	7,722	21,860	21,126
Deposits at call	38,039	59,077	89,575
	45,761	**80,937**	**110,701**

(in U.S. dollars, in thousands) (b) Reconciliation of net cash flows used in operations with loss after income tax	Year Ended June 30, 2017	2016	2015
Loss for the period	(76,815)	(4,127)	(96,244)
Add/(deduct) net loss for non-cash items as follows:			
Commercialization revenue	—	(37,509)	(15,004)
Depreciation and amortization	3,057	2,192	1,601
Foreign exchange (gains)/losses	38	1,090	(9,729)
Remeasurement of contingent consideration	130	(28,112)	10,670
Equity settled share-based payment	5,276	3,389	6,976
Deferred tax benefit	(13,400)	(86,694)	—
Impairment of intangible assets	—	61,919	—
Change in operating assets and liabilities:			
(Increase)/decrease in trade and other receivables	(859)	(531)	697
Decrease/(increase) in prepayments	(10,201)	495	(7,439)
(Increase)/decrease in tax assets	1,282	626	38
(Decrease)/increase in trade creditors and accruals	(5,740)	2,425	7,721
(Decrease)/increase in provisions	1,761	(3,159)	(323)
Net cash outflows used in operations	**(95,471)**	**(87,996)** (1)	**(101,036)** (2)

(1) Within operating cash flows are share issue costs of $0.3 million associated with the Nasdaq IPO equity raising incurred during the year ended June 30, 2016.

(2) Within operating cash flows are share issue costs of $2.4 million associated with the Nasdaq IPO equity raising incurred during the year ended June 30, 2015.

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(f) 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).

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	Term deposits at fixed rates	Sensitivity analysis	Vary length of term deposits
Credit risk	Cash and cash equivalents, and trade and other receivables	Aging analysis Credit ratings	Only transact with 'A' rated banks
Liquidity risk	Cash and cash equivalents	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 certain clinical, regulatory and manufacturing activities which are being conducted internationally. The main currency exposure to the Group is the clinical trial activities which are primarily occurring in the United States of America and manufacturing activities occurring in Singapore. As a result of these activities, the Group has foreign currency amounts owing primarily in USD and Singapore dollars ("SGD"), as well as some smaller amounts in various other currencies as tabled below. 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.

The Group manages the currency risk by evaluating the trend of the relevant foreign currency rates ("FX rates") to the AUD and making decisions as to the levels to hold in each currency by assessing its future activities which will likely be incurred in those currencies.

As of June 30, 2017, the Group held 95% of its cash in USD, and 5% in AUD. As of June 30, 2016, the Group held 71% of its cash in USD, and 29% 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, 2017 and June 30, 2016 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, 2017	Foreign currency balance held	+20% Profit/(Loss) USD	-20% Profit/(Loss) USD
Bank accounts - USD	USD 447	$ (74)	$ 112
Bank accounts - CHF	CHF 183	$ 35	$ (35)
Bank accounts - SGD	SGD 325	$ 90	$ (90)
Trade and other receivables - SGD	SGD 48	$ 13	$ (13)
Trade and other receivables - USD	USD 40	$ (7)	$ 10
Trade and other receivables - CHF	CHF 1	$ 0	$ (0)
Trade payables and accruals - USD	(USD 2,016)	$ 336	$ (504)
Trade payables and accruals - AUD	(AUD 441)	$ (115)	$ 115
Trade payables and accruals - SGD	(SGD 197)	$ (54)	$ 54
Trade payables and accruals - EUR	(EUR 42)	$ (7)	$ 7
Trade payables and accruals - CHF	(CHF 19)	$ (4)	$ 4
Provisions - SGD	(SGD 65)	$ (18)	$ 18
		$ 195	**$ (322)**

(in U.S. dollars, in thousands) As of June 30, 2016	Foreign currency balance held	+20% Profit/(Loss) USD	-20% Profit/(Loss) USD
Bank accounts - USD	USD 359	$ (60)	$ 90
Bank accounts - CHF	CHF 77	$ 15	$ (15)
Bank accounts - SGD	SGD 95	$ 26	$ (26)
Trade and other receivables - SGD	SGD 63	$ 17	$ (17)
Trade and other receivables - CHF	CHF 7	$ 1	$ (1)
Trade payables and accruals - USD	(USD 2,090)	$ 348	$ (522)
Trade payables and accruals - AUD	(AUD 285)	$ (77)	$ 77
Trade payables and accruals - SGD	(SGD 162)	$ (44)	$ 44
Trade payables and accruals - GBP	(GBP 31)	$ (3)	$ 2
Trade payables and accruals - EUR	(EUR 15)	$ 3	$ (4)
Trade payables and accruals - CHF	(CHF 7)	$ (1)	$ 1
Trade payables and accruals - NZD	(NZD 1)	$ (0)	$ 0
Provisions - SGD	(SGD 26)	$ (7)	$ 7
		$ 218	**$ (364)**

(ii) Interest rate risk

The Group is not exposed to typical interest rate risk, being the impact of fixed versus floating interest rates on debt. The Group's exposure is to interest rate movements which impacts interest income earned on its deposits. The interest income derived from these balances can fluctuate due to interest rate changes. This interest rate risk is managed by spreading the maturity date of our deposits across various periods. 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, 2017 and June 30, 2016. The effect on profit is shown if interest rates change by 10%, in either direction, is as follows:

(in U.S. dollars, in thousands, except percent data)	As of June 30, 2017			As of June 30, 2016		
USD	**Low**	**High**		**Low**	**High**	
Funds invested - USD	0.55%	0.55%	USD 37,577	0.55%	0.90%	USD 47,796
Rate increase by 10%	0.61%	0.61%	USD 21	0.61%	0.99%	USD 35
Rate decrease by 10%	0.50%	0.50%	(USD 21)	0.50%	0.81%	(USD 35)
AUD	**Low**	**High**		**Low**	**High**	
Funds invested - AUD	2.42%	2.42%	AUD 600	3.00%	3.04%	AUD 15,191
Rate increase by 10%	2.66%	2.66%	AUD 1	3.30%	3.34%	AUD 46
Rate decrease by 10%	2.18%	2.18%	(AUD 1)	2.70%	2.74%	(AUD 46)

(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, other than foreign currency rates and interest rates. 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.

(in U.S. dollars, in thousands)	As of June 30, 2017	2016
Cash and cash equivalents		
Deposits at call (Note 5(a)) - minimum A rated	38,039	59,077
Cash at bank (Note 5(a)) - minimum A rated	7,722	21,860
Trade and other receivables		
Receivable from the Australian Government (Income Tax)	1,631	2,818
Receivable from other parties (non-rated)	1,067	495
Receivable from the Australian Government (Goods and Services Tax)	86	21
Receivable from the United States Government (Income Tax)	27	8
Receivable from minimum A rated bank deposits (interest)	12	26
Receivable from the Swiss Government (Value-Added Tax)	1	3

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(ii).

All financial liabilities, excluding contingent consideration, held by the Group as of June 30, 2017 and June 30, 2016 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.

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

Material subsidiaries

The Group's principal subsidiaries as of June 30, 2017 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.

	Country of incorporation	Class of shares	Equity holding	
			As of June 30,	
			2017	2016
			%	%
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

13. Contingent assets and liabilities

a. Contingent assets

The Group did not have any contingent assets outstanding as of June 30, 2017 and June 30, 2016.

b. Contingent liabilities

(i) Central Adelaide Local Health Network Incorporated ("CALHNI") (formerly Medvet)

Mesoblast will be required to make a milestone payment to CALHNI of $0.3 million on completion of Phase 3 (human) clinical trials and $0.4 million on FDA marketing approval for products in the orthopaedic field. The Group will pay CALHNI a commercial arm's length royalty based on net sales by the Group of licensed products in the orthopaedic field each quarter.

The Group may also be required to pay consideration to CALHNI upon successful completion of subsequent clinical milestones in fields other than orthopedic.

(ii) Other contingent liabilities

The Group has entered into a number of agreements with 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, 2017 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, 2017 and June 30, 2016.

b. Lease commitments: Group as lessee

The Group leases various offices under non-cancellable operating leases expiring within 1 to 5 years. The leases have varying terms, escalation clauses and renewal rights. On renewal, the terms of the leases are renegotiated. Excess office space is sub-let to a third party also under a non-cancellable operating lease.

(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	5,574	1,733	2,954	887	—
Total commitments	**5,574**	**1,733**	**2,954**	**887**	—

Lease commitments include amounts in AUD and Singapore dollars which have been translated to USD as of June 30, 2017 foreign exchange rates published by the Reserve Bank of Australia.

c. Lease commitments: Group as lessor

The Group sub-leases under non-cancellable operating leases expiring within 3 years. Future minimum lease payments expected to be received in relation to non-cancellable operating sub-leases are set out below:

(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	390	161	229	—	—
Total commitments	**390**	**161**	**229**	**—**	—

d. Purchase commitments

The Group did not have any purchase commitments as of June 30, 2017.

15. Events occurring after the reporting period

In August 2017, the Group announced a fully underwritten entitlement offer to existing eligible shareholders (on a 1 for 12 basis) in Australia and New Zealand and institutional shareholders in certain other countries in private placements. US$38.2 million of net proceeds from the entitlement offer is expected to be received and recognized in cash and cash equivalents in September 2017.

There were no other events that have occurred after June 30, 2017 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, 2017	2016
Short-term employee benefits	2,592,456	1,979,885
Long-term employee benefits	17,742	19,710
Post-employment benefits	70,915	72,398
Share based payments	552,174	102,635
	3,233,287	**2,174,628**

d. Transactions with other related parties

Accounts receivable from revenues, accounts payable to expenses and loans from subsidiaries as at the end of the financial 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, 2017, 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. No new options were issued to the directors during the year. 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/Cancelled 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	AUD 8.48	340,000	—	—	(340,000)	—	—
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	—	—	(1,948,333)	—	—
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(1)	25/03/2015	30/06/2018	AUD 5.00	650,000	—	—	—	650,000	650,000
30b(1)	25/03/2015	25/01/2018	AUD 5.00	235,000	—	—	—	235,000	235,000
30c(1)	25/03/2015	25/01/2019	AUD 5.00	135,000	—	—	—	135,000	135,000
30d(1)	25/03/2015	30/06/2019	AUD 5.00	300,000	—	—	—	300,000	300,000
30e(1)	25/03/2015	23/07/2019	AUD 5.00	165,000	—	—	—	165,000	165,000
30f(1)	25/03/2015	23/07/2019	AUD 5.00	200,000	—	—	—	200,000	200,000
30g(1)	25/03/2015	20/01/2019	AUD 4.71	300,000	—	—	—	300,000	200,000
30h(1)	25/03/2015	25/01/2018	AUD 4.71	400,000	—	—	—	400,000	266,668
30i(1)	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	6/10/2019	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)**	**(7,186,665)**	**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 a 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/Cancelled No. (during the year)	Closing Balance	Vested and exercisable No (end of year)
INC	7/12/2010	7/07/2015	USD 0.046	287,903	—	(287,903)	—	—	—
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	127,956
INC	7/12/2010	2/05/2017	USD 0.444	127,956	—	—	—	127,956	127,956
13	22/09/2010	21/09/2015	AUD 2.64	135,000	—	(135,000)	—	—	—
14	29/11/2010	29/11/2015	AUD 3.48	1,453,350	—	—	(1,453,350)	—	—
15/LF1	22/12/2011	30/06/2016	AUD 7.99	3,413,334	—	—	(3,413,334)	—	—
16/LF2	24/02/2012	23/02/2017	AUD 8.48	340,000	—	—	—	340,000	340,000
17/LF3	9/07/2012	8/07/2018	AUD 6.69	250,000	—	—	—	250,000	250,000
18/LF4	21/09/2012-29/10/2012	30/06/2017	AUD 6.70	2,276,667	—	—	(328,334)	1,948,333	1,948,333
19/LF5	25/01/2013-29/01/2013	24/01/2018-28/01/2018	AUD 6.29	100,000	—	—	—	100,000	100,000
20/LF6	24/05/2013	23/05/2018	AUD 6.36	865,000	—	—	(270,000)	595,000	595,000
21/LF7	3/09/2013	30/06/2018	AUD 5.92	2,741,667	—	—	(311,667)	2,430,000	1,878,336
22/LF8	4/09/2013	27/08/2018	AUD 6.28	275,000	—	—	(50,000)	225,000	150,002
23a	26/11/2013	10/10/2018	AUD 6.20	50,000	—	—	(16,667)	33,333	33,333
24	17/12/2013	16/12/2018	AUD 6.25	148,333	—	—	(123,333)	25,000	16,666
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	16,667
25	1/07/2014	6/04/2019	AUD 5.80	15,000	—	—	(5,000)	10,000	10,000
26/LF11	24/07/2014	23/07/2019	AUD 4.71	215,000	—	—	(90,000)	125,000	41,667
27/LF12	5/09/2014	30/06/2019	AUD 4.71	3,380,000	—	—	(515,000)	2,865,000	961,670
27(ii)	4/08/2014	3/08/2019	AUD 4.60	50,000	—	—	—	50,000	16,667
27(iv)	25/08/2014	24/08/2019	AUD 4.67	75,000	—	—	—	75,000	25,000
28/LF13	9/10/2014	8/10/2019	AUD 4.54	235,000	—	—	—	235,000	78,333
29	25/11/2014	24/11/2019	AUD 4.02	240,000	—	—	—	240,000	80,001
30a(1)	25/03/2015	30/06/2018	AUD 5.00	650,000	—	—	—	650,000	650,000
30b(1)	25/03/2015	25/01/2018	AUD 5.00	235,000	—	—	—	235,000	235,000
30c(1)	25/03/2015	25/01/2019	AUD 5.00	135,000	—	—	—	135,000	135,000
30d(1)	25/03/2015	30/06/2019	AUD 5.00	300,000	—	—	—	300,000	200,000
30e(1)	25/03/2015	23/07/2019	AUD 5.00	165,000	—	—	—	165,000	165,000
30f(1)	25/03/2015	23/07/2019	AUD 5.00	200,000	—	—	—	200,000	200,000
30g(1)	25/03/2015	20/01/2019	AUD 4.71	300,000	—	—	—	300,000	100,000
30h(1)	25/03/2015	25/01/2018	AUD 4.71	400,000	—	—	—	400,000	133,334
30i(1)	25/03/2015	25/01/2019	AUD 4.46	600,000	—	—	—	600,000	400,000
30j	25/03/2015	30/06/2019	AUD 4.71	150,000	—	—	—	150,000	50,000
LF14	6/01/2015	16/12/2019	AUD 4.66	150,000	—	—	—	150,000	50,000
31	16/03/2015	16/02/2020	AUD 4.73	60,000	—	—	(60,000)	—	—
31a	27/04/2015	16/02/2020	AUD 4.73	20,000	—	—	—	20,000	6,667
31b	12/05/2015	16/02/2020	AUD 4.30	400,000	—	—	(200,000)	200,000	200,000
32	10/07/2015	30/06/2022	AUD 4.22	—	4,800,000	—	(960,000)	3,840,000	—
33	26/08/2015	16/08/2022	AUD 4.07	—	125,000	—	—	125,000	—
34	27/04/2016	6/03/2023	AUD 2.82	—	5,255,000	—	(115,000)	5,140,000	—
34a	27/04/2016	17/04/2023	AUD 2.76	—	200,000	—	—	200,000	—
35	30/06/2016	6/10/2019	AUD 2.22	—	1,500,000	—	—	1,500,000	—
June 30, 2016				**21,869,078**	**11,880,000**	**(422,903)**	**(7,911,685)**	**25,414,490**	**10,574,500**
Weighted average share purchase price				AUD 5.49	AUD 3.32	AUD 0.88	AUD 5.93	AUD 4.39	AUD 5.38

(1) 30a to 30i were granted as a 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/Cancelled No. (during the year)	Closing Balance	Vested and exercisable No (end of year)
INC	7/12/2010	7/07/2015	USD 0.046	287,903	—	—	—	287,903	287,903
INC	7/12/2010	26/10/2018	USD 0.305	195,999	—	(41,935)	—	154,064	154,064
INC	7/12/2010	26/10/2019	USD 0.340	703,761	—	(255,913)	—	447,848	447,848
INC	7/12/2010	25/04/2017	USD 0.444	127,956	—	—	—	127,956	127,956
INC	7/12/2010	2/05/2017	USD 0.444	127,956	—	—	—	127,956	127,956
10	30/11/2009	30/11/2014	AUD 1.73	150,000	—	(150,000)	—	—	—
11	30/11/2009	30/11/2014	AUD 1.58	480,000	—	(480,000)	—	—	—
13	22/09/2010	21/09/2015	AUD 2.64	135,000	—	—	—	135,000	135,000
14	29/11/2010	29/11/2015	AUD 3.48	1,569,300	—	(115,950)	—	1,453,350	1,453,350
15/LF1	22/12/2011	30/06/2016	AUD 7.99	4,243,334	—	—	(830,000)	3,413,334	3,413,334
16/LF2	24/02/2012	23/02/2017	AUD 8.48	340,000	—	—	—	340,000	340,000
17/LF3	9/07/2012	8/07/2018	AUD 6.69	250,000	—	—	—	250,000	166,665
18/LF4	21/09/2012-29/10/2012	30/06/2017	AUD 6.70	2,653,333	—	—	(376,666)	2,276,667	1,863,337
19/LF5	25/01/2013-29/01/2013	24/01/2018-28/01/2018	AUD 6.29	100,000	—	—	—	100,000	66,668
20/LF6	24/05/2013	23/05/2018	AUD 6.36	1,000,000	—	—	(135,000)	865,000	576,676
21/LF7	3/09/2013	30/06/2018	AUD 5.92	3,290,000	—	—	(548,333)	2,741,667	1,206,671
22/LF8	4/09/2013	27/08/2018	AUD 6.28	325,000	—	—	(50,000)	275,000	91,668
23a	26/11/2013	10/10/2018	AUD 6.20	50,000	—	—	—	50,000	16,666
23b	30/11/2013	29/11/2018	AUD 6.79	200,000	—	—	(200,000)	—	—
24	17/12/2013	16/12/2018	AUD 6.25	180,000	—	—	(31,667)	148,333	51,666
24a (i)	10/02/2014	9/02/2019	AUD 6.41	100,000	—	—	(100,000)	—	—
24a (ii)	17/02/2014	16/02/2019	AUD 6.33	25,000	—	—	(25,000)	—	—
LF9.4	11/12/2013	30/06/2017	AUD 6.70	165,000	—	—	(165,000)	—	—
LF9.7	3/09/2013	30/06/2018	AUD 5.92	200,000	—	—	(200,000)	—	—
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	—
25c	21/09/2014	2/09/2014	AUD 5.43	—	60,000	—	(60,000)	—	—
25	1/07/2014	6/04/2019	AUD 5.80	—	15,000	—	—	15,000	5,000
26/LF11	24/07/2014	23/07/2019	AUD 4.71	—	575,000	—	(360,000)	215,000	—
27/LF12	5/09/2014	30/06/2019	AUD 4.71	—	3,960,000	—	(580,000)	3,380,000	—
27(i)	28/07/2014	27/07/2019	AUD 4.54	—	100,000	—	(100,000)	—	—
27(ii)	4/08/2014	3/08/2019	AUD 4.60	—	50,000	—	—	50,000	—
27(iii)	11/08/2014	10/08/2019	AUD 4.43	—	100,000	—	(100,000)	—	—
27(iv)	25/08/2014	24/08/2019	AUD 4.67	—	75,000	—	—	75,000	—
LF12a	5/09/2014	30/06/2019	AUD 4.46	—	600,000	—	(600,000)	—	—
28/LF13	9/10/2014	8/10/2019	AUD 4.54	—	235,000	—	—	235,000	—
29	25/11/2014	24/11/2019	AUD 4.02	—	240,000	—	—	240,000	—
30a(1)	25/03/2015	30/06/2018	AUD 5.00	—	650,000	—	—	650,000	650,000
30b(1)	25/03/2015	25/01/2018	AUD 5.00	—	235,000	—	—	235,000	156,666
30c(1)	25/03/2015	25/01/2019	AUD 5.00	—	135,000	—	—	135,000	135,000
30d(1)	25/03/2015	30/06/2019	AUD 5.00	—	300,000	—	—	300,000	100,000
30e(1)	25/03/2015	23/07/2019	AUD 5.00	—	165,000	—	—	165,000	165,000
30f(1)	25/03/2015	23/07/2019	AUD 5.00	—	200,000	—	—	200,000	133,334
30g(1)	25/03/2015	20/01/2019	AUD 4.71	—	300,000	—	—	300,000	—
30h(1)	25/03/2015	25/01/2018	AUD 4.71	—	400,000	—	—	400,000	—
30i(1)	25/03/2015	25/01/2019	AUD 4.46	—	600,000	—	—	600,000	200,000
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	—
31	16/03/2015	16/02/2020	AUD 4.73	—	60,000	—	—	60,000	—
31a	27/04/2015	16/02/2020	AUD 4.73	—	20,000	—	—	20,000	—
31b	12/05/2015	16/02/2020	AUD 4.30	—	400,000	—	—	400,000	—
June 30, 2015				**17,549,542**	**9,825,000**	**(1,043,798)**	**(4,461,666)**	**21,869,078**	**12,722,428**
Weighted average share purchase price				AUD 5.58	AUD 4.69	AUD 1.49	AUD 5.91	AUD 5.49	AUD 5.78

(1) 30a to 30i were granted as a 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, 2017, 2016 and 2015 were AUD 3.28, AUD 3.68 and AUD 4.06 respectively.

The weighted average remaining contractual life of share options and loan funded shares outstanding as of June 30, 2017, 2016 and 2015 were 4.09 years, 3.85 years and 2.43 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:

Series 10 Options granted to the Chairman were approved by shareholders at the Annual General Meeting held on November 30, 2010. The options were granted in four equal tranches vesting on the achievement of certain milestones, being the date on which:

- Mesoblast signs a commercial partnering contract, e.g. a commercial license to one of its products (vested December 7, 2010);
- Mesoblast receives IND clearance from the FDA for its first clinical trial for Intervertebral Disc Repair (vested March 17, 2011);
- Mesoblast completes patient enrollment for its first clinical trial under IND for Intervertebral Disc Repair (vested October 12, 2012);
- Mesoblast obtains a license from the Therapeutics Goods Administration (TGA) for the manufacture (vested July 20, 2010).

All the remaining options under series 10 were exercised during the years ended June 30, 2015 and 2014.

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.

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.

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 4.46 to AUD 5.00 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. There were no modifications made to share-based payment arrangements during the years ended June 30, 2016 and 2017.

c. Fair values of share based payments

The weighted average fair value of share options and loan funded shares granted during the years ended June 30, 2017, 2016 and 2015 were AUD 1.46, AUD 1.07 and AUD 1.22, 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, 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 2.08.

The model inputs for the valuations of options approved and granted during the year ended June 30, 2016 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
32	2016	4.22	3.87	40.38%	5.2 yrs	0%	2.22%
33	2016	4.07	3.19	40.38%	5.1 yrs	0%	2.00%
34	2016	2.82	2.41	53.33%	5.0 yrs	0%	2.13%
34a	2016	2.76	2.41	53.33%	5.1 yrs	0%	2.13%
35	2016	2.22	1.05	53.33%	3.0 yrs	0%	1.65%

(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, 2016 was AUD 1.08.

The model inputs for the valuations of options approved and granted during the year ended June 30, 2015 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
25	2015	5.80	4.48	38.09%	3.5 yrs	0%	2.99%
25b	2015	4.51	4.33	38.40%	3.7 yrs	0%	2.45%
25c	2015	5.43	4.89	38.38%	3.7 yrs	0%	3.19%
26/LF11	2015	4.71	4.04	37.89%	3.7 yrs	0%	2.80%-2.94%
27/LF12	2015	4.71	5.49	38.44%	3.5 yrs	0%	3.12%
27(i)	2015	4.54	4.13	38.44%	3.7 yrs	0%	3.12%
27(ii)	2015	4.60	4.19	38.44%	3.7 yrs	0%	3.12%
27(iii)	2015	4.43	4.03	38.44%	3.7 yrs	0%	3.12%
27(iv)	2015	4.67	4.24	38.44%	3.7 yrs	0%	3.12%
LF12a	2015	4.46	5.49	38.36%	3.5 yrs	0%	2.81%
28/LF13	2015	4.54	4.11	38.33%	3.7 yrs	0%	2.86%
29	2015	4.02	4.02	38.09%	3.7 yrs	0%	2.71%
30a	2015	5.00	3.96	38.70%	2.4 yrs	0%	1.87%
30b	2015	5.00	3.96	38.70%	2.1 yrs	0%	1.87%
30c	2015	5.00	3.96	38.70%	2.8 yrs	0%	1.87%
30d	2015	5.00	3.96	38.70%	2.8 yrs	0%	1.87%
30e	2015	5.00	3.96	38.70%	2.1 yrs	0%	1.87%
30f	2015	5.00	3.96	38.70%	2.8 yrs	0%	1.87%
30g	2015	4.71	3.96	38.70%	3.2 yrs	0%	1.87%
30h	2015	4.71	3.96	38.70%	3.2 yrs	0%	1.87%
30i	2015	4.46	3.96	38.70%	3.2 yrs	0%	1.87%
30j	2015	4.71	3.96	38.70%	3.2 yrs	0%	1.87%
LF14	2015	4.66	4.33	38.58%	3.7 yrs	0%	2.27%
31	2015	4.73	3.86	38.92%	3.6 yrs	0%	1.99%
31a	2015	4.73	3.56	40.98%	3.6 yrs	0%	2.02%
31b	2015	4.30	3.72	40.82%	3.5 yrs	0%	2.42%

(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, 2015 was AUD 3.76.

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, 2017	2016	2015
a. PricewaterhouseCoopers Australia			
Audit and other assurance services			
Audit and review of financial reports	729,598	437,373	271,926
Other audit services[1]	42,306	345,965	1,003,706
Total remuneration of PricewaterhouseCoopers Australia	**771,904**	**783,338**	**1,275,632**
b. Network firms of PricewaterhouseCoopers Australia			
Audit and other assurance services			
Audit and review of financial reports	77,723	95,315	90,991
Total remuneration of Network firms of PricewaterhouseCoopers Australia	**77,723**	**95,315**	**90,991**
Total auditors' remuneration[2]	**849,627**	**878,653**	**1,366,623**

(1) Audit and review of financial reports and registration statements in connection with the United States initial public offering, filing on Form S-8, F-3 and related Australian prospectuses.

(2) All services provided are considered audit services for the purpose of SEC classification.

19. Losses per share

	Year Ended June 30, 2017	2016	2015
Losses per share			
(in cents)			
(a) Basic losses per share			
From continuing operations attributable to the ordinary equity holders of the company	(19.43)	(1.14)	(29.99)
Total basic losses per share attributable to the ordinary equity holders of the company	**(19.43)**	**(1.14)**	**(29.99)**
(b) Diluted losses per share			
From continuing operations attributable to the ordinary equity holders of the company	(19.43)	(1.14)	(29.99)
Total basic losses per share attributable to the ordinary equity holders of the company	**(19.43)**	**(1.14)**	**(29.99)**
(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	(76,815)	(4,127)	(96,244)
Diluted losses per share			
Losses from continuing operations attributable to the ordinary equity holders of the company:			
Used in calculating basic losses per share	(76,815)	(4,127)	(96,244)
Losses attributable to the ordinary equity holders of the company used in calculating diluted losses per share	(76,815)	(4,127)	(96,244)

	2017 Number	2016 Number	2015 Number
Weighted average number of ordinary shares used as the denominator in calculating basic losses per share	395,307,599	360,799,983	320,867,433
Weighted average number of ordinary shares and potential ordinary shares used in calculating diluted losses per share	395,307,599	360,799,983	320,867,433

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, 2017, 2016 and 2015. Shares that may be paid as contingent consideration (see Note 13(b)) 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, 2017, 2016 and 2015.

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)	**2017**	**2016**
Balance Sheet		
Current Assets	7,276	28,625
Total Assets	**666,357**	**601,249**
Current Liabilities	6,400	4,699
Total Liabilities	**6,815**	**4,972**
Shareholders' Equity		
Issued Capital	830,424	770,272
Reserves		
Foreign Currency Translation Reserve	(146,840)	(169,248)
Share Options Reserve	55,265	50,344
(Accumulated losses)	(79,307)	(55,091)
	659,542	**596,277**
Loss for the period	**(24,216)**	**(22,334)**
Total comprehensive loss for the period	**(24,216)**	**(22,334)**

b. Contingent liabilities of the parent entity

(i) Central Adelaide Local Health Network Incorporated ("CALHNI") (formerly Medvet)

Mesoblast Limited will be required to make a milestone payment to CALHNI of $0.3 million on completion of Phase 3 (human) clinical trials and $0.4 million on FDA marketing approval for products in the orthopaedic field. The Group will pay CALHNI a commercial arm's length royalty based on net sales by the Group of licensed products in the orthopaedic field each quarter.

The Group may also be required to pay consideration to CALHNI upon successful completion of subsequent clinical milestones in fields other than orthopedic.

21. 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. 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. Historical cost convention

These financial statements have been prepared under the historical cost convention, as modified by the revaluation of available-for-sale financial assets, financial assets and liabilities (including derivative instruments) at fair value through profit or loss, certain classes of property, plant and equipment and investment property.

ii. Change in reporting currency

Mesoblast Limited changed its reporting currency from Australian dollars to U.S. dollars and has recast its consolidated financial statements for the year ended June 30, 2015. The reporting currency was changed to align with the expectations of the users of the financial statements.

iii. Change in comparative figures

Comparative figures, are, where appropriate, reclassified to be comparable with figures presented in the current period.

The Company routinely reviews the financial statements for opportunities to improve the quality of financial reporting. 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.

The impact of the reclassification of the prior period financial statements is summarized below:

	Year Ended June 30,					
	2016			2015		
(in U.S. dollars, in thousands)	Previously reported	Currently reported	Effect of change	Previously reported	Currently reported	Effect of change
Fair value remeasurement of contingent consideration	37,423	28,112	(9,311)	(6,830)	(15,336)	(8,506)
Finance costs	(9,311)	—	9,311	(8,506)	—	8,506

iv. New and amended standards adopted by the Group

There were no new or amended accounting standards that were applicable to the Group for the June 30, 2017 reporting period.

iv. 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, 2017 reporting period. The Group has not elected to apply any pronouncements before their operative date in the annual reporting period beginning July 1, 2016.

Initial application of the following Standards is not expected to affect any of 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.

The following standards applicable to the Group but are not yet adopted are summarized below:

Title	Key requirements	Effective Date
IFRS 9 *Financial Instruments*	IFRS 9 introduced revisions in the following areas: • Classification and measurement – replacement of the existing complex rule-based requirements with a principle-based approach which is driven by cash flow characteristics and business model; • Impairment – a single impairment model to be applied to all financial instruments where expected credit losses must be accounted for from when the financial instruments are first recognized. This requirement lowers the threshold for recognition of full lifetime expected losses. • Hedge accounting – a reformed model for hedge accounting with enhanced disclosures about risk management activity.	Annual reporting periods commencing on or after January 1, 2018 The Group does not intend to adopt IFRS 9 before its mandatory date. The Group is currently evaluating the effect that the updated IFRS 9 will have on the consolidated financial statements and related disclosures.

IFRS 15 *Revenue from Contracts with Customers*	IFRS 15 provides a single, principles based five-step model to be applied to all contracts with customers. The five steps in the model are as follows: • Identify the contract with the customer • Identify the performance obligations in the contract • Determine the transaction price • Allocate the transaction price to the performance obligations in the contracts • Recognize revenue when (or as) the entity satisfies a performance obligation. Guidance is provided on topics such as the point in which revenue is recognized, accounting for variable consideration, costs of fulfilling and obtaining a contract and various related matters. New disclosures about revenue are also introduced.	Annual reporting periods commencing on or after January 1, 2018 The Group does not intend to adopt IFRS 15 before its mandatory date. While currently not considered material to the Group, the Group is evaluating the impact of IFRS 15 on key contracts and the effect the updated standard will have on the consolidated financial statements and related disclosures.
IFRS 16 *Leases*	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.	Annual reporting periods commencing on or after January 1, 2019 The Group does not intend to adopt IFRS 16 before its mandatory date. Refer to Notes 14 (b) and (c) for the lease commitments the Group holds as a lessee and lessor. The Group is currently evaluating the effect that the updated IFRS 16 will have on the consolidated financial statements and related disclosures.

b. 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, 2017 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.

c. Segment reporting

The Group predominately operates in one segment as set out in Note 2.

d. 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 available for sale financial assets 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.

e. Revenue recognition

Revenue is measured at the fair value of the consideration received or receivable. Amounts disclosed as revenue are net of returns, trade allowances, rebates and amounts collected on behalf of third parties.

The Group recognizes revenue when the amount of revenue can be reliably measured, it is probable that future economic benefits will flow to the entity and specific criteria have been met for each of the Group's activities as described below. The Group bases its estimates on historical results, taking into consideration the type of customer, the type of transaction and the specifics of each arrangement.

Revenue is recognized for the major business activities as follows:

(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.

Cephalon arrangement

In December 2010, the Group entered into a development and commercialization agreement (the "DCA") with Cephalon, Inc., now a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd (collectively "Teva"), which allowed for Teva to obtain world-wide rights to commercialize specific products based on the Group's proprietary adult stem cell technology platform. As part of the DCA, the Group received $130.0 million as a non-refundable up-front payment. In the month of June 2016, Teva exercised a contractual right under the DCA to end the joint development of the lead asset in the Group's cardiovascular portfolio, product candidate MPC-150-IM, and the Group regained full world-wide rights on this product candidate.

As the joint development of product candidate MPC-150-IM was ended in June 2016, the remaining full amounts of deferred revenues were brought to account, resulting in a total of $37.5 million of commercialization revenue recognized during the year ended June 30, 2016. The recognition of commercialization revenue relating to the deferred revenue amounts in the year ended June 30, 2016 had no impact to cash flows as the cash receipt pertaining to these deferred revenues recognized was received in the year ended June 30, 2011. There are no further performance obligations required of us in relation to this product candidate.

For the year ended June 30, 2015, the Group recognized $15.0 million of revenue, being the amortization of the initial payment over the estimated development program term. During the period from the initial recognition date until June 2016, the revenue was being recognized on a straight line basis over the estimated development period of product candidate, MPC-150-IM and had no impact to cash flows as the cash receipt pertaining to this revenue was received in the year ended June 30, 2011. The Group's policy of reviewing the estimated development program term was on a quarterly basis.

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 we are entitled, as JCR has the right to terminate the agreement at any time.

JCR is responsible for all development and manufacturing costs including sales and marketing expenses. Under the JCR Agreement, JCR has the right to develop the Group's 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 is entitled to payments when JCR reaches certain development and 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. Royalty revenue is recognized upon the sale of the related products provided we have no remaining performance obligations under the arrangement.

For the years ended June 30, 2017 and 2016, the Group recognized $1.4 million and $0.4 million, respectively, in commercialization revenue relating to royalty income earned on sales of TEMCELL in Japan since the launch of the product on February 24, 2016, 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, 2017, the Group recognized $0.5 million in milestone revenue upon our licensee, JCR, reaching cumulative net sales milestone for sales of TEMCELL in Japan. For the year ended June 30, 2016, the Group recognized $3.5 million of milestone revenue from JCR for the receipt of full regulatory approval of TEMCELL in Japan, which is a milestone under the Group's agreement with JCR. These amounts were recorded in revenue as there are no further performance obligations are required of the Group in relation to this income.

(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. A refundable tax offset is available to eligible companies with an annual aggregate turnover of less than AUD 20.0 million. Eligible companies can receive a refundable tax offset for a percentage of their of their research and development spending at the rate of 45% for periods prior to June 30, 2016 and an expected rate of 43.5% for periods from July 1, 2016. .

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.

f. 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.

g. 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 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.

h. 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.

Lease income from operating leases where the Group is sub-leasing to a third party is recognized in income on a straight-line basis over the lease term.

i. 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.

j. 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.

k. 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.

l. Trade and other receivables

Trade receivables and other receivables represent the principal amounts due at balance date less, where applicable, any provision for doubtful debts. An estimate for doubtful debts is made when collection of the full amount is no longer probable and there is objective evidence of impairment. Debts which are known to be uncollectible are written off in the statement of comprehensive income. 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.

m. Investments and other financial assets

(i) Classification

The Group classifies its financial assets in the following categories:

- financial assets at fair value through profit or loss,
- available-for-sale financial assets,
- loans and receivables, and
- held-to-maturity investments.

The classification depends on the purpose for which the investments were acquired. Management determines the classification of its investments at initial recognition and, in the case of assets classified as held-to-maturity, re-evaluates this designation at the end of each reporting period. See Note 5 for details about each type of financial asset.

(ii) Reclassification.

The Group may choose to reclassify a non-derivative trading financial asset out of the held for trading category if the financial asset is no longer held for the purpose of selling it in the near term. Financial assets other than loans and receivables are permitted to be reclassified out of the held for trading category only in rare circumstances arising from a single event that is unusual and highly unlikely to recur in the near term. In addition, the Group may choose to reclassify financial assets that would meet the definition of loans and receivables out of the held for trading or available-for-sale categories if the Group has the intention and ability to hold these financial assets for the foreseeable future or until maturity at the date of reclassification

Reclassifications are made at fair value as of the reclassification date. Fair value becomes the new cost or amortized cost as applicable, and no reversals of fair value gains or losses recorded before reclassification date are subsequently made. Effective interest rates for financial assets reclassified to loans and receivables and held-to-maturity categories are determined at the reclassification date. Further increases in estimates of cash flows adjust effective interest rates prospectively.

(iii) 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.

When securities classified as available-for-sale are sold, the accumulated fair value adjustments recognized in other comprehensive income are reclassified to profit or loss as gains and losses from investment securities.

(iv) 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, transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at fair value through profit or loss are expensed in profit or loss.

Loans and receivables and held-to-maturity investments are subsequently carried at amortized cost using the effective interest method. Available-for-sale financial assets and financial assets at fair value through profit or loss are subsequently carried at fair value. Gains or losses arising from changes in the fair value are recognized as follows:

- for 'financial assets at fair value through profit or loss' – in profit or loss within other income or other expenses
- for available for sale financial assets that are monetary securities denominated in a foreign currency – translation differences related to changes in the amortized cost of the security are recognized in profit or loss and other changes in the carrying amount are recognized in other comprehensive income
- for other monetary and non-monetary securities classified as available for sale in other comprehensive income.

Dividends on financial assets at fair value through profit or loss and available-for-sale equity instruments are recognized in profit or loss as part of revenue from continuing operations when the Group's right to receive payments is established.

Interest income from financial assets at fair value through profit or loss is included in the net gains/(losses). Interest on available-for-sale securities calculated using the effective interest method is recognized in the income statement as part of revenue from continuing operations.

Details on how the fair value of financial instruments is determined are disclosed in Note 5(f).

(v) Impairment

The Group assesses at the end of each reporting period whether there is objective evidence that a financial asset or a group of financial assets is impaired. A financial asset or a group of financial assets is impaired and impairment losses are incurred only if there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the asset (a 'loss event') and that loss event (or events) has an impact on the estimated future cash flows of the financial asset or group of financial assets that can be reliably estimated. In the case of equity investments classified as available-for-sale, a significant or prolonged decline in the fair value of the security below its cost is considered an indicator that the assets are impaired.

Assets carried at amortized cost

For loans and receivables, the amount of the loss is measured as the difference between the asset's carrying amount and the present value of estimated future cash flows (excluding future credit losses that have not been incurred) discounted at the financial asset's original effective interest rate. The carrying amount of the asset is reduced and the amount of the loss is recognized in profit or loss. If a loan or held-to-maturity investment has a variable interest rate, the discount rate for measuring any impairment loss is the current effective interest rate determined under the contract. As a practical expedient, the Group may measure impairment on the basis of an instrument's fair value using an observable market price.

If, in a subsequent period, the amount of the impairment loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognized (such as an improvement in the debtor's credit rating), the reversal of the previously recognized impairment loss is recognized in profit or loss.

Assets classified as available-for-sale

If there is objective evidence of impairment for available-for-sale financial assets, the cumulative loss –measured as the difference between the acquisition cost and the current fair value, less any impairment loss on that financial asset previously recognized in profit or loss – is removed from equity and recognized in profit or loss.

Impairment losses on equity instruments that were recognized in profit or loss are not reversed through profit or loss in a subsequent period.

If the fair value of a debt instrument classified as available-for-sale increases in a subsequent period and the increase can be objectively related to an event occurring after the impairment loss was recognized in profit or loss, the impairment loss is reversed through profit or loss

n. 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.

o. 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.

p. Intangible assets

(i) Goodwill

Goodwill is measured as described in Note 21(i) – Business combinations. 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 2).

(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 fourth 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.

q. 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.

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 financial 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

Amounts in the financial statements have been rounded off to the nearest thousand dollars, or in certain cases, the nearest dollar, unless mentioned otherwise.

Australian Disclosure Requirements
Directors' Declaration

In accordance with a resolution of directors of Mesoblast Limited,

In the directors' opinion:

(a) the financial statements and Notes set out on pages 140 to 193 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 of June 30, 2017 and of its performance for the financial 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 21(a) '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/ Brian Jamieson	/s/ Silviu Itescu
Brian Jamieson	Silviu Itescu
Chairman	Chief Executive Officer

Melbourne, August 30, 2017

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Item 19. Exhibits

Item	
1.1	Constitution of Mesoblast Limited (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
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†	Development and Commercialization Agreement by and between Angioblast Systems, Inc. and Cephalon, Inc., dated December 7, 2010 (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.4	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).
4.5	Subscription Deed by and between Mesoblast Limited and Cephalon International Holdings, Inc., dated December 2010 (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).
4.6†	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).
4.7	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).
4.8	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).
4.9†	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).
4.10†	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).
4.11	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).
4.12	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).
4.13	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).
4.14	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).
4.15	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).
4.16#	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).
4.17#	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).
4.18#	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).
4.19	Agreement of Sub-Sublease, by and between Mesoblast Limited and Carlo Pazolini (USA), LLC, dated September 23, 2013 (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form F-1 filed with the SEC on November 2, 2015).

4.20	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).
4.21	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).
4.22	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).
4.23	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).
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, 2017.
99.2	Auditor's independence declaration, dated August 30, 2017.

#	Indicates management contract or compensatory plan.
†	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.

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/ Brian Jamieson
Name:	Brian Jamieson
Title:	Chairman
By:	/s/ Silviu Itescu
Name:	Silviu Itescu
Title:	Chief Executive Officer

Dated: August 30, 2017

Exhibit 8.1

Significant Subsidiaries of Mesoblast Limited

Legal Entity	**Jurisdiction of Organization**
Mesoblast International Sarl	Switzerland
Mesoblast UK Limited	United Kingdom
Mesoblast, Inc.	United States

Exhibit 10

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 (No. 333-210935) of Mesoblast Limited of our report dated August 30, 2017 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, 2017

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, 2017

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, Paul Hodgkinson, 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, 2017

By: /s/ Paul Hodgkinson
Paul Hodgkinson
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, 2017 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, 2017

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, 2017 as filed on the date hereof (the "Report"), I, Paul Hodgkinson, 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, Paul Hodgkinson, 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, 2017

By: /s/ Paul Hodgkinson

Paul Hodgkinson
Chief Financial Officer

Appendix 4E

Preliminary final report for the twelve months to 30 June 2017

Name of entity

MESOBLAST LIMITED **ABN 68 109 431 870**

1. Reporting period

Report for the financial year ended	30 June 2017
Previous corresponding period is the financial year ended	30 June 2016

2. Results for announcement to the market

	Up/down	% change		Amount reported for the year ended 30 June 2017 USD'000
Revenues from ordinary activities *(item 2.1)*	Down	94.3%	to	2,412
Loss from ordinary activities after tax attributable to members (*item 2.2*)	Up*	1761.3%	to	76,815
Net loss for the period attributable to members *(item 2.3)*	Up*	1761.3%	to	76,815

**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 2017.

3. Net tangible assets per security

	30 June 2017	30 June 2016
Net tangible asset/(liability) backing per ordinary security (in USD cents)	10.11 cents	17.51 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 – "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 See subheading – "Business strategies and prospects for future years"
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 2017

This preliminary final report has been based on accounts which have been audited. The independent auditors report includes the following statement:

Without qualifying our opinion, we draw attention to note 1 in the financial report, which indicates that the consolidated entity incurred net cash outflows from operations of US$95,471,000. As a result, the Company is dependent upon entering into an arrangement with a third party partner on one or more of its four Tier 1 product candidates that would result in non-dilutive funding and/or raising further capital, together with various cost containment and deferment strategies being completed including the reprioritization of certain projects . These conditions, along with other matters set forth in Note 1, indicate the existence of a material uncertainty that may cast significant doubt about the company's ability to continue as a going concern and therefore, the company may be unable to realise its assets and discharge its liabilities in the normal course of business and at the amounts stated in the financial report.

A copy of the audited Financial Statements for the year ended 30 June 2017 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.