asx announcement

mesoblast
the regenerative medicine company

Mesoblast Lists On Nasdaq

Gross proceeds of approximately $A95.8 million ($US68.3 million) expected at closing on 18 November

Melbourne, Australia; and New York, USA; 16 November 2015: Mesoblast Limited (ASX:MSB; NASDAQ:MESO) today announced it had listed on the Nasdaq Global Market on 13 November under the symbol 'MESO'.

Mesoblast expects to receive gross proceeds of approximately A$95.8 million (US$68.3 million), before deduction of underwriting discounts and commissions and expenses, for the public offering of 8,535,059 American Depositary Shares (ADSs), which includes the underwriters partial exercise of their over-allotment option. This issue represents approximately 12.6% of Mesoblast's issued share capital. The ADSs were issued at a public offering price of US$8.00 per ADS.

Mesoblast intends to use the net proceeds of this offering for ongoing clinical programs, research and development expenses, commercial manufacturing requirements, and general and administrative purposes.

Mesoblast has established a diverse portfolio of product candidates based on its proprietary allogeneic, off-the-shelf mesenchymal lineage cell-based technology, with multiple active Phase 3 clinical programs. Mesoblast's lead product candidates target major diseases with significant unmet medical needs despite existing therapies. These include chronic heart failure, chronic low back pain due to degenerative disc disease, and immune-mediated conditions such as acute graft versus host disease and biologic refractory rheumatoid arthritis.

J.P. Morgan and Credit Suisse are acting as the joint book-running managers and the representatives of the underwriters, with Maxim and Ladenburg Thalmann co-managers.

A registration statement relating to these securities was declared effective by the Securities and Exchange Commission on 12 November 2015; the final registration statement is attached to this ASX announcement.

The offering will be made only by means of a prospectus, copies of which may be obtained from the offices of J.P. Morgan Securities LLC, c/o Broadridge Financial Solutions, 1155 Long Island Avenue, telephone: 866-803-9204, or by e-mail at prospectus-eq_fi@jpmchase.com; or Credit Suisse Securities (USA) LLC, c/o Prospectus Department, One Madison Avenue, New York, NY 10010, telephone: 800-221-1037 or by e-mail at newyork.prospectus@credit-suisse.com.

This announcement shall not constitute an offer to sell or a solicitation of an offer to buy nor shall there be any sale of these securities in any state or jurisdiction in the United States, Australia or anywhere else in the world in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Mesoblast

Mesoblast Limited (ASX: MSB; NASDAQ: MESO) is a global leader in regenerative medicine. The Company has leveraged its proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, to establish a broad portfolio of late-stage product candidates. Mesoblast's allogeneic, 'off-the-shelf' cell product candidates target advanced stages of diseases where there are highly unmet medical needs, including cardiovascular conditions, orthopedic disorders, immunologic and inflammatory disorders and oncology/hematology conditions.

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Prospectus

7,479,617 American Depositary Shares representing 37,398,085 ordinary shares

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Mesoblast Limited

This is an initial public offering in the United States of American depositary shares, or ADSs, representing 37,398,085 ordinary shares of Mesoblast Limited, or Mesoblast. Mesoblast is offering 7,479,617 ADSs. Each ADS represents five ordinary shares, no par value, deposited with JPMorgan Chase Bank, N.A., as depositary.

Our ordinary shares currently trade on the Australian Securities Exchange under the symbol "MSB." The initial public offering price of the ADSs is US$8.00 per ADS. We have received approval to list our ADSs on the NASDAQ Global Select Market under the symbol "MESO".

Investing in our ADSs involves a high degree of risk. See "Risk Factors" beginning on page 13.

	Per ADS	Total
Initial public offering price	US$8.00	US$59,836,936
Underwriting discounts and commissions(1)	US$0.56	US$ 4,188,586
Proceeds before expenses, to us	US$7.44	US$55,648,351

(1) See "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters the right to purchase up to an additional 1,121,942 ADSs from us at the initial public offering price less underwriting discounts and commissions.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the ADSs to purchasers on or about November 18, 2015.

Joint Bookrunners

J.P. Morgan **Credit Suisse**

Co-managers

Ladenburg Thalmann **Maxim Group LLC**

November 12, 2015

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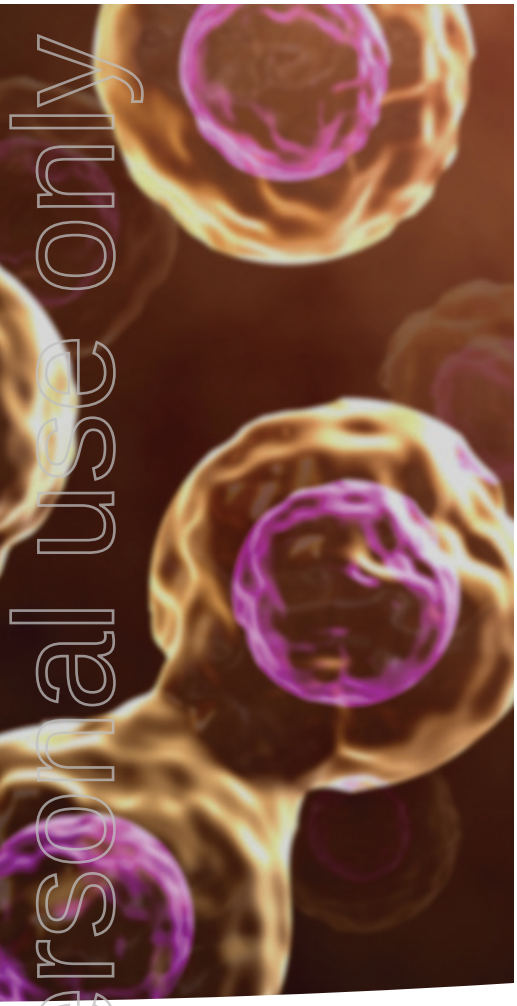

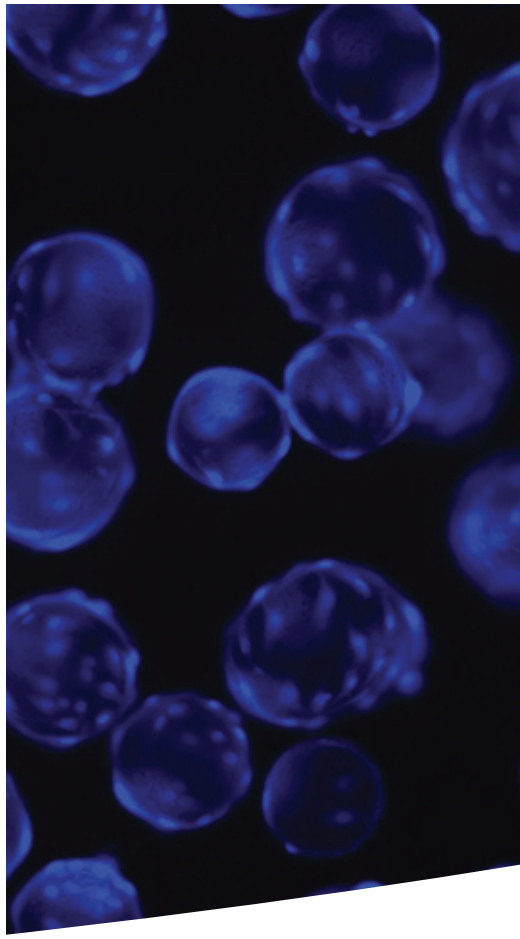

We are a global leader in regenerative medicine

Our proprietary technology platform is based on specialized cells known as mesenchymal lineage adult stem cells, or MLCs. We are leveraging this platform to build what we believe is the most advanced regenerative medicine portfolio in the industry, with the potential to address multiple conditions with significant unmet medical needs.

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You should rely only on the information contained in this prospectus and any related free-writing prospectus that we authorize to be distributed to you. We and the underwriters have not authorized any person to provide you with information different from that contained in this prospectus or any related free-writing prospectus that we authorize to be distributed to you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus speaks only as of the date of this prospectus unless the information specifically indicates that another date applies, regardless of the time of delivery of this prospectus or of any sale of the securities offered hereby.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the ADSs or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of the prospectus applicable to that jurisdiction.

Until December 7, 2015 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade in our ADSs, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

STATISTICAL AND OTHER INDUSTRY AND MARKET DATA

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus and we believe these industry publications and third-party research, surveys and studies are reliable.

TRADEMARKS

We own or have rights to trademarks and trade names that we use in connection with the operation of our business, including our corporate name, logos, product names and website names. Other trademarks and trade names appearing in this prospectus are the property of their respective owners. Solely for your convenience, some of the trademarks and trade names referred to in this prospectus are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks and trade names.

CONVENTIONS THAT APPLY TO THIS PROSPECTUS

Except where the context requires otherwise and for purposes of this prospectus only:

- "ADSs" refers to our American depositary shares, each of which represents five ordinary shares, and "ADRs" refers to the American depositary receipts that evidence our ADSs.
- "ASX" refers to the Australian Securities Exchange, where our ordinary shares are listed.
- "Mesoblast," "we," "us" or "our" refer to Mesoblast Limited and its subsidiaries.
- "A$" or "Australian dollars" refers to the legal currency of Australia.
- "IFRS" refers to the International Financial Reporting Standards as issued by the International Accounting Standards Board, or IASB.
- "GAAP" refers to the Generally Accepted Accounting Principles in the United States.
- "FDA" refers to the United States Food and Drug Administration.
- "NIH" refers to the United States National Institutes of Health.
- "US$" 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.

Unless otherwise indicated, the consolidated financial statements and related notes included in this prospectus have been presented in U.S. dollars and also comply with IFRS, which differs in certain significant respects from GAAP. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Certain Differences Between IFRS and GAAP." For us and our subsidiaries that use a functional currency that is not U.S. dollars, the assets and liabilities have been translated at the closing exchange rate, while the income and expenses have been translated at the exchange rate at the transaction date. The resulting exchange differences are recognized in our consolidated statement of comprehensive income. See note 21(d) in the notes to our consolidated financial statements and the related notes thereto included elsewhere in this prospectus for more information.

Certain information in this prospectus is expressed in Australian dollars, such as share option exercise prices and transaction values in "Related Party Transactions," among others. We make no representation that the Australian dollar or U.S. dollar amounts referred to in this prospectus could have been converted into U.S. dollars or Australian dollars, as the case may be, at any particular rate or at all. See "Risk Factors—Risks Related to Ownership of Our ADSs, Our Trading Market and This Offering—We are subject to risk associated with currency fluctuations, and changes in foreign currency exchange rates could impact our results of operations."

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and consolidated financial statements and the related notes thereto included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our ADSs. You should read this entire prospectus carefully, including "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and the related notes thereto included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to "Mesoblast," "we," "us" and "our" refer to Mesoblast Limited and its subsidiaries. Clinical milestone event dates in this prospectus refer to calendar year periods.

Overview

We are a global leader in the field of regenerative medicine. We have leveraged our proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, or MLCs, to establish what we believe to be the most advanced regenerative medicine product portfolio in the industry. We have what we believe to be an extensive safety profile for our product candidates, with over 1,340 patients treated. Based on outcomes in Phase 2 trials across multiple indications, we now have five MLC product candidates that are in active Phase 3 trials or are Phase 3-ready.

In September 2015, our licensee JCR Pharmaceuticals Co. Ltd, or JCR, received full approval for the first "allogeneic" cell-based product in Japan, meaning a product containing cells from a single donor expanded and used in many unrelated patients. We believe we are well positioned to have the first industrially-manufactured allogeneic stem cell product approved in the United States.

Our deep understanding of the fundamental mechanisms of action of MLCs and our proprietary manufacturing processes have been leveraged to create a portfolio of independent, non-interchangeable MLC-derived product candidates. Each of our product candidates has its own distinct technical characteristics, target indications, individual reimbursement strategy, separate commercialization potential, and unique partnering opportunities.

We have focused on significantly advanced stages of diseases where specific subpopulations of patients have high unmet medical needs, as this provides potential accelerated development pathway opportunities and the potential for attractive pricing. Our goal is to first gain broad acceptance of our approved products based on our technology as treatment options for these severely ill patients, then expand the applications of such products over time to broader patient populations.

Our lead products have been prioritized into tiers based on stage of development, market opportunity, and expected time to market, and we allocate resources based on such prioritization. Our Tier 1 product candidates are being developed for the treatment of chronic congestive heart failure, or CHF, chronic low back pain, or CLBP, acute graft versus host disease, or aGVHD, a condition where donor cells attack a patient receiving a bone marrow transplant, resulting in tissue damage that is often fatal, and for chronic inflammatory conditions, such as biologic-refractory rheumatoid arthritis, or RA, and diabetic kidney disease, or DKD. Our Tier 2 lead product candidates are being developed for the treatment of acute cardiac ischemia and for the treatment of Crohn's disease, among other indications.

We expect a number of important clinical and commercial milestone events to occur over the next 12 to 24 months for our most advanced product candidates, including:

- By the end of 2015, we expect to announce 6 month results from the first cohort in the Phase 2 trial of our product candidate for RA. Results from the second cohort are expected during the first half of 2016. We believe positive results from this trial would support progression towards Phase 3 and potential partnering discussions.

- During the first quarter 2016, we expect that our licensee JCR will launch TEMCELL® Hs. Inj. (JR-031), or TEMCELL, its MSC-based product for aGVHD in Japan. Decisions by Japanese regulators on price reimbursement for JCR's product TEMCELL are pending. Under our agreement with JCR, we are entitled to receive milestone payments on product regulatory approvals, escalating double-digit royalties in the twenties and other payments at pre-defined thresholds of cumulative net sales.
- During the first quarter 2016, we expect to announce the outcome of the first interim analysis of safety and efficacy from a Phase 3 trial of our product candidate for advanced CHF. We expect the second interim analysis for futility, resizing and possible overwhelming efficacy to occur in the first quarter 2017. Phase 2b trial results for our product candidate for end-stage CHF are expected in middle 2017. This product candidate is partnered on a global basis with Teva Pharmaceutical Industries, Ltd., or Teva.
- During the third quarter 2016, we expect to announce top-line results from an interim analysis of a Phase 3 trial of our product candidate for aGVHD. This interim analysis may support a BLA filing by the end of 2016. We expect to complete recruitment of this Phase 3 trial in the fourth quarter 2016 and to have top-line results of the trial in the first quarter 2017.
- During the third quarter 2016, we expect to complete enrollment of the first Phase 3 trial of our product candidate for CLBP.

Proprietary Platform

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, or 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, or 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.

MLCs are present around blood vessels in all tissues, where they can respond to signals associated with tissue damage. This response includes the secretion by MLCs of a diverse variety of biomolecules that affect various reparative and immunomodulatory mechanisms responsible for maintaining tissue health. Understanding the mechanisms of action by which these biomolecules induce tissue restoration has broad applicability in treating diseases for which current standards of care are inadequate. Our lead MLC product candidates have been developed through proprietary manufacturing processes to optimize expression of certain biomolecules. The expressed biomolecules are those implicated in the mechanisms of action by which the MLC product candidate is thought to modify outcomes for the target condition for which it is being developed.

Scalable Manufacturing

MLCs have two additional, distinct characteristics that, when combined with our proprietary manufacturing processes, enable allogeneic or "off-the-shelf" use of our product candidates. First, we have developed proprietary methods that enable the isolation of MLCs from healthy donors and their large-scale expansion while maintaining their ability to produce key biomolecules associated with tissue health and repair. In addition, unlike other categories of stem cells, 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. These characteristics allow us to produce large quantities of off-the-shelf MLC-based product candidates from a few donors for use in thousands of unrelated recipients, with consistent, well-defined therapeutic properties, batch-release criteria and established potency assays, all with accompanying manufacturing and distribution economies-of-scale.

Our Lead Product Candidates

We have developed product candidates to target specific disease states by understanding and capitalizing on the mechanisms of action of our proprietary MLCs, including induction of new tissue growth, new blood vessel network formation, reduction in fibrosis and scarring, and immunomodulation.

A summary of our lead programs, their corresponding stage of development, and strategic collaboration status are captured in the table below.

Tier 1 Programs

Product Candidates	Programs	Collaborator/ Geographic Rights	Stage of Development	Anticipated Milestones
MPC-150-IM	Class II/III CHF	Teva (Global)	• Phase 2 trial completed • Phase 3 trial enrollment ongoing • Enrollment of the patients for first interim analysis completed	• Outcome of first Phase 3 interim analysis for safety and efficacy in first quarter 2016 • Second interim analysis for futility, resizing and possible overwhelming efficacy in first quarter 2017 • Phase 3 trial complete in 2018 with potential to accelerate based on second interim analysis
	End-stage CHF	Teva (Global)	• Phase 2a trial completed • Phase 2b trial enrollment ongoing, funded by the NIH	• Phase 2b trial results expected in middle 2017
MPC-06-ID	CLBP	Proprietary (Global)	• Phase 2 trial completed • Phase 3 trial enrollment ongoing	• Complete enrollment of first Phase 3 trial in third quarter 2016 • Design being finalized for interim analysis in fourth quarter 2016 • Phase 3 program complete in first half 2018
TEMCELL/ MSC-100-IV	Acute GVHD	JCR (Japan)	• JCR received full approval in September 2015	• Launch in Japan in first quarter 2016
	Acute steroid-refractory GVHD	Proprietary (Global, ex-Japan)	• Enrollment ongoing for U.S. pediatric Phase 3 trial	• U.S. Phase 3 pediatric trial top-line results from an interim analysis in third quarter 2016, positive results may support BLA filing by end of 2016 • Complete recruitment of Phase 3 trial in fourth quarter 2016 • Top-line results of Phase 3 trial in first quarter 2017
MPC-300-IV	Rheumatoid arthritis (biologic refractory)	Proprietary (Global)	• Phase 2 trial ongoing • First cohort enrollment completed • Second cohort enrolling	• 6 month data for first cohort by the end of 2015 • Second cohort results in first half 2016
	Diabetic kidney disease	Proprietary (Global)	• Phase 2 trial ongoing, enrollment completed	• Phase 2b/3 trial design ongoing

All time periods refer to calendar year periods.

Tier 2 Programs

Product Candidates	Programs	Collaborator/ Geographic Rights	Stage of Development/ Anticipated Milestones
MPC-25-IC	Acute cardiac ischemia	Teva (Global)	• Phase 2 trial ongoing
MPC-25-Osteo	Spinal fusion	Proprietary (Global)	• Phase 2 trial completed • Phase 3 trial design ongoing
MPC-CBE	Bone marrow transplantation (BMT)	Teva (Global)	• Phase 3 trial ongoing
MSC-100-IV	Crohn's disease (biologic refractory)	Proprietary (Global)	• Phase 3 trial ongoing

All time periods refer to calendar year periods.

For product registration purposes, Phase 3 programs may require more than one trial.

MPC-150-1M for CHF

MPC-150-IM is our Phase 3 product candidate partnered with Teva, which is being developed as a treatment for both advanced and end-stage CHF. With respect to advanced CHF, we have completed a Phase 2 trial in Class II/III CHF where results showed that a single 150 million dose treatment with MPC-150-IM, as compared to control and other dose levels, led to the greatest positive effects on clinical outcomes, including significant improvement in left ventricular volumes, and prevention of any heart failure-related major adverse cardiovascular events, or HF-MACE, over 3 years. The most substantial benefit seen in MPC-150-IM treated patients was in the subset with the greatest contractile deficiency and advanced heart failure. Advanced heart failure patients represent a major unmet clinical need which continues to exist despite recent advances in drug therapy, and where we believe product success would result in highest reimbursement.

Teva recently completed discussions with the FDA, during which important changes to the Phase 3 program for advanced CHF using MPC-150-IM were agreed to. In particular, the total number of subjects to be recruited for the ongoing Phase 3 trial, using a time to first event analysis of HF-MACE as the primary endpoint, will be reduced from approximately 1,730 to 1,165. Additionally, a second interim analysis will be performed in the ongoing Phase 3 trial when 50% of the HF-MACE have occurred. We expect the outcome of the first Phase 3 interim analysis for safety and efficacy in the first quarter of 2016. We expect the second interim analysis for futility, resizing and possible overwhelming efficacy in the first quarter of 2017.

A confirmatory study is planned to be conducted in parallel in a similar patient population of approximately 500 subjects using recurrent HF-MACE as the primary endpoint. The use of recurrent HF-MACE as a primary endpoint in the confirmatory study is supported by a new analysis of the completed Phase 2 trial, where patients treated with MPC-150-IM had no HF-MACE over 36 months of follow-up, compared with 11 recurrent HF-MACE in the control group ($p<0.001$, log rank test). The clinical data from these two studies will be supportive to each other for full product approval. Based on our discussions with the FDA, we believe that positive clinical data from these two studies will be sufficient for product approval.

With respect to end-stage CHF, a Phase 2b trial of MPC-150-IM has been initiated by the Cardiothoracic Surgical Trials Network, or CSTN, and funded by the U.S. National Institutes of Health, or NIH, in 120 patients with end-stage CHF requiring mechanical support by a left ventricular assist device, or LVAD. This trial builds on an earlier Phase 2a clinical trial that demonstrated feasibility and safety, and suggested that a single low-dose injection of our proprietary MLCs improved cardiac function and had an early benefit on survival. Results of this new Phase 2b trial are expected in mid-2017.

If we receive BLA approval for MPC-150-IM, we expect to participate in a market for CHF that in the U.S. alone has 5.7 million adult patients and 870,000 new diagnoses per year.

MPC-06-ID for CLBP

MPC-06-ID is our proprietary Phase 3 product candidate for the treatment of CLBP resulting from degenerative disc disease, or DDD. In a Phase 2 study, compared to controls, MPC-06-ID treatment resulted in a significantly greater proportion of patients achieving reduced back pain and improved back function over 24 months of follow-up. Based upon meetings with the FDA, we will conduct two double-blinded Phase 3 trials with approximately 330 patients each, and we expect to complete enrollment of the first of the two Phase 3 trials in the third quarter of 2016. We expect to complete the Phase 3 program in the first half of 2018. The first of these trials has been initiated. Because current treatments for CLBP focus only on pain relief rather than addressing the underlying degenerative nature of the disease, we believe MPC-06-ID could fill an unmet treatment gap for the large population of patients with DDD.

MSC-100-IV for aGVHD

Our third Tier 1 product is an intravenously-delivered MLC product candidate for the treatment of aGVHD following allogeneic bone marrow transplantation, or BMT. JCR, our partner in Japan for aGVHD, received

Japanese regulatory approval for TEMCELL in September 2015. Decisions by Japanese regulators on price reimbursement for JCR's product TEMCELL are pending. During the first quarter 2016, we expect that JCR will launch TEMCELL in Japan. We are developing an MLC product candidate for the treatment of aGVHD globally, outside Japan. Data from a pediatric Expanded Access Program, or EAP, in the United States, from the first 160 children treated for severe, multi-line refractory aGVHD, showed a significant response and survival benefit. A pediatric Phase 3 trial has commenced and is actively enrolling in the U.S. We expect top-line results from an interim analysis of this trial in the third quarter of 2016, and top-line results of the completed trial in the first quarter 2017. Based on our discussions with the FDA, we believe positive data from this trial will be sufficient for conditional approval in the United States, and an additional pediatric or adult Phase 3 trial will be required for full product approval. Interim analysis may support BLA filing by the end of 2016.

MPC-300-IV for Chronic Inflammatory Conditions

MPC-300-IV, our fourth Tier 1 product, is an intravenously-delivered immunomodulatory product candidate for the treatment of chronic inflammatory conditions, including biologic-refractory rheumatoid arthritis and diabetic kidney disease. A Phase 2 trial of MPC-300-IV is ongoing in patients with biologic-refractory rheumatoid arthritis, where the first dose cohort has completed recruitment, the second dose cohort is actively enrolling, and where 6 month results for the first cohort are expected by the end of 2015 and results from the second cohort are expected during the first half of 2016. A Phase 2 trial of MPC-300-IV in insufficiently controlled type 2 diabetes patients showed a dose-dependent response on improvement in HbA1c, or hemoglobin A1c, the primary measure of glycemic control for diabetes, which may be consistent with an immunomodulatory effect on disease pathogenesis. In addition, a Phase 2 trial of MPC-300-IV in patients with diabetic kidney disease has completed recruitment and six months of follow-up, and we announced the three month primary endpoint as well as six month results in June 2015.

Competitive Strengths

We hold a leadership position in regenerative medicine and believe we have more product candidates in late stage clinical trials than any other stem cell based regenerative medicine company. The key strengths underpinning our leadership position include:

- ***Disruptive technology platform.*** Our proprietary MLC platform allows us to develop product candidates that have the potential to significantly improve the treatment of a number of serious and debilitating conditions. Unlike other stem cell technologies, MLCs are allogeneic, "off-the-shelf" therapies that can be developed from a small number of healthy adult donors and administered to many patients, with batch-to-batch consistency, commercial scale capabilities and predictable therapeutic properties, without any material immune response in patients.
- ***Broad portfolio of distinct and advanced product candidates.*** We have advanced a significant number of clinical product candidates that target a wide range of diseases, including five Phase 3 or Phase 3-ready product candidates, and potentially the first allogeneic industrially manufactured product candidate to be approved in the United States, all backed by an extensive patient safety data file.
- ***Target markets with high unmet needs where technology shows greatest prospects.*** Our strategy is to develop product candidates that target the significantly advanced stages of certain diseases where specific sub-populations have high unmet medical needs. As a result, we will potentially benefit from accelerated development pathways and attractive pricing, as well as the opportunity to expand over time into broader patient populations with less severe stages of a targeted disease.
- ***Scalable manufacturing capabilities.*** We have developed proprietary manufacturing processes that we expect will enable production at commercial scale with reproducibility and batch-to-batch consistency. To further support our efforts, we have established a strategic alliance with Lonza, a global leader in biopharmaceutical manufacturing, and we are currently manufacturing in their state-of-the-art facility in Singapore on an exclusive basis for cell therapies.

- ***Intellectual property leadership.*** We have a large patent portfolio of issued and pending claims covering compositions of matter and methods of use for MLCs, as well as for elements of our manufacturing processes. As of August 31, 2015, we had 72 patent families, including 661 patents or patent applications. We believe our intellectual property position provides us with substantial competitive advantages for the commercial development of regenerative medicine products.
- ***Strategic alliances.*** We have established strategic relationships that provide clinical development, manufacturing and commercial capabilities, as well as financial support to advance our product candidates. These alliances include Teva, Lonza and JCR. We will evaluate and, where appropriate, enter into additional collaborations with industry leading biopharmaceutical and other organizations to further advance our product candidate portfolio and to gain access to product development and funding support.
- ***Experienced management team.*** Our CEO, Dr. Silviu Itescu, is a pioneer in the study and clinical development of stem cell therapeutics, and a globally recognized leader in the field of regenerative medicine. Our broader management team, through prior employment at leading drug development companies and regulatory agencies, has substantial experience in the clinical development, manufacturing, regulatory management and commercialization of biopharmaceuticals.

Recent Developments

In April 2015, Celgene Alpine Investment Company III, LLC, a member of the Celgene Corporation Group, or Celgene, purchased 15.3 million ordinary shares in Mesoblast Limited for a consideration of A$58.5 million (US$45 million) and agreed to a six-month right of first refusal with respect to our proprietary mesenchymal lineage adult stem cell product candidates for the prevention and treatment of aGVHD, certain oncologic diseases, inflammatory bowel diseases, and organ transplant rejection. On October 16, 2015, we announced that we agreed with Celgene to extend Celgene's right of first refusal for an additional six months.

Risk Factors

Our business and the successful execution of our strategies are subject to certain risks and uncertainties related to our business and our industry, regulation of our business and our corporate structure, doing business in Australia and ownership of our ADSs, our trading market and this offering. The risks and uncertainties related to our business and our industry include, but are not limited to:

- We have never generated any revenue from product sales and may never be profitable.
- Our product candidates are based on our novel MLC technology, which makes it difficult to predict the time and cost of product development and subsequently obtaining regulatory approval. To date, no industrially manufactured stem cell products have been approved in the United States.
- We may encounter substantial delays in our clinical studies or we may fail to demonstrate safety and efficacy, particularly in multi-national clinical trials, to the satisfaction of applicable regulatory agencies.
- We have incurred net operating losses and as of June 30, 2015, have an accumulated deficit of US$264.0 million since our inception. We anticipate that we will continue to incur substantial operating losses for the foreseeable future. It is possible that we may never achieve or sustain profitability.
- Even if this offering is successful, we will 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.

- We may find it difficult to enroll patients in our clinical trials, especially for indications such as aGVHD which have a limited patient population. As such, this could delay or prevent development of our product candidates.
- 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.
- We are substantially dependent on the expertise of Teva and JCR to develop and commercialize our product candidates in certain indications. If we fail to maintain our current strategic relationships with Teva and JCR, our business, commercialization prospects and financial condition may be materially adversely affected.
- We rely on Lonza as our sole supplier and manufacturer of certain of our product candidates. Our business could be harmed if significant quantities of our product candidates cannot be manufactured at acceptable quality levels or costs.
- We may not be able to adequately protect our proprietary technology.

See "Risk Factors" and "Forward-Looking Statements" for a more detailed discussion of these and other risks and uncertainties that we may face.

Our Corporate Information

We were formed in 2004 as an Australian company. In December 2004 we completed an initial public offering of our ordinary shares and listing of these shares on the Australian Securities Exchange, or the ASX, under the symbol "MSB." In 2005, our ADSs began to be quoted on the Over-The-Counter Market under the symbol "MBLTY." In 2010, we acquired Angioblast Systems, Inc., a Delaware corporation created by our founder and Chief Executive Officer, Dr. Silviu Itescu, and previously owned in part by Mesoblast Limited, focusing on the development of therapeutic products based on MPCs for certain applications. In October 2013, we acquired the culture-expanded, or cells cultured with media that provides nutrients to allow them to divide and replicate, mesenchymal stem cell, or MSC, assets of Osiris Therapeutics, Inc.

Our principal executive offices are located at Level 38, 55 Collins Street, Melbourne 3000, Australia. Our telephone number at this address is +61 (3) 9639-6036. Our office in the United States is located at Level 3, 505 Fifth Avenue, New York, NY 10017. Our telephone number at this address is (212) 880-2060. Our website is *www.mesoblast.com*. Information contained on our website is not part of this prospectus. Our agent for service of process in the United States is our wholly-owned subsidiary, Mesoblast, Inc., a Delaware corporation, located at Level 3, 505 5th Ave, New York, NY 10017.

Implications of Being a Foreign Private Issuer

We qualify as a "foreign private issuer" as defined in Section 405 of the Securities Act of 1933, as amended. As a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as a company that files as a domestic issuer whose securities are registered under the Exchange Act, nor are we generally required to comply with the SEC's Regulation FD, which restricts the selective disclosure of material non-public information. We intend to take advantage of these exemptions as a foreign private issuer. We also qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, but we do not intend to take advantage of the benefits and exemptions available to us as such.

THE OFFERING

ADSs offered by us	7,479,617 ADSs
ADSs to be outstanding immediately after this offering	7,753,214 ADSs
Ordinary shares to be outstanding immediately after this offering	374,395,814 ordinary shares (380,005,524 ordinary shares, if the underwriters exercise their over-allotment option in full)
Over-allotment option	We have granted the underwriters an option, which is exercisable within 30 days from the date of this prospectus, to purchase up to 1,121,942 additional ADSs from us at the public offering price less the underwriting discount to cover over-allotments, if any.
The ADSs	Each ADS represents five ordinary shares, no par value. The ADSs are evidenced by ADRs issued by the depositary. The depositary will be the holder of the ordinary shares underlying the ADSs and you will have the rights of an ADS holder as provided in the deposit agreement among us, the depositary and owners and beneficial owners of ADSs from time to time. You may surrender your ADSs to the depositary to withdraw the ordinary shares underlying your ADSs. The depositary will charge you a fee for such an exchange. We may amend or terminate the deposit agreement for any reason without your consent. If an amendment becomes effective, you will be bound by the deposit agreement as amended if you continue to hold your ADSs.
Use of proceeds	We anticipate that the net proceeds from this offering will be approximately US$50.9 million, or approximately US$59.3 million if the underwriters exercise their option to purchase additional ADSs in full, at our initial public offering price of US$8.00 per ADS, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering as follows: • approximately $21.0 million to support commercial manufacturing requirements for our Tier 1 and Tier 2 product candidates, through development and implementation of our proprietary manufacturing processes and expansion of our manufacturing capabilities and resources, including, but not limited to, finalizing the development and implementation of the 3D bioreactor-based manufacturing of our products, finalizing the development of our proprietary fetal bovine serum, or FBS, -free media, and expansion of the scale of manufacturing to support commercial production of our products at our collaborator Lonza;

- approximately $22.0 million to fund the costs of ongoing Clinical Tier 1 Programs, including approximately $5.0 million for our Phase 3 clinical trial of MSC-100-IV for the treatment of aGVHD; approximately $8.0 million for our Phase 3 clinical trial of MPC-06-ID for the treatment of CLBP; and approximately $9.0 million for our Phase 2b/3 clinical trial of MPC-300-IV for the treatment of biologic-refractory rheumatoid arthritis and diabetic kidney disease; and
- approximately $7.9 million for general and administrative expenses (including personnel-related costs), working capital and other general corporate purposes, including funding general corporate overhead and the costs of operating as a public company, and general research and development expenses associated with our technology platform and earlier stage product development costs.

See "Use of Proceeds."

Depositary . . . . . JP Morgan Chase Bank, N.A.

Risk factors . . . . . See "Risk Factors" and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the ADSs.

Lock-up . . . . . We have agreed for a period of 180 days after the date of this prospectus not to sell, transfer or otherwise dispose of any of our ordinary shares, ADSs or similar securities, subject to certain exceptions. Furthermore, each of our directors, our chief executive officer, our chief financial officer and Cephalon, Inc. have agreed to a similar 180-day lock-up. See "Underwriting."

Listing . . . . . We have received approval to list our ADSs on the NASDAQ Global Select Market.

Trading symbol . . . . . "MESO".

The number of ordinary shares to be outstanding following the offering is based on 336,997,729 fully paid ordinary shares outstanding at June 30, 2015, and excludes:

- the exercise of employee options outstanding at June 30, 2015 to purchase 18,369,078 fully paid ordinary shares issuable upon at a weighted average exercise price of A$5.25 per ordinary share;

and includes:

- an aggregate of 3,500,000 ordinary shares at a weighted average exercise price of A$6.78 held in trust as part of our loan funded share plan, or LFSP.

Pursuant to our LFSP, we make limited recourse, interest free loans to non-executive employees to purchase our ordinary shares. We generally issue new ordinary shares (rather than purchasing such shares in the open market) and place such shares in a trust to be held on behalf of the employee. The trustee holds the corresponding ordinary shares on behalf of the employee until the employee chooses to settle the loan pertaining to such shares and all vesting conditions have been satisfied, at which point ownership of such shares is fully transferred to the employee. See "Remuneration—Non-CEO Executive Remuneration—Australian Loan Funded Share Plan (LFSP)."

Except as otherwise indicated, all information contained in this prospectus assumes:

- no exercise of options after June 30, 2015; and
- no exercise by the underwriters of their right to purchase up to an additional 1,212,942 ADSs from us to cover over-allotments.

SUMMARY CONSOLIDATED FINANCIAL AND OPERATING DATA

The following summary consolidated financial data presented below as of and for the years ended June 30, 2015, 2014 and 2013 has been derived from our audited consolidated financial statements included elsewhere in this prospectus. Historical results are not necessarily indicative of results to be expected in the future. The summary consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes thereto included elsewhere in this prospectus.

Our financial statements are presented in U.S. dollars and have been prepared in accordance with IFRS.

	Year Ended June 30,		
	US$ 2015	**US$ 2014**	**US$ 2013**
	(in thousands except per share information)		
Consolidated Income Statement Data:			
Revenue:			
Commercialization revenue	15,004	15,004	18,685
Milestone revenue	2,000	—	—
Interest revenue	2,757	8,386	10,616
Revenue from continuing operations	19,761	23,390	29,301
Other income:			
Foreign exchange gains	10,478	—	—
Research & development tax incentive	4,418	7,775	5,495
Other revenue	407	—	—
Rental income	96	—	—
Release of excess provision for services	—	2,344	—
Other income	15,399	10,119	5,495
Total revenue from continuing operations	35,160	33,509	34,796
Expenses from continuing operations:			
Research and development	(62,649)	(50,929)	(48,513)
Manufacturing commercialization	(23,783)	(25,434)	(23,082)
Management and administration	(29,636)	(24,403)	(22,899)
Finance costs	(8,506)	(4,078)	—
Other expenses	(6,830)	(4,195)	(952)
Total expenses from continuing operations	(131,404)	(109,039)	(95,446)
Loss before income tax	(96,244)	(75,530)	(60,650)
Income tax expense	—	(4)	(1,470)
Loss attributable to the owners of Mesoblast Limited	(96,244)	(75,534)	(62,120)
Losses per share from continuing operations attributable to the ordinary equity holders of Mesoblast Limited:	**Cents**	**Cents**	**Cents**
Basic—losses per share(1)	(29.99)	(23.65)	(21.02)
Diluted—losses per share(1)	(29.99)	(23.65)	(21.02)

(1) Please refer to Note 20 to our consolidated financial statements included elsewhere in this prospectus for a calculation of basic and diluted losses per share.

	As of June 30,	
	Actual	As adjusted(1)
	US$ 2015	US$ 2015
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	110,701	161,631
Total current assets	122,460	173,390
Total assets	781,766	832,696
Total current liabilities	48,407	48,407
Total liabilities	313,779	313,779
Total equity	467,987	518,917

(1) The unaudited as adjusted consolidated balance sheet data has been adjusted to reflect the issuance and sale of 37,398,085 ordinary shares in the form of ADSs by us in this offering and our receipt of the estimated net proceeds from such issuance and sale in this offering, each based on our initial public offering price of US$8.00 per ADS, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

You should carefully consider the risks described below and all other information contained in this prospectus 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 prospectus 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 prospectus.

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. As of June 30, 2015, we had a comprehensive loss of US$122.0 million. Our net loss for the year ended June 30, 2015 was US$96.2 million. As of June 30, 2015, we have an accumulated deficit of US$264.0 million since our inception. We do not know whether or when we will become profitable. To date, we have not generated any revenues from the sale of products. 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 potential licensing revenue from sales of TEMCELL 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 FDA, the European Medicines Agency, or the EMA, or other regulatory agencies, domestic or foreign, to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Even if this offering is successful, we will 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, 2015, our cash and cash equivalents were US$110.7 million. We are in the process of finalizing our financial closing and reporting process for the first quarter ended September 30, 2015. We reported that we had approximately US$77.8 million in cash and cash equivalents as of September 30, 2015. This number is unaudited and does not present all information necessary for an understanding of our financial condition as of September 30, 2015 and our results of operations for the three months ended September 30, 2015. PricewaterhouseCoopers has not audited, reviewed, compiled or performed any procedures with respect to these results and does not express an opinion or any other form of assurance with respect thereto. We anticipate making a public announcement of our results of operations for the first quarter ended September 30, 2015 on or about December 15, 2015. 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, even if this offering is successful, 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 CHF), MPC-06-ID (CLBP), MSC-100-IV (aGVHD) and MPC-300-IV (inflammatory conditions) product candidates;
- initiate and advance our product candidates into larger and more expensive clinical studies, including a Phase 3 clinical trial for our MPC-25-Osteo (spinal fusion) product candidate;
- 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. 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.

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

Our product candidates are based on our novel 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.

We have not commercially marketed, distributed or sold any products. The success of our business depends on our ability to develop and commercialize our lead product candidates. We have concentrated our product research and development efforts on our 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 never obtained regulatory approval for a product. 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 collaborator may be prevented or delayed in obtaining marketing approval for our product candidates.

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

- delays in raising, or inability to raise, sufficient capital to fund the planned trials;
- delays 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, or CROs, and clinical trial sites;
- delays in obtaining required Institutional Review Board, or 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, or cGCP, or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays caused by 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 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 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;
- different standards 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, or 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, MSC-100-IV, which will focus on steroid-refractory aGVHD, and MPC-CBE, which will focus on bone marrow transplants after high dose chemotherapy. 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 frequently and may continue to change in the future. For example, in November 2014, Japan's parliament enacted new legislation to promote the safe and accelerated development of treatments using stem cells. The new Pharmaceuticals, Medical Devices and Other Therapeutic Products Act, or PMD Act, establishes a framework for expedited approval in Japan for certain regenerative medical products. As this is a new regulation, it is not clear yet what impact it will have on the operation of our business. 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, or 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 for use in 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.

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 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, including both federal and state requirements in the United States. 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, or 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;
- 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;
- product seizure or detention, or refusal to permit the import or export of products; and
- 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, or 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. We may in the future seek fast track designation for 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 a patient population of fewer than 200,000 in the United States, or 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. In the European Union, or 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 this or other product candidates in other indications or in other jurisdictions, such as for MSC-100-IV in the EU, 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, in any event, 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. In his proposed budget for fiscal years 2014 and 2015, President Obama proposed to cut this 12-year period of exclusivity down to seven years. The President has also proposed to prohibit additional periods of exclusivity due to minor changes in product formulations, a practice often referred to as "evergreening." 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 Our Strategic Alliances

We are substantially dependent on the expertise of Teva and JCR to develop and commercialize our product candidates in certain indications. If we fail to maintain our current strategic relationships with Teva and JCR, our business, commercialization prospects and financial condition may be materially adversely affected.

We have entered into agreements with Cephalon, Inc. (a wholly owned subsidiary of Teva), or Cephalon, and JCR, under which Teva and JCR are responsible for certain development and commercialization activities related to the respective product candidates. Teva is responsible for Phase 3 trials, and for the commercialization (excluding manufacturing) of certain of our stem cell product candidates in specified indications, namely in the cardiovascular, central nervous system and bone marrow transplant fields. Currently, we are collaborating with Teva, and Teva has commenced a Phase 3 trial for our MPC-150-IM product candidate for CHF. JCR is responsible for the development and commercialization of TEMCELL for the treatment of aGVHD in the Japanese market. The prospects for these product candidates to be successfully developed and commercialized depend on the expertise and financial strength of Teva and JCR.

Our collaborations with Teva or JCR may not be successful, and we may not realize the expected benefits from such collaborations, due to a number of important factors, including but not limited to the following:

- Teva or JCR may terminate their agreement with us as described below prior to completing development or commercialization of our product candidates, in whole or in part, adversely impacting our potential approval and revenue from licensed products;
- the timing and amount of any payments we may receive under these agreements will depend on, among other things, the efforts, allocation of resources, and successful commercialization of the relevant product candidates by Teva or JCR, as applicable, under our agreements;
- the timing and amounts of expense reimbursement that we may receive are uncertain; or
- Teva or JCR may change the focus of their development or commercialization efforts or pursue or emphasize higher-priority programs.

In particular, with the exception of the cardiovascular field, in which Teva has committed to conduct and fund the Phase 3 clinical trial in CHF at least through the first interim analysis, Teva has the right to terminate their agreement with us upon advance notice to us. JCR has the right to terminate their agreement with us upon advance notice to us.

A failure by Teva or JCR to successfully develop our product candidates which are covered by the collaboration, or commercialize such, or the termination of our agreement with Teva or JCR, as applicable, may have a material adverse effect on our business, results of operations and financial condition.

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 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. For example, in April 2015, we entered into an agreement with Alpine Investment Company III, LLC, a member of the Celgene Corporation Group, or Celgene, under which Celgene purchased 15.3 million of our ordinary shares for US$45 million and received a six-month right of first refusal with respect to our product candidates for the prevention and treatment of aGVHD, certain oncologic diseases, inflammatory bowel diseases, and organ transplant rejection. On October 16, 2015, we announced that we have agreed with Celgene to extend Celgene's right of first refusal for an additional six months. 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 and we are in the process of establishing a new manufacturing facility and processes for clinical supply for our MSC product candidates. 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 MPC product candidates in our manufacturing facilities, owned by Lonza Walkersville, Inc. and Lonza Bioscience Singapore Pte. Ltd., collectively referred to as Lonza. With respect to MSCs, successful clinical production of MSCs was established prior to our acquisition of the MSC assets. We are now establishing MSC production in a Lonza facility in Singapore. 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, or 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 foreign 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 under our relationship with Teva or otherwise.

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. For example, under our collaboration with Teva, we are obligated to supply our product candidates subject to that collaboration at our expense. In return, we are paid a transfer price equal to an escalating double-digit percentage of Teva's net sales price for our product candidates. 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-IC, the collagen sponge used in spinal fusion, 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, or FBS. This material comes from limited sources, and as a result is expensive. As a result, 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 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 for cell count, viability and appearance. 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 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; and
- the effectiveness of our, and our collaborators', sales and marketing efforts.

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. Examples of

potential competitors for our Tier 1 products include, but are not limited to, Novartis Pharmaceuticals and Servier Laboratories for CHF; Johnson & Johnson, Pfizer, Inc. and ISTO Technologies for CLBP; Amgen Inc., Pfizer, Inc. and Johnson & Johnson for aGVHD; and NephroGenex, Inc. and AbbVie Inc. for diabetic nephropathy. Many of our potential competitors, potentially including the aforementioned, 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, or 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.

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, where our licensee, JCR is awaiting a decision on price reimbursement from Japanese regulators, 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 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, evidenced by JCR receiving full approval for the first "allogeneic" cell-based product in Japan, 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.

Certain of our research and product development focuses on treatments for small patient populations, including orphan or niche markets. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with 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 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. 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, or the 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.

Recent 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 affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has and continues to develop and implement regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act. 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, 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 recent 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 will be a listed company in the United States following the completion of this offering, 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 in 2013, which we are still working to integrate into our business. 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, 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 Australian corporate taxation. As of June 30, 2015, our cumulative operating losses have a potential tax benefit of $69.9 million at local tax rates. 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. 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 which may increase our available cash flow. We currently project to benefit from these incentives in future taxable years. 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. If these incentives are revoked or modified 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, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or 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, as amended, the ACA, 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, or 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.

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, or 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.

Risks Related to Ownership of Our ADSs, Our Trading Market and This Offering

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

The market price of the ADSs may be highly volatile and subject to wide fluctuations. In addition, the trading volume of the ADSs may fluctuate and cause significant price variations to occur. If the market price of the ADSs declines significantly, you may be unable to resell your ADSs at or above the offering price, if at all. We cannot assure you that the market price of the ADSs will not fluctuate or significantly decline in the future.

Some specific factors that could negatively affect the price of the 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 stocks; and
- conditions in the U.S. or Australian financial markets or changes in general economic conditions.

An active trading market for the ADSs may not develop in the United States and the trading price for our ordinary shares may fluctuate significantly.

Our ADSs began trading on the over-the-counter market in 2005. Since trading began on this market, our ADSs have not traded on many days and the highest trading volume recorded in a single day was 24,000 ADSs. If an active public market in the United States for the ADSs does not develop after this offering, the market price and liquidity of the ADSs may be materially and adversely affected. While we have received approval for the listing of the ADSs on the NASDAQ Global Select Market, a liquid public market in the United States for the ADSs may not develop or be sustained after this offering. The initial public offering price for the ADSs will be determined by negotiation among us and the underwriters, and the price at which the ADSs are traded after this offering may decline below the initial public offering price, which means you may experience a decrease in the value of your ADSs regardless of our operating performance or prospects. 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. Investors purchasing the ADSs in this offering will suffer immediate and substantial dilution.

The public offering price for the ADSs will be substantially higher than the net tangible book value per share of our outstanding ordinary shares immediately after this offering. If you purchase ADSs in this offering, you will incur substantial and immediate dilution in the net tangible book value of your investment. Net tangible book value per ordinary share represents the amount of total tangible assets less total liabilities, divided by the number of ordinary shares, respectively, then outstanding. To the extent that performance rights and options that are currently outstanding are exercised or converted, there will be further dilution in your investment. We may also issue additional ordinary shares, performance rights, options and other securities in the future that may result in further dilution of your ordinary shares. See "Dilution" for a calculation of the extent to which your investment will be diluted.

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

Following this offering and after the ADSs are listed on the NASDAQ Global Select Market, our ordinary shares will continue to be 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.

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 Singapore dollars, U.S. dollars and Australian dollars. Approximately 64% of our cash and cash equivalents as of June 30, 2015 were denominated in U.S. dollars and 36% 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. To the extent that we need to convert U.S. dollars we

receive from our initial public offering into Australian dollars for our operations, appreciation of the Australian dollar against the U.S. dollar would have an adverse effect on the Australian dollar amount we would receive from the conversion. Consequently, 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.

Future sales of our ordinary shares or ADSs, or the perception that such sales may occur, could depress the price of our ADSs.

After the completion of this offering, we expect to have 374,395,814 ordinary shares outstanding, including the shares underlying the ADSs we are selling in this offering, almost all of which may be resold in the public market immediately after this offering. We, all of our directors, our chief executive officer, our chief financial officer and Cephalon, Inc. have signed lock-up agreements for a period of 180 days following the date of this prospectus, subject to extension in the case of an earnings release, material news or a material event relating to us and we have agreed with the underwriters that we will not release the lock-up on the shares owned by Celgene prior to its expiration in April 2016. See "Underwriting."

The underwriters may, in their sole discretion and without notice, release all or any portion of the ordinary shares subject to lock-up agreements. As restrictions on resale end, the market price of our ADSs could drop significantly if the holders of these ordinary shares sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our ordinary shares, ADSs or other securities.

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, or 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, or 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.

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 establish and 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, or the Sarbanes-Oxley Act, requires that, beginning with our annual report for the year ending June 30, 2017, 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. Although Section 404(b) of the Sarbanes-Oxley Act requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal controls over financial reporting, we have opted to rely on the exemptions provided to us by virtue of being a foreign private issuer, and consequently will not be required to comply with SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act until we file our second annual report with the SEC.

Our first Section 404(a) assessment will take place beginning with our annual report for the year ending June 30, 2017. As of the date of this filing, we have not 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. Specifically, we have limited accounting personnel to enable effective segregation of duties to allow for appropriate monitoring of financial reporting matters and internal control over financial reporting. Consequently we have determined there is a material weakness in the internal control over financial reporting. This material weakness did not result in material adjustments to the financial statements, however there is a reasonable possibility that a material misstatement of

the annual financial statements would not have been prevented or detected on a timely basis due to the failure to design and implement appropriate segregation of duty controls.

In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal controls over financial reporting, we will need to expend significant resources and provide significant management oversight. We have commenced the process of reviewing and improving our internal controls over financial reporting for compliance with Section 404(a) of the Sarbanes-Oxley Act. We have made efforts to improve our internal controls and accounting policies and procedures, including hiring new accounting personnel and engaging external temporary resources. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If either we are unable to conclude that we have effective internal controls over financial reporting or, at the appropriate time, 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 will 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 be required to devote substantial time to new compliance initiatives.

As a company whose ADSs will be publicly traded in the United States, we will 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 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 will 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.

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.

You 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.

We may be or become classified as a passive foreign investment company, which could result in adverse U.S. federal income tax consequences to U.S. holders of our ADSs or ordinary shares.

Based on our business projections and the anticipated composition of our income and assets for the current and future years, we do not expect that we will be a "passive foreign investment company," or PFIC, for the taxable year ending June 30, 2016. 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. 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. 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 this offering. 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 or any future taxable year. If we are treated as a PFIC for any taxable year, then U.S. holders

generally would be subject to adverse U.S. federal income tax consequences (regardless of whether we continued to be a PFIC) unless a U.S. holder makes a "mark-to-market" election or a "Qualified Electing Fund" election. We intend to provide U.S. holders with the information necessary to make and maintain a "Qualified Electing Fund" election if we are treated as a PFIC for any taxable year. See "Taxation—Default PFIC Rules."

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 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 ADSs will likely only occur if our ADS price appreciates. There is no guarantee that our ADSs will appreciate in value after this offering or even maintain the price at which you purchase the ADSs. You may not realize a return on your investment in our ADSs and you may even lose your entire investment in our ADSs.

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.

Our management has discretion as to the use of the net proceeds from this offering, and such use may not produce income or increase the market price of our ADSs.

We intend to use the net proceeds of this offering to among other things, support commercial manufacturing requirements for our Tier 1 and Tier 2 product candidates, fund the costs of our ongoing clinical Tier 1 programs and for general and administrative expenses, working capital and other general corporate purposes, and general research and development expenses. However, our management will have considerable discretion in the

application of the net proceeds received by us. For more information, see "Use of Proceeds." You will not have the opportunity, as part of your investment decision, to assess whether proceeds are being used appropriately. You must rely on the judgment of our management regarding the application of the net proceeds from this offering. The net proceeds may be used for corporate purposes that do not improve our efforts to maintain profitability or increase our ADS price. Moreover, the net proceeds from this offering may be placed in investments that do not produce income or that lose value.

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.

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

Your 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 senior management and the experts named in this prospectus.

Several of our officers, directors and the experts named in this prospectus 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 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.

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, or 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. See "Description of Share Capital—Change of Control."

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. You should carefully review the summary of these matters set forth under the section entitled, "Description of Share Capital" as well as our Constitution, which is included as an exhibit to this registration statement to which this prospectus forms a part, prior to investing in the ADSs.

FORWARD-LOOKING STATEMENTS

This prospectus 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;
- our use of proceeds from this offering;
- 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 prospectus 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 prospectus 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 prospectus also contains third-party data relating to the biopharmaceutical market in Australia 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 prospectus relate only to events or information as of the date on which the statements are made in this prospectus. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

We anticipate that the net proceeds from this offering will be approximately US$50.9 million, or approximately US$59.3 million if the underwriters exercise their option to purchase additional shares in full, at our initial public offering price of US$8.00 per ADS, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our financial flexibility, create a U.S. public market for our ADSs in addition to our existing Australian public market thereby enhancing our access to public equity markets.

We currently intend to use the net proceeds from this offering as follows:

- approximately $21.0 million to support commercial manufacturing requirements for our Tier 1 and Tier 2 product candidates, through development and implementation of our proprietary manufacturing processes and expansion of our manufacturing capabilities and resources, including, but not limited to, finalizing the development and implementation of the 3D bioreactor-based manufacturing of our products, finalizing the development of our proprietary FBS-free media, and expansion of the scale of manufacturing to support commercial production of our products at our collaborator Lonza;
- approximately $22.0 million to fund the costs of ongoing Clinical Tier 1 Programs, including approximately $5.0 million for our Phase 3 clinical trial of MSC-100-IV for the treatment of aGVHD; approximately $8.0 million for our Phase 3 clinical trial of MPC-06-ID for the treatment of CLBP; and approximately $9.0 million for our Phase 2b/3 clinical trial of MPC-300-IV for the treatment of biologic-refractory rheumatoid arthritis and diabetic kidney disease; and
- approximately $7.9 million for general and administrative expenses (including personnel-related costs), working capital and other general corporate purposes, including funding general corporate overhead and the costs of operating as a public company, and general research and development expenses associated with our technology platform and earlier stage product development costs.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. Due to the many variables inherent to the development of product candidates, we cannot currently predict the stage of development we expect the net proceeds of this offering to achieve for our clinical trials and product candidates.

As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. We may find it necessary or advisable to use the net proceeds from this offering for other purposes, and we will have broad discretion in the application of net proceeds. Although we may use a portion of the net proceeds of this offering for the acquisition or licensing, as the case may be, of additional technologies, other assets or businesses, we have no current understandings, agreements or commitments to do so.

We are in the process of finalizing our financial closing and reporting process for the first quarter ended September 30, 2015. We reported that we had approximately US$77.8 million in cash and cash equivalents as of September 30, 2015. This number is unaudited and does not present all information necessary for an understanding of our financial condition as of September 30, 2015 and our results of operations for the three months ended September 30, 2015. PricewaterhouseCoopers has not audited, reviewed, compiled or performed any procedures with respect to these results and does not express an opinion or any other form of assurance with respect thereto. We anticipate making a public announcement of our results of operations for the first quarter ended September 30, 2015 on or about December 15, 2015. Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

PRICE RANGE OF OUR ORDINARY SHARES

The following tables present, for the periods indicated, the high and low market prices for our ordinary shares reported on the ASX under the symbol "MSB" for the periods indicated in Australian dollars and U.S. dollars. U.S. dollar per ordinary share amounts have been translated into U.S. dollars at a rate of A$1.00 to US$0.7103 based on the foreign exchange rates published by the Reserve Bank of Australia on October 29, 2015.

	Price per ordinary share (A$)		Price per ordinary share (US$)	
Period	**High**	**Low**	**High**	**Low**
Annual:				
Fiscal Year Ended 30 June, 2011	9.95	1.72	7.07	1.22
Fiscal Year Ended 30 June, 2012	10.04	5.44	7.13	3.86
Fiscal Year Ended 30 June, 2013	7.49	4.22	5.32	3.00
Fiscal Year Ended 30 June, 2014	6.80	4.18	4.83	2.97
Fiscal Year Ended 30 June, 2015	5.88	3.17	4.18	2.25
Quarterly				
Fiscal Year ended June 30, 2013:				
First quarter ended September 30, 2012	7.37	5.52	5.23	3.92
Second quarter ended December 31, 2012	6.88	4.22	4.89	3.00
Third quarter ended March 31, 2013	7.49	5.17	5.32	3.67
Fourth quarter ended June 30, 2013	6.43	5.14	4.57	3.65
Fiscal Year ended June 30, 2014:				
First quarter ended September 30, 2013	6.22	5.19	4.42	3.69
Second quarter ended December 31, 2013	6.80	5.37	4.83	3.81
Third quarter ended March 31, 2014	6.13	5.15	4.35	3.66
Fourth quarter ended June 30, 2014	5.45	4.18	3.87	2.97
Fiscal Year ended June 30, 2015:				
First quarter ended September 30, 2014	5.88	3.91	4.18	2.78
Second quarter ended December 31, 2014	4.59	3.64	3.26	2.59
Third quarter ended March 31, 2014	4.60	3.50	3.27	2.49
Fourth quarter ended June 30, 2015	4.16	3.17	2.95	2.25
Fiscal Year ended June 30, 2016:				
First quarter ended September 30, 2015	4.06	2.91	2.88	2.07
Most Recent Six Months:				
Month ended April 30, 2015	4.07	3.17	2.89	2.25
Month ended May 31, 2015	3.97	3.58	2.82	2.54
Month ended June 30, 2015	4.16	3.65	2.95	2.59
Month ended July 31, 2015	4.06	3.71	2.88	2.64
Month ended August 31, 2015	4.02	2.91	2.86	2.07
Month ended September 30, 2015	3.78	3.10	2.68	2.20

DIVIDENDS AND 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 "Description of American Depositary Shares—Ordinary Share Dividends and Other Distributions."

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2015. Our capitalization is presented on:

- an actual basis; and
- an as adjusted basis to reflect the issuance and sale of 37,398,085 ordinary shares in the form of ADSs by us in this offering and our receipt of the estimated net proceeds from such issuance and sale in this offering, each based on our initial public offering price of US$8.00 per ADS, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table in conjunction with our consolidated financial statements and the related notes thereto included elsewhere in this prospectus and the information under "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of June 30, 2015	
	Actual	As adjusted
	US$	US$
	(in thousands)	
Cash and cash equivalents	110,701	161,631
Liabilities:		
Non-current liabilities	265,372	265,372
Current liabilities	48,407	48,407
Total liabilities	313,779	313,779
Equity:		
Issued capital (336,997,729 ordinary shares (no par value) issued as of June 30, 2015; 374,395,814 ordinary shares (no par value), pro forma as adjusted)	709,191	760,121
Reserves	22,756	22,756
Accumulated losses	(263,960)	(263,960)
Total equity	467,987	518,917
Total capitalization	781,766	832,696

The table above excludes:

- the exercise of employee options outstanding at June 30, 2015 to purchase 18,369,078 fully paid ordinary shares issuable upon at a weighted average exercise price of A$5.25 per ordinary share.

The table above includes:

- an aggregate of 3,500,000 ordinary shares at a weighted average exercise price of A$6.78 held in trust as part of our LFSP.

DILUTION

As of June 30, 2015, our net tangible book value was US$(0.54) per ordinary share and US$(2.70) per ADS. Net tangible book value per ordinary share represents total tangible assets minus total liabilities divided by the total number of ordinary shares outstanding. Dilution is determined by subtracting net tangible book value per ordinary share from our initial public offering price per ordinary share.

Without taking into account any other changes in net tangible book value after June 30, 2015, other than giving effect to our sale of 7,479,617 ADSs in the offering at our initial public offering price of US$8.00 per ADS and after deducting underwriting discounts and commissions and estimated expenses of the offering payable by us, the net tangible book value per ordinary share would increase to US$(0.35) per ordinary share (or US$(1.75) per ADS), or US$(0.32) per ordinary share (or US$(1.60) per ADS) if the underwriters' over-allotment option is exercised in full. This represents an immediate increase in net tangible book value of US$0.19 per ordinary share (or US$0.95 per ADS) to our existing shareholders (or US$0.22 per ordinary share (or US$1.10 per ADS) if the underwriters' over-allotment option is exercised in full), and an immediate dilution of US$1.95 per ordinary share (or US$9.75 per ADS) to purchasers of ADSs in the offering (or US$1.92 per ordinary share (or US$9.60 per ADS), if the underwriters' over-allotment option is exercised in full).

The following table illustrates this dilution on a per ordinary share basis and a per ADS basis assuming that all ADSs are exchanged for ordinary shares:

	Per ordinary share	Per ADS
Initial public offering price	1.60	8.00
Net tangible book value as of June 30, 2015	(0.54)	(2.70)
Increase attributable to the sale of the ADSs	0.19	0.95
Pro forma as adjusted net tangible book value after this offering	(0.35)	(1.75)
Dilution to purchasers of ADSs in the offering	1.95	9.75

The following table summarizes, on a pro forma basis as of June 30, 2015, the differences between our existing shareholders as of such date and the new investors with respect to the number of ordinary shares purchased from us, the total consideration paid and the average price per ordinary shares paid at our initial public offering price of US$8.00 per ADS before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Ordinary shares purchased		Total consideration		Average price per ordinary share	Average price per ADS
	Number	Percent	Amount	Percent		
	(in millions, except percent and share data)					
Existing shareholders	336,997,729	90.0%	US$709.2	92.2%	US$2.10	US$10.52
Purchasers of ADSs	37,398,085	10.0%	US$ 59.8	7.8%	US$1.60	US$ 8.00
Total	374,395,814	100.0%	US$769.0	100.0%		

A US$1.00 increase (decrease) in the assumed initial public offering price of US$8.00 per ADS would increase (decrease) total consideration paid by new investors, total consideration paid by all shareholders and the average price per ADS paid by existing shareholders by US$7.5 million, US $7.5 million and US$Nil, respectively, assuming no change in the number of ADSs sold by us as set forth on the cover page of this prospectus and without deducting underwriting discounts and commissions.

The number of ordinary shares to be outstanding following the offering is based on 336,997,729 fully paid ordinary shares outstanding at June 30, 2015, and excludes:

- the exercise of employee options outstanding at June 30, 2015 to purchase 18,369,078 fully paid ordinary shares issuable upon at a weighted average exercise price of A$5.25 per ordinary share;

and includes:

- an aggregate of 3,500,000 ordinary shares at a weighted average exercise price of A$6.78 held in trust as part of our LFSP.

To the extent all options outstanding at June 30, 2015 are exercised and all LFSP outstanding at June 30, 2015 are exercised and paid, the number of ordinary shares to be outstanding immediately following the offering would increase to 392,764,892 and the total consideration would increase to US$861.6 million. Our existing shareholders would hold 355,366,807 ordinary shares or 90.5% of the number of ordinary shares outstanding immediately following the offering for which they paid US$801.8 million or 93.1% of the total consideration. The purchasers of ADSs in the offering would hold 9.5% of the number of ordinary shares outstanding immediately following the offering and would experience immediate dilution in net tangible book value of US$1.70 per ordinary share (or US$8.50 per ADS). In addition, we may in the future elect to raise additional capital as a result of favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of such securities could result in further dilution to our shareholders. See “Risk Factors—Risks related to Ownership of Our ADSs, Our Trading Market and This Offering—An active trading market for the ADSs may not develop in the United States and the trading price for our ordinary shares may fluctuate significantly.”

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data presented below as of and for the years ended June 30, 2015, 2014 and 2013 has been derived from our audited consolidated financial statements included elsewhere in this prospectus. The following selected consolidated financial data presented below as of and for the years ended June 30, 2012 and 2011 has been derived from our consolidated financial statements not included elsewhere in this prospectus. Historical results are not necessarily indicative of results to be expected in the future. The summary consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes thereto included elsewhere in this prospectus.

Our financial statements are presented in U.S. dollars and have been prepared in accordance with IFRS.

	For the Year Ended June 30,				
	US$ 2015	US$ 2014	US$ 2013	US$ 2012	US$ 2011
	(in thousands, except per share information)				
Consolidated Income Statement Data:					
Revenue:					
Commercialization revenue	15,004	15,004	18,685	28,771	15,513
Milestone revenue	2,000	—	—	—	—
Interest revenue	2,757	8,386	10,616	10,821	4,739
Revenue from continuing operations	19,761	23,390	29,301	39,592	20,252
Other income:					
Foreign exchange gains	10,478	—	—	—	—
Research & development tax incentive	4,418	7,775	5,495	—	—
Other revenue	407	—	—	—	—
Rental income	96	—	—	—	—
Release of excess provision for services	—	2,344	—	—	—
Government grant revenue	—	—	—	134	—
Gain on revaluation of investment to fair value	—	—	—	—	88,357
Share of losses of equity accounted associates written back on acquisition	—	—	—	—	14,306
Other income	15,399	10,119	5,495	134	102,662
Total revenue from continuing operations	35,160	33,509	34,796	39,726	122,914
Expenses from continuing operations:					
Research and development	(62,649)	(50,929)	(48,513)	(37,840)	(12,359)
Manufacturing commercialization	(23,783)	(25,434)	(23,082)	(25,295)	(3,483)
Management and administration	(29,636)	(24,403)	(22,899)	(24,816)	(12,199)
Finance costs	(8,506)	(4,078)	—	—	(15)
Share of losses of equity accounted associates	—	—	—	—	(1,557)
Other expenses	(6,830)	(4,195)	(952)	(1,067)	—
Total expenses from continuing operations	(131,404)	(109,039)	(95,446)	(89,018)	(29,614)
(Loss)/Profit before income tax	(96,244)	(75,530)	(60,650)	(49,292)	93,301
Income tax expense	—	(4)	(1,470)	(22,782)	(1,692)
(Loss)/Profit attributable to the owners of Mesoblast Limited	(96,244)	(75,534)	(62,120)	(72,074)	91,609
(Losses)/Earnings per share from continuing operations attributable to the ordinary equity holders:	**Cents**	**Cents**	**Cents**	**Cents**	**Cents**
Basic—(losses)/earnings per share(1)	(29.99)	(23.65)	(21.02)	(25.48)	42.26
Diluted—(losses)/earnings per share(1)	(29.99)	(23.65)	(21.02)	(25.48)	40.22

(1) Please refer to Note 20 to our consolidated financial statements and the related notes thereto included elsewhere in this prospectus for a calculation of basic and diluted losses per share.

	As of June 30,				
	US$ 2015	US$ 2014	US$ 2013	US$ 2012	US$ 2011
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	110,701	185,003	292,449	209,518	278,946
Total current assets	122,460	191,931	307,789	220,716	281,348
Total assets	781,766	847,153	819,663	734,247	808,828
Total current liabilities	48,407	40,199	46,921	45,344	32,634
Total liabilities	313,779	308,594	235,071	246,223	262,180
Equity:					
Issued capital 336,997,729, 321,640,094, 316,468,901, 285,835,106, and 280,345,258 ordinary shares (no par value) issued as of June 30, 2015, 2014, 2013, 2012 and 2011, respectively)	709,191	662,722	642,378	467,760	459,771
Reserves	22,756	43,553	34,396	50,326	44,864
Accumulated loss	(263,960)	(167,716)	(92,182)	(30,062)	42,012
Total equity	467,987	538,559	584,592	488,024	546,648

	Year Ended June 30,				
	US$ 2015	US$ 2014	US$ 2013	US$ 2012	US$ 2011
	(in thousands)				
Cash Flow Data:					
Net cash (outflows)/inflows in operating activities	(101,036)	(74,906)	(55,746)	(64,575)	112,247
Net cash (outflows)/inflows in investing activities	(5,064)	(38,202)	(4,801)	(4,355)	1,946
Net cash inflows by financing activities	45,852	2,196	174,415	4,980	127,488

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with "Selected Consolidated Financial Data," and our consolidated financial statements included elsewhere in this prospectus. We present our consolidated financial statements in U.S. dollars and in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board, or IFRS.

For us and our subsidiaries that use a functional currency that is not U.S. dollars, the assets and liabilities have been translated at the closing exchange rate, while the income and expenses have been translated at the exchange rate at the transaction date. The resulting exchange differences are recognized in our consolidated statement of comprehensive income. See note 21(d) in the notes to our consolidated financial statements and the related notes thereto included elsewhere in this prospectus for more information.

The statements in this discussion regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and other non-historical statements are forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in "Risk Factors" and "Forward-Looking Statements" in this prospectus. Our actual results may differ materially from those contained in or implied by any forward-looking statements.

Our fiscal year ends each year on June 30. Reference to a year relates to the fiscal year, ended in June 30 of the year indicated, rather than the calendar year, unless indicated by a specific date. "FY2015" refers to the year ended June 30, 2015, "FY2014" refers to the year ended June 30, 2014 and "FY2013" refers to the year ended June 30, 2013.

Overview

We are a global leader in the field of regenerative medicine. We have leveraged our proprietary technology platform, which is based on specialized cells known as MLCs to establish what we believe to be the most advanced regenerative medicine product portfolio in the industry. We have what we believe to be an extensive safety profile for our product candidates, with over 1,340 patients treated. Based on outcomes in Phase 2 trials across multiple indications, we now have five MLC product candidates that are in active Phase 3 trials or are Phase 3-ready.

In September 2015, our licensee JCR Pharmaceuticals Co. Ltd, or JCR, received full approval for the first "allogeneic" cell-based product in Japan, meaning a product containing cells from a single donor expanded and used in many unrelated patients. We believe we are well positioned to have the first industrially-manufactured allogeneic stem cell product approved in the United States.

We have incurred net losses during most of our fiscal periods since our inception. For the year ended June 30, 2015, we had a comprehensive loss of US$122.0 million.

Mergers and Acquisitions

On October 11, 2013, we acquired all of Osiris Therapeutics, Inc.'s business and assets related to culture-expanded mesenchymal stem cells, or MSCs, for US$126.9 million in cash, securities and contingent consideration. See Note 12 to our consolidated financial statements and the related notes thereto included elsewhere in this prospectus for more information regarding the acquisition consideration. We believe the acquisition is complementary to our business in its nature with many commercial and strategic benefits. The acquired assets included:

- MSC-100-IV for aGVHD;
- broadened late-stage clinical programs in other strategic areas of focus, including Crohn's disease and acute myocardial infarction, or AMI;
- long-term clinical data from approximately 1,000 patients treated with MSCs, including safety, efficacy and repeat dosing data; and
- MSC-focused intellectual property and know-how.

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 have never generated any sales revenues ourselves or royalty revenues from sales of our products by our collaborators and we may never be profitable.

We expect our future capital requirements will continue as we:

- continue the research and clinical development of our product candidates, including our MPC-150-IM (Class II-IV CHF), MPC-06-ID (CLBP), MSC-100-IV (aGVHD) and MPC-300-IV (inflammatory conditions) product candidates;
- initiate and advance our product candidates into larger and more expensive clinical studies, including a Phase 3 clinical trial for our MPC-25-Osteo (spinal fusion) product candidate;
- 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.

We expect that our Research and development and Management and administration expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our products and to continue as a going concern. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates.

Revenue from Continuing Operations

We derive revenue from continuing operations as follows:

Commercialization Revenue. Commercialization revenue refers to upfront and milestone payments received under development and commercialization agreements.

In the year ended June 30, 2015, we recognized as revenue US$2.0 million from JCR for the completion of a milestone pertaining to the filing of TEMCELL for regulatory approval 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, 2011, we received upfront payments of US$130.0 million under a development and commercialization agreement, or the DCA, with Teva. See "Business—Our Strategic Alliances—Teva/ Cephalon, Inc.—Cardiovascular, Neurological and Bone Marrow Collaboration."

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 management cannot readily estimate the costs required to complete the development program pursuant to the DCA, management has concluded that the revenue is earned over the estimated development period of MPC-150-IM. Therefore, revenues are being recognized on straight line basis over the development period of this product candidate. If we were to shorten or lengthen the development period then we would be required to change the amount of revenue we recognize.

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

Other Income. Other income primarily comprises tax incentive payments from the Australian Government's Innovation Australia Research and Development Tax Incentive Plan for research and development activities conducted in Australia in relation to our qualifying research that meets the regulatory criteria. 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. Up to June 30, 2013, the rate of the refundable tax offset was 45% and after that date the rate is 43.5%.

Other income also includes unrealized foreign exchange gains on U.S. dollar deposits plus realized gains on any foreign currency payments to our suppliers. Foreign exchange gains of US$10.5 million and US$Nil were recorded for the year ended June 30, 2015 and June 30, 2014, respectively. For the year ended June 30, 2014, the net result of foreign exchange movements for us was a US$4.0 million loss, and this loss was recorded in Other expenses. Other income also includes rental income from subleasing our office space.

Expenses from Continuing Operations

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 comprise all external expenditure on our Research and development programs such as fees paid to Contract Research Organizations, or 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 consist 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); and
- intellectual property support costs comprise payments to our patent attorneys to progress patent applications and all costs of renewing of our granted patents.

Our R&D 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.

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.

Finance Costs. Finance costs relate to the unwinding of contingent consideration items pertaining to the MSC assets of Osiris. We did not have any borrowings outstanding as of June 30, 2015.

Other Expenses. Other expenses comprise remeasurement of contingent consideration and foreign exchange losses.

Remeasurement of contingent consideration pertains to the acquisition of assets from Osiris. This remeasurement expense is as a result of changes to the key assumptions of the contingent consideration valuation such as market population, market penetration, product pricing and developmental timelines. The net result of changes to the key assumptions was an increase in the valuation of contingent consideration payable to Osiris on royalties from sales and on the achievement of certain pre-determined milestones as we draw closer to potential product approval. Remeasurement of contingent consideration was US$6.8 million for the year ended June 30, 2015 compared with US$0.2 million for the year ended June 30, 2014.

Other expenses comprise unrealized foreign exchange losses on our U.S. dollar deposits plus realized losses on any foreign currency payments to our suppliers. Any unrealized foreign exchange gains on our U.S. dollar deposits or realized gains on any foreign currency payments to our suppliers would be included in Other Income. Foreign exchange losses was $Nil for the year ended June 30, 2015 compared with US$4.0 million for the year ended June 30, 2014. The US$4.0 million foreign exchange losses recognized in the year ended June 30, 2014 was due to movements in exchange rates as the A$ appreciated against the US$ during the year ended June 30, 2014.

Results of Operations

Comparison of Our Results for the Year Ended June 30, 2015 with the Year Ended June 30, 2014

The following table summarizes our results of operations for the years ended June 30, 2015 and 2014, together with the changes in those items in dollars and as a percentage.

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2015	US$ 2014		
	(in thousands except per share information)			
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	15,004	15,004	—	0%
Milestone Revenue	2,000	—	2,000	NM
Interest Revenue	2,757	8,386	(5,629)	(67%)
Revenue from continuing operations	19,761	23,390	(3,629)	(16%)
Other Income:				
Foreign exchange gains	10,478	—	10,478	NM
Research & development tax incentive	4,418	7,775	(3,357)	(43%)
Other revenue	407	—	407	NM
Rental income	96	—	96	NM
Release of excess provision for services	—	2,344	(2,344)	(100%)
Other Income	15,399	10,119	5,280	52%
Total Revenue from continuing operations	35,160	33,509	1,651	5%
Expenses from continuing operations:				
Research & development	(62,649)	(50,929)	(11,720)	23%
Manufacturing commercialization	(23,783)	(25,434)	1,651	(6%)
Management and administration	(29,636)	(24,403)	(5,233)	21%
Finance costs	(8,506)	(4,078)	(4,428)	109%
Other expenses	(6,830)	(4,195)	(2,635)	63%
Total expenses from continuing operations	(131,404)	(109,039)	(22,365)	21%
Loss before income tax	(96,244)	(75,530)	(20,714)	27%
Income tax expense	—	(4)	4	(100%)
Loss attributable to the owners of Mesoblast Limited	(96,244)	(75,534)	(20,710)	27%
Losses per share from continuing operations attributable to the ordinary equity holders:				
Basic—losses per share(1)	(29.99)	(23.65)	(6.34)	27%
Diluted—losses per share(1)	(29.99)	(23.65)	(6.34)	27%

* NM = not meaningful.

(1) Please refer to Note 20 to our consolidated financial statements and the related notes thereto included elsewhere in this prospectus for a calculation of basic and diluted losses per share.

Revenue from Continuing Operations

Revenues were US$19.8 million for the year ended June 30, 2015, compared with US$23.4 million for the year ended June 30, 2014, a decrease of US$3.6 million. The following table shows the movement within revenue for the year ended June 30, 2015 and 2014, together with the changes in those items.

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2015	US$ 2014		
	(in thousands)			
Revenue:				
Commercialization revenue	15,004	15,004	—	0%
Milestone revenue	2,000	—	2,000	NM
Interest revenue	2,757	8,386	(5,629)	(67%)
Revenue from continuing operations	19,761	23,390	(3,629)	(16%)

There has been no change in commercialization revenue in the year ended June 30, 2015 when compared with the year ended June 30, 2014.

The US$2.0 million increase in milestone revenue has been recognized upon our partner, JCR, achieving a substantive milestone being the filing for marketing approval of MSC product TEMCELL in Japan. We have no further performance obligations in relation to this revenue.

The US$5.6 million decrease in interest revenue from the year ended June 30, 2015 compared with June 30, 2014 is driven by a decline in cash reserves and since we held a higher proportion of cash reserves in U.S. dollars compared with Australian dollars in the year ended June 30, 2015, when compared with the year ended June 30, 2014. These changes in cash reserve holdings decreased revenue as yields on U.S. dollar cash deposits are lower than yields on Australian dollar cash deposits. We increased the proportion of cash reserves held in U.S. dollars to reduce currency risk. Currency risk is minimized by matching cash reserves for each currency with the expected rate of spend of each currency.

Other Income

Other income was US$15.4 million for the year ended June 30, 2015, compared with US$10.1 million for the year ended June 30, 2014, an increase of US$5.3 million. The following table shows movements within other income for the year ended June 30, 2015 and 2014, together with the changes in those items:

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2015	US$ 2014		
	(in thousands)			
Other income:				
Foreign exchange gains	10,478	—	10,478	NM
Research & development tax incentive income	4,418	7,775	(3,357)	(43%)
Other revenue	407	—	407	NM
Rental income	96	—	96	NM
Release of excess provision for services	—	2,344	(2,344)	(100%)
Other income	15,399	10,119	5,280	52%

US$10.5 million of foreign exchange gains were recognized for the year ended June 30, 2015, compared with US$Nil for the year ended June 30, 2014. For the year ended June 30, 2015 we recognized a foreign exchange gain due to movements in exchange rates as the A$ depreciated against the US$ during the year ended June 30, 2015. Within our Australian company, we hold certain cash and term deposit balances in US$, resulting in foreign exchange gains on the revaluation of foreign currency denominated monetary assets and liabilities into our functional currency of A$. As of June 30, 2015, in addition to our A$ cash reserves, we held a total of US$70.6 million of our cash reserves in US$. For the year ended June 30, 2014 the net result of foreign exchange movements was a US$4.0 million loss and this loss was recorded in Other expenses.

Research & development tax incentive income decreased by US$3.4 million from US$7.8 million for the year ended June 30, 2014 to US$4.4 million for the year ended June 30, 2015. 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 offset available to us based on available information at the time. This estimate is also reviewed by external tax advisors. Of the US$4.4 million Research and development tax incentive recorded in other income for the year ended June 30, 2015, US$0.5 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, 2014.

Other revenue increased by US$0.4 million for the year ended June 30, 2015 as we recognized a one-off insurance recovery. Rental income increased by US$0.1 million for the year ended June 30, 2015 as we entered into a sublease agreement for a portion of the Melbourne office space in December 2014.

For the year ended June 30, 2014, other income includes a one off release of a provision of services that has been settled during the year. The settlement was US$2.3 million less than the recorded provision.

Research and Development

Research and development expenses were US$62.6 million for the year ended June 30, 2015, compared with US$50.9 million for the year ended June 30, 2014, an increase of US$11.7 million. The US$11.7 million net increase in Research and development expenses reflects the continued clinical development of the MSC assets acquired from Osiris, the clinical advancement of our MPC programs as they transition to late-stage development, and our continued investment in resources to execute our clinical programs.

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2015	US$ 2014		
	(in thousands)			
Research and Development expense:				
Third party costs	30,612	19,114	11,498	60%
Product support costs	29,361	29,202	159	1%
Intellectual property support costs	2,676	2,613	63	2%
Research and development expenses	62,649	50,929	11,720	23%

Third party costs, which consist of all external expenditure on our research and development programs, have increased by US$11.5 million for the year ended June 30, 2015 compared with the year ended June 30, 2014.

Within this US$11.5 million, there was a US$12.8 million increase in third party costs for the period relates to the advancement of our Tier 1 products, and in particular the clinical programs for CLBP and aGVHD. Third party costs for the MPC-150-IM product for CHF are predominantly funded by our collaborators, Teva (advanced heart failure) and the NIH (end-stage heart failure with mechanical support). This increase in Tier 1 costs was offset by a US$1.3 million decrease in third party costs for our Tier 2 and pipeline products for the year ended June 30, 2015, compared with the year ended June 30, 2014 as the Tier 1 programs were prioritized ahead of Tier 2 clinical trials and pipeline activities.

Product support costs, which consist primarily of salaries and related overhead expenses for personnel in research and development functions, have increased by US$0.2 million for the year ended June 30, 2015 compared with the year ended June 30, 2014. This increase is across all programs primarily reflecting the costs of the additional resources required to run the MSC-100-IV product late-stage programs acquired in October 2013, together with increased development costs for our MPC-06-ID product for CLBP as we progress to Phase 3 clinical development. In the year ended June 30, 2015, full time equivalents in our research and development group increased by 18 from 64 for the year ended June 30, 2014 to 82 for the year ended June 30, 2015.

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, which have risen by US$0.1 million in the year ended June 30, 2015 compared with the year ended June 30, 2014. This increase reflects the purchase of MSC patent families from Osiris.

We expect that our Research and development expenses will modestly increase as we continue to fund our programs through to market. We believe these increases will likely include increased costs paid to CROs and increased costs related to laboratory supplies.

Manufacturing Commercialization expenses

Manufacturing commercialization expenses were US$23.8 million for the year ended June 30, 2015, compared with US$25.4 million for the year ended June 30, 2014, a decrease of US$1.6 million.

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2015	US$ 2014		
	(in thousands)			
Manufacturing Commercialization expenses:				
MSC-based manufacturing commercialization	11,388	3,330	8,058	242%
MPC-based manufacturing commercialization	8,855	18,583	(9,728)	(52%)
Manufacturing commercialization support expenses	3,540	3,521	19	1%
Manufacturing Commercialization expenses	23,783	25,434	(1,651)	(6%)

MSC-based manufacturing commercialization expenses, which consist of fees paid to our contract manufacturing organizations and laboratory supplies used in manufacturing commercialization of our MSC-based products, increased by US$8.1 million for the year ended June 30, 2015 compared to the year ended June 30, 2014. This increase reflects a full year of expenditure, whereas in the prior year, expenditure only commenced after the acquisition of the MSC assets in October 2013. In the year ended June 30, 2015, expenses related to production and the manufacturing development process in anticipation of upcoming clinical and commercial production requirements were incurred.

This abovementioned increase was offset by a decrease of US$9.7 million on MPC-based manufacturing commercialization expenses. MPC-based manufacturing commercialization expenses consist of fees paid to our contract manufacturing organizations and laboratory supplies used in manufacturing commercialization of our MPC-based products. The decrease in these expenses was due to a reduction in clinical grade production for MPC-based products as we focused on establishing the manufacturing process for our acquired MSC-based products.

Manufacturing commercialization support expenses, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, increased by US$0.1 million for the year ended June 30, 2015, compared with the year ended June 30, 2014, as full time equivalents increased in this group by 2 from 8 for the year ended June 30, 2014 to 10 in the year ended June 30, 2015.

In addition to the above, we continue to invest cash to (i) further establish our manufacturing processes in Lonza's Singapore facility, (ii) produce MPCs and MSCs to support clinical trial activities, (iii) optimize clinical production processes, including transitioning away from bovine serum, and (iv) continue bioreactor manufacturing development.

We expect that our Manufacturing commercialization expenses will remain relatively consistent as we continue to develop our manufacturing processes in anticipation of commercial and clinical demands, and further invest in bioreactor manufacturing development.

Management and administration

Management and administration expenses were US$29.6 million for the year ended June 30, 2015, compared with US$24.4 million for the year ended June 30, 2014, an increase of US$5.2 million.

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2015	US$ 2014		
	(in thousands)			
Management and administration:				
Labor and associated expenses	14,309	12,573	1,736	14%
Corporate overheads	9,803	7,530	2,273	30%
Legal and professional fees	5,524	4,300	1,224	28%
Management and administration	29,636	24,403	5,233	21%

Labor and associated expenses increased by US$1.7 million from US$12.6 million for the year ended June 30, 2014, to US$14.3 million for the year ended June 30, 2015, as a result of increased full time equivalents during the year ended June 30, 2015. Corporate overhead increased by US$2.3 million from US$7.5 million for the year ended June 30, 2014, to US$9.8 million for the year ended June 30, 2015, primarily as a result of increased full time equivalents, in this group, and to a lesser extent due to rent and depreciation expenses. Full time equivalents increased by 5 from 22 for the year ended June 30, 2014 to 27 for the year ended June 30, 2015.

Legal and professional fees increased by US$1.2 million from US$4.3 million for the year ended June 30, 2014 to US$5.5 million for the year ended June 30, 2015, on intellectual property management and associated legal, taxation and accounting compliance advice.

We expect that our Management and administration expenses will remain relatively consistent as our product candidates develop towards commercialization.

Finance Costs

Finance costs increased by US$4.4 million from US$4.1 million for the year ended June 30, 2014 to $8.5 million for the year ended June 30, 2015, primarily due to a full 12 months impact in the year ended June 30, 2015, compared with a partial year impact in the year ended June 30, 2014. The Finance costs in the years ended June 30, 2015 and June 30, 2014 represent the change in fair value of contingent consideration financial liabilities pertaining to the acquired MSC assets of Osiris. These costs relate to the unwinding of the risk adjusted discount as the time period shortens between the valuation date and the potential settlement date of the 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.

We expect that these Finance costs will continue to increase as we continue to develop towards commercialization of the MSC-based products as the discounting of the contingent consideration unwinds with time and/or achievement of milestones.

Other Expenses

Other expenses were US$6.8 million for the year ended June 30, 2015 compared with US$4.2 million for the year ended June 30, 2014, an increase of US$2.6 million.

Remeasurement of contingent consideration was US$6.8 million for the year ended June 30, 2015 compared with US$0.2 million for the year ended June 30, 2014, an increase of US$6.6 million. The US$6.8 million remeasurement of contingent consideration recognized in the year ended June 30, 2015 pertains to the acquisition of assets from Osiris. This remeasurement expense is as a result of changes to the key assumptions of the contingent consideration valuation such as market population, market penetration, product pricing and developmental timelines. The net result of changes to the key assumptions was an increase in the valuation of

contingent consideration payable to Osiris on royalties from sales and on the achievement of certain pre-determined milestones as we draw closer to potential product approval.

Foreign exchange losses was $Nil for the year ended June 30, 2015, compared with US$4.0 million for the year ended June 30, 2014, a decrease of US$4.0 million. The US$4.0 million foreign exchange losses recognized in the year ended June 30, 2014 was due to movements in exchange rates as the A$ appreciated against the US$ during the year ended June 30, 2014.

We expect that Other expenses will continue to fluctuate as a result of the movement in the Australian dollar to U.S. dollar exchange rate going forward.

Net Operating Losses

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2015	US$ 2014		
	(in thousands)			
Loss before income tax	96,244	75,530	20,714	27%
Income tax expense	—	(4)	(4)	(100%)
Loss after income tax	**96,244**	**75,534**	**20,710**	**27%**

Loss after income tax was US$96.2 million for the year ended June 30, 2015 compared with US$75.5 million for the year ended June 30, 2014, an increase of US$20.7 million. This increase reflects the continued clinical development of our programs as they transition to late-stage development and our continued investment in resources to execute our clinical programs.

As of June 30, 2015 and 2014, our cumulative operating losses have a potential tax benefit of US$69.9 million and US$57.0 million at local tax rates, 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, 2014 with the Year Ended June 30, 2013

The following table summarizes our results of operations for the years ended June 30, 2014 and 2013, together with the changes in those items in dollars and as a percentage:

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2014	US$ 2013		
	(in thousands except per share information)			
Consolidated Income Statement Data:				
Revenue:				
Commercialization revenue	15,004	18,685	(3,681)	(20%)
Interest Revenue	8,386	10,616	(2,230)	(21%)
Revenue from continuing operations	23,390	29,301	(5,911)	(20%)
Other Income:				
Research & development tax incentive	7,775	5,495	2,280	41%
Release of excess provision for services	2,344	—	2,344	NM
Other Income	10,119	5,495	4,624	84%
Total Revenue from continuing operations	33,509	34,796	(1,287)	(4%)
Expenses from continuing operations:				
Research & development	(50,929)	(48,513)	(2,416)	5%
Manufacturing commercialization	(25,434)	(23,082)	(2,352)	10%
Management and administration	(24,403)	(22,899)	(1,504)	7%
Finance costs	(4,078)	—	(4,078)	NM
Other expenses	(4,195)	(952)	(3,243)	341%
Total expenses from continuing operations	(109,039)	(95,446)	(13,593)	14%
Loss before income tax	(75,530)	(60,650)	(14,880)	25%
Income tax expense	(4)	(1,470)	1,466	(100%)
Loss attributable to the owners of Mesoblast Limited	(75,534)	(62,120)	(13,414)	22%
Losses per share from continuing operations attributable to the ordinary equity holders:				
Basic—losses per share(1)	(23.65)	(21.02)	(2.63)	13%
Diluted—losses per share(1)	(23.65)	(21.02)	(2.63)	13%

* NM = not meaningful

(1) Please refer to Note 20 to our consolidated financial statements and the related notes thereto included elsewhere in this prospectus for a calculation of basic and diluted losses per share.

Revenue from Continuing Operations

Revenues were US$23.4 million for the year ended June 30, 2014, compared to US$29.3 million for the year ended June 30, 2013, a decrease of US$5.9 million. The following table shows movement within revenue for the years ended June 30, 2014 and 2013, together with the changes in those items:

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2014	US$ 2013		
	(in thousands)			
Revenue:				
Commercialization revenue	15,004	18,685	(3,681)	(20%)
Interest revenue	8,386	10,616	(2,230)	(21%)
Revenue from continuing operations	23,390	29,301	(5,911)	(20%)

The US$3.7 million decrease in commercialization revenue from FY2014 to FY2013 is based on the increase in the estimated development period of the upfront milestone payment from Cephalon, Inc. (a wholly-owned subsidiary of Teva), or Cephalon.

The US$2.2 million decrease in interest revenue is due to a decline in market interest rates over the period, and a move towards investing in shorter term deposits. We have also held a higher ratio of U.S. dollars to Australian dollars in FY2014 compared with FY2013, which decreased revenue as yields on U.S. dollar bank accounts were lower than yields on Australian dollar bank accounts.

Other Income

Other income was US$10.1 million for the year ended June 30, 2014, compared to US$5.5 million for the year ended June 30, 2013, an increase of US$4.6 million. The following table shows movement within other income for the years ended June 30, 2014 and 2013, together with the changes in those items:

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2014	US$ 2013		
	(in thousands)			
Other income:				
Research and development tax incentive scheme	7,775	5,495	2,280	41%
Release of excess provision of services	2,344	—	2,344	NM
Other income	10,119	5,495	4,624	84%

* NM = not meaningful

The US$2.3 million increase in research and development tax incentive, from US$5.5 million for the year ended June 30, 2013 to US$7.8 million for the year ended June 30, 2014, is due to additional research and development tax incentive income being received in FY2014 for qualifying research and development. The change in estimate was due to the fact that research and development tax incentives were estimated based on the level of qualifying research and development expenditures made during the year, which was higher than estimated.

Of the US$7.8 million research and development tax incentive recorded in other income for the year ended June 30, 2014, US$3.1 million relates to the incentive we received from the Australian Government for the year ended June 30, 2013 following a change in the original assessment. The change in estimate was due to the fact that research and development tax incentives were dependent on the level of qualifying research and development expenditure and as such we estimated amounts we deemed probable of collection in the year ended June 30, 2013 until we had better information related to the implementation of the relevant regulations with the assistance of our tax advisors.

Other income includes a one-time release of a provision regarding a dispute with a service provider that has been settled during FY2014. A provision of US$7.8 million had been taken up in 2010 and, on finalization of this matter in April 2014, the excess provision of US$2.3 million was recorded as other income.

Research and Development

	For the Year Ended June 30,		Dollar Change	% Change
	US$ 2014	US$ 2013		
	(in thousands)			
Research and Development expenses:				
Third party costs	19,114	21,040	(1,926)	(9%)
Product support costs	29,202	25,952	3,250	13%
Intellectual property support costs	2,613	1,521	1,092	72%
Total Research and Development expenses	50,929	48,513	2,416	5%

Research and development expenses were US$50.9 million for the year ended June 30, 2014, compared to US$48.5 million for the year ended June 30, 2013, an increase of US$2.4 million. The US$2.4 million net increase in Research and development expenses reflects the clinical development of the MSC assets acquired

from Osiris, the clinical advancement of our MPC programs as they transition to late-stage development, and our continued investment in resources to execute our late-stage clinical programs.

Third party costs have decreased by US$1.9 million in FY2014 compared with FY2013. Within this US$1.9 million decrease, third party costs for our Tier 1 products increased US$0.9 million. This increase for the year relates to the advancement of our Tier 1 products, and in particular the clinical programs for aGVHD and Crohn's Disease. These programs form part of our MSC-100-IV product portfolio acquired from Osiris. The third party costs for our Tier 1 product MPC-06-ID for the treatment of CLBP are consistent with the prior year, while Third party costs for the MPC-150-IM product for CHF are predominantly funded by our collaborators, Teva (advanced heart failure) and the NIH (end-stage heart failure with mechanical support).

Tier 2 and pipeline product third party costs in FY2014 decreased by US$2.8 million compared to FY2013. FY2013 included significant expenditures on site start-up and study initiation costs of our MPC-25-IC product candidate that were not repeated in FY2014. This was offset by increased expenditures on patient recruitment, which we undertook during FY2014 for our three programs within the MPC-300-IV product (which has since been elevated to Tier 1), in particular, the treatment of glucose control in patients with type 2 diabetes, diabetic nephropathy and rheumatoid arthritis.

Product support costs in FY2014 across all programs increased by US$3.3 million compared to FY2013, primarily reflecting the costs of the additional resources required to run the MSC-100-IV product late-stage programs acquired during FY2014, together with increased development costs for our MPC-06-ID product for chronic low back pain as we progress to Phase 3 clinical development.

Also included in Research and development expenses are intellectual property support costs, which have risen in FY2014 by US$1.1 million compared with FY2013. This reflects the purchase of MSC patent families from Osiris.

Manufacturing Commercialization

Manufacturing commercialization expenses were US$25.4 million for the year ended June 30, 2014, compared with US$23.1 million for the year ended June 30, 2013, an increase of US$2.3 million. US$3.3 million of the US$2.3 million net increase in Manufacturing commercialization expenses is attributable to production of MSC-100-IV. This also includes the purchase of MSC master cell banks from Lonza, as well as review and transfer of the MSC production process from the Lonza facility in the U.S. to the facility in Singapore.

In support of MSC production and our ongoing transition from research grade production to commercial production, the manufacturing department has grown in employees from six as of June 30, 2013 to twelve as of June 30, 2014, resulting in a US$1.2 million increase in salaries, share-based compensation and associated expenses for FY2014.

The increases mentioned above were offset by a decrease US$2.2 million on MPC-based manufacturing commercialization expenses. MPC-based manufacturing commercialization expenses consist of fees paid to our contract manufacturing organizations and laboratory supplies used in manufacturing commercialization of our MPC-based products. The decrease in these expenses was due to a reduction in clinical grade production for MPC-based products as we focused on establishing the manufacturing process for our MSC-based products.

We are also continuing to invest in bioreactor manufacturing processes. During FY2013, this development work was partially funded by a third party supplier in anticipation of future work being carried out with such supplier, hence our expenses were relatively low compared to the work performed. During FY2014 the funding from the third party supplier decreased and the arrangement will be completed by December 2014.

Management and Administration Expenses

Management and administration expenses were US$24.4 million for the year ended June 30, 2014, compared with US$22.9 million for the year ended June 30, 2013, an increase of US$1.5 million. The US$1.5 million increase in Management and administration expenses is primarily the result of additional costs incurred as a result of the increased head count of 116 staff at June 30, 2014 compared with 75 at June 30, 2013, such as rent costs due to increased office space, information technology support and general compliance.

Finance Costs

Finance costs of US$4.1 million in FY2014 represent the change in fair value of contingent consideration financial liabilities pertaining to the acquisition of the MSC assets of Osiris. These costs relate to the unwinding of the risk adjusted discount as the time period shortens between the valuation date and the potential settlement date of the 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.

Other Expenses

Other expenses were US$4.2 million for the year ended June 30, 2014, compared with US$1.0 million for the year ended June 30, 2013, an increase of US$3.2 million. US$3.0 million of this increase is attributable to foreign exchange losses on revaluation of foreign currency denominated monetary assets and liabilities, mostly due to the appreciation of the Australian dollar relative to the U.S. dollar during the second half of FY2014. US$0.2 million of this increase is due to remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris.

Net Operating Losses

As of June 30, 2014, our cumulative operating losses have a potential tax benefit of US$57.0 million at local tax rates 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.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses from operations since our inception in 2004 and as of June 30, 2015, we had an accumulated deficit of US$264.0 million. We expect that the net proceeds from this offering and our existing cash and cash equivalents will be sufficient to fund our current operations through at least the next twelve months. We expect that our Research and development and Management and administration expenses will continue to increase and, as a result, 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.

From our inception through June 30, 2015, we have funded our operations principally with US$709.2 million in proceeds received from the sale of our ordinary shares including receipt of US$45.0 million upon signing of a stock placement agreement with Celgene Corporation during the financial year ended June 30, 2015. In April 2015, we entered into an agreement with Celgene Corporation, under which Celgene purchased 15.3 million of our ordinary shares for US$45 million and received a six-month right of first refusal with respect to our product candidates for the prevention and treatment of aGVHD, certain oncologic diseases, inflammatory bowel diseases, and organ transplant rejection. On October 16, 2015, we announced that we have agreed with Celgene to extend Celgene's right of first refusal for an additional six months. In addition to proceeds received from the sale of ordinary shares, we received US$130.0 million upon signing a development and commercialization agreement with Cephalon during the financial year ended June 30, 2011. As of June 30, 2015 we had cash and cash equivalents of US$110.7 million. Cash in excess of immediate requirements is invested primarily in money market funds in order to maintain liquidity and preserve capital.

We are in the process of finalizing our financial closing and reporting process for the first quarter ended September 30, 2015. We reported that we had approximately US$77.8 million in cash and cash equivalents as of September 30, 2015. This number is unaudited and does not present all information necessary for an understanding of our financial condition as of September 30, 2015 and our results of operations for the three months ended September 30, 2015. PricewaterhouseCoopers has not audited, reviewed, compiled or performed

any procedures with respect to these results and does not express an opinion or any other form of assurance with respect thereto. We anticipate making a public announcement of our results of operations for the first quarter ended September 30, 2015 on or about December 15, 2015.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods set forth below:

	For the Year Ended June 30,		
	US$ 2015	**US$ 2014**	**US$ 2013**
		(in thousands)	
Cash Flow Data:			
Net cash (outflows) in operating activities	(101,036)	(74,906)	(55,746)
Net cash (outflows) in investing activities	(5,064)	(38,202)	(4,801)
Net cash inflows in financing activities	45,852	2,196	174,415
Net (decrease)/increase in cash and cash equivalents	(60,248)	(110,912)	113,868

Cash Flows from Operating Activities. Net cash outflows for operating activities were US$101.0 million for the year ended June 30, 2015, compared with US$74.9 million for the year ended June 30, 2014, an increase of US$26.1 million. Outflows increased by US$9.4 million due to an increase in payments to suppliers and employees for the advancement of our clinical programs and manufacturing commercialization costs for our MPC and MSC programs, as they transition to late-stage development and our continued investment in associated resources. Outflows increased by US$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. Inflows decreased as interest receipts reduced by US$8.5 million due to a decline in cash reserves and because we held a higher proportion of cash reserves in US$ compared with A$ in the year ended June 30, 2015, when compared with the year ended June 30, 2014. Inflows decreased as receipts for the research and development tax incentive were US$4.3 million lower due to the receipts of both the FY2012 and FY2013 claims occurring in the year ended June 30, 2014, while only the FY2014 claim was received in the year ended June 30, 2015.

Inflows increased by US$2.0 million due the receipt of a US$2.0 million milestone payment. The milestone was received upon the filing for marketing approval in Japan for MSC product TEMCELL. Inflows decreased by US$2.3 million due to a tax refund of overpaid US taxes in the year ended June 30, 2014 which was not repeated. Other inflows increased by US$0.5 million due to increased rent income received and receipts from other operating revenue items which included receipts from insurance settlements.

Net cash outflows for operating activities were US$74.9 million for the year ended June 30, 2014, compared with US$55.7 million for the year ended June 30, 2013, an increase of US$19.2 million. Outflows increased by US$27.7 million due to an increase in payments to suppliers and employees for the advancement of our clinical programs and manufacturing commercialization costs for our MPC and MSC programs, as they transition to late-stage development and our continued investment in associated resources. Inflows increased by US$8.7 million due to the both the FY2012 and FY2013 research and development tax incentive claims being receipted in the year ended June 30, 2014, while there was no claim received in the year ended June 30, 2013. Receipts from other operating revenue items reduced inflows by US$0.2 million.

Cash Flows from Investing Activities. Net cash outflows for investing activities were US$5.1 million for the year ended June 30, 2015, compared with US$38.2 million for the year ended June 30, 2014, a decrease of US$33.1 million. US$31.3 million of the decrease was due to a reduction in payments for business combination. US$1.9 million decrease due to payments for deposits on commencement of leases in the year June 30, 2014 for our New York and Melbourne offices.

Net cash outflows for investing activities were US$38.2 million for the year ended June 30, 2014, compared with US$4.8 million for the year ended June 30, 2013, an increase of US$33.4 million. US$31.8 million of the increase was due to an increase in payments for business combinations. US$1.6 million of the increase was due to payments for deposits on commencement of leases in the year ended June 30, 2014 for our New York and Melbourne offices.

Cash Flows from Financing Activities. Net cash inflows for financing activities were US$45.9 million for the year ended June 30, 2015, compared with US$2.2 million for the year ended June 30, 2014, an increase of US$43.7 million. Celgene Corporation, a global biopharmaceutical company engaged in the development and commercialization of innovative therapies for the treatment of cancer and immune-inflammatory related diseases, bought Mesoblast stock for US$45.0 million in a private placement. This increase was offset by a US$0.9 million decrease in receipts from the exercise of the employee share options. US$0.4 million decrease was due to an increase in transaction costs arising on share issues.

Net cash inflows for financing activities were US$2.2 million for the year ended June 30, 2014, compared with US$174.4 million for the year ended June 30, 2013, a decrease of US$172.2 million. US$169.4 million of the decrease relates to the placement of shares in the year ended June 30, 2013. Mesoblast made a share placement of 26,970,979 shares to institutional and sophisticated investors in March 2013 at a price of A$6.30. Net of transaction costs this placement raised US$169.4 million. Additionally receipts from the exercise of the employee share options increase of US$2.8 million in the year ended June 30, 2014.

Operating Capital Requirements

To date, we have not generated any revenues from our product sales. We do not know when, or if, we will generate any revenue from our product sales. 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. 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 incident 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. Upon the completion of this offering, we expect to incur additional costs associated with operating as a U.S. public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We expect that our Research and development and Management and administration expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our ordinary shares. If we incur 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.

Contractual Obligations and Commitments

Lease Commitments: Group as Lessee

We lease various offices under non-cancellable operating leases expiring within 1 to 6 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.

(US$ 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	14,116	2,592	7,448	4,076	—
Total Commitments	14,116	2,592	7,448	4,076	—

Lease commitments include amounts in AUD and Singapore dollars which have been translated to USD as of June 30, 2015 using foreign exchange rates published by the Reserve Bank of Australia.

Sub-Lease Commitments: Group 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:

(US$ 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 sub-lease	712	161	483	67	—
Total commitments	712	161	483	67	—

Sub-lease commitment includes amounts in AUD which have been translated to USD as of June 30, 2015 foreign using exchange rate published by the Reserve Bank of Australia.

In addition to the obligations in the table above, as of June 30, 2015 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 US$0.25 million on completion of each Phase 3 (human) clinical trial and US$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. These payments are not included in the table above due to the uncertainty of their timing.

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, 2015 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, 2015.

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 above, as defined under SEC rules.

Certain Differences Between IFRS and GAAP

IFRS differs from GAAP in certain respects. Management has not assessed the materiality of differences between IFRS and GAAP. Our significant accounting policies are described in Note 21 to our consolidated financial statements and the related notes thereto included elsewhere in this prospectus.

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.

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 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. We ensure that sufficient funds are available, in at-call accounts, to meet our cash flow requirements.

Foreign Currency Exchange Risk

We have certain clinical, regulatory and manufacturing activities which are being conducted internationally. Our primary currency exposure is the clinical trial activities which are occurring in the United States of America and manufacturing activities occurring in Singapore. As a result of these activities, we have foreign currency amounts owing primarily in U.S. dollars and Singapore dollars, as well as some smaller amounts in various other currencies. 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 the trend of the relevant foreign currency rates, or FX rates, to the Australian dollar and making decisions as to the levels to hold in each currency by assessing our future activities which will likely be incurred in those currencies. We engage professional advice when considering forward foreign exchange contracts.

As of June 30, 2015, we held 64% of our cash in U.S. dollars, and 36% in Australian dollars. We have entered these financial derivative contracts to take advantage of enhanced interest rates yields available on Australian dollar deposit when compared to U.S. dollar deposits. We sell U.S. dollars and buy Australian dollars from the bank at a pre-agreed FX rate and agree to then sell those Australian dollars and buy U.S. dollars from the bank on maturity also at a pre-agreed rate. As these FX rates are known at the outset, there is no currency risk.

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 appearing elsewhere in this prospectus, 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 Revenue

Development and commercialization 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, or the DCA, with Cephalon, Inc., now a wholly-owned subsidiary of Teva, which allows 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 US$130 million as a non-refundable up-front payment.

Further payments of up to US$1.7 billion may be received on achievement of certain regulatory milestones with respect to each product Teva may choose to commercialize. The milestones are based on approvals of the product for treatment in various territories. We would also be entitled to receive future royalty payments for supply of commercialized product as a percentage of net sales. No such payments have been received.

We analyzed the arrangement to determine whether the components which include a license, participation in a joint steering committee, a development program, and manufacturing and supply services, can be separated or must be treated as a single transaction in assessing revenue recognition criteria.

As our obligations in relation to the joint steering committee and the development program are substantive and cannot be readily separated from the initial license transfer, we have not accounted for the license as a separate component. As management cannot readily estimate the costs required to complete the development program, due to significant uncertainties relating to success of the development program, revenue has been recognized on a straight line basis over the estimated development period of MPC-150-IM. If we were to shorten or lengthen the development period then we would be required to change the amount of revenue we recognize.

For the years ended June 30, 2015, 2014 and 2013 we recognized US$15.0 million, US$15.0 million and US$18.7 million of revenue, respectively, being the amortization of the initial payment over the estimated development program term. No revenue has been recognized for any future development milestones or royalties specified in the agreement as we cannot reliably estimate whether we would become entitled to such payments. We changed our estimate for the development period in the year ended June 30, 2013 following the approval of the program protocol and associated program timelines by the Joint Steering Committee.

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 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. With respect to the First JCR Field, we are 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 year ended June 30, 2015, we recognized US$2.0 million commercial milestone revenue upon our partner, JCR, filing for marketing approval of its MSC-based product TEMCELL in Japan, which is a substantive milestone. We have no further performance obligations in relation to this revenue. No milestone revenue was recognized during FY2014 and FY2013.

Government Grant Revenue

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 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 A$20 million. Eligible companies can receive a refundable tax offset for a percentage of their research and development spending. Up to June 30, 2013 the rate of the refundable tax offset was 45%, after that date the rate is 43.5%.

Our 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 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.

Business Combinations

We record business combinations in accordance with IFRS 3 *Business Combinations*.

IFRS 3 *Business Combinations* requires that the acquisition of business be accounted for under the acquisition method of accounting. The definition of a business in IFRS 3 *Business Combinations* is: a business consists of inputs and processes applied to those inputs that have the ability to create outputs.

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 business comprises the fair values of the assets transferred, the liabilities incurred and the equity interests issued by us. The consideration transferred also includes the fair value of any asset or liability resulting from a contingent consideration arrangement. 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.

The excess of the consideration transferred over the fair value of the net identifiable assets acquired is recorded as goodwill. If those amounts were to be less than the fair value of the net identifiable assets acquired and the measurement of all amounts has been reviewed, the difference would be recognized directly in the consolidated income statement 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 is determined based on required rates of returns of comparable companies (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.

In October 2013 we acquired the MSC business of Osiris. In accordance with the guidance in IFRS 3 *Business Combinations* management determined that, although no equity interests were acquired, the asset purchased in this acquisition did constitute a business under the definition.

In accordance with IFRS 3 *Business Combinations* the acquisition method of accounting was used to account for the business combination. An independent valuation expert provided the fair value of the consideration paid and assets transferred, the liabilities incurred and the equity interests issued by us.

The purchase agreement also included a component of contingent consideration which was made up of certain pre-determined milestone and royalties. At acquisition this contingent consideration was recognized as a financial liability at its fair value which was provided by an independent valuation expert. See Notes 5 and 12 of our consolidated financial statements and the related notes thereto included elsewhere in this prospectus for more information regarding the contingent consideration. This financial liability is subsequently remeasured to fair value with changes in fair value recognized in the consolidated income statement.

We recognized goodwill on acquisition which was the excess of the consideration transferred over the fair value of the net identifiable assets acquired.

An independent valuation expert calculated all valuations on the basis of fair value less costs to sell by using the income approach.

Goodwill

We have recognized goodwill as a result of two separate acquisitions. Goodwill of US$118.4 million was recognized on acquisition of Angioblast Systems Inc. in 2010 and US$13.9 million was recognized on the acquisition of assets from Osiris in 2013. In the year ended June 30, 2015, there was a US$2.1 million out of period adjustment to goodwill on finalization of the MSC business combination of Osiris. 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 on May 31. 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 elsewhere in this prospectus 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 US$387.0 million was recognized on the acquisition of Angioblast Systems Inc. in 2010 and US$126.7 million was recognized on the acquisition of assets from Osiris in 2013.

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 at May 31 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.

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.

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 elsewhere in this prospectus 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 valuation are continually reviewed by management and consideration is given as to whether there are indicators of impairment which would warrant impairment testing.

The impairment testing completed at May 31, 2015 showed the recoverable amount of our cash generating unit, including goodwill and in-process research and development, exceeded the carrying amounts, and therefore no impairment was identified.

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);
- 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.

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).

Our level 3 asset consists of an investment in unlisted equity securities in biotechnology sector. Level 3 assets were 100% of total assets measured at fair value as of June 30, 2015. There were no level 3 assets as of June 30, 2014 and 2013.

Our level 3 liabilities consist of a contingent consideration provision related to the acquisition of Osiris' MSC business. Level 3 liabilities were 100% and 99.6% of total liabilities measured at fair value as of June 30, 2015 and 2014. There were no level 3 liabilities as of June 30, 2013. 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:

Description	Fair value as of June 30, 2015	Fair value as of June 30, 2014	Valuation technique	Unobservable Inputs*	Range of inputs (weighted average) for the year ended June 30, 2015	Range of inputs (weighted average) for the year ended June 30, 2014	Relationship of unobservable inputs to fair value
Contingent consideration provision	91,890	81,247	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	2015: A change in the discount rate by 0.5% would increase/ decrease the fair value by 3%
							2014: A change in the discount rate by 0.5% would increase/ decrease the fair value by 3%
				Expected unit revenues	n/a	n/a	2015: A 10% increase in the price assumptions adopted would increase the fair value by 8%
							2014: A 10% increase in the price assumptions adopted would increase the fair value by 5%

* 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. We have had a history of net losses since inception, and as a result, we have not recognized our net deferred tax assets due to our plans to consolidate certain intellectual property assets and therefore taxable temporary differences will not be available to offset the deferred tax assets. If circumstances change and we determine that we will be able to realize some or all of these deferred tax assets in the future, we will record an adjustment for the recognition of deferred tax assets.

Currently, our pipeline is at various stages of development and our intangible intellectual property assets are held by a number of our entities across multiple jurisdictions. We are seeking to consolidate certain intellectual property assets and are currently contemplating the steps to achieve this objective.

As required under IFRS, we do not recognize the impact of any potential future corporate re-organizations to remeasure our deferred tax liabilities until they are in place. Our deferred tax liabilities are measured at the relevant rate in the relevant jurisdiction at each balance date. Any potential future changes arising from a re-organization could be material to our future operations.

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.

BUSINESS

Overview

We are a global leader in the field of regenerative medicine. We have leveraged our proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells, or MLCs, to establish what we believe to be the most advanced regenerative medicine product portfolio in the industry. We have what we believe to be an extensive safety profile for our product candidates, with over 1,340 patients treated. Based on outcomes in Phase 2 trials across multiple indications, we now have five MLC product candidates that are in active Phase 3 trials or are Phase 3-ready.

In September 2015, our licensee JCR Pharmaceuticals Co. Ltd, or JCR, received full approval for the first "allogeneic" cell-based product in Japan, meaning a product containing cells from a single donor expanded and used in many unrelated patients. We believe we are well positioned to have the first industrially-manufactured allogeneic stem cell product approved in the United States.

Our deep understanding of the fundamental mechanisms of action of MLCs and our proprietary manufacturing processes have been leveraged to create a portfolio of independent, non-interchangeable MLC-derived product candidates. Each of our product candidates has its own distinct technical characteristics, target indications, individual reimbursement strategy, separate commercialization potential, and unique partnering opportunities.

We have focused on significantly advanced stages of diseases where specific subpopulations of patients have high unmet medical needs, providing accelerated development pathway opportunities and the potential for attractive pricing. Our goal is to first gain broad acceptance of any approved products as treatment options for these severely ill patients, then expand the applications of such products over time to broader patient populations.

We expect a number of important clinical and commercial milestone events to occur over the next 12 to 24 months for our most advanced product candidates, including:

- By the end of 2015, we expect to announce 6 month results from the first cohort in the Phase 2 trial of our product candidate for RA. Results from the second cohort are expected during the first half of 2016. We believe positive results from this trial would support progression towards Phase 3 and potential partnering discussions.
- During the first quarter 2016, we expect that our licensee JCR will launch TEMCELL® Hs. Inj. (JR-031), or TEMCELL, its MSC-based product for aGVHD in Japan. Decisions by Japanese regulators on price reimbursement for JCR's product TEMCELL are pending. Under our agreement with JCR, we are entitled to receive milestone payments on product regulatory approvals, escalating double-digit royalties in the twenties and other payments at pre-defined thresholds of cumulative net sales.
- During the first quarter 2016, we expect to announce the outcome of the first interim analysis of safety and efficacy from the Phase 3 trial of our product candidate for advanced CHF. We expect the second interim analysis for futility, resizing and possible overwhelming efficacy to occur in the first quarter 2017. Phase 2b trail results for our product candidate for end-stage CHF are expected in middle 2017. This product candidate is partnered on a global basis with Teva Pharmaceutical Industries, Ltd., or Teva.
- During the third quarter 2016, we expect to announce top-line results from an interim analysis of a Phase 3 trial of our product candidate for aGVHD. This interim analysis may support a BLA filing by the end of 2016. We expect to complete recruitment of this Phase 3 trial in the fourth quarter 2016 and to have top-line results of the trial in the first quarter 2017.
- During the second half 2016, we expect to complete enrollment of the first Phase 3 trial for our product candidate for CLBP.

Proprietary Platform and Scalable Manufacturing

MLCs are present around blood vessels in all tissues, where they can respond to signals associated with tissue damage. This response includes the secretion of a variety of biomolecules that affect various reparative and immunomodulatory mechanisms responsible for maintaining tissue health. Understanding the mechanisms of action by which these biomolecules induce tissue restoration has broad applicability in treating diseases for which current standards of care are inadequate or for which no approved therapy currently exists. Our lead MLC product candidates have been developed through proprietary manufacturing processes to optimize expression of certain biomolecules. The expressed biomolecules are those implicated in the mechanisms of action by which the MLC product candidate is thought to modify outcomes for the target condition for which it is being developed.

MLCs have two additional distinct characteristics that, when combined with our proprietary manufacturing processes, enable allogeneic or "off-the-shelf" use of our product candidates. First, we have developed proprietary methods that enable the isolation of MLCs from healthy donors and their large-scale expansion while maintaining their ability to produce key biomolecules associated with tissue health and repair. In addition, unlike other categories of stem cells, 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. These characteristics allow us to produce large quantities of off-the-shelf MLC-based product candidates from a few donors for use in thousands of unrelated recipients, with consistent, well-defined therapeutic properties, batch-release criteria and established potency assays, all with accompanying manufacturing and distribution economies-of-scale.

We have developed multiple distinct product candidates derived from our MLC platform by applying an approach that we refer to as "Product-by-Process" in which we modify the manufacturing, formulation, dosage and route of administration for each product to optimize an MLC-derived product for a specific target condition. For example, products for treating systemic inflammatory or immunologic conditions are delivered intravenously, while products for tissue repair and regeneration are delivered locally, and differences in formulation give rise to distinct disc repair and spinal fusion product candidates. This allows for the development of independent, non-interchangeable products, each of which has distinct pricing and strategic partnering opportunities. We have also established what we believe to be a leading intellectual property position covering compositions, uses and methods of manufacturing of MLCs, which we believe provides us with substantial competitive advantages for the commercial development of regenerative medicine products.

Lead Product Candidates

We have prioritized our portfolio into tiers based on stage of development, largest market opportunities and anticipated time to market. 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. Additionally, we have a significant pipeline of earlier-stage programs.

We expect a number of important clinical milestone events to occur over the next 12 to 24 months for our most advanced product candidates in both Tier 1 and Tier 2. By the end of 2015, we expect to report data from our ongoing Phase 2 trial in patients with biologic-refractory rheumatoid arthritis. In 2016, we expect to report outcomes from two Phase 3 trials and a Phase 2 trial.

For each product candidate, we evaluate whether to pursue development and commercialization on our own or with a strategic collaborator who can provide the appropriate resources and expertise to maximize each opportunity. Teva is our global collaborator for the late-stage clinical development and commercialization of certain cardiovascular, central nervous system and bone marrow transplant fields, and is currently enrolling a Phase 3 program in patients with advanced CHF. JCR is our collaborator in Japan for the treatment of aGVHD.

A summary of our lead programs, their corresponding stage of development and our strategic collaboration status, are captured in the tables below.

Tier 1 Programs

Product Candidates	Programs	Collaborator/ Geographic Rights	Stage of Development	Anticipated Milestones
MPC-150-IM	Class II/III CHF	Teva (Global)	• Phase 2 trial completed • Phase 3 trial enrollment ongoing • Enrollment of the patients for first interim analysis completed	• Outcome of first Phase 3 interim analysis for safety and efficacy in first quarter 2016 • Second interim analysis for futility, resizing and possible overwhelming efficacy in first quarter 2017 • Phase 3 trial complete in 2018 with potential to accelerate based on second interim analysis
	End-stage CHF	Teva (Global)	• Phase 2a trial completed • Phase 2b trial ongoing, funded by the NIH	• Phase 2b trial results expected in middle 2017
MPC-06-ID	CLBP	Proprietary (Global)	• Phase 2 trial completed • Phase 3 trial enrollment ongoing	• Design being finalized for interim analysis in second half 2016 • Complete enrollment of first Phase 3 trial in second half 2016 • Phase 3 program complete in first half 2018
TEMCELL/ MSC-100-IV	Acute GVHD	JCR (Japan)	• JCR received full approval in September 2015	• Launch in Japan in first quarter 2016
	Acute steroid-refractory GVHD	Proprietary (Global, ex-Japan)	• Enrollment ongoing for U.S. pediatric Phase 3 trial	• U.S. Phase 3 pediatric trial top-line results from an interim analysis in third quarter 2016, positive results may support BLA filing by end of 2016 • Complete recruitment of Phase 3 trial in fourth quarter 2016 • Top-line results of Phase 3 trial in first quarter 2017
MPC-300-IV	Rheumatoid arthritis (biologic refractory)	Proprietary (Global)	• Phase 2 trial ongoing • First cohort enrollment completed • Second cohort enrolling	• 6 month data for first cohort by the end of 2015 • Second cohort results in first half 2016
	Diabetic kidney disease	Proprietary (Global)	• Phase 2 trial ongoing, enrollment completed	• Phase 2b/3 trial design ongoing

All time periods refer to calendar year periods.

Tier 2 Programs

Product Candidates	Programs	Collaborator/ Geographic Rights	Stage of Development/ Anticipated Milestones
MPC-25-IC	Acute cardiac ischemia	Teva (Global)	• Phase 2 trial ongoing
MPC-25-Osteo	Spinal fusion	Proprietary (Global)	• Phase 2 trial completed • Phase 3 trial design ongoing
MPC-CBE	Bone marrow transplantation (BMT)	Teva (Global)	• Phase 3 trial ongoing
MSC-100-IV	Crohn's disease (biologic refractory)	Proprietary (Global)	• Phase 3 trial ongoing

All time periods refer to calendar year periods.
For product registration purposes, Phase 3 programs may require more than one trial.

Our Competitive Strengths

We have a leadership position in regenerative medicine due to our MLC platform, broad portfolio of product candidates targeting attractive markets, stem cell manufacturing capabilities, intellectual property portfolio, key strategic alliances and experienced management team.

Disruptive technology platform

Our proprietary MLC platform allows us to develop product candidates that have the potential to significantly improve the treatment of a number of serious and debilitating conditions due to the MLCs' ability to secrete biomolecules that induce tissue repair through multiple diverse mechanisms. Regenerative medicines aim to restore affected cells and tissues, and therefore may have broad applicability in treating diseases where current standards of care are often inadequate or where no approved therapy currently exists.

Our MLC platform has two additional technical advantages that are not shared by other cell types. The first is that we use proprietary processes to isolate MLCs from a few healthy donors and significantly expand them in culture, while maintaining their innate therapeutic characteristics. The second is that MLCs do not materially activate the immune system. Together, these two unique characteristics enable MLCs to be used as allogeneic, off-the-shelf therapies that can be developed from a small number of donors and administered to many patients, with batch-to-batch consistency, commercial scale capabilities and predictable therapeutic properties, all without any material immune responses in patients.

Broad portfolio of distinct and advanced product candidates

While all of our product candidates are based on our MLC platform, our Product-by-Process approach allows for the development of distinct, non-interchangeable products, each of which has distinct pricing and partnering opportunities. Using this approach, we have created a broad portfolio of product candidates that target a wide range of diseases, including five Phase 3 or Phase 3-ready product candidates, and potentially the first industrially manufactured culture-expanded allogeneic stem cell product to be approved in the United States. We have an extensive patient safety data file on our MLC-based product candidates.

Target markets with high unmet needs where technology shows greatest prospects

Our strategy is to develop product candidates that target significantly advanced stages of certain diseases where specific sub-populations have high unmet needs. These include advanced CHF, moderate to severe CLBP, aGVHD, and rheumatoid arthritis and diabetic kidney disease. As a result, if our clinical trials prove successful at demonstrating improved safety and efficacy against existing treatment options, we believe we may benefit from accelerated development pathways, potentially attractive pricing and reimbursement, and enhanced likelihood of entering into commercial partnerships. As any of our products obtain market approval and acceptance in the medical community, we believe we will have the opportunity to expand over time into broader patient populations with less severe stages of a targeted disease.

Scalable manufacturing capabilities

We have developed proprietary manufacturing processes that we expect will enable production at commercial scale with reproducibility and batch-to-batch consistency, supported by robust quality assurance procedures and lot release assays. Our manufacturing processes have met stringent criteria required by international regulatory agencies, including the FDA. We have built an internal team with significant experience in the production of cell therapy products and the commercial production of approved biopharmaceuticals.

We have established a strategic alliance with Lonza, a global leader in biopharmaceutical manufacturing, which includes exclusive access to their large-scale biologics production facility in Singapore, a major international hub for biopharmaceutical development and manufacturing, for cell therapy products. Our exclusive long-term access to this Singapore facility allows us to utilize our proprietary manufacturing processes in a controlled environment.

Intellectual property leadership

We have a large patent portfolio of issued and pending claims covering compositions of matter and methods of use for MLCs, irrespective of the tissue source for donated MLCs (e.g., our patents cover MLCs from bone marrow, adipose, placenta, umbilical cord and dental pulp tissues). Our patents also cover elements of our manufacturing processes. As of August 31, 2015, we had 72 patent families, including 661 patents or patent applications. We maintain trade secrets covering a significant body of know-how and proprietary information related to our core product candidates and technologies. As a result, we believe we have a leading intellectual property position in the MLC space that provides us with substantial competitive advantages for the commercial development of regenerative medicine products.

Strategic alliances

We have established strategic relationships with several industry leaders to support the development and potential commercialization of our product candidates. Our collaborators provide clinical development, manufacturing and commercial capabilities as well as financial support to enhance the potential for the success of our product candidates, which mitigates our capital obligations and commercial risk.

Teva is our global collaborator for the late-stage clinical development and commercialization of certain cardiovascular, central nervous system and bone marrow transplant fields, and is currently enrolling a Phase 3 program in patients with advanced CHF. JCR is our collaborator in Japan for the treatment of aGVHD. Lonza is our collaborator for cell therapy manufacturing. Our relationship with the Singapore Economic Development Board, or EDB, provides us with various financial incentives associated with our activities in Singapore.

Experienced management team

Our CEO, Dr. Silviu Itescu, is a pioneer in the study and clinical development of stem cell therapeutics, and a globally recognized leader in the field of regenerative medicine. Our broader management team, through prior employment at leading drug development companies and regulatory agencies, has substantial experience in the clinical development, manufacturing, regulatory management and commercialization of biopharmaceuticals.

Our Strategic Alliances

We have established strategic alliances to provide clinical development, manufacturing and commercial capabilities, which mitigates our capital obligations and commercial risk. Key terms of these strategic alliances are summarized below. We will evaluate and, where appropriate, enter into additional collaborations with biopharmaceutical or other organizations to further advance our product candidate portfolio and to gain access to scientific expertise or funding support.

Teva/Cephalon, Inc.—Cardiovascular, Neurological and Bone Marrow Collaboration

In December 2010, we entered into a development and commercialization agreement, or DCA, with Cephalon, Inc., now a wholly-owned subsidiary of Teva. We refer in this discussion to Cephalon and Teva together as Teva. Under the DCA, which will continue in existence for so long as Teva or its affiliates or sublicensees are developing any product covered by the DCA, we and Teva are collaborating to develop certain MPC-based product candidates, including MPC-150-IM for CHF. The collaboration is limited to certain specified indications within cardiovascular, central nervous system, and BMT. Teva has the right and responsibility to fund late-stage clinical development (Phase 2b and Phase 3 clinical trials) and to commercialize certain of our product candidates for specified indications throughout the world. The most advanced of the programs is our CHF program, and Teva is currently enrolling a Phase 3 trial in this indication.

In conjunction with signing the DCA, Teva has paid us US$130 million and purchased A$197 million of our ordinary shares. Under the DCA, Teva has agreed to pay us up to an additional US$1.7 billion in milestone payments for certain of our product candidates that are approved in specified indications in certain major jurisdictions. In addition, Teva agreed to pay us a transfer price for our supply of commercial quantities of certain of our product candidates equal to a percentage of its global annual net sales, commencing in the twenties and up to 40%, based on achieving over US$2 billion in annual global net sales.

In September 2013, we and Teva amended the DCA. As a result of the amendment, the ongoing Phase 3 clinical trial for MPC-150-IM in CHF, which Teva is conducting and funding, now includes two interim analyses of efficacy and/or safety. Subject to the trial reaching specified enrollment rates, Teva is obligated to conduct and fund the Phase 3 clinical trial for CHF at least until the first interim analysis is completed.

All activities under the DCA are overseen by a joint steering committee with an equal number of representatives appointed by us and Teva. Generally, we are responsible for development costs for product candidates through Phase 2a clinical studies, except that Teva is obligated to reimburse us for a certain portion of our costs related to the development of such product candidates for the central nervous system field. Generally, Teva is responsible for development costs beyond Phase 2a clinical studies. We are the exclusive supplier for each of our product candidates for development and commercialization activities for the specified indications. Teva is responsible for obtaining and maintaining regulatory approvals as well as for all commercialization costs.

During the term of the DCA, we and Teva agreed to mutual non-compete obligations with respect to stem cell therapeutic products in the specified indications. However, any entities that we may acquire or may acquire us may continue any existing competing activities subject to certain requirements to keep those activities separate from our collaboration with Teva, and in such circumstances, Teva would have the right to take over sole control of the development of our covered product candidates for the specified indications under the DCA.

With the exception of the cardiovascular field, in which Teva committed to conduct and fund the Phase 3 clinical trial in CHF at least through the first interim analysis, Teva has the right to terminate the DCA upon advance notice to us. We have the right to terminate the DCA in the event Teva materially breaches the DCA and has not cured within certain time periods, except that once Teva has received regulatory approval for any covered product in any of the U.S., the EU or Asia, we may not terminate with respect to that same geographic location.

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 TEMCELL orphan drug status in December 2013. JCR received full approval in September 2015. TEMCELL is the first allogeneic cell-based product to be approved in Japan. Decisions by Japanese regulators on price reimbursement for JCR's product TEMCELL are pending. During the first quarter 2016, we expect that JCR will launch TEMCELL 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 payments of up to US$6.5 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.

Under the MSA, as long as we continue to meet certain annual spending commitments with respect to activities in Singapore, Lonza agreed not to supply third parties with allogeneic cell therapy products from Singapore, including from its existing biologics production facility, subject to certain exceptions. During the term of the MSA, we will have access to this facility, which allows us to utilize our proprietary manufacturing processes in this controlled environment.

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.

Cell-Based Therapeutics

We are a global leader in the development of regenerative medicine product candidates due in large part to the therapeutic and commercial advantages offered by our MLC-based platform.

Introduction to Mesenchymal Lineage Stem Cells

Stem cells can be characterized as either embryonic or adult in origin. Embryonic stem cells, or ESCs, are pluripotent, and differentiate during embryonic and fetal development into all specialized tissues in the body, including nerve, muscle, skin, blood, and bone. ESCs and the related induced-pluripotent stem cells have two characteristics that complicate use as therapeutic products. First, ESCs have a relatively high proliferative capacity that can give rise to certain cancers called teratomas. Secondly, ESCs can activate the immune system of treated patients and may require co-administration of immunosuppressive agents. In contrast, we develop products based on MLCs, which are adult stem cells that play an important role in tissue repair and organ maintenance throughout life, have less proliferative potential, are more restricted in their differentiation properties, and to date have not been shown to cause teratomas. The number and quality of MLCs progressively decline with advancing age, which we believe may be associated with the development of degenerative conditions. As such, we obtain our MLCs from young, healthy adults.

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, that 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, or 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, or 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.

Mechanisms of Action Underpin Product Development

The unique combination of properties based on secretion of diverse biomolecules underscores the importance of MLCs as a platform for the development of cell based regenerative medicine therapies.

Our lead MLC product candidates have been developed through proprietary manufacturing processes optimized to express certain biomolecules implicated in the mechanisms of action by which the MLC product candidate is thought to modify outcomes for the target condition for which it is being developed. Examples of these biomolecules as they relate to characterization of our products are as follows:

- *MPC-150-IM:* this product candidate is designed for local delivery to damaged heart muscle and to allow our MLCs to secrete biomolecules involved in enhanced myocardial neovascularization, cardiomyocyte survival, cardiomyocyte precursor migration and proliferation, and reduction in fibrosis and myocardial scar. These biomolecules include stromal cell-derived factor 1, or SDF-1, Angiopoietin-1, vascular endothelial growth factor, or VEGF, hepatocyte growth factor, or HGF, and matrix metalloproteinases, or MMPs.
- *MPC-06-ID:* this product candidate is designed for local delivery to degenerating intervertebral discs and to allow our MLCs to secrete biomolecules involved in enhanced migration and proliferation of intervertebral disc progenitor cells, and in enhanced proteoglycan and collagen synthesis in the disc nucleus and annulus. These biomolecules include Angiopoietin-1 and transforming growth factor beta, or TGF-beta.
- *MPC-300-IV, TEMCELL and MSC-100-IV:* these product candidates have been designed for intravenous delivery in systemic conditions of excessive inflammation, and to allow our MLCs to secrete biomolecules involved in immunomodulation, particularly prostaglandin E2, or PGE2, and indoleamine 2, 3-dioxygenase, or IDO, in response to activation by pro-inflammatory cytokines such as tumor necrosis factor-alpha, or TNF-alpha, and interleukin-1, or IL-1. Release of immunomodulatory biomolecules by these MLC products acts to polarize pro-inflammatory M1 monocytes to anti-inflammatory M2 monocytes, and to switch activated T helper cells 1 and 17, or Th1 and Th17, respectively, to Th2 cells and FOXP3 T regulatory cells.
- *MPC-25-Osteo:* This product is designed to allow our MLCs secrete biomolecules involved in osteoblast migration and bone vasculature, both features of new bone formation; these biomolecules include various bone morphogenic proteins, or BMPs, and VEGF.

While our MLCs play very active roles in tissue repair, our products have what we believe to be a uniquely extensive safety profile. We have an extensive patient safety data file on our MLC-based product candidates as a result of having now treated approximately 1,340 patients.

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.

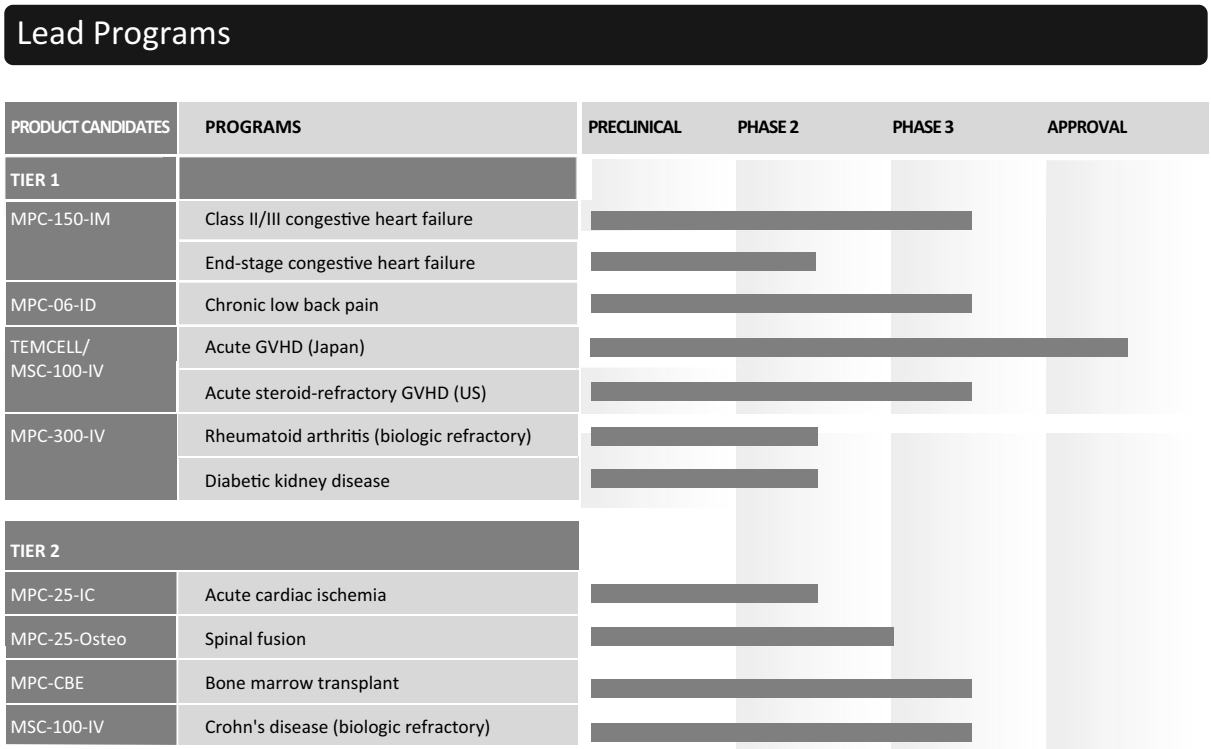
In contrast, autologous stem cell products, which are produced from the patient's own stem cells, require individual product regulatory testing and do not benefit from manufacturing economies of scale. Moreover, autologous therapies are vulnerable to significant patient-to-patient variability, resulting in a corresponding variability in the results derived from clinical use.

Despite these weaknesses, many autologous products have been advanced into clinical trials by academic and industry developers, who may understand the therapeutic potential of MLCs, but who may not have the requisite intellectual property or manufacturing capabilities and infrastructure needed to facilitate cost-effective allogeneic product development.

Our Product Candidates

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 will be discussed in detail below. We are developing additional product candidates that have the potential to advance into Tier 1 and Tier 2 going forward.

We expect a number of important clinical milestone events to occur over the next 12 to 24 months for our most advanced product candidates in both Tier 1 and Tier 2. By the end of 2015, we expect to report data from our ongoing Phase 2 trial in RA. In 2016, we expect to report outcomes from two Phase 3 trials and a Phase 2 trial.



This chart is figurative and does not purport 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

MPC-150-IM for the Treatment of Advanced and End-Stage Congestive Heart Failure (CHF)

Overview

MPC-150-IM for the treatment of chronic CHF is our product candidate partnered with Teva. MPC-150-IM consists of 150 million MPCs administered by direct cardiac injection in patients suffering from chronic heart failure 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 scarring and fibrosis, and regeneration of heart muscle through activation of 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, and a Phase 2 dose-ranging study in patients with heart failure of either ischemic or non-ischemic etiology which 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 death.

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.

The American Heart Association reports 5.7 million adults in the United States with diagnosed CHF, or about 2% of the adult population, with 870,000 new cases diagnosed each year. CHF prevalence is expected to grow 46% by 2030, affecting more than 8 million Americans. The estimated annualized cost for CHF care in the United States is approximately $32 billion, and is projected to grow to approximately $77 billion by 2030.

CHF is classified in relation to the severity of the symptoms experienced by the patient. The most commonly used classification system for severity of heart failure, established by the New York Heart Association, or 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 death increases progressively with increase in left ventricular volumes, reduction in ejection fraction, and progression in NYHA grade. About 30% 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 disease 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, or BNP, levels, have been reported to have an incidence of death or cardiovascular hospitalization approaching 50% 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 transplant, due to limited supply there were only 2,378 transplants performed in the United States in 2012.

Results from our Phase 2 trials in patients with Class II/III CHF and in patients with end-stage CHF requiring assisted mechanical assist devices have shown that our MPCs appear to have the greatest efficacy in patients with the most advanced forms of CHF. We believe that targeting advanced heart failure patients with the most unmet need can provide us with the shortest Phase 3 program, the fastest time to market, and the opportunity for the most attractive pricing.

Current Status and Anticipated Milestones

Teva is conducting a double-blinded, 1:1 randomized, placebo-controlled Phase 3 trial to evaluate a single dose of MPC-150-IM in advanced CHF patients across multiple sites in North America. The enrollment criteria for this trial, including a prior heart failure hospitalization within the previous 9 months and high levels of NT-proBNP, a protein used in diagnosis and screening of CHF, are expected to result in enrichment for patients with substantial left ventricular contractile abnormality, advanced heart failure and higher risk of recurrent hospitalizations and death. The ongoing Phase 3 trial continues to recruit well.

Teva recently completed discussions with the FDA, during which important changes to the Phase 3 program for advanced CHF using MPC-150-IM were agreed to. In particular, the total number of subjects to be recruited for the ongoing Phase 3 trial, using a time to first event analysis of HF-MACE as the primary endpoint, will be reduced from approximately 1,730 to 1,165. Additionally, a second interim analysis will be performed in the ongoing Phase 3 trial when 50% of the HF-MACE have occurred. We expect this second interim analysis for futility, resizing and possible overwhelming efficacy to occur in the first quarter of 2017.

A confirmatory study is planned to be conducted in parallel in a similar patient population of approximately 500 subjects using recurrent HF-MACE as the primary endpoint. The use of recurrent HF-MACE as a primary endpoint in the confirmatory study is supported by a new analysis of the completed Phase 2 trial, where patients treated with MPC-150-IM had no HF-MACE over 36 months of follow-up, compared with 11 recurrent HF-MACE in the control group ($p<0.001$, log rank test). Based on our discussions with the FDA, we believe that positive clinical data from these two studies will be sufficient for product approval.

We have completed enrollment of the patients to be evaluated in the first interim analysis of the ongoing Phase 3 trial. This interim analysis will be conducted after these patients complete six months of follow-up and will include results for changes in left ventricular volumes and ejection fraction as surrogate parameters of heart failure. We expect the outcome of this first interim analysis in the first quarter of 2016. We believe that positive results from this interim analysis will reinforce and validate the Phase 3 trial design assumptions that we made based on our Phase 2 trial results. We expect that our Phase 3 trial of 1,165 patients will be complete in 2018, subject to a potential early stop based on overwhelming efficacy.

We originally filed an investigational new drug, or IND, application to begin a Phase 2 trial for CHF in March 2007. Teva then filed an IND application for a Phase 3 trial for CHF in September 2013.

A Phase 2b trial in patients with end-stage advanced heart failure whose circulation is supported mechanically by a left ventricular assist device, or LVAD, has commenced enrollment and will be funded by the NIH. We expect that results from this trial will be available in mid-2017. This trial will be conducted by a multi-center team of researchers within the NIH-funded Cardiothoracic Surgical Trials Network, or CSTN, led by Icahn School of Medicine at Mount Sinai, New York. The same investigative group conducted an earlier pilot trial in MPCs for this patient population.

Program for Advanced CHF

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

Trial Design

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 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.

Patients with NYHA Class II or III heart failure who had a left ventricular ejection fraction, or LVEF, of less than 40% by baseline screening echocardiogram were recruited across multiple sites. All patients were between 20 and 80 years old, had either non-ischemic or ischemic cardiomyopathy that was not amenable to further percutaneous or surgical revascularization, and were on a prescribed regimen of maximally tolerated heart failure medications.

Patients were randomized to either an injection of 25, 75 or 150 million MPC by endomyocardial catheter or scripted mock injections (control group) in the catheterization laboratory. MPCs were administered into the left ventricle (approximately 15-20 injections of 0.2ml/injection) using the J&J Myostar™ injection catheter and NOGASTAR™ Mapping Catheter system that identifies viable/hibernating myocardium based on electrical voltage, theoretically making targeting of healthy but at risk tissue easier. We believe this catheter has the largest safety profile for this application and has been used in over 1,000 patients across multiple trials. Measurement of functional efficacy involved left ventricular end systolic volume, or LVESV, and left ventricular end diastolic volume, or LVEDV, measurements as well as left ventricular ejection fraction, or LVEF. An additional time-to-first event analysis of heart failure-related major adverse cardiac events, or HF-MACE, was performed. HF-MACE was defined as a composite of cardiac related death or resuscitated cardiac death, or non-fatal decompensated heart failure events.

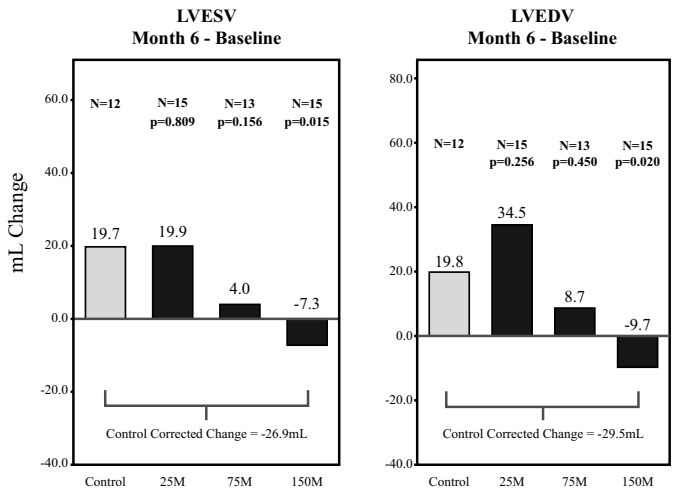
Trial Results

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 HF-MACE long-term. More specifically:

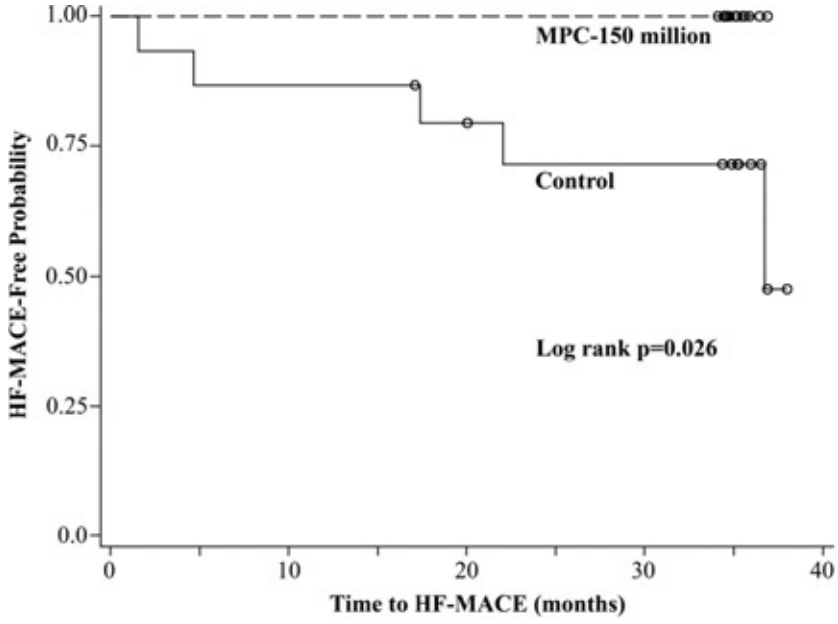
- There was a dose-related effect on both LVESV and LVEDV, with the 150 million cell dose showing the greatest effect compared to controls for LV remodeling (LVESV and LVEDV both $p<0.02$) at month 6 post treatment and functional exercise capacity as measured by six minute walk test (6MTW: $p=0.062$) at month 12 post treatment. A p-value is a probability, ranging in value from 0 to 1, which indicates the likelihood that the results of a study are different between treatment and control groups. The lower the p-value, the harder it would be to see the results by chance alone. P-values below 0.05 are typically referred to as statistically significant.

MPCs show dose-dependent effect in cardiac remodeling (based on LV volumes)



- 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.

HF-MACE by Kaplan-Meier Curve-36 Months Post-Treatment



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 less than or greater than 100 ml as a surrogate for significant myocardial contractile abnormality and advanced heart failure. The 100 ml LVESV threshold was chosen because it falls more than 3 standard deviations above 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:

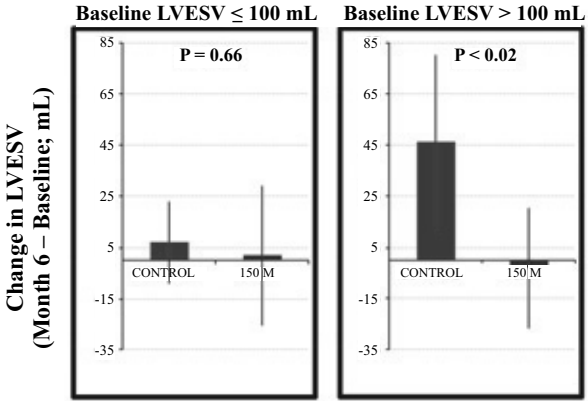
- the therapeutic benefit of the 150 million dose on parameters of LV remodeling were markedly amplified by focusing on the target population with substantial baseline LV contractile abnormality and advanced heart failure (LVESV greater than 100 ml).

Comparison of All Subjects versus Subjects With LVESV > 100 mL (ITT, or intention to treat population)

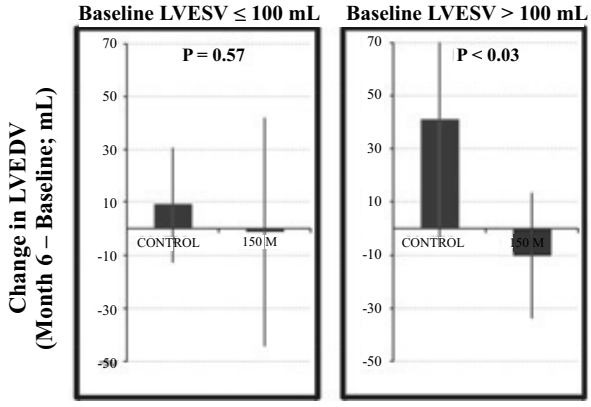
	Change (Entire Cohort) Baseline to Month 6			Change (LVESV > 100 mL Cohort) Baseline to Month 6			
	Control (n=15)	MPC-IM-150 (n=15)	Change Relative to Control	Control (n=7)	MPC-IM-150 (n=11)	Change Relative to Control	P-values
LVESV (mL)	**+20**	**-7**	**-27**	**+46**	**-8**	**-54**	**<0.02**
LVEDV (mL)	**+20**	**-10**	**-30**	**+41**	**-10**	**-51**	**<0.03**
LVEF (%)	**-2.3**	**+0.6**	**+2.9**	**-6.4**	**+1.7**	**+8.1**	**<0.05**

- control patients with advanced heart failure (baseline LVESV > 100 ml) were the fastest progressors over 6 months in terms of significant worsening in LVESV and LVEDV volumes, and loss of 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).

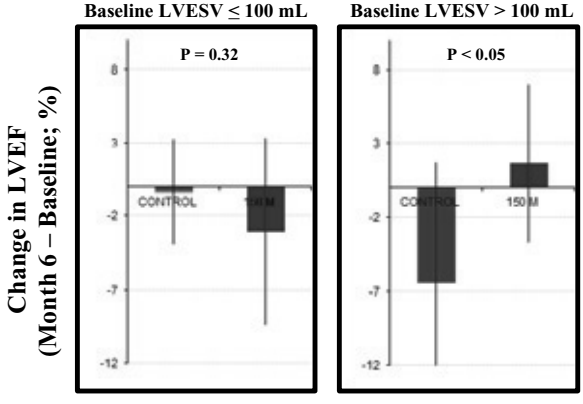
Change in LVESV from Baseline at 6 Months in Treated Patients versus Control Group



Change in LVEDV from Baseline at 6 Months in Treated Patients versus Control Group

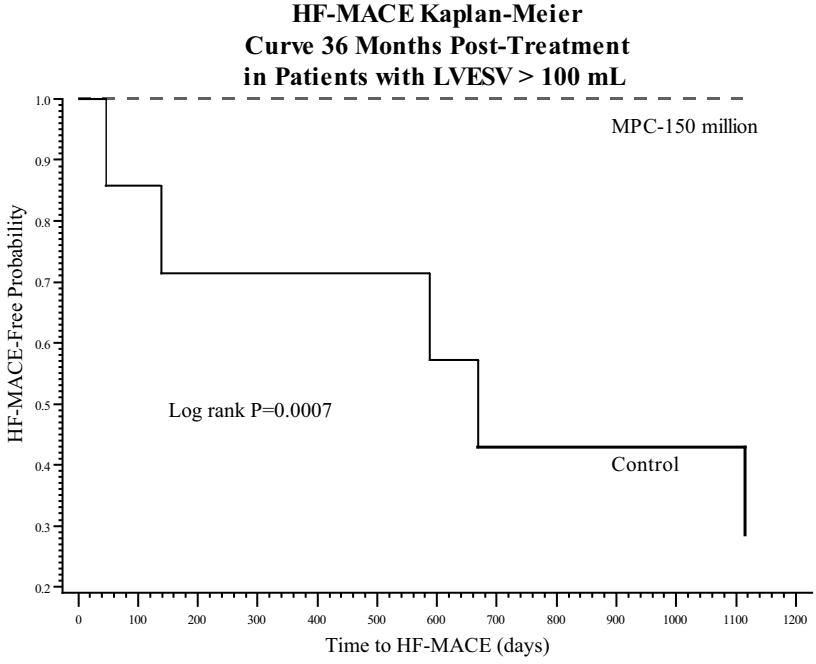


Change in LVEF from Baseline at 6 Months In Treated Patients versus Control Group



- all of the HF-MACE events over 36 months of follow-up occurred exclusively in the controls with advanced heart failure.
- the annualized HF-MACE rate in these fast progressors was 24%, compared with 11% in all of the controls in the Phase 2 trial.
- more specifically, among 18 Class II/III CHF patients with baseline LVESV > 100 ml, 5/7 (71%) placebo-treated versus 0/11 150 million MPC-treated experienced one or more HF-MACE events over 36 months ($p=0.0007$).

- 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 and this may represent the optimal target patient population for MPC therapy.



Ongoing Phase 3 Clinical Trial

The Phase 3 trial is being conducted by our partner Teva and is actively enrolling in the United States. The clinical protocol was designed after consultation with both the FDA and the European Medicines Agency. The Phase 3 trial design is a double-blinded, 1:1 randomized, sham-procedure-controlled study evaluating a single dose of 150 million MPCs, delivered via endomyocardial injection catheter to the left ventricle, in NYHA Class II/III heart failure patients with an ejection fraction of less than 40%.

The primary efficacy endpoint of the trial is a time-to-first-event analysis of HF-MACE, defined as a composite of cardiac related death or resuscitated cardiac death, or non-fatal decompensated heart failure events. These non-fatal decompensated heart failure events require use of intravenous diuretics during an in-hospital stay or during an outpatient visit. Adjudication of HF-MACE will be performed by an independent, blinded clinical endpoint committee. The trial is an event-driven trial.

In order to enrich the trial for advanced heart failure patients, additional enrollment criteria for this trial are high NT-proBNP levels, and a heart failure-related hospitalization within the past nine months, two inclusion criteria known to predict adverse outcomes in CHF. This enrichment is expected to result in the majority of enrolled patients having LV systolic dysfunction, baseline LVESV>100 mL and high rates of HF-MACE. While initially powered for an estimated annualized HF-MACE event rate of 20%, we expect that the annualized HF-MACE event rate in this enriched population is in fact likely to be closer to the 24% seen in our own Phase 2 trial and contemporary cohorts in other studies.

Teva recently completed discussions with the FDA, during which important changes to the Phase 3 program for advanced CHF using MPC-150-IM were agreed to. In particular, the total number of subjects to be recruited for the ongoing Phase 3 trial, using a time to first event analysis of HF-MACE as the primary endpoint, will be reduced from approximately 1,730 to 1,165. Additionally, a second interim analysis will be performed in the ongoing Phase 3 trial when 50% of the HF-MACE have occurred, which will include a test for superiority allowing for the possibility of stopping of the trial early based on overwhelming efficacy.

A confirmatory study is planned to be conducted in parallel in a similar patient population of approximately 500 subjects using recurrent HF-MACE as the primary endpoint. The use of recurrent HF-MACE as a primary endpoint in the confirmatory study is supported by a new analysis of the completed Phase 2 trial, where patients treated with MPC-150-IM had no HF-MACE over 36 months of follow-up, compared with 11 recurrent HF-MACE in the control group ($p<0.001$, log rank test). Based on our discussions with the FDA, we believe that positive clinical data from these two studies will be sufficient for product approval.

The ongoing Phase 3 trial is enrolling according to plan. We have completed enrollment of the patients to be evaluated in the first interim analysis of MPC-150-IM for the treatment of advanced CHF. This interim analysis will be conducted after these patients complete six months of follow-up and will include results for left ventricular volumes and ejection fraction as surrogate parameters of heart failure.

If MPC-150-IM is successful in this difficult-to-treat population facing high risk of hospitalization or death, we should be well-positioned for potential product approval and a target population that remains underserved despite maximal standard of care. If our clinical trials prove successful at demonstrating improved safety and efficacy against existing treatment option, we believe this may also lead to attractive pricing and reimbursement.

Program for End-Stage CHF

Completed Pilot Phase 2a Trial in Patients With Advanced Heart Failure Requiring Mechanical Support

Trial Design

A multi-center, randomized, double-blind, sham-procedure controlled trial evaluated 30 patients 2:1 randomized to endomyocardial injection of 25 million MPCs or medium (control) during LVAD implantation for either bridge-to-transplant or as a destination therapy. The primary safety endpoint was incidence of infectious myocarditis, myocardial rupture, neoplasm, hypersensitivity reaction, and immune sensitization (90 days post-randomization). The key efficacy endpoints are functional status and ventricular function, while temporarily weaned from LVAD support (90 days post-randomization). Patients were followed until transplant or 12 months post-randomization, whichever came first. The two treatment groups were similar with respect to baseline characteristics. The mean age was 57.4 years (±13.6) and 83.3% were male. The mean LVEF was 18.1% (± 4.3), 36.7% had ischemic cardiomyopathy, and all patients were implanted with HeartMate II® LVADs (Thoratec Corp.), 66.7% of which were implanted for destination therapy indication.

Trial Results

The preliminary 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 the 90 day primary endpoint analysis of the trial, 50% of MPC treated patients were able to successfully tolerate weaning off of LVAD support for 30 minutes compared to 20% in the control group. At 90 days, there were three deaths (30%) in the control group and none in the MPC 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 to date 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 and which is the basis of the Phase 2b study discussed below.

Phase 2b Trial of MPC-150-IM in Patients With Advanced Heart Failure Requiring Mechanical Support

A 120-patient trial, to be conducted by the NIH-funded CSTN, will evaluate the effects of a single injection of MPC-150-IM into the hearts of patients with end-stage heart failure. This is a prospective, multi-center, double-blind, 2:1 randomized, single dose cohort, sham procedure controlled 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 may be eligible to participate in the trial. All patients will be followed until 12 months post randomization.

The primary objectives of this trial are to evaluate the safety and efficacy of injecting 150 million MPCs into the native myocardium of LVAD recipients. The primary efficacy endpoint of this study is survival over six months, and the co-primary endpoint is functional status, while temporarily weaned from LVAD support, over the six months post randomization. Functional status is defined by the ability to tolerate wean from LVAD support to low flow for 30 minutes. Secondary endpoints will include physiological parameters (which include echocardiography assessment of cardiac function and remodeling) and neurocognitive assessments.

CSTN is currently completing submissions and interactions with the FDA and Health Canada. CSTN has initiated enrollment for the trial, and results are expected in mid-2017.

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

Overview

MPC-06-ID is our proprietary Phase 3 product candidate for the treatment of CLBP caused by DDD. MPC-06-ID comprises a unit dose of 6 million MPCs by injection 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

Approximately 5.7 million patients in the U.S. alone suffer from CLBP caused by DDD. After failure of conservative measures (medication, injections, 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 only remaining 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. MPC-06-ID is being developed to target the population of patients suffering from moderate to severe chronic low back pain 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.

Current Status and Anticipated Milestones

We originally filed an IND application to begin a Phase 2 trial for CLBP in 2011. In September 2014, after an end of Phase 2 meeting with the FDA where full 12 month results were presented, we amended the IND and filed our Phase 3 clinical study protocol. This Phase 3 program was initiated in the fourth quarter 2014.

At the start of the first quarter 2015, we announced 24-month results from the Phase 2 trial of MPC-06-ID. These results demonstrated that the treatment benefit seen at 12 months largely persists for 24 months. We believe this evidence of sustained clinical treatment effect for 24 months against existing treatment options should support attractive pricing and reimbursement, and our ability to enter into a commercial partnership.

Enrollment of the first of two Phase 3 trials is expected to be completed in the third quarter of 2016. We expect to complete the Phase 3 program in the first half of 2018.

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. Full 6, 12 and 24 month data are now available.

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. 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.

Phase 2 Clinical Trial Results

With respect to the primary endpoint, allogeneic MPC treatment, including MPC-06-ID, was well tolerated with the most frequently reported adverse event, back pain, occurring across all patient groups.

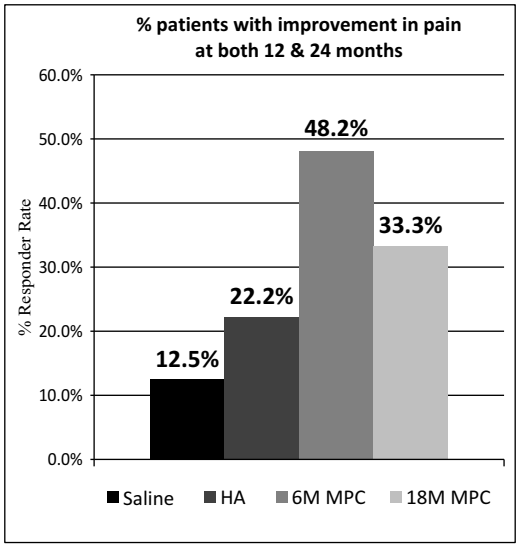
With respect to primary efficacy endpoints, the FDA has provided guidelines on how to evaluate patient response, utilizing a composite endpoint based on achieving minimally important clinical differences, or MICD, in both pain and function from baseline. Such a composite endpoint for restorative or replacement disc therapies is different than that typically used by pharmacologic agents developed solely for palliative improvement in symptoms, such as analgesics, where short term improvement in mean pain scores between groups is sufficient to support a label for short term pain reduction. The FDA and key opinion leaders, or KOLs, have deemed that for restorative or replacement disc therapies the MICD for pain reduction should be at least a 30% improvement from baseline and for functional improvement at least a 30% improvement or 10 point improvement from baseline using a 100-point functional scale. We believe that achieving success in long-term improvement in both pain and function using even higher threshold levels than the MICD with durable outcomes for up to two years from a single dose should support a broad label for disc restoration and attractive pricing and reimbursement from payors.

We have utilized this composite-based endpoint and associated guidelines, among other measures, in the evaluation of our Phase 2 results.

- *Improvement in chronic low back pain*. At 12 months, a responder analysis showed that there was clear separation between both treatment groups and both control groups at every decile increase in response beyond the MICD of 30% reduction in pain from baseline. In line with guidance from KOLs and from payers, a responder analysis was performed targeting at least 50% reduction in pain from baseline. At both 6 and 12 months, a reduction in pain from baseline of 50% or more, without any additional intervention, was seen in 59.3% of the MPC-06-ID group, 44.8% of the 18 million MPC group, 18.8% of the saline group, and 15.8% of the HA group, as measured by visual analog scale, or VAS (p = 0.006 across all four groups, p=0.023 for 6 million MPC against saline and p=0.006 against HA). Statistical significance denotes the mathematical likelihood that the results observed are real and not due to chance.

MPC groups have a greater proportion of patients with at least a 50% improvement in back pain at both 6 and 12 months relative to controls

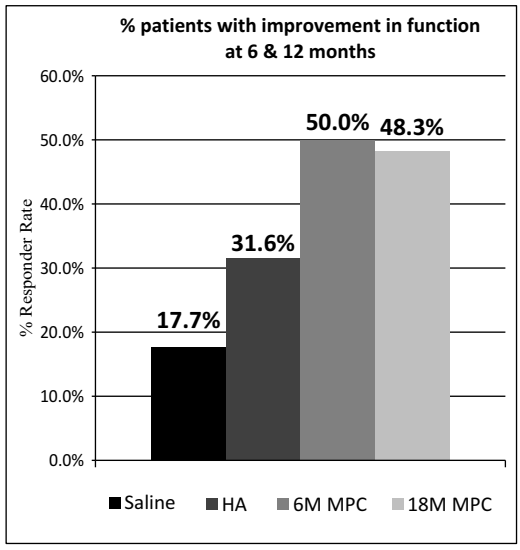
% patients with 50% VAS reduction from baseline and no intervention



- *Improvement in function*: At 12 months, a responder analysis showed that there was clear separation between both treatment groups and both control groups at every decile increase in response at or beyond the MICD of 30% improvement in function from baseline. In line with historical FDA preference for spine fusion and artificial disc replacement marketing application approvals, a responder analysis was performed targeting at least a 15 point improvement in function through 24 months from baseline. At both 6 and 12 months, an improvement in function from baseline of 15 points or more, as measured by Oswestry Disability Index, or ODI, without any additional intervention, was seen in 50.0% of the MPC-06-ID group. 48.3% of the 18 million MPC group, 31.6% of the HA group, and 17.7% of the saline group (p=0.05 MPC-06-ID versus saline, p=0.06 18 million MPC versus saline).

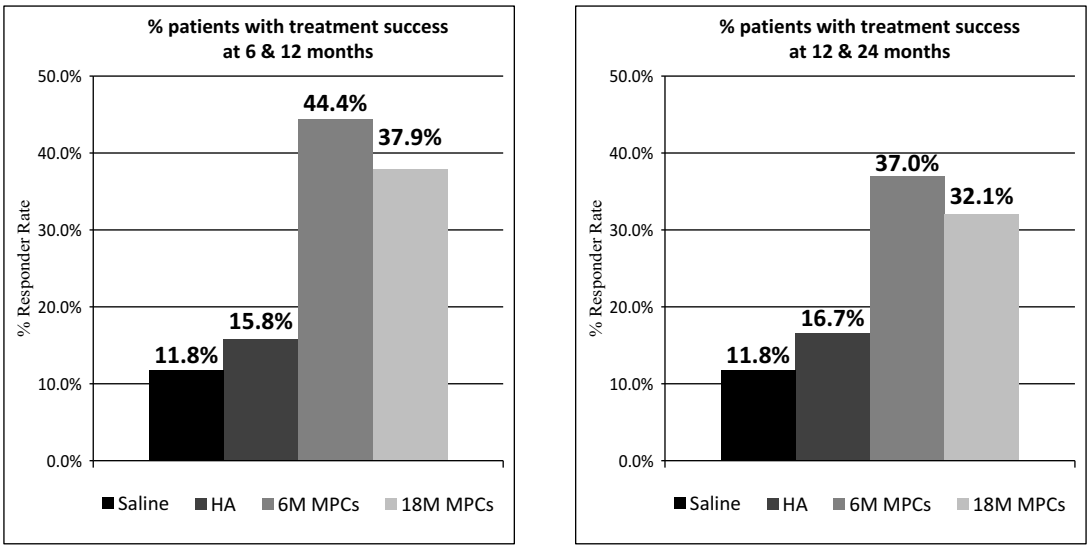
MPC groups have a greater proportion of patients with at least a 15 point improvement in function from baseline as measured by ODI at both 6 and 12 months, relative to controls

% patients with 15 point ODI improvement and no intervention



- *Reduced need for additional surgical and non-surgical interventions*: MPC-treated patients had a significantly reduced need for additional interventions at the treated disc level, including surgical intervention (spinal fusion, discectomy or artificial disc replacement) or injection (epidural steroid injection, rhizotomy or transforaminal injections), than saline controls. By 12 months, 25% of patients in the saline control group had undergone an additional intervention, compared with 15% of patients in the HA control group, 6.9% of patients in the MPC-06-ID group and only 3.3% of patients who received 6 or 18 million MPCs. By Kaplan-Meier analysis of time to a first additional treatment intervention, treatment with either MPC-06-ID or 18 million MPC significantly reduced the need for additional interventions compared with saline treatment (p=0.024 and p=0.010, respectively).
- *Radiographic measurements*: In patients with early disc degeneration (Pfirrmann MRI degenerative grades below 5), increased translational movement of the disc is a potential indicator of instability associated with early disc degeneration and annular fissures seen on MRI and pathologic examination. This is an FDA validated measurement that has previously been used in Phase 3 trials of surgical devices for discogenic back pain. At 12 months, MPC-treated patients demonstrated a reduction in radiographically-determined translational movement of the disc, suggesting a treatment effect on disc degeneration, anatomy, and improved disc stability. The 18 million MPC group had a mean translational movement of only 1.3%, the MPC-06-ID group 2.0%, the HA group 2.5%, and the saline group 3.5% (p=0.021 between groups). In this study, 85% of patients had early disc degeneration as evidenced by Pfirrmann grade <5 on MRI. At 12 months, no significant differences were seen between groups in overall Pfirrmann grade by MRI.
- *Composite endpoint*: Based on precedent and FDA feedback from our end-of-Phase 2 meeting, we developed a composite endpoint requiring at least a 50% improvement in low back pain, 15 point improvement in ODI and no treatment intervention (surgical or injection) that we believe would be sufficient to meet FDA's requirements for approval. Utilizing this composite endpoint in a post-hoc analysis of Phase 2 data, separation between treatment and control arms was first seen at 3 months, maximal at 6 months, and sustained for at least 12 months. More specifically, the MPC-06-ID group, the 18 million MPC group, the HA control and the saline control groups had 44.4%, 37.9%, 15.8% and 11.8% of subjects meet the composite endpoint criteria at both 6 and 12 months. (MPC-06-ID vs. saline p<0.05). Moreover, the MPC-06-ID group had three times (3x) the proportion of patients achieving treatment success at both 12 and 24 months compared with saline controls (37.0% versus 11.8%, p=0.09).

Proportion of patients with 50% VAS reduction, 15 point ODI reduction and no intervention over 24 months (treatment success)



This sustained treatment benefit in the MPC-06-ID group suggests a disc regenerative mechanism of action rather than a simple analgesic effect, which would not have been sustained without repeated treatment. We believe the ability to meet this composite endpoint at both 12 and 24 months would demonstrate a robust and durable benefit for the patient consistent with a potential disease modifying mechanism of action.

Phase 3 Design

Based on an end-of-Phase 2 meeting with the FDA, the first of two Phase 3 clinical trials has been initiated, and will use a composite primary end point of pain relief and improved function, consisting of a 50% reduction in lower back pain as measured by VAS and a 15 point improvement in ODI with no intervention. Our Phase 3 program will evaluate a single 6 million MPC dose either alone or with HA carrier against saline control. The studies will be double-blinded, and include approximately 330 patients each. The Phase 3 program is planned to be international in scope including sites in the U.S., Australia, Canada and potentially Europe. A first interim analysis is expected to be performed in the second half of 2016. Each study is expected to enroll in 18 months, with up to 24 months of follow-up.

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

Overview

In a BMT, donor cells may 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.

MLCs are thought 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, or 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.

TEMCELL, an intravenously administered MSC-based product, has been developed in Japan for the treatment of aGVHD by our partner, JCR. TEMCELL received full approval in Japan in September 2015. Mesoblast is developing an intravenously delivered MLC product candidate for the treatment of aGVHD

globally, outside Japan. Mesoblast's product candidate, 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.

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.

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 25% 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 audience for aGVHD will primarily be board-certified in hematology-oncologists 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. In the U.S., there were more than 8,300 allogeneic BMTs in 2013, of which 50% developed aGVHD. In Japan, there were 4,807 BMTs in 2010, 67.5% of which were allogeneic. Assuming a 3% growth rate per annum, the projected number of allogeneic BMT patients in 2015 is 3,700, of whom 40% will develop aGVHD.

Current Status and Anticipated Milestones

Japan. Our licensee, JCR, received full approval for its aGVHD MSC based product TEMCELL in Japan in September 2015. Decisions by Japanese regulators on price reimbursement for JCR's product TEMCELL are pending. During the first quarter 2016, we expect that JCR will launch TEMCELL in Japan. TEMCELL is the first allogeneic cell-based product approved in Japan. Under our agreement with JCR, we are entitled to receive milestone payments on product regulatory approvals, escalating double-digit royalties in the twenties and other payments at pre-defined thresholds of cumulative net sales.

U.S. For the pediatric indication, we have initiated a Phase 3 trial and expect to report top-line results from an interim analysis of this trial in the third quarter of 2016. This pre-specified interim analysis may support a BLA filing by the end of 2016. We expect to complete recruitment of this Phase 3 trial in the fourth quarter 2016 and to have top-line results of the trial in the first quarter 2017. Based on our discussions with the FDA, we believe positive data from this trial will be sufficient for conditional approval in the United States, and an additional pediatric or adult Phase 3 will be required for full product approval. 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 liver or gut aGVHD. Osiris originally filed an IND application to begin a Phase 1 trial for aGVHD in September 1998. We acquired the MSC assets to which this application relates from Osiris in October 2013.

Completed Clinical Trials/EAP

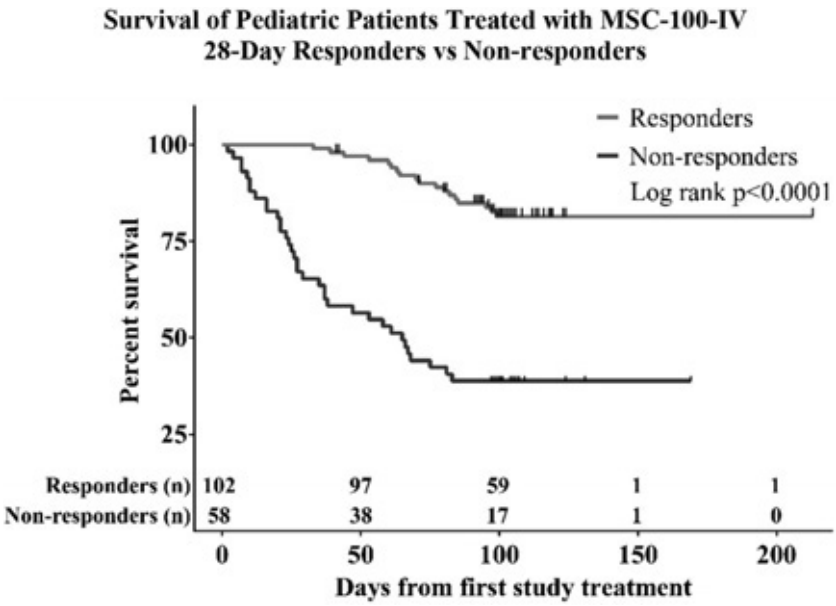
Pediatric Population

Since 2008 an expanded access program, or EAP, called Protocol 275, has been conducted for a group of pediatric patients with SR-aGVHD treated with an MLC product candidate consisting of 100 million MLCs/unit dose (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. An EAP may be offered on an individual basis or for a group of patients. Although some of our

EAP participants previously participated in controlled clinical trials, none of the patients in our EAP are currently participating in our controlled clinical trials and the EAP itself is not a controlled trial.

Our Protocol 275 includes defined eligibility and treatment plan, controlled data and safety collection and pre-specified endpoints and data analysis. All trial components are designed to assure the conduct is consistent and data are valid for interpretation. It is an open label program with single arm design so all patients enrolled receive the treatment.

Over 240 pediatric patients with SR-aGVHD have been treated on this protocol. As such, we believe that the results from the Protocol 275 EAP provide us with valuable data which may support possible product approval. The results of the first 75 patients from Protocol 275 were published in 2013, and additional analysis of data from the first 160 patients has recently been completed. Use of our MSC-100-IV, resulted in a clear, significant survival benefit among responding pediatric BMT recipients with SR-aGVHD. Of the 160 children treated, 64% achieved a response at day 28. Among responders, 81% were alive at day 100, compared to 39% survival at 100 days among non-responders ($p<0.0001$, log rank test). Day 28 response to MLC treatment was a significant predictor of improved day 100 survival ($p<.001$). The EAP protocol and data generated for MSC-100-IV represent the largest prospective program of its kind in pediatric patients with SR-aGVHD.



In this Protocol 275 the FDA has acknowledged that the results 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 or 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 a single-arm, open-label Phase 3 study of 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, discussed further below) 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.

MSC-100-IV as first line therapy in children with SR-aGVHD

Response at Day 28	Protocol 275 (All Grades)	Protocol 280 (All Grades)	
		MSC-100-IV	Placebo
Responder	25/32 (78.1%)	9/14 (64.3%)	3/14 (21.4%)
Non-responder	7/32 (21.9%)	5/14 (35.7%)	11/14 (78.6%)
		p-value = 0.0014	

Compared with placebo control patients, MSC-100-IV produced markedly superior overall response at day 28, a clinically meaningful endpoint, with both Protocol 275 and Protocol 280 showing similarly high overall response rates (P=0.0014). The between group comparison in protocol 280 showed a significant treatment benefit for MSC-100-IV relative to placebo (p=0.024).

The FDA has indicated that should the 60 patient Phase 3 trial meet its designated endpoints, the resulting data from this trial will be the basis for an accelerated approval pathway for a BLA filing using our MLC product candidate.

The Rare Pediatric Disease Priority Review Voucher Program, set forth in Section 529 of the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, provides that the FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet the criteria specified in that section. We believe that MSC-100-IV for pediatric aGVHD meets such criteria and, upon BLA approval, could qualify for the issuance of such a voucher. The authority to provide vouchers under Section 529 of the FD&C Act will expire on March 17, 2016, after which no further vouchers will be issued unless the program is reauthorized by Congress. If the program is reauthorized, we plan to apply to have MSC-100-IV designated as a rare pediatric disease and receive a fully transferable priority review voucher upon submitting a BLA.

Adult Population

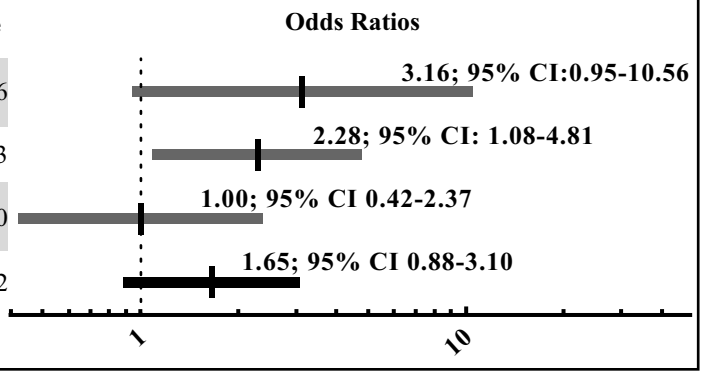
Protocol 280 was a Phase 3 trial of MSC-100-IV conducted between 2006 and 2009 in 260 adult (n=232) and pediatric patients (n=28) with Grades B-D SR-aGVHD. This trial included patients with skin, liver and lower GI complications. This trial had a rigorous primary endpoint of complete and durable response, meaning complete resolution of all clinical signs of aGVHD that had to be maintained for at least 28 consecutive days (durable complete response, or DCR). Additional efficacy endpoints included overall response for each organ at day 28 and day 100; survival at 100 and 180 days post first infusion; time to complete response; and cumulative steroid usage. Overall, treatment with MSC-100-IV was safe and resulted in improved clinical responses, particularly in patients with generally more serious visceral organ involvement. Overall clinical response correlated with improved survival, as was also demonstrated in the ongoing pediatric EAP.

In the per-protocol population, MSC-100-IV outperformed placebo on the primary endpoint, with a DCR rate of 40% versus 28% (p=0.087), but did not reach statistical significance. In the pre-specified modified intention-to-treat, or mITT, subgroup analysis, MSC-100-IV treated patients showed significant improvements in overall response rates in the difficult to treat liver and lower GI aGVHD subgroup: in subjects with liver aGVHD, MSC-100-IV improved day 100 overall response to 78% versus 53% in controls (p=0.06, n=58); for subjects with lower-GI aGVHD, MSC-100-IV improved day 100 overall response to 83% versus 68% in controls (p=0.03, n=170).

The incidence of adverse events observed in this study were what would otherwise be expected for patients recovering from BMT and battling SR-aGVHD, with no difference reported between the MSC-100-IV and placebo treatment groups overall.

Patient Response By Day 100 By Organ (Odds Ratio)

	Remestemcel-L	Placebo	P-value
Liver	32/41 (78.0%)	9/17 (52.9%)	0.06
GI	94/113 (83.2%)	39/57 (68.4%)	0.03
Skin	72/90 (80.0%)	40/50 (80.0%)	1.00
All	133/161 (81.6%)	59/81 (72.8%)	0.12



Phase 3 Trials

During the conduct of our open-label Phase 3 study of approximately 60 children, we expect to have discussions with the FDA regarding the trial design for a potential Phase 3 trial of our MLC product candidate to support approval of this product for adults with liver or gut aGVHD.

MPC-300-IV for 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, insulin resistance, and the end-organ complications of diabetes, 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, or RA. The product candidate is being evaluated at both 1 and 2 million MPC/kg dose(s) via intravenous infusion.

Proinflammatory 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, we have shown 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 may have an additional benefit in reducing cardiovascular risk associated with RA.

Market Opportunity

RA is a disease that affects approximately 1.7 million people in the U.S. The incidence increases with age, climbing from 8.7 per 100,000 for those 18-34 years of age, to 89 per 100,000 for those 65-74 years of age. Rheumatoid arthritis is responsible for approximately 250,000 hospitalizations and 9 million physician visits per year in the U.S. If left untreated, RA can lead to joint destruction, deformity, disability, and decreased quality of life. Existing biologic therapies have made major inroads to the treatment of RA, often by targeting single pathways of inflammation in a disease that is driven by multiple inflammatory cytokine pathways. Despite the variety of options currently available, approximately one third of patients either do not respond or cannot tolerate these therapies. Such patients are in need of effective treatment. Additionally, these therapies have been associated with significant risk of opportunistic infections or malignancies. As doses are pushed in order to achieve acceptable response, such as ACR 50, ACR 70, or remission, such risks are increased. There is therefore a segment of the population who would benefit from an alternative therapeutic approach which is both safe and effective.

Ongoing Phase 2 Trial

We initiated a Phase 2 trial to evaluate the safety, tolerability and effectiveness of a single intravenous infusion of either of two MPC dose levels for the treatment of active RA in patients who have failed at least one TNF-alpha inhibitor. This randomized, double-blind, placebo-controlled, sequential dose-escalation trial is currently enrolling, with recruitment already completed for 24 patients in cohort 1 who received a single dose of 1 million MPCs per kg. These patients continue to be followed-up, while patients in the second cohort receive an MPC dose of 2 million per kg. The results of the Phase 2 program will guide the future direction of this program.

Current Status and Anticipated Milestones

Our Phase 2 trial of MPC-300-IV for the treatment of biologic refractory RA is ongoing and is evaluating in a 2:1 randomization trial design two doses ranges versus placebo. The first dose cohort has completed six months of follow-up and the second dose cohort is actively enrolling. We expect to announce top-line 6 month results from this Phase 2 placebo-controlled, dose-ranging study for the first cohort in this study by the end of 2015 and results from the second cohort during the first half of 2016. If we see a positive treatment effect following a single intravenous injection of MPC-300-IV, we will be in a position to discuss Phase 2b/3 clinical trial designs with the FDA and we believe we will be in a position to have discussions with potential strategic partners. We originally filed an IND application to begin a Phase 2 trial for biologic refractory RA in December 2012.

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 Tier 1 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.

Current Status and Anticipated Milestones

In June 2015, we announced the three month primary endpoint as well as six-month results of a placebo-controlled, dose-ranging study (2 doses) in 30 grade 3b diabetic nephropathy patients using MPC-300-IV. Both treatment cohorts are being followed up per protocol through 60 weeks. The Phase 2 trial is ongoing in Australia under an Australian Clinical Trial Application, or CTA. This trial is not being conducted in the U.S. The positive treatment effect 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.

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. Due to a severe shortage of kidneys, in 2012 approximately 92,000 persons in the US died while on the renal transplant list. 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.

Results for Diabetes Type 2 Diabetes Phase 2 Trial

As a first step in developing an MPC-based immunomodulatory therapy for the treatment of type 2 diabetes and its complications, we performed a dose-ranging study which evaluated three escalating doses in patients with type 2 diabetes and poor glycemic control, without kidney disease. The Phase 2 randomized, single-blind, placebo-controlled, dose escalation trial was conducted across 18 sites in the United States and evaluated the effects of a single intravenous infusion of 0.3, 1.0 or 2.0 million MPCs/kg or placebo over 12 weeks in 61 patients with a mean diabetes duration of 10 years. These patients had normal renal function.

The results of the trial were presented at the 74th Annual Meeting of the American Diabetes Association in 2014 and have been published in the peer-reviewed journal of the American Diabetes Association, *Diabetes Care*. The results support the safety and tolerability of a single intravenous infusion of MPCs in type 2 diabetes. Additionally, there was an improvement in glycemic control as evidenced by reduction in hemoglobin A1c (HbA1c) which, according to the FDA Guidance for Industry 2008, is the primary endpoint of choice for glycemic control in subjects with type 2 diabetes. These results may be consistent with an immunomodulatory mechanism of action of the MPCs on diabetes disease pathogenesis.

Key findings in the trial were:

- The MPCs were safe and well tolerated with no treatment-related adverse events, meeting the trial's primary endpoint.
- Following a single intravenous MPC infusion, overall HbA1c levels were reduced over the 12-week study period when compared to placebo.

- The highest dose showed the greatest overall reduction in HbA1c, with a peak decrease of 0.4% at 8 weeks compared with placebo ($p<0.05$), and a decrease of 0.3% at 12 weeks.
- In the less well-controlled subjects, as defined by a baseline HbA1c >8.0%, a 0.6% decrease in HbA1c was seen at 8 weeks in the high dose cohort compared with placebo.
- In those with baseline HbA1c <8%, a target of HbA1c <7% at week 12 was achieved in 63% (5/8) of high-dose treated subjects compared with 0/7 placebo controls ($p<0.05$).

Having established the safety of a single intravenous infusion of MPCs at up to 2.0 million cells/kg in diabetic patients without kidney disease, we moved forward with a Phase 2 trial evaluating 150 million or 300 million MPCs as a single intravenous infusion in patients with diabetes and advanced kidney disease.

Ongoing Phase 2 Trial for Kidney Disease Complicating Type 2 Diabetes

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.

In June of 2015, at the 75th annual meeting of the American Diabetes Association, we announced the results of a Phase 2 trial in patients with diabetic nephropathy. The results showed that at the trial's primary endpoint of 12 weeks, a single infusion of MPC-300-IV had a safety profile similar to placebo, reduced damaging inflammation, and preserved or improved renal function. These results were sustained for at least 24 weeks. As such, MPC-300-IV is potentially useful in patients with moderate to severe 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, or 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, or 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.

Key findings at 12 and 24 weeks in the MPC-300-IV trial were:

- Safety profile for MPC treatment was similar to placebo, with no treatment-related infusion or other events.

- Efficacy testing showed that MPC-treated subjects had improved renal function relative to placebo, as defined by preservation or improvement in GFR at both 12 and 24 weeks; these effects were seen even though this trial was not powered to show statistical significance of treatment.
- While all three groups had similar mean GFR at baseline, 34.6, 35.7 and 34.6 ml/min/1.73m2, at 12 weeks the placebo group showed a decline in measured GFR of 4.0 ml/min/1.73m2 and 3.9 ml/min/1.73m2 relative to the groups receiving a single infusion of either 150M MPC or 300M MPC, respectively; the difference in creatinine-based estimated GFR decline between placebo and the 150M group reached significance (p=0.05).
- By isotope-measured GFR, in patients with GFR>30 ml/min/1.73m2 at baseline, the placebo group showed a GFR decline at 12 weeks of 6.2 ml/min/1.73m2 relative to the pooled MPC-treated patients (p=0.07).
- By creatinine-based estimated GFR, the placebo group with GFR>30 ml/min/1.73m2 at baseline showed a GFR decline at 12 weeks of 4.5 ml/min/1.73m2 and at 24 weeks of 4.6 ml/min/1.73m2 relative to the pooled MPC treated patients (p=0.04 and p=0.13, respectively).
- There was a correlation between increased baseline IL-6 levels and improvement at 12 weeks in both serum creatinine and GFR (r=0.57, p=0.008) in MPC-treated patients.
- MPC treatment was associated with a dose-dependent inhibition of IL-6 increase over 12 weeks; serum IL-6 levels increased by 2.5 pg/dl at 12 weeks in the placebo group compared to a reduction of 0.2 pg/dl in the 300M MPC group (p=0.01).

In sum, the safety profile and the potential efficacy signals of allogeneic MPC therapy for prevention or reversal of renal functional decline in diabetic nephropathy supported advancing the clinical program in patients with the highest medical need, e.g. rapid progression towards dialysis or renal transplantation, defined as an annual GFR decline of >5ml/min/1.73m2, and high risk of cardiovascular events.

In addition, in any future trials, positive response to MPC therapy may be enhanced by the presence of viable, but at risk, renal tissue and an aberrant pro-inflammatory milieu in the kidney. Also, baseline GFR>30 ml/min/1.73 m2 and high IL-6 levels may be biomarkers that predict efficacy with MPC treatment.

More broadly, the reduction in IL-6 levels seen in this trial suggests that the mechanism of action by MPCs may involve reduction of pro-inflammatory M1 monocyte cytokines in the diabetic kidney. As such, it is possible that MPC therapy may have applications in diverse renal conditions where inflammation plays a central role.

Tier 2 Programs

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

Overview

MLCs release factors that induce functional cardiac recovery by simultaneous regeneration of endogenous vascular network formation as well as of endogenous cardiomyocytes or cardiomyocyte precursors. In preclinical studies, when injected into ischemic myocardium, MLCs are very potent inducers of large caliber arteriogenesis compared to only small vessel angiogenesis obtained with hematopoietic stem cells which only give rise to the endothelium of capillaries. Based on this mechanism, and positive results of a sheep intracoronary preclinical study, we commenced the Phase 2 Allogeneic MPC Infusion in myoCardial Infarction, or AMICI trial, of MPC-25-IC, the first clinical study to evaluate an allogeneic cellular therapy for AMI delivered by intracoronary infusion.

Market Opportunity

The majority of heart attack patients undergo angioplasty and stent procedures successfully. However, a high risk subset of patients progress over the ensuing two years to develop heart failure despite maximal therapy. For these patients, a therapy that can protect at-risk heart muscle cells from dying by delivery via intra-coronary administration at the time of the angioplasty, could prevent this major complication.

Current Status

Our Phase 2 trial for MPC-25-IC for the treatment of acute myocardial infarction is ongoing.

Phase 2 Design

The AMICI trial is a prospective, randomized, placebo-controlled, double blind clinical trial that will analyze the effect of intracoronary infusion of MPCs in patients with an ST-elevation myocardial infarction of the anterior wall. The therapy will be initiated directly following revascularization of the left anterior descending artery, along with standard therapies for AMI. Up to 225 patients with a first anterior wall AMI will be enrolled. After successful revascularization, the patients will be 1:1:1 randomized to receive 12.5 or 25 million MPC or placebo via intracoronary infusion. The primary safety endpoint is defined as the occurrence of major adverse cardiac events, or MACE, at 30 days follow up. The secondary efficacy endpoint is defined as reduction in the left ventricular end-systolic volume. Additional efficacy parameters from cardiac magnetic resonance and echocardiography will also be evaluated. The Phase 2a/2b trial is actively recruiting in Europe, Australia, and New Zealand under country-specific CTAs. The trial is not being conducted in the U.S.

MPC-25-Osteo for Spinal Fusion

Overview

MPC-25-Osteo for spinal fusion is a proprietary Phase 3-ready product candidate. All doses of MPC-25-Osteo for the treatment of spinal fusion consist of 25 million MPCs delivered on a collagen ceramic carrier material into the disk space with stabilizing hardware.

Market Opportunity

According to Millennium Research Group, or MRG, in the U.S. there were approximately 392,000 thoracolumbar spinal fusion procedures performed in 2012 of which lumbar fusion procedures form a significant part. MRG estimates the overall worldwide market for bone graft substitutes to be nearly $1.6 billion in 2012 with the majority of bone graft revenues, approximately 70%, coming from spinal fusion procedures.

Current Status

Our Phase 2 trial for MPC-25-Osteo for the treatment of spinal fusion is completed and our Phase 3 trial design is ongoing. We originally filed an IND application to begin a Phase trial for spinal fusion in November 2006. We view MPC-25-Osteo as a potential collaboration or partnership opportunity.

Phase 2 Design

We conducted a 24 patient Phase 2 study of 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).

Phase 2 Top Line Results

Treatment with MPC-25-Osteo was equivalent to hip autograft, the gold standard for this procedure, at 12 months in terms of fusing the spinal segment, reducing pain and improving function, without the need for a second surgical procedure to harvest the patient's own bone, which can cause blood loss, infection and chronic pain at the bone harvest site.

Importantly, there were no cell-related serious adverse events such as excessive bone formation or nerve compression, which have been reported with other biologic therapies in lumbar spinal fusion.

Phase 3 Design

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. While we prepare this product for Phase 3, we intend to continue our analysis of strategic options for the development and distribution of this product, which include a potential collaboration or partnering options.

MPC-CBE for Use in Bone Marrow Transplant (BMT)

Overview

MPC-CBE for BMT is a proprietary Phase 3 product candidate. All doses of MPC-CBE for use in BMT consist of hematopoietic stem cells expanded *ex vivo* by incubation with MPCs, administered intravenously.

Market Opportunity

BMT is the primary treatment option for many patients who have undergone treatment for advanced blood cancers, such as acute myeloid leukemia. At present, approximately 30,000 allogeneic BMTs are performed globally each year. The vast majority of these transplants use adult donor sources.

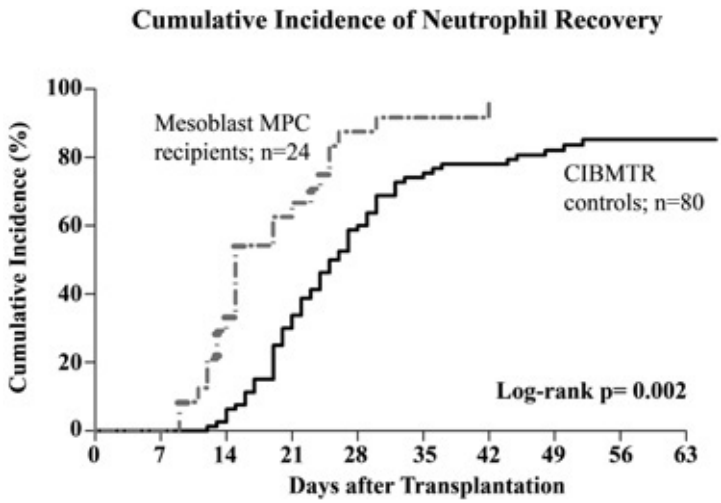
We believe the number of BMTs performed could be significantly increased if there was a safe alternative to the existing donor match material used to treat these patients. Our Phase 3 clinical trial using MPCs to expand hematopoietic precursors from cord blood for transplantation in cancer patients is ongoing. If this product is successful, it has the potential to increase the total number of unrelated donor transplants, and provide therapy for patients with malignant diseases for which transplantation is the only option for a potential successful treatment. We expect to complete our Phase 3 trial for BMT in 2018. This product falls under the Teva collaboration.

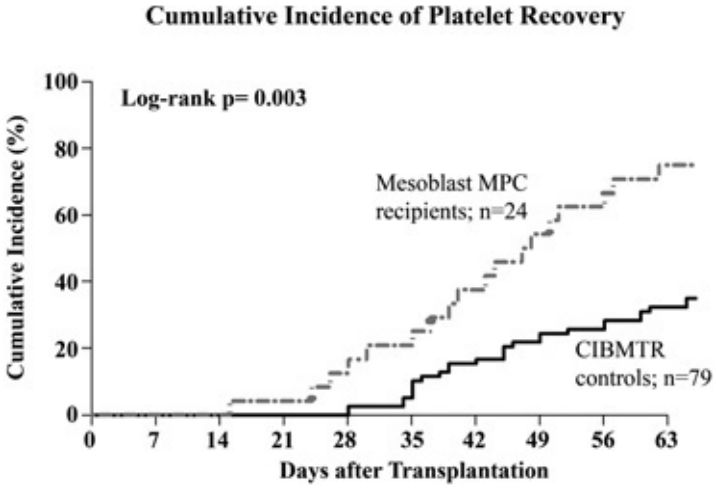
Current Status

Our Phase 3 trial for MPC-CBE for use in BMT patients is ongoing. We originally filed an IND application to begin a Phase 3 trial for BMT in June 2011.

Phase 2 Design

A 24 patient Phase 2 trial was conducted where patients were given MPC-expanded cord blood cells. Targeted patients were adults with hematologic cancers.





Phase 2 Top-Line Results

MPC-expanded cord blood significantly improved engraftment. Median time to neutrophil engraftment was 15 versus 24 days with unexpanded cord blood. Median time to platelet engraftment was 42 days for patients receiving MPC-CBE versus 49 days with expanded cord blood.

Ongoing Phase 3 Trial

A 240 patient Phase 3 study comparing patients receiving a cord blood unit expanded with our MPCs (MPC-CBE) (active arm) versus patients receiving an unexpanded cord blood unit (control arm), in evaluating reconstitution of bone marrow after high-dose chemotherapy is ongoing. Primary endpoint is time to neutrophil and platelet recovery.

Tier 2 Programs

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

Overview

MSC-100-IV for the treatment of Crohn's disease refractory to steroids and immune suppressants is a proprietary product candidate currently being evaluated in a Phase 3 trial. All doses of MSC-100-IV for the treatment of Crohn's disease consist of 100 to 200 million MSCs delivered intravenously in a multiple dose regime. An additional pivotal Phase 3 program will be needed for approval.

MSC-100-IV has demonstrated immunomodulatory properties to regulate T-cell mediated inflammatory responses by inhibiting T-cell proliferation and down-regulating the production of the pro-inflammatory cytokines, including tumor necrosis factor-alpha, or TNF-alpha, and interferon gamma. More critically, MLCs have been shown to be capable of effective down-regulation of Th17 cells, reduction in IL-17 levels, and induction of FOXP3 regulatory T cells. These inflammatory pathways are acknowledged to be central to the pathogenesis of Crohn's disease and other inflammatory conditions.

Market Opportunity

Crohn's Disease, or CD, is a chronic inflammatory disorder of the gastrointestinal tract, characterized by periods of remission and symptomatic relapse. The burden of CD is substantial, accounting for more than 1 million cases in the seven major pharmaceutical markets in 2012.

The U.S. has the highest prevalence of the disease, with more than 600,000 people afflicted and approximately 20,000 new cases diagnosed each year. Of the 600,000 U.S. patients, studies have shown that

approximately 8-20% are unresponsive, resistant or intolerant to existing treatments, which include corticosteroids, immunosuppressants and biologics. The global CD therapeutics market was estimated to be worth $4.4 billion in 2012.

A treatment to induce rapid remission is highly needed, particularly in high-risk patients such as those with biologic-resistant disease and those with fistulas, a complication of CD which occurs in 20-40% of patients and often requires invasive surgical procedures.

Current Status

Our Phase 3 trial for MSC-100-IV for the treatment of CD is ongoing. Osiris originally filed an IND application to begin a Phase 2 trial for CD in November 2005. We acquired the MSC assets to which this application relates from Osiris in October 2013.

Clinical Data and Design

A 9 patient pilot Phase 1/2 study was conducted in 2006, where there was a statistically significant decrease in mean Crohn's Disease Activity Index, or CDAI, scores of 105 points (reduced from 341 to 236) in MSC-100-IV treated patients by day 28 post-treatment, compared to control (p=0.004). The CDAI is a research tool used to quantify the symptoms of patients with Crohn's disease.

Based on those results, a 330 patient Phase 3 multi-centered, double-blind, randomized, placebo-controlled was initiated in 2007. 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 CDAI score below 150.

An interim analysis in 2009 suggested that one of the doses reached statistical significance for disease remission in the targeted population. As a result of that analysis, enrollment was restarted in 2010 utilizing only the best-performing (but undisclosed) dose and placebo.

This trial is ongoing, and when 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.

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:

- 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.

Manufacturing and Supply Chain

Overview

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.
- Distribution—with the exception of procurement and creation of master cell banks, our manufacturing is conducted in Lonza's Singapore facility, and products will be frozen, 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 our MLC product candidate for aGVHD led 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.

For other future product candidates, we are transitioning the manufacturing processes to three-dimensional, or 3D, bioreactors with greater capacity to improve efficiency and yields, with resulting lower-cost of goods.

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

Key Manufacturing Activities

The following represent current key manufacturing activities:

- Establishment of commercial manufacturing processes: we are currently manufacturing clinical grade MLC products in Lonza's Singapore facility, and are establishing a commercial process in this facility.
- Introduction of defined FBS-free media: we have developed a proprietary FBS-free media that has the potential to greatly enhance the yields achieved in production. We have made substantial progress in this development effort, and once complete, we intend to conduct "comparability" studies to illustrate that products produced with this media are equivalent to those produced using FBS based media.
- Establishment of 3D bioreactor production: we have made significant advances in the development of 3D bioreactor processes. When finalized, our proprietary 3D bioreactor process will be used solely for our clinical and commercial production. We expect to evaluate products produced in 3D bioreactors in our Phase 3 clinical trials.

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.

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 over 72 patent families, including 661 patents or patent applications as of August 31, 2015.

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 and Japan. 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 provide commercial support for 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 all of 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, and Australia and file independent and/or counterpart patents and patent applications in other jurisdictions globally that we deem appropriate under the circumstances, including China, Taiwan, India, Canada, Hong Kong, Israel, Korea, New Zealand, and Singapore. Our patent portfolio includes the following patents and patent applications in the following major jurisdictions: 59 granted U.S. patents and 48 pending U.S. patent applications; 20 granted Japanese patents and 43 pending Japanese patent applications; 19 granted European patents and 44 pending European patent applications; and 37 granted Australian patents and 28 pending Australian patent applications.

We recently strengthened and extended the coverage of our MLC patent portfolio by acquiring the MSC assets of Osiris in October 2013. These assets included a significant number of new patent families. As a result, our current patent portfolio now includes 72 patent families. Over the past year alone, we have been granted an additional 34 new patents including 6 Japanese patents, 9 United States patents, 5 Chinese patents, and 14 in other jurisdictions. As of August 31, 2015, our worldwide patent portfolio includes the following:

- 141 patents or patent applications (filed in the U.S., Europe, Australia, Canada, China, Japan, South Korea, India, Argentina, Brazil, South Africa, Mexico, New Zealand and Hong Kong) are related to specific compositions-of-matter or methods of purifying our MLCs as follows:
    - 58 patents or patent applications that we own related to MPC compositions of matter or methods of isolation, expansion or manufacture of MPCs. Granted patents under this portion of the current portfolio will begin to expire in 2020 and extend until approximately 2029 (worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid. Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will begin to expire in 2020 and extend until approximately 2026 (worldwide, excluding possible patent term extensions).
    - 51 granted patents that we own related to MSC compositions or manufacture of MSCs. Granted patents under this portion of the current portfolio will, if the appropriate maintenance, renewal, annuity, or other governmental fees are paid, begin to expire in 2018 and extend until approximately 2029 (excluding possible patent term extensions). Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will include patent coverage which will begin to expire in 2027 and extend until approximately 2035.
    - 32 patents or patent applications that we have in-licensed from the NIH related to dental pulp stem cells, or DPSCs. Granted patents under this portion of the current portfolio will begin to expire in 2021 and extend until approximately 2024 (worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid. Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will begin to expire in 2021 and extend until approximately 2024 (worldwide, excluding possible patent term extensions).
- 382 patents or patent applications (filed in the U.S., Europe, Australia, Canada, China, Japan, South Korea, India, Brazil, Singapore, Israel and Hong Kong) are related to specific therapeutic applications of our MLC-based product candidates broken down as follows:
    - 100 patents or patent applications that we own related to therapeutic applications of our MLC-based products for treatment of immunologic/inflammatory disorders (including Type 2 diabetes and complications thereof, RA, Crohn's disease and asthma, and which we believe cover uses of our product candidates MPC-300-IV for the treatment of RA and diabetic kidney disease and

MSC-100-IV for the treatment of Crohn's disease). Granted patents under this portion of the current portfolio will begin to expire in 2019 and extend until approximately 2025 (worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid. Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will begin to expire in 2025 and extend until approximately 2035 (worldwide, excluding possible patent term extensions).

- 69 patents or patent applications that we own related to therapeutic applications of our MLC-based products for treatment of cardiovascular disorders (including CHF and acute myocardial infarction and ischemic stroke, and which we believe cover our product candidates MPC-150-IM for the treatment of CHF and MPC-25-IC for the treatment of acute cardiac ischemia). Granted patents under this portion of the current portfolio will begin to expire in 2018 and extend until approximately 2024 (worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid. Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will begin to expire in 2018 and extend until approximately 2024 (worldwide, excluding possible patent term extensions).
- 65 patents or patent applications that we own related to therapeutic applications of our MLC-based products for treatment of orthopedic disorders, which we believe cover uses of our product candidates MPC-06-ID for CLBP and MPC-25-Osteo for spinal fusion. Granted patents under this portion of the current portfolio will begin to expire in 2017 and extend until approximately 2029 (worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid. Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will include patent coverage which will begin to expire in 2029 and extend until approximately 2032 (worldwide, excluding possible patent term extensions).
- 96 patents or patent applications that we own related to therapeutic applications of our MLC-based products for oncology/hematology (including GVHD and bone marrow transplantation, and which we believe cover uses of our product candidates MSC-100-IV for GVHD and MPC-CBE for bone marrow transplantation). Granted patents under this portion of the current portfolio will begin to expire in 2019 and extend until approximately 2029 (worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid. Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will begin to expire in 2029 and extend until approximately 2030 (worldwide, excluding possible patent term extensions).
- 52 patents or patent applications that we own related to other additional therapeutic applications of our MLC-based product candidates (including treatment of CNS disorders, genetic disorders and eye diseases). Granted patents under this portion of the current portfolio will begin to expire in 2027 and extend until approximately 2029 (worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid. Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will begin to expire in 2027 and extend until approximately 2032 (worldwide, excluding possible patent term extensions).

- 138 patents or patent applications (filed in the U.S., Europe, Australia, Canada, China, Japan, South Korea, India, Hong Kong, Israel, New Zealand and Singapore) are related to complementary technologies and additional product candidates as follows:
  - 63 patents or patent applications that we own related to cell-based complementary technologies supporting our cell-based pipeline and lifecycle management. Granted patents under this portion of the current portfolio will begin to expire in 2017 and extend until approximately 2022

(worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid. Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will include patent coverage which will begin to expire in 2017 and extend until approximately 2030 (worldwide, excluding possible patent term extensions).

- 27 patents or patent applications that we own related to compositions of matter comprising improved forms of SDF-1 or uses thereof. Granted patents under this portion of the current portfolio will expire in 2027 (worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid . Patent applications filed under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will begin to expire in 2027 and extend until approximately 2032 (worldwide, excluding possible patent term extensions).
- 48 patents or patent applications that we have exclusively licensed from the Trustees of Columbia University in relation to uses of various factors derived from MLCs or other biological agents for treatment of cardiovascular diseases or other fibrotic conditions. Granted patents under this portion of the current portfolio will begin to expire in 2021 and extend until approximately 2024 (worldwide, excluding possible patent term extensions) if appropriate maintenance, renewal, annuity, or other governmental fees are paid . Patent applications under this portion of the current portfolio, if granted and the appropriate maintenance, renewal, annuity, or other governmental fees are paid, will begin to expire in 2021 and extend until approximately 2023 (worldwide, excluding possible patent term extensions).

We anticipate filing additional patent applications covering our product candidates and other cellular products under development, and core technologies such as manufacturing.

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 Agreements

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 Medvet 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 we are a leader in the development of regenerative medicine products, and that we do not have any direct competitors which are currently capable of operating at a similar scale to develop products based on stem cells. As a result, we believe our competition is more indirect and general in nature, and falls into two broad categories:

- ***Biopharmaceutical companies who may develop their own approach to regenerative medicine.*** As adult stem cell therapies advance in human clinical trials and potentially gain market approvals, we expect larger biotechnology and pharmaceutical companies may become more interested in regenerative medicine. Certain of these companies, including Celgene Corporation and Johnson & Johnson, have filed patent applications relating to the use of genetically modified cells to treat disease, disorder or injury. In the future, large biopharmaceutical companies may decide to significantly increase their efforts to internally develop their own approaches, or acquire other companies or technologies, in the field of regenerative medicine.
- ***Biopharmaceutical companies who may develop competing products using other technologies.*** Products developed using our MLC platform technology will face competition in the market, including from products which have been developed using traditional biotechnology and pharmaceutical approaches. This includes both products that are already approved and distributed, as well as products currently under development or those that will begin development 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. All of our product candidates are regulated as biological products by the FDA. Within the FDA, the Center for Biologics Evaluation and Research, or CBER, regulates biological products. In the United States, biological products are subject to federal regulation under the FDCA, the Public Health Service Act, or 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 exemption, or IND, to FDA, which must include, among other information, the proposed clinical study protocol. To obtain marketing authorization once clinical testing has concluded, a BLA must be submitted for FDA approval. The process of obtaining regulatory authorizations and approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals.

U.S. Product Development Process

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 FDA's cGLP 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 or 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 and any 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;
- submission to the FDA of a BLA for marketing approval demonstrating the safety, purity and potency of the product which must be supported by substantial evidence from adequate and well-controlled clinical investigations;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, purity and potency;
- potential FDA inspection of the nonclinical and 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. Nonclinical laboratory studies that support research or marketing applications must be done in accordance with FDA's cGLP regulations.

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 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 biological 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 and monitored in accordance with the FDA's cGCP regulations and guidance, including the requirement that written informed consent to participate in the study be obtained from all participants. 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.

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

- Phase 1. The biological product 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, and, if possible, to gain early evidence of on 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 to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study, to assess side effects and risks, and
- Phase 3. Assuming preliminary evidence suggesting effectiveness has been obtained, 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. 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. 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 biological product, 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, or 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, or 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 potent, or 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 requirements 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, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the application identified by the FDA. Additionally, the complete response letter may include recommended 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, sometimes referred to as Phase 4 clinical studies, designed 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 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. 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 the 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 an 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.

A drug or biological product can 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. On February 2, 2015, President Obama released his proposed budget for fiscal year 2016 and proposed to cut this 12-year period of exclusivity down to seven years. He also proposed to prohibit additional periods of exclusivity for reference biologics due to minor changes in product formulations, a practice often referred to as "evergreening." The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a

lawsuit challenging the biologics' patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

Government Regulation Outside of the U.S.

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. The EU has vested centralized authority in the EMA and Committee on Proprietary Medicinal Products to standardize review and approval across EU member nations. Any product candidates we seek to commercialize in the EU are subject to review and approval by the EMA. In Japan, the Pharmaceuticals and Medical Device Agency, or PDMA, a division of the Ministry of Health, Labour and Welfare, or 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 new Pharmaceuticals, Medical Devices and Other Therapeutic Products Act, or PMD Act, took effect in November 2014 in Japan. The PMD Act establishes a framework for expedited approval in Japan for certain regenerative medical products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries 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, or 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 requirements and process governing the conduct of clinical studies, product licensing, coverage, pricing and reimbursement vary from country to country. In all cases, 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.

European Union Regulation

To obtain regulatory approval of an investigational biological product under EU regulatory systems, we must submit a marketing authorization application, or 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

The Pharmaceuticals, Medical Devices and Other Therapeutic Products Act, or 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 will 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.

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, the President 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. Among other things, the ACA revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the full effect of the ACA, the new law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the President 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 the President 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 new 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.

We expect that the ACA, as well as other 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. 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. 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, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. 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, and 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.

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, or 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.

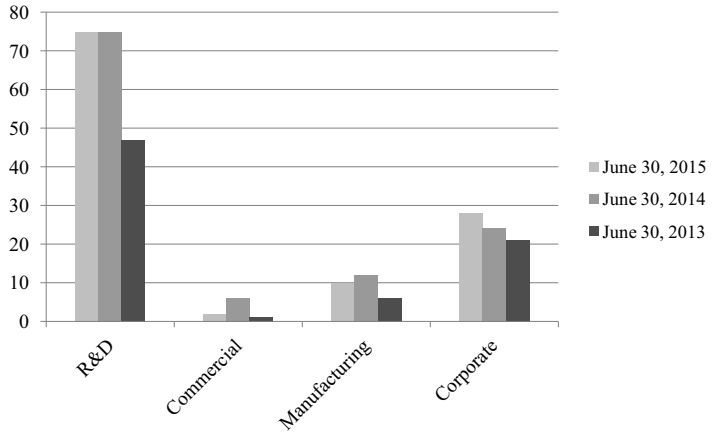
In addition, we may be subject to, or our marketing activities may be limited by, data privacy and security regulation by both the federal government and the states in which we conduct our business. For example, HIPAA and its implementing regulations established uniform federal standards for certain "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, or 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. 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 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, 2015, we had 115 full-time employees, 80 of whom are based in the United States, 26 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 117 and 75 full-time employees as of June 30, 2014, and 2013, 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. The composition of our employee base breaks down as follows:



Facilities

We lease approximately 11,150 square feet of office space in Melbourne, Australia, where our headquarters are located. We currently pay approximately A$699,000 per year for this lease, which expires in April 2020. We also lease approximately 31,000 square feet in New York City, where significant development and commercial activities are conducted. We currently pay US$1,749,000 per year for this lease, which expires in May 2021. We also lease a total of approximately 5,400 square feet of office and laboratory space in Houston. We currently pay US$195,000 per year for these leases, which expire in January 2017 and December 2015, respectively. We also lease laboratory space in Singapore. We pay approximately 231,000 Singapore dollars per year for this lease, which expires in January 2016. All of our manufacturing operations are currently located at Lonza's manufacturing facilities. See "Business—Manufacturing and Supply Chain."

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.

MANAGEMENT

Directors and Senior Management

The table below sets forth the certain information relating to our directors and senior management as of the date of this prospectus.

Name	Age	Position
Silviu Itescu	58	Chief Executive Officer and Managing Director
Paul Hodgkinson	47	Chief Financial Officer
Peter Howard	47	Corporate Executive and General Counsel
Sue MacLeman	51	Head of Commercial
John McMannis	59	Head of Manufacturing
Michael Schuster	38	Investor Relations
Paul Simmons	56	Head of Research
Donna Skerrett	58	Chief Medical Officer
Darin Weber	47	Head of Regulatory & Quality Management
Brian Jamieson	71	Chairman of the Board of Directors
William Burns	68	Director
Donal O'Dwyer	62	Director
Eric Rose	64	Director
Michael Spooner	58	Director
Ben-Zion Weiner	71	Director

Senior Management

Silviu Itescu, MBBS (Hons), FRACP, FACP, FACRA, Dr. Itescu is our Chief Executive Officer. He has served on our board of directors since our founding in 2004, was Executive Director from 2007 to 2011, and became Chief Executive Officer 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.

We believe Dr. Itescu is qualified to serve as a member of our board of directors because he 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.

Paul Hodgkinson, MA (Hons) FCA, has served as our Chief Financial Officer since June 2014. Mr. Hodgkinson 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 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 Chief Financial Officer 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 has 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), 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.

Sue MacLeman, BPharm, MMktg, MLaw, FACPP, FAICD, has been Senior Vice President since 2011 and is Commercial Head. Mrs. MacLeman has more than 20 years of experience as a pharmaceutical executive and has held roles in corporate, medical, marketing, business development and sales management roles at Schering-Plough Corporation (now Merck) (1991-1994), at Amgen Inc. (1993-1996), and at Bristol-Myers Squibb Company (1996-2002). Mrs. MacLeman also served as Chief Executive Officer at EQiTX Ltd (2004-2006), Benitec Biopharma Ltd (2007-2010), Progen Pharmaceuticals Ltd (2010-2011) and in the past served as a board member of AusBiotech Ltd, EQiTX Ltd, Benitec Biopharma Ltd and is currently a non-executive director at Reproductive Health Sciences Ltd. Before her work in the pharmaceutical industry, Mrs. MacLeman worked in various hospital roles including as a pharmacist and as an executive (1985-1991). Mrs. MacLeman has been a member of the Pharmaceutical Industry Council since 2007 and a member of the Australian Government Pharmaceutical Working Group since 2007. In 2011, Mrs. MacLeman was appointed to the Victorian Biotechnology Advisory Council.

John McMannis, PhD has served as our Head of Manufacturing since 2011. Dr. McMannis 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.

Michael Schuster, MBA has been a founding executive holding multiple executive roles with Mesoblast for the last ten years. He has served as our Executive Vice President of Global Therapeutic Programs, Director of Business Development and Vice President of Operations and Investor Relations. Mr. Schuster holds an undergraduate degree in science from Tufts University, a master's degree in Immunology & Microbiology from New York Medical College, and a MBA from Fordham University in New York.

Donna Skerrett, MD 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.

Paul Simmons, PhD has served as our Head of Research and Development since 2011. Dr. Simmons 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*.

Darin Weber, PhD has served as our Global Head of Regulatory Affairs since June 2011. Since October 2012, he also served as Head of Quality Management. Dr. Weber has 18 years of experience in cellular and tissue-based regenerative medicine products and serves on the United States Pharmacopeia Expert Committee and on committees within the International Society for Cellular Therapy and Alliance for Regenerative Medicine. Before joining Mesoblast, Dr. Weber worked as a senior consultant at Biologics Consulting Group, Inc. from February 2004 to May 2011. Prior to that, Dr. Weber worked at the FDA Center for Biologics Evaluation and Research as a regulatory management officer from 1996 to 1998, as a regulatory review officer from 1998 to 2003, and as the Chief of the Cellular Therapy Branch in the Office of Cellular, Tissue and Gene Therapies from 2002 to 2004. During his employment with the FDA, Dr. Weber held a Commission in the United States Public Health Service Commissioned Corps, with a rank of Lieutenant Commander at the conclusion of his service.

Directors

Brian Jamieson, FCA, has served on our board of directors as Chairman since 2007. Mr. Jamieson was Chief Executive of Minter Ellison, Melbourne, a major Australian law firm, 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 Bionic Ear Institute. He is a fellow of the Institute of Chartered Accountants in Australia.

We believe Mr. Jamieson is qualified to serve as a member of our board of directors because he has over 30 years of experience in providing advice and audit services to a diverse range of public and large private companies.

William Burns, BA, has served on our board of directors since March 2014. Mr. Burns has 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. Mr. Burns has also served on the board of directors of Roche Holdings AG from 2010 to 2014, Chugai Pharmaceutical Co. and Genentech from 2002 to 2014, and Crucell from 2010 to 2011. Mr. Burns is also a member of the oncology Advisory Board of the Universities of Cologne/Bonn. Mr. Burns is currently the Chairman of the board of directors of Biotie Therapies Corp. and is a non-executive director of Shire PLC. In October 2014 Mr. Burns was appointed a trustee of the Institute of Cancer Research, London, UK.

We believe Mr. Burns is qualified to serve as a member of our board of directors because of his extensive experience in the pharmaceuticals industry, specifically as a member of the board of directors of other pharmaceutical companies.

Donal O'Dwyer, BE, MBA, has served on our board of directors since 2004. Mr. O'Dwyer 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 for 12 years 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, has an MBA and is on the board of directors of a number of companies including Cochlear Limited, Atcor Medical Holdings Ltd and Fisher & Paykel Healthcare Ltd.

We believe Mr. O'Dwyer is qualified to serve as a member of our board of directors because of his extensive experience in the cardiovascular and medical devices industries.

Eric Rose, MD, has served on our board of directors since 2013. Dr. Rose is currently Chairman and Chief Executive Officer of SIGA Technologies and Executive Vice President, Life Sciences at MacAndrews & Forbes,

Inc., the holding company of Ronald O. Perelman. 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.

We believe Dr. Rose is qualified to serve on our board of directors because of his years of experience as a surgeon, researcher and businessman.

Michael Spooner, BCom, ACA, MAICD, 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 IPO in 2004 until 2007, Chair of the Audit and Risk Committee as well as a member of our 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). 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.

We believe Mr. Spooner is qualified to serve on our board of directors because of his business experience and relationships with investment firms and business communities worldwide.

Ben-Zion Weiner, BSc, MSc, PhD, has served on our board of directors since 2012. Prior to joining Mesoblast, Dr. Weiner spent 37 years at Teva until he retired in 2012. During his tenure at Teva, he served as the Vice President of Research and Development from 1986 to 2002, the Global Vice President of Global Products from 2002 to 2006, and the Chief R&D Officer from 2006 to 2012. Dr. Weiner is currently on the board of directors at Novaremed Ltd., the scientific advisory board at E-QURE Corp. and Breed IT, Corp. and has in the past served on the board of directors at Geffen Biomed Investments Ltd (2010-2013), XTL Biopharmaceuticals Limited (2012-2013) and Breed IT, Corp.

We believe Dr. Weiner is qualified to serve on our board of directors because of his experience in our industry and prior board service.

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 3000, Australia.

Board of Directors

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. Spooner and Jamieson will expire at the annual shareholders' meeting in 2015, the current terms of Messrs. Rose and Burns will expire at the annual shareholders' meeting in 2016 and the current terms of Messrs. O'Dwyer and Weiner will expire at the annual shareholders' meeting in 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; 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.

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 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 Committee. The members of our Audit and Risk 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 the 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.

Foreign Private Issuer Exemption

We qualify as a "foreign private issuer" as defined in Section 405 of the Securities Act of 1933, as amended. As a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. Under the NASDAQ listing standards, a foreign private issuer is subject to less stringent corporate governance requirements. Subject to certain exceptions, NASDAQ listing standards permit a foreign private issuer to follow its home country practice in lieu of NASDAQ listing standards.

Remuneration

Directors' Fee Structure

We have six non-executive directors, three based in Australia, one in the United States, one in Switzerland and one in Israel. Non-executive director fees are paid in accordance with Australian regulations and vary depending on the time commitment required of each director. They have been set at market rates for our industry and company size in order to attract those directors who have considerable expertise both in our industry and in the Australian capital markets.

Our aim is to establish a board of directors with global expertise in the biopharmaceutical industry and capital markets. Therefore, our non-executive directors' 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.

In keeping with our aim to attract directors with international experience, we sought and obtained shareholder approval at our annual general meeting on November 25, 2014 for a grant of options to three relatively new non-executive directors.

Director Fee Structure

Non-executive directors receive fixed fees for their services, as approved by shareholders at the 2013 annual general meeting, not to exceed a maximum fee pool of $1,250,000. Board and committee fees are structured as

outlined below which were adopted on November 1, 2013. This structure reflects advice provided by Towers Watson in October 2012 with reference to companies of comparable size and complexity.

Fees (per annum) FY15	Chair A$	Member A$
Board	328,230	128,250
Committee fees		
Audit & Risk Committee	25,000	12,500
Nomination & Remuneration Committee	20,000	10,000
Science & Technology Committee	20,000	10,000

Non-executive directors do not receive performance-related remuneration and are not provided with retirement benefits other than statutory superannuation. Non-executive directors are reimbursed for costs directly related to conducting Mesoblast business. The key terms of Non-executive directors service are documented in a letter of appointment to the Board.

Performance Review

During each year, our board of directors conducts a self-review of its performance and its operations as whole. The review is conducted internally using questionnaires and interviews between the Chairman and each individual director.

CEO Remuneration

Silviu Itescu is our CEO and founder and serves on our board of directors. Our CEO is our single largest shareholder and has been since our inception in 2004.

Our CEO's remuneration is comprised of the following components:

- Fixed remuneration, comprising base salary and statutory superannuation; and
- Performance based remuneration, comprising short-term incentives up to a maximum entitlement of 100% of fixed remuneration, based on business and individual performance.

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 the Company's share performance to align his interests in value creation. The Board reviews the CEO's remuneration package annually, including the remuneration mix.

Since June 30, 2014, a benchmarking study on CEO remuneration was performed by an independent service provider. The findings of this exercise show our CEO's overall remuneration package resides between the 25th percentile and the median of the comparison group. The comparison group included Australian-based companies with a similar market capitalization to ours, of between A$1 billion to A$1.5 billion.

Fixed Remuneration

Our CEO's annual fixed pay pursuant to his contract of employment dated April 1, 2014 is A$960,000 plus statutory superannuation. This reflected a 0.1% increase over the year ended June 30, 2014, due to a slight increase in the statutory superannuation.

Performance-Based Incentives

In order to align our CEO with our shorter-term success and the achievement of milestones which are designed to ultimately lead to long-term shareholder wealth, our CEO has 50% of his total target opportunity at risk, which is paid subject to meeting annual key performance indicators, or KPIs. These KPIs are set by our board of directors, with reference to the upcoming strategic milestones needed to be achieved in order for us to grow and set the foundation for long-term shareholder wealth.

At the end of each year, our board of directors assesses the overall performance of our company, and our CEO's individual performance against the set KPIs. The achievement of these KPIs is always assessed in the context of total corporate performance against budget which ensures cost control is always part of the performance framework and is regularly measured and reported.

Our board of directors approved the following KPIs for the CEO in the following performance categories for the year ended June 30, 2015:

KPI	Percentage	Achievement
Clinical Trial Management: regulatory and enrollment targets	40	Achieved
Manufacturing achievements	25	Substantially achieved
• Advances in technology transfers		
• Progress with commercial manufacturing capabilities		
Financial Performance	25	Substantially achieved
• company performance versus budget		
• development of strategic and capital market initiatives		
Organizational development	10	Achieved

For the year ended June 30, 2015, the total performance assessment of the achievement of the above KPIs was 90% of the target/maximum short-term incentive.

Non-CEO Executive Remuneration

Our executive management team, also referred to in this prospectus as "officers" or "senior management," consists of nine people as of June 30, 2015. Our executive team is currently located across both the United States and Australia and includes Silviu Itescu, Paul Hodgkinson, Peter Howard, Sue MacLeman, John McMannis, Michael Schuster, Paul Simmons, Donna Skerrett and Darin Weber.

Our executive team remuneration packages are designed to be competitive in each of the jurisdictions in which they are based, with close alignment across the team where skill sets and experience are similar, to ensure cohesion.

Certain compensation disclosures are provided herein with respect to our "key management personnel," which is a defined term under Australian law. Our key management personnel consist of our directors (including our CEO, Silviu Itescu) and our CFO, Paul Hodgkinson, and we are required to make certain compensation disclosures with respect to these individuals.

Remuneration Structure

The aim of our executive remuneration structure is to ensure the remuneration package reflects the skills, responsibilities and experience of our people. It is also designed to align the achievement of our goals that are ultimately set to achieve long-term shareholder value. We are committed to adhering to appropriate corporate governance standards for executive (including the CEO) remuneration, having regard to the ASX Corporate Governance Principles and Recommendations and relevant stakeholder bodies, together with mindfulness of the industry and environment we are operating within.

Our remuneration arrangements for our executive team (excluding the CEO whose details are discussed above) are comprised of both fixed and performance-based remuneration. The fixed remuneration component allows us to recruit and retain highly specialized experts in a small and competitive market. The at-risk components of short-term incentives, or STIs, and long-term incentives, or LTIs, seek to reward our executives for achieving the operational objectives that are essential to reaching our long-term objective of creating regenerative medicine therapies for major unmet clinical needs.

When conducting our annual executive remuneration review, the Nomination and Remuneration Committee considers the following:

- our operational performance and current financial position;

- the achievement of our strategic goals for the year; and
- the individual performance of our executive team members.

The Nomination and Remuneration Committee benchmarks the various components of our executive remuneration to packages paid by other publicly listed companies in our peer group, incorporates compensation data from recruitment processes and an international life sciences survey, and considers recommendations from our CEO (other than for his own salary). From time to time the Nomination and Remuneration Committee engages the services of outside compensation consultants.

As approximately 70% of our employees are in the United States, it is critical that our approach to remuneration in that market is appropriate and competitive, to ensure we can hire and retain the key individuals we need to give us the best opportunity for success.

Fixed Remuneration

Fixed remuneration consists of base salary, and in keeping with local market practices our Australian executives receive employer superannuation contributions, up to the statutory limits, and our United States executives receive medical and insurance benefits.

Performance-Based Remuneration

Our performance-based remuneration components consist of at-risk STIs and LTIs. Annual STI and LTI grants are determined each year by the CEO together with the Nomination and Remuneration Committee, with regard to both individual performance and overall corporate performance. STI and LTI recommendations are then subject to approval by our board of directors.

Short-Term Incentives (STIs). Our approach to STI setting is influenced by the fact that we are in development stage, as follows:

- we set STIs at a smaller proportion of our total target remuneration than LTIs to conserve cash outflow; and
- we measure performance against the following:
  - achievement of individual KPIs;
  - key corporate and budgetary milestones; and
  - achievement of strategic goals.

All of the factors lead to long-term shareholder value creation.

KPIs for the executive team are closely aligned to our strategy and objectives, and our CEO's own KPIs. This ensures that by their achievement they will contribute to the overall corporate goals.

STI allocations for the executive team start with an assessment of overall company performance against key milestones, strategic goals and budget performance. The STIs are then adjusted up or down based on each executive's operational ability to contribute to our goals and their individual performance against their own individual KPIs. For the year ended June 30, 2015, executive STI allocations were between 80% and 100% of target. STIs are paid in cash.

The following is a summary of the key features of our Short-Term Incentive Plan, or STIP:

What is the STIP?	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 STIP grant paid to eligible employees?	The STIP amount will be paid to each participant who satisfies applicable performance measures in August of each year following assessment of performance against the applicable measures during our fiscal year end.
Who participates in the STIP?	All employees hired on or before March 31 of the relevant year are eligible for consideration. Employees hired during the year are recognized on a pro-rata basis.
Why does our board of directors consider the STIP an appropriate incentive?	The STIP 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 STIP?	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 fiscal 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 example, if we achieve an 85% company performance assessment, then 85% of the total bonus pool will be available for allocation to individual employees. The executives evaluate individual performance contributions 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.
What is the period over which our performance is assessed?	The assessment period is the fiscal year preceding the payment date of the STIP (July 1 through June 30).

Long-Term Incentives (LTIs). As a biotechnology company which is still in the clinical trial development stage, we aim to conserve our cash resources in order to fund our programs, therefore we place significant weight on the LTI component of our remuneration mix. This focuses our executives on the value creation that occurs as our products move through development process and ultimately to therapeutic treatment.

In designing a LTI mechanism which aims to reward and retain talent across our locations, and considering a large portion 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.

In view of the points outlined above our approach is to issue LTIs to executives that are time based. They are generally approved at a premium to the actual share price. It is our belief that this approach is the appropriate one for us at this stage as we believe that the addition of performance hurdles to our LTI program would make it problematic for us to attract and retain the people we need, particularly in the United States, and would ultimately be negative for our company. This is an area we continue to review and assess on an ongoing basis.

In Australia, most LTIs made prior to July 1, 2015 consisted of our limited recourse loan-funded shares pursuant to the rules of the Loan-funded Share Plan, or LFSP. Changes to the tax treatment of employee share schemes in Australia became effective on July 1, 2015. These changes alter the relevance of using a LFSP for Australian participants. As a result, we returned to using a single plan, our Employee Share Option Plan, or ESOP, for all participants, effective July 10, 2015. Existing grants under the LFSP generally remain the same until the grants vest and the loans have been repaid. Outside Australia prior to July 1, 2015 and globally thereafter, LTIs consist of options over our ordinary shares under the rules of the Employee Share Ownership Plan, or ESOP. Both the ESOP and LFSP were approved by shareholders at the annual general meeting held in November 2013. Both plans operate in a similar manner, with the shares/options typically having a purchase/ exercise price premium applied, over a three-year vesting schedule. Grants made prior to July 1, 2015 had a five-year term. Recognizing that option grants in the U.S. where the majority of our LTI participants reside typically have a ten-year term, the grant made on July 10, 2015 was issued with a seven-year term. Our board of directors considers the appropriate term at the time each grant is approved.

Executive 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/loan funded shares reflecting the Board's assessment that this grant size will deliver the desired value to the executives over time.

Shares issued in the LFSP are generally issued as new equity, and we do not buy shares on-market under this plan in an effort to conserve cash.

The following is a summary of the key features of the ESOP and LFSP (collectively, the LTI Plans):

Long Term Incentive Plans:

Why does our board of directors consider the LFSP/ ESOP an appropriate long-term incentive?	The LTI Plans are designed to reward participants for our performance and to align long-term interests of shareholders, participating employees and us, by linking a significant proportion of at-risk remuneration to our future performance, currently assessed over a three-year period from the date of grant of the shares.
In what circumstances are LTI entitlements forfeited?	The LTI will be forfeited upon cessation of employment prior to the conclusion of the performance period in circumstances where a participant is a "bad leaver" as defined in the LTI Plan rules, or breaches any term of the loan agreement under the LFSP, or the Loan Agreement, in the case of the LFSP. Otherwise a leaver may retain vested loan funded shares or options subject to repayment of the loan or exercising the option within 60 days of cessation of employment or within a longer period if so determined by our board of directors.

What are the performance conditions under the LTI scheme?	Shares and options are generally issued at a 10% premium above the volume weighted average share price calculated at grant date. In addition participants have to remain in employment with us for the LTIs to vest.
Why did our board of directors choose the above performance conditions/hurdles?	High volatility makes it difficult to set meaningful performance hurdles other than price premiums, and applying such hurdles may have a severe impact on the competitiveness of remuneration.
What is the relationship between our performance and allocation of shares/options?	Equity-based remuneration is an integral part of remuneration in the biotechnology industry as companies in that sector reward share price growth and seek to conserve cash. Our board of directors believes that share price growth is an appropriate measure of success as it is the prime driver of investment in the biotechnology sector, and is simply and clearly rewarded using equity-based remuneration.
What is the maximum number of shares/options that may be granted to a participant to the LTI scheme?	The maximum number of shares or options that may be granted is determined by the level of equity based remuneration applicable to each applicant.
When do the shares/options vest?	Shares/options vest in three equal tranches, one year, two years and three years after the date of grant, provided performance conditions are met.
Is the benefit of participation in the LTI scheme affected by changes in the share price?	Yes, participants in the both ESOP and LFSP will be affected in the same way as all other shareholders by changes in our share price. The value participants receive through participation in the LTI Plans will be reduced if the share price falls during the performance period and will increase if the share price rises over the performance period.
Australian Loan Funded Share Plan (LFSP):	
What is the LFSP?	An incentive plan under which eligible employees are granted our limited recourse, interest free, loan-funded ordinary shares.
Who participates in the LFSP?	All of our eligible non-director and non-officer Australian based employees 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 LFSP?	Loan funded shares are issued with a price per share that is typically 10% higher than the five-day volume weighted average share price calculated at grant date. The loan funded shares are subject to a Loan Agreement between the participant and us. Once all conditions are met and the participant no longer has any outstanding obligations pursuant to the Loan Agreement, the loan funded shares revert to being fully paid ordinary shares.

How are shares provided to participants under the LFSP?	Shares issued in the LFSP are generally issued as new equity and we do not buy shares on-market under this plan in an effort to conserve cash.

ESOP:

The ESOP operates as a traditional option plan, and is used for non-Australian based employees:

What is the ESOP?	An incentive plan under which eligible employees are granted options over our ordinary shares.
Who participates in the ESOP?	All of our employees, 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?	Options are issued with an exercise price that is typically 10% higher than the volume weighted average share price calculated at grant date. High volatility makes it difficult to set meaningful performance hurdles and applying such hurdles may have a severe impact on the competitiveness of remuneration.
How are 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).

Employment Agreements

The employment of our CEO and CFO are formalized in contracts of employment, the key terms of which are as follows:

Name	Term	Notice Period	Termination Benefit
Silviu Itescu	Initial term of 3 years commencing April 1, 2014, and continuing subject to a 12 month notice period	12 months	12 months base salary
Paul Hodgkinson	Ongoing employment agreement until notice is given by either party	6 months	6 months base salary

On termination of employment, key management personnel (and executive directors, including Dr. Itescu, and Mr. Hodgkinson) are entitled to receive their statutory entitlements of accrued annual and long service leave, together with any superannuation benefits.

Non-executive directors are not provided with retirement benefits other than statutory superannuation which is only applicable to Australian resident directors.

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. Five members of the executive team have employment contracts with initial terms ranging from 15 months to three years, with notice periods ranging from six to twelve months. The remaining four members have continuous employment contracts with no fixed term and notice periods ranging from “at will” to twelve months. Two contracts have contractual CPI increases—there are no other contractual increases in remuneration.

Remuneration Details

Details of the remuneration of our individual directors and key management personnel for the year ended June 30, 2015 are set out below (amounts are presented in various currencies as detailed in the table):

		Short-Term Benefits					Post-Employment Benefits	Long-Term Benefits	Share-Based Payments	Other	
	Currency	Salary and Fees	Cash Bonus(1)	Annual Leave	Non-Monetary Benefits	Other	Super-annuation	Long-Service Leave	Options	Termination Benefits	Total
Silviu Itescu (CEO)	A$	960,000	864,000	59,078	—	—	18,783	19,052	—	—	1,920,913
Paul Hodgkinson(2) (CFO)	A$	367,233	212,500	7,968	—	63,128	25,088	690	228,589	—	905,196
William Burns	A$	134,278	—	—	—	—	—	—	37,799	—	172,077
Brian Jamieson	A$	328,320	—	—	—	—	18,783	—	—	—	347,103
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	—	—	—	—	—	—	37,799	—	176,049
Eric Rose	A$	148,250	—	—	—	—	—	—	37,799	—	186,049
Total directors and executive KMP	**A$**	**2,400,331**	**1,076,500**	**67,046**	**—**	**63,128**	**93,434**	**19,742**	**341,986**	**—**	**4,062,168**
Total directors and executive KMP(3)	**US$**	**1,980,274**	**888,113**	**55,313**	**—**	**52,080**	**77,083**	**16,287**	**282,138**	**—**	**3,351,288**

(1) STI bonus payable for performance in the year ended June 30, 2015, not paid as of June 30, 2015.
(2) Appointed as KMP on August 25, 2014. Paul Hodgkinson was paid a sign on bonus of A$72,000 in July 2014 which has been excluded from the table above as it predated his appointment as a KMP.
(3) The US$ results has been translated at the average weighted exchange rate for the year ended June 30, 2015.

Details of the remuneration of our individual directors and key management personnel for the year ended June 30, 2014 are set out below (amounts are presented in various currencies as detailed on the table):

2014		Short-term benefits					Post-employment benefits	Long-term benefits	Share-based payments	Other	
Name	Currency	Salary & fees	Cash Bonus(5)	Annual Leave	Non-monetary benefits	Other	Super-annuation	Long service leave	Options	Termination benefits	Total
Silviu Itescu (CEO)	A$	960,000	840,000(2)	38,493(3)	—	—	17,775	23,173(4)	—	—	1,879,441
William Burns(1)	A$	44,145	—	—	—	—	—	—	—	—	44,145
Brian Jamieson	A$	325,547	—	—	—	—	17,775	—	—	—	343,322
Donal O'Dwyer	A$	159,667	—	—	—	—	14,769	—	—	—	174,436
Michael Spooner	A$	162,167	—	—	—	—	15,000	—	—	—	177,167
Ben-Zion Weiner	A$	134,667	—	—	—	—	—	—	—	—	134,667
Eric Rose	A$	142,167	—	—	—	—	—	—	—	—	142,167
Total directors	**A$**	**1,928,360**	**840,000**	**38,493**	**—**	**—**	**65,319**	**23,173**	**—**	**—**	**2,895,345**
Total directors(6)	**US$**	**1,772,163**	**771,960**	**35,375**	**—**	**—**	**60,028**	**21,296**	**—**	**—**	**2,660,822**

(1) William Burns joined the Board on March 6, 2014;
(2) STI payable for the year ended June 30, 2014. This represents 87.5% of target bonus, and therefore an amount of A$120,000 (12.5%) was forfeited.
(3) Annual leave has been amended from what was reported in 2014.
(4) Long service leave has been amended from what was reported in 2014.
(5) STI bonus payable for performance in the year ended June 30, 2014, not paid as at June 30, 2014.
(6) The US$ results has been translated at the average weighted exchange rate for the year ended June 30, 2014.

Performance-Based Remuneration

Performance-based remuneration consists of STIs and LTIs. The relative proportions of remuneration that are linked to performance and those that are fixed, for executives that are key management personnel, are as follows:

	Fixed remuneration		At risk - STI		At risk - LTI	
	2015	2014	2015	2014	2015	2014
Name	%	%	%	%	%	%
Silviu Itescu	55	54	45	46	0	0
Paul Hodgkinson	55	N/A	22	N/A	23	N/A

The proportion of at-risk performance remuneration that was awarded and forfeited during the periods presented was as follows:

	At-Risk STI	
Name	Awarded %	Forfeited %
Silviu Itescu (for the year ended June 30, 2015)	90	10
Silviu Itescu (for the year ended June 30, 2014)	87.5	12.5
Paul Hodgkinson (for the year ended June 30, 2015)	100	—

Remuneration Consultants

During the year ended June 30, 2015, the Nomination and Remuneration Committee of our board of directors engaged KPMG, to provide a report on the following matters:

- review and benchmarking of the CEO's remuneration;
- review of FY14 Remuneration Report;
- review of fee structure for overseas Non-executive directors;
- advice regarding transition of loan funded share plan for Australian participants; and
- disclosure advice for KMP.

Their report did not include any remuneration recommendations within the meaning of section 9B of the Corporations Act, and consequently they are not considered to be remuneration consultants in relation to Mesoblast as defined by section 9B of the Corporations Act.

Share Based Compensation

Share options granted to key management personnel (our directors, including Dr. Itescu and Mr. Hodgkinson) in the year ended June 30, 2015 were 450,000 share options granted to Mr. Hodgkinson, and 80,000 share options granted to each of Mr. Burns, Mr. Rose and Mr. Zion-Weiner. 300,000 of Mr. Hodgkinson's options were originally granted on August 8, 2014 under our LFSP and were changed from loan funded shares to options under ESOP on March 25, 2015. There were no changes made to the terms pertaining to the exercise price or the expiry date during this modification.

There were no grants of share options made to key management personnel, including to our directors, in the year ended June 30, 2014. There has been no modification to any terms and conditions of share-based payment transactions during the year ended June 30, 2014.

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, 2015 and 2014 and the period from July 1, 2015 through to November 10, 2015 are set out in the tables below:

Remuneration Values

The following table provides the remuneration values:

	Remuneration consisting of options(1)	Value of options granted(2)	Value of options exercised(3)	Value of options lapsed(4)
Paul Hodgkinson (from July 1, 2015 through November 10, 2015)	27.5%	A$280,000	—	—
Donal O'Dwyer (from July 1, 2015 through November 10, 2015)	—	—	A$1,079,474	—
William Burns (for the year ended June 30, 2015)	22.0%	A$103,616	—	—
Eric Rose (for the year ended June 30, 2015)	20.3%	A$103,616	—	—
Ben-Zion Weiner (for the year ended June 30, 2015)	21.5%	A$103,616	—	—
Brian Jamieson (for the year ended June 30, 2015)	—	—	A$328,500	—
Paul Hodgkinson (for the year ended June 30, 2015)	25.3%	A$411,840	—	—
Brian Jamieson (for the year ended June 30, 2014)	—	—	A$582,750	—

(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 IFRS2 Share-based payments.

(2) The accounting value at grant date of options that were granted during the year presented as part of remuneration, determined using Black-Scholes valuation model and in accordance with IFRS2 Share-based payments.

(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.

Number of Options

The following table provides the number of options:

	No. of options granted during the period	No. of options vested during the period	No. of options lapsed during the period
Paul Hodgkinson (from July 1, 2015 through November 10, 2015)	200,000	—	—
William Burns (for the year ended June 30, 2015)	80,000	—	—
Eric Rose (for the year ended June 30, 2015)	80,000	—	—
Ben-Zion Weiner (for the year ended June 30, 2015)	80,000	—	—
Brian Jamieson (for the year ended June 30, 2015)	—	—	—
Paul Hodgkinson (for the year ended June 30, 2015)(1)	450,000	450,000	—

(1) Paul Hodgkinson was granted 450,000 share options. Of this 450,000 options, 300,000 were granted as a result of the planned repurchase and cancellation of 300,000 loan-funded shares in anticipation of this offering are in compliance with the Sarbanes-Oxley Act. Those 450,000 have vested, however they may not be exercised until their escrow period have lapsed.

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
Brian Jamieson (for the year ended June 30, 2015)	75,000	75,000	October 27, 2014	A$3.86	A$1.73
Brian Jamieson (for the year ended June 30, 2015)	75,000	75,000	November 11, 2014	A$3.98	A$1.73
Brian Jamieson (for the year ended June 30, 2014)	75,000	75,000	September 2, 2013	A$5.65	A$1.73
Brian Jamieson (for the year ended June 30, 2014)	75,000	75,000	December 13, 2013	A$5.58	A$1.73
Donal O'Dwyer (from July 1, 2015 through November 10, 2015)	287,903	287,903	July 6, 2015	A$3.81	US$0.046

Options Granted as Remuneration

The following table presents options and loan-funded shares that have been granted over unissued shares during or since the end of the years ended June 30, 2015 and 2014, to our key management personnel and our next 4 highest remunerated officers that are not also designated as key management personnel.

Name of Officer	Grant Date	Exercise Price	Number of shares, under option or loan-funded
Silviu Itescu	—	—	—
Paul Hodgkinson	July 10, 2015	A$4.22	200,000
Paul Hodgkinson(2)	March 25, 2015	A$4.71	450,000
William Burns	November 25, 2014	A$4.02	80,000
Eric Rose	November 25, 2014	A$4.02	80,000
Ben-Zion Weiner	November 25, 2014	A$4.02	80,000
Peter Howard(1)(3)	March 25, 2015	A$4.46	600,000
Peter Howard(1)(3)	March 25, 2015	A$5.00	850,000
Michael Schuster(1)	July 10, 2015	A$4.22	200,000
Michael Schuster(1)	September 5, 2014	A$4.71	200,000
Donna Skerrett(1)	July 10, 2015	A$4.22	200,000
Donna Skerrett(1)	September 5, 2014	A$4.71	200,000
Darin Weber(1)	July 10, 2015	A$4.22	200,000
Darin Weber(1)	September 5, 2014	A$4.71	200,000

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

(2) 300,000 of Mr. Hodgkinson's options were originally granted on August 8, 2014 under the LFSP and were changed from loan funded shares to options on March 25, 2015. There were no changes made to the terms pertaining to the exercise price or the expiry date during this modification.

(3) On March 25, 2015, we repurchased and correspondingly cancelled 1,450,000 loan-funded shares that had previously been granted to Mr. Howard (including 600,000 that were issued on September 5, 2014). As compensation for the repurchase and cancellation of these loan-funded shares, replacement share options were issued under our ESOP. The changes to Mr Howard's options were consistent with changes made to all options issued to Australian based executives.

PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding the beneficial ownership of our ordinary shares at September 30, 2015 by:

- each of our directors and key management personnel; and
- each person known by us to own more than 5% of our ordinary shares.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the persons named in the following table have sole voting and investment power with respect to all ordinary shares that they beneficially own, subject to applicable community property laws.

The percentage ownership of each listed person before this offering is based upon 337,420,632 ordinary shares outstanding at September 30, 2015.

which excludes:

- the exercise of employee options outstanding at September 30, 2015 to purchase 22,650,841 fully paid ordinary shares issuable upon at a weighted average exercise price of A$5.09 per ordinary share;

and includes:

- an aggregate of 3,500,000 ordinary shares at a weighted average exercise price of A$6.78 held in trust as part of our loan funded share plan, or LFSP.

As of September 30, 2015, we had 20 holders of record in the United States, which represented approximately 17.1% of our ordinary shares outstanding. The percentage ownership of each listed person after the offering is based upon 374,818,717 ordinary shares outstanding immediately after the closing of this offering, including the ordinary shares identified in the immediately preceding sentence plus the ordinary shares to be sold by us in this offering.

In computing the number of ordinary shares beneficially owned by a person and the percentage ownership of that person, we deemed outstanding ordinary shares subject to options held by that person that are currently exercisable or exercisable within 60 days of September 30, 2015. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

We have granted the underwriters the right to purchase up to an additional 1,121,942 ADSs from us at the initial public offering price less underwriting discounts and commissions.

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.

Name	Ordinary Shares beneficially owned before offering		Ordinary Shares beneficially owned after offering (assuming no exercise of the over-allotment option)(9)	
	Number	%	Number	%
5% or Greater Shareholders:				
M&G Investment Group(1)	38,967,697	11.5%	38,967,697	10.4%
Cephalon, Inc.(2)	55,785,806	16.5%	55,785,806	14.9%
Silviu Itescu(3)	68,244,642	20.2%	68,244,642	18.2%
Capital Research Global Investors(4)	26,600,000	7.9%	26,600,000	7.1%
Thorney Holdings(5)	19,015,000	5.6%	19,015,000	5.1%
Directors and key management personnel:				
Silviu Itescu(3)	68,244,642	20.2%	68,244,642	18.2%
William Burns	26,667	*	26,667	*
Brian Jamieson(6)	610,000	*	610,000	*
Paul Hodgkinson	150,000	*	150,000	*
Eric Rose	26,667	*	26,667	*
Donal O'Dwyer(7)	1,104,727	*	1,104,727	*
Ben-Zion Weiner	26,667	*	26,667	*
Michael Spooner(8)	1,059,000	*	1,059,000	*
All directors and key management personnel as a group (8 persons)	**71,248,370**	**21.1%**	**71,248,370**	**19.0%**

* Less than 1% of the outstanding ordinary shares.

(1) 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 EC4R 0HH, United Kingdom.

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

(3) 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.

(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.

(6) Includes (a) 335,000 ordinary shares owned by Mr. Jamieson, (b) 275,000 ordinary shares owned by Mr. Jamieson through Brians Maserati Pty Ltd.

(7) Includes (a) 300,000 ordinary shares owned by Mr. O'Dwyer, (b) 292,903 ordinary shares owned by Dundrum Investments Ltd. as trustee for The O'Dwyer Family Trust, and (c) 511,824 ordinary shares subject to options currently exercisable held by Dundrum Superannuation Fund. Mr. O'Dwyer and his spouse are the sole shareholders of Dundrum Investments Ltd.

(8) Includes (a) 868,272 ordinary shares owned by Mr. Spooner, (b) 181,728 ordinary shares owned by Spooner Superannuation Fund, and (c) 9,000 ordinary shares owned by Mr. Spooner's family.

(9) Excludes purchases made in connection with this offering.

RELATED PARTY TRANSACTIONS

Other than compensation arrangements which are described under "Management—Remuneration" or as disclosed below, from July 1, 2012 through November 10, 2015 we did not enter into any transactions or loans with any: (i) enterprises that directly or indirectly, through one or more intermediaries, control, are controlled by or are under common control with us; (ii) associates; (iii) individuals owning, directly or indirectly, an interest in our voting power that gives them significant influence over us, and close members of any such individual's family; (iv) key management personnel and close members of such individuals' families; or (v) enterprises in which a substantial interest in our voting power is owned, directly or indirectly, by any person described in (iii) or (iv) or over which such person is able to exercise significant influence.

Teva/Cephalon

In December 2010, we entered into a development and commercialization agreement, or DCA, with Cephalon, Inc., now a wholly-owned subsidiary of Teva, and one of our largest equity holders. See "Principal Shareholders." In this section, we refer to Cephalon and Teva together as Teva. In September 2013, we and Teva amended the DCA. See "Business—Our Strategic Alliances—Teva/Cephalon, Inc.—Cardiovascular, Neurological and Bone Marrow Collaboration" for a description of the DCA, as amended.

In December 2010, we also entered into a subscription deed with Teva, or the Deed. Pursuant to the Deed, for so long as Teva holds at least 10% of our outstanding ordinary shares, in connection with any future placements of our ordinary shares or issues of ordinary shares on the conversion of convertible securities, Teva has the right to subscribe, on the same terms and at the same time, for additional ordinary shares that would result in Teva maintaining its same percentage ownership in Mesoblast immediately before and after the issuance. Teva's subscription right does not apply to issuances made (i) under an option plan or pursuant to remuneration arrangements for employees or directors, (ii) under a dividend reinvestment plan or (iii) pursuant to an acquisition agreement. Teva's subscription right is conditioned upon the ASX granting a waiver of Listing Rule 6.18, which restricts options from being exercisable over a percentage of an ASX listed company's capital.

Loan-Funded Share Plan

Our loan-funded share plan, or LFSP, is our incentive plan under which eligible non-director and non-officer employees are granted limited recourse, interest free, loan-funded ordinary shares of Mesoblast. As of June 30, 2015, we had A$23.7 million of loans outstanding under the LFSP. During the period from July 1, 2012 through June 30, 2015, the largest amount outstanding under the LFSP was A$41.4 million. On April 13, 2015, in anticipation of this offering and in compliance with the Sarbanes-Oxley Act, we repurchased an aggregate amount of A$17.7 million of loans under our LFSP and correspondingly cancelled 2,985,000 of our ordinary shares held in trust for certain of our officers. As remuneration for the repurchase of loans and cancellation of these ordinary shares under our LFSP, we granted options to purchase 2,985,000 of our ordinary shares at exercise prices ranging from A$4.46 to A$5.00 under our ESOP. As of the date of this prospectus, we had A$23.7 million of loans outstanding under the LFSP corresponding to 3,500,000 ordinary shares held in trust for non-directors and non-officers. See "Management-Remuneration-Non-CEO Executive Remuneration-Performance-Based Remuneration-Long-Term Incentives (LTIs)-Australian Loan Funded Share Plan (LFSP)" for a more detailed description of the LFSP.

Indemnification Agreements and Directors' and Officers' Liability Insurance

Under our Constitution, to the extent permitted by the Corporations Act we may indemnify or insure any person who is or has been our or any of our subsidiaries' officer, which indemnity or insurance policy may be in such terms as the directors approve and, in particular, may apply to acts or omissions prior to or after the time of entering into the indemnity or policy. Under Australian law, an "officer" includes any director.

We have entered into Deeds of Indemnity, Insurance and Access, or Indemnity Deeds, with each director.

Under the Indemnity Deeds, we have agreed to indemnify (to the maximum extent permitted under Australian law and subject to certain specified exceptions) each director and certain of our officers against all liabilities incurred in their capacity as our or our subsidiaries' director or officer and any and all legal costs incurred by such director or officer in defending an action for a liability incurred in their capacity as our or our subsidiaries' director or officer. The Indemnity Deeds provide that the indemnities are unlimited as to amount, continuous and irrevocable.

Separately, we have obtained insurance for each of our directors, as required by the Indemnity Deeds, and each of our officers.

DESCRIPTION OF SHARE CAPITAL

General

The following description of our ordinary shares is only a summary. We encourage you to read our Constitution, which is included as an exhibit to the registration statement of which this prospectus forms a part.

We are a public company limited by shares registered under the Corporations Act by the Australian Securities and Investments Commission, or ASIC. Our corporate affairs are principally governed by our Constitution, the Corporations Act and the ASX Listing Rules. Our ordinary shares trade on the ASX, and we have received approval to list our ADSs on the NASDAQ Global Select Market.

The Australian law applicable to our Constitution is not significantly different than a U.S. company's charter documents except we do not have the concept of, or a limit on, our authorized share capital, the concept of par value is not recognized under Australian law and as further discussed under "—Our Constitution."

Subject to restrictions on the issue of securities in our Constitution, the Corporations Act and the ASX Listing Rules and any other applicable law, we may at any time issue ordinary shares and grant options or warrants on any terms, with the rights and restrictions and for the consideration that our board of directors determines.

The rights and restrictions attaching to ordinary shares are derived through a combination of our Constitution, the common law applicable to Australia, the ASX Listing Rules, the Corporations Act and other applicable law. A general summary of some of the rights and restrictions attaching to our ordinary shares is set forth below. Each shareholder is entitled to receive notice of, and to be present, vote and speak at, general meetings.

Changes to Our Share Capital

As of June 30, 2015, we had (i) 333,497,729 fully paid ordinary shares outstanding, (ii) employee options outstanding to purchase 18,369,078 of our ordinary shares at a weighted average exercise price of A$5.25, and (iii) an aggregate of 3,500,000 ordinary shares held in trust as part of our LFSP at a weighted average exercise price A$6.78.

During the three years ended June 30, 2015, 2014 and 2013, the following changes have been made to our ordinary share capital:

- On March 14, 2013, we issued 26,970,979 ordinary shares to institutional investors in a private placement in Australia and certain other countries. Consideration per share was A$6.30;
- On October 29, 2013, we issued 70,164 ordinary shares as consideration for the acquisition of certain assets from Provasculon, Inc. Consideration per share was A$5.96;
- On December 18, 2013, we issued 2,948,729 ordinary shares to Osiris Therapeutics, Inc. as consideration for taking delivery of the assigned and other assets pursuant to the purchase agreement for the acquisition of the entire culture expanded mesenchymal stem cell assets of Osiris Therapeutics, Inc. Consideration per share was A$5.69; and
- On April 15, 2015, we issued 15,298,837 ordinary shares to Celgene Corporation as consideration for $45 million investment at a price per share of A$3.82.

In addition, we issued the following fully-paid ordinary shares upon exercise of employee options:

- 1,043,798 ordinary shares in the year ended June 30, 2015;
- 987,300 ordinary shares in the year ended June 30, 2014; and
- 2,552,816 ordinary shares in the year ended June 30, 2013.

Our Constitution

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 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. Our Constitution is filed as an exhibit to the registration statement of which this prospectus forms a part.

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 installment.

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 by those members 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.

Foreign Ownership Regulation

There are no limitations on the rights to own securities imposed by our Constitution. However, acquisitions and proposed acquisitions of shares in Australian companies may be subject to review and approval by the Australian Federal Treasurer under the Foreign Acquisitions and Takeovers Act 1975, or the FATA, which generally applies to acquisitions or proposed acquisitions:

- by a foreign person (as defined in the FATA) or associated foreign persons that would result in such persons having an interest in 15% or more of the issued shares of, or control of 15% or more of the voting power in, an Australian company; and
- by non-associated foreign persons that would result in such foreign person having an interest in 40% or more of the issued shares of, or control of 40% or more of the voting power in, an Australian company.

The Australian Federal Treasurer may prevent a proposed acquisition in the above categories or impose conditions on such acquisition if the Treasurer is satisfied that the acquisition would be contrary to the national interest. If a foreign person acquires shares or an interest in shares in an Australian company in contravention of the FATA, the Australian Federal Treasurer may order the divestiture of such person's shares or interest in shares in Mesoblast. The Australian Federal Treasurer may order divestiture pursuant to the FATA if he determines that the acquisition has resulted in that foreign person, either alone or together with other non-associated or associated foreign persons, controlling Mesoblast and that such control is contrary to the national interest.

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. Upon becoming a U.S. listed public company, our shareholders will also be 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 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.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

American Depositary Receipts

JPMorgan Chase Bank, N.A., as depositary will issue the ADSs which you will be entitled to receive in this offering. Each ADS will represent an ownership interest in five ordinary shares which we will deposit with the custodian, as agent of the depositary, under the deposit agreement among ourselves, the depositary and yourself as an ADR holder. In the future, each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to you. Unless certificated ADRs are specifically requested by you, all ADSs will be issued on the books of our depositary in book-entry form and periodic statements will be mailed to you which reflect your ownership interest in such ADSs. In our description, references to American depositary receipts, or ADRs, shall include the statements you will receive which reflect your ownership of ADSs.

The depositary's office is located at 4 New York Plaza, Floor 12, New York, New York, 10004.

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder, we will not treat you as a shareholder of ours and you will not have any shareholder rights. Australian law governs shareholder rights. Because the depositary or its nominee will be the shareholder of record for the ordinary shares represented by all outstanding ADSs, shareholder rights rest with such record holder. Your rights are those of an ADR holder. Such rights derive from the terms of the deposit agreement to be entered into among us, the depositary and all registered holders from time to time of ADSs issued under the deposit agreement. The obligations of the depositary and its agents are also set out in the deposit agreement. Because the depositary or its nominee will actually be the registered owner of the ordinary shares, you must rely on it to exercise the rights of a shareholder on your behalf. The deposit agreement and the ADSs are governed by New York law. Under the deposit agreement, as an ADR holder, you agree that any legal suit, action or proceeding against or involving us or the depositary, arising out of or based upon the deposit agreement or transactions contemplated thereby, may only be instituted in a state or federal court in New York, New York, and you irrevocably waive any objection which you may have to the laying of venue of any such proceeding and irrevocably submit to the exclusive jurisdiction of such courts in any such suit, action or proceeding.

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. For more complete information, you should read the entire deposit agreement and the form of ADR which contains the terms of your ADSs. You can read a copy of the deposit agreement which is filed as an exhibit to the registration statement of which this prospectus forms a part. You may also obtain a copy of the deposit agreement at the SEC's Public Reference Room which is located at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-732-0330. You may also find the registration statement and the attached deposit agreement on the SEC's website at http://www.sec.gov.

Ordinary Share Dividends and Other Distributions

How will I receive dividends and other distributions on the ordinary shares underlying my ADSs?

We may make various types of distributions with respect to our securities. The depositary has agreed that, to the extent practicable, it will pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after converting any cash received into U.S. dollars (if it determines such conversion may be made on a reasonable basis) and, in all cases, making any necessary deductions provided for in the deposit agreement. The depositary may utilize a division, branch or affiliate of JPMorgan Chase Bank,

N.A., to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement. Such division, branch and/or affiliate may charge the depositary a fee in connection with such sales, which fee is considered an expense of the depositary. You will receive these distributions in proportion to the number of underlying securities that your ADSs represent.

Except as stated below, the depositary will deliver such distributions to ADR holders in proportion to their interests in the following manner:

- *Cash.* The depositary will distribute any U.S. dollars available to it resulting from a cash dividend or other cash distribution or the net proceeds of sales of any other distribution or portion thereof (to the extent applicable), on an averaged or other practicable basis, subject to (i) appropriate adjustments for taxes withheld, (ii) such distribution being impermissible or impracticable with respect to certain registered ADR holders, and (iii) deduction of the depositary's and/or its agents' expenses in (1) converting any foreign currency to U.S. dollars to the extent that it determines that such conversion may be made on a reasonable basis, (2) transferring foreign currency or U.S. dollars to the United States by such means as the depositary may determine to the extent that it determines that such transfer may be made on a reasonable basis, (3) obtaining any approval or license of any governmental authority required for such conversion or transfer, which is obtainable at a reasonable cost and within a reasonable time and (4) making any sale by public or private means in any commercially reasonable manner. *If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, you may lose some or all of the value of the distribution*.

- *Ordinary shares.* In the case of a distribution in ordinary shares, the depositary will issue additional ADRs to evidence the number of ADSs representing such ordinary shares. Only whole ADSs will be issued. Any ordinary shares which would result in fractional ADSs will be sold and the net proceeds will be distributed in the same manner as cash to the ADR holders entitled thereto.

- *Rights to receive additional ordinary shares.* In the case of a distribution of rights to subscribe for additional ordinary shares or other rights, if we timely provide evidence satisfactory to the depositary that it may lawfully distribute such rights, the depositary will distribute warrants or other instruments in the discretion of the depositary representing such rights. However, if we do not timely furnish such evidence, the depositary may:

  - sell such rights if practicable and distribute the net proceeds in the same manner as cash to the ADR holders entitled thereto; or

  - if it is not practicable to sell such rights by reason of the non-transferability of the rights, limited markets therefor, their short duration or otherwise, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing and the rights may lapse.

  We have no obligation to file a registration statement under the Securities Act in order to make any rights available to ADR holders.

- *Other Distributions*. In the case of a distribution of securities or property other than those described above, the depositary may either (i) distribute such securities or property in any manner it deems equitable and practicable or (ii) to the extent the depositary deems distribution of such securities or property not to be equitable and practicable, sell such securities or property and distribute any net proceeds in the same way it distributes cash.

- *Elective Distributions*. In the case of a dividend payable at the election of our shareholders in cash or in additional ordinary shares, we will notify the depositary at least 30 days prior to the proposed distribution stating whether or not we wish such elective distribution to be made available to ADR holders. The depositary shall make such elective distribution available to ADR holders only if (i) we shall have timely requested that the elective distribution is available to ADR holders, (ii) the depositary shall have determined that such distribution is reasonably practicable and (iii) the depositary shall have received satisfactory documentation and opinions within the terms of the deposit agreement. If the

above conditions are not satisfied, the depositary shall, to the extent permitted by law, distribute to the ADR holders, on the basis of the same determination as is made in the local market in respect of the ordinary shares for which no election is made, either (i) cash or (ii) additional ADSs representing such additional ordinary shares. If the above conditions are satisfied, the depositary shall establish procedures to enable ADR holders to elect the receipt of the proposed dividend in cash or in additional ADSs. There can be no assurance that ADR holders generally, or any ADR holder in particular, will be given the opportunity to receive elective distributions on the same terms and conditions as the holders of ordinary shares.

If the depositary determines in its discretion that any distribution described above is not practicable with respect to any specific registered ADR holder, the depositary may, after consultation with us if practicable, choose any method of distribution that it deems practicable for such ADR holder, including the distribution of foreign currency, securities or property, or it may retain such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items.

Any U.S. dollars will be distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

The depositary is not responsible if it decides that it is unlawful or not reasonably practicable to make a distribution available to any ADR holders.

There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, ordinary shares or other securities at a specified price, nor that any of such transactions can be completed within a specified time period. For further information about the general sale and/or purchase of securities see https://www.adr.com.

Deposit, Withdrawal and Cancellation

How does the depositary issue ADSs?

The depositary will issue ADSs if you or your broker deposit ordinary shares or evidence of rights to receive ordinary shares with the custodian and pay the fees and expenses owing to the depositary in connection with such issuance. In the case of the ADSs to be issued under this prospectus, we will arrange with the underwriters named herein to deposit such ordinary shares.

Ordinary shares deposited in the future with the custodian must be accompanied by certain delivery documentation and shall, at the time of such deposit, be registered in the name of JPMorgan Chase Bank, N.A., as depositary for the benefit of holders of ADRs or in such other name as the depositary shall direct.

The custodian will hold all deposited ordinary shares (including those being deposited by or on our behalf in connection with the offering to which this prospectus relates) for the account of the depositary. ADR holders thus have no direct ownership interest in the ordinary shares and only have such rights as are contained in the deposit agreement. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited ordinary shares. The deposited ordinary shares and any such additional items are referred to as "deposited securities".

Upon each deposit of ordinary shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs in the name or upon the order of the person entitled thereto evidencing the number of ADSs to which such person is entitled. All of the ADSs issued will, unless specifically requested to the contrary, be part of the depositary's direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in such holder's name. An ADR holder can request that the ADSs not be held through the depositary's direct registration system and that a certificated ADR be issued.

How do ADR holders cancel an ADS and obtain deposited securities?

When you turn in your ADR certificate at the depositary's office, or when you provide proper instructions and documentation in the case of direct registration ADSs, the depositary will, upon payment of certain applicable fees, charges and taxes, deliver the underlying ordinary shares to you or upon your written order. At your risk, expense and request, the depositary may deliver deposited securities at such other place as you may request.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary or the deposit of ordinary shares in connection with voting at a shareholders' meeting, or the payment of dividends;
- the payment of fees, taxes and similar charges; or
- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs or to the withdrawal of deposited securities.

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

Record Dates

The depositary may, after consultation with us if practicable, fix record dates for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of ordinary shares;
- to give instructions for the exercise of voting rights at a meeting of holders of ordinary shares;
- to pay the fee assessed by the depositary for administration of the ADR program and for any expenses as provided for in the ADR; or
- to receive any notice or to act in respect of other matters,

all subject to the provisions of the deposit agreement.

Voting Rights

How do I vote?

If you are an ADR holder and the depositary asks you to provide it with voting instructions, you may instruct the depositary how to exercise the voting rights for the ordinary shares which underlie your ADSs. As soon as practicable after receiving notice of any meeting or solicitation of consents or proxies from us, the depositary will distribute to the registered ADR holders a notice stating such information as is contained in the voting materials received by the depositary and describing how you may instruct the depositary to exercise the voting rights for the ordinary shares which underlie your ADSs, including instructions for giving a discretionary proxy to a person designated by us. For instructions to be valid, the depositary must receive them in the manner, and on or before the date specified. The depositary will try, as far as is practical, subject to the provisions of and governing the underlying ordinary shares or other deposited securities, to vote or to have its agents vote the ordinary shares or other deposited securities as you instruct. The depositary will only vote or attempt to vote as you instruct. Holders are strongly encouraged to forward their voting instructions to the depositary as soon as possible. Voting instructions will not be deemed to be received until such time as the ADR department responsible for proxies and voting has received such instructions notwithstanding that such instructions may have been physically received by the depositary prior to such time. The depositary will not itself exercise any voting discretion. Furthermore, neither the depositary nor its agents are responsible for any failure to carry out any voting instructions, for the manner in which any vote is cast or for the effect of any vote. Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of the stock exchange on which the ADSs are listed, in lieu of distribution of the materials provided to the depositary in connection with any meeting of, or solicitation of consents or

proxies from, holders of deposited securities, distribute to the registered holders of ADRs a notice that provides such holders with, or otherwise publicizes to such holders, instructions on how to retrieve such materials or receive such materials upon request (i.e., by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

There is no guarantee that you will receive voting materials in time to instruct the depositary to vote and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Reports and Other Communications

Will ADR holders be able to view our reports?

The depositary will make available for inspection by ADR holders at the offices of the depositary and the custodian and a designated transfer office the deposit agreement, the provisions of or governing deposited securities, and any written communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities.

Additionally, if we make any written communications generally available to holders of our ordinary shares, and we furnish copies thereof (or English translations or summaries) to the depositary, it will distribute the same to registered ADR holders.

Fees and Expenses

What fees and expenses will I be responsible for paying?

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of ordinary shares, issuances in respect of ordinary share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADRs are cancelled or reduced for any other reason, US$5.00 or less for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of an ordinary share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional charges shall be incurred by the ADR holders, by any party depositing or withdrawing ordinary shares or by any party surrendering ADSs or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of US$1.50 per ADR or ADRs for transfers of certificated or direct registration ADRs;
- a fee of up to US$0.05 per ADS for any cash distribution made pursuant to the deposit agreement;
- a fee of up to US$0.05 per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- a fee for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian and expenses incurred on behalf of holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment) in connection with the servicing of the ordinary shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's

compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such holders or by deducting such charge from one or more cash dividends or other cash distributions);

- a fee for the distribution of securities (or the sale of securities in connection with a distribution), such fee being in an amount equal to the US$0.05 per ADS issuance fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities (treating all such securities as if they were ordinary shares) but which securities or the net cash proceeds from the sale thereof are instead distributed by the depositary to those holders entitled thereto;
- stock transfer or other taxes and other governmental charges;
- cable, telex and facsimile transmission and delivery charges incurred at your request in connection with the deposit or delivery of ordinary shares;
- transfer or registration fees for the registration of transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities;
- in connection with the conversion of foreign currency into U.S. dollars, JPMorgan Chase Bank, N.A. shall deduct out of such foreign currency the fees, expenses and other charges charged by it and/or its agent (which may be a division, branch or affiliate) so appointed in connection with such conversion; and
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

JPMorgan Chase Bank, N.A. and/or its agent may act as principal for such conversion of foreign currency. For further details see https://www.adr.com.

We will pay all other charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary. The charges described above may be amended from time to time by agreement between us and the depositary.

Our depositary has agreed to reimburse us for certain expenses we incur that are related to establishment and maintenance of the ADR program upon such terms and conditions as we and the depositary may agree from time to time. The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary collects its fees for issuance and cancellation of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions, or by directly billing investors, or by charging the book-entry system accounts of participants acting for them. The depositary will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

The fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary. You will receive prior notice of the increase in any such fees and charges.

Payment of Taxes

ADR holders must pay any tax or other governmental charge payable by the custodian or the depositary on any ADS or ADR, deposited security or distribution. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited

securities (by public or private sale) and deduct the amount owing from the net proceeds of such sale. In either case the ADR holder remains liable for any shortfall. Additionally, if any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, such tax or other governmental charge shall be paid by the holder thereof to the depositary and by holding or having held an ADR the holder and all prior holders thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect thereof. If any tax or governmental charge is unpaid, the depositary may also refuse to effect any registration, registration of transfer, split-up or combination of deposited securities or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto.

By holding an ADR or an interest therein, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained.

Reclassifications, Recapitalizations and Mergers

If we take certain actions that affect the deposited securities, including (i) any change in par value, split-up, consolidation, cancellation or other reclassification of deposited securities or (ii) any distributions of ordinary shares or other property not made to holders of ADRs or (iii) any recapitalization, reorganization, merger, consolidation, liquidation, receivership, bankruptcy or sale of all or substantially all of our assets, then the depositary may choose to, and shall if reasonably requested by us:

- amend the form of ADR;
- distribute additional or amended ADRs;
- distribute cash, securities or other property it has received in connection with such actions;
- sell any securities or property received and distribute the proceeds as cash; or
- none of the above.

If the depositary does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADSs without your consent for any reason. ADR holders must be given at least 30 days notice of any amendment that imposes or increases any fees or charges (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses), or otherwise prejudices any substantial existing right of ADR holders. Such notice need not describe in detail the specific amendments effectuated thereby, but must identify to ADR holders a means to access the text of such amendment. If an ADR holder continues to hold an ADR or ADRs after being so notified, such ADR holder is deemed to agree to such amendment and to be bound by the deposit agreement as so amended. Notwithstanding the foregoing, if any governmental body or regulatory body should adopt new laws, rules or regulations which would require amendment or supplement of the deposit agreement or the form of ADR to ensure compliance therewith, we and the depositary may amend or supplement the deposit agreement and the ADR at any time in accordance with such changed laws, rules or regulations, which amendment or supplement may take effect before a notice is given

or within any other period of time as required for compliance. No amendment, however, will impair your right to surrender your ADSs and receive the underlying securities, except in order to comply with mandatory provisions of applicable law.

How may the deposit agreement be terminated?

The depositary may, and shall at our written direction, terminate the deposit agreement and the ADRs by mailing notice of such termination to the registered holders of ADRs at least 30 days prior to the date fixed in such notice for such termination; provided, however, if the depositary shall have (i) resigned as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders unless a successor depositary shall not be operating under the deposit agreement within 45 days of the date of such resignation, and (ii) been removed as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders of ADRs unless a successor depositary shall not be operating under the deposit agreement on the 90th day after our notice of removal was first provided to the depositary. After termination, the depositary's only responsibility will be (i) to deliver deposited securities to ADR holders who surrender their ADRs, and (ii) to hold or sell distributions received on deposited securities. As soon as practicable after the expiration of six months from the termination date, the depositary will sell the deposited securities which remain and hold the net proceeds of such sales (as long as it may lawfully do so), without liability for interest, in trust for the ADR holders who have not yet surrendered their ADRs. After making such sale, the depositary shall have no obligations except to account for such proceeds and other cash.

Limitations on Obligations and Liability to ADR holders

Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders and holders of ADSs

Prior to the issue, registration, registration of transfer, split-up, combination, or cancellation of any ADRs, or the delivery of any distribution in respect thereof, and from time to time in the case of the production of proofs as described below, we or the depositary or its custodian may require:

- payment with respect thereto of (i) any stock transfer or other tax or other governmental charge, (ii) any stock transfer or registration fees in effect for the registration of transfers of ordinary shares or other deposited securities upon any applicable register and (iii) any applicable fees and expenses described in the deposit agreement;
- the production of proof satisfactory to it of (i) the identity of any signatory and genuineness of any signature and (ii) such other information, including without limitation, information as to citizenship, residence, exchange control approval, beneficial ownership of any securities, compliance with applicable law, regulations, provisions of or governing deposited securities and terms of the deposit agreement and the ADRs, as it may deem necessary or proper; and
- compliance with such regulations as the depositary may establish consistent with the deposit agreement.

The issuance of ADRs, the acceptance of deposits of ordinary shares, the registration, registration of transfer, split-up or combination of ADRs or the withdrawal of ordinary shares, may be suspended, generally or in particular instances, when the ADR register or any register for deposited securities is closed or when any such action is deemed advisable by the depositary; provided that the ability to withdraw ordinary shares may only be limited under the following circumstances: (i) temporary delays caused by closing transfer books of the depositary or our transfer books or the deposit of ordinary shares in connection with voting at a shareholders' meeting, or the payment of dividends, (ii) the payment of fees, taxes, and similar charges, and (iii) compliance with any laws or governmental regulations relating to ADRs or to the withdrawal of deposited securities.

The deposit agreement expressly limits the obligations and liability of the depositary, ourselves and our respective agents, provided, however, that no such disclaimer of liability under the Securities Act of 1933 is

intended by any of the limitations of liabilities provisions of the deposit agreement. The deposit agreement it provides that neither we nor the depositary nor any such agent will be liable if:

- any present or future law, rule, regulation, fiat, order or decree of the United States, Australia or any other country, or of any governmental or regulatory authority or securities exchange or market or automated quotation system, the provisions of or governing any deposited securities, any present or future provision of our charter, any act of God, war, terrorism, nationalization or other circumstance beyond our, the depositary's or our respective agents' control shall prevent or delay, or shall cause any of them to be subject to any civil or criminal penalty in connection with, any act which the deposit agreement or the ADRs provide shall be done or performed by us, the depositary or our respective agents (including, without limitation, voting);
- it exercises or fails to exercise discretion under the deposit agreement or the ADR including, without limitation, any failure to determine that any distribution or action may be lawful or reasonably practicable;
- it performs its obligations under the deposit agreement and ADRs without gross negligence or willful misconduct;
- it takes any action or refrains from taking any action in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, any registered holder of ADRs, or any other person believed by it to be competent to give such advice or information; or
- it relies upon any written notice, request, direction, instruction or document believed by it to be genuine and to have been signed, presented or given by the proper party or parties.

Neither the depositary nor its agents have any obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities or the ADRs. We and our agents shall only be obligated to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities or the ADRs, which in our opinion may involve us in expense or liability, if indemnity satisfactory to us against all expense (including fees and disbursements of counsel) and liability is furnished as often as may be required. The depositary and its agents may fully respond to any and all demands or requests for information maintained by or on its behalf in connection with the deposit agreement, any registered holder or holders of ADRs, any ADRs or otherwise related to the deposit agreement or ADRs to the extent such information is requested or required by or pursuant to any lawful authority, including without limitation laws, rules, regulations, administrative or judicial process, banking, securities or other regulators. The depositary shall not be liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system. Furthermore, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, the insolvency of any custodian that is not a branch or affiliate of JPMorgan Chase Bank, N.A. Notwithstanding anything to the contrary contained in the deposit agreement or any ADRs, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, any act or omission to act on the part of the custodian except to the extent that the (i) custodian committed fraud or willful misconduct in the provision of custodial services to the depositary or (ii) failed to use reasonable care in the provision of custodial services to the depositary as determined in accordance with the standards prevailing in the jurisdiction in which the custodian is located. The depositary shall not have any liability for the price received in connection with any sale of securities, the timing thereof or any delay in action or omission to act nor shall it be responsible for any error or delay in action, omission to act, default or negligence on the part of the party so retained in connection with any such sale or proposed sale.

The depositary has no obligation to inform ADR holders or other holders of an interest in any ADSs about the requirements of Australian law, rules or regulations or any changes therein or thereto.

Additionally, none of us, the depositary or the custodian shall be liable for the failure by any registered holder of ADRs or beneficial owner therein to obtain the benefits of credits on the basis of non-U.S. tax paid against such holder's or beneficial owner's income tax liability. Neither we nor the depositary shall incur any liability for any tax consequences that may be incurred by holders or beneficial owners on account of their ownership of ADRs or ADSs.

Neither the depositary nor its agents will be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any such vote is cast or for the effect of any such vote. The depositary may rely upon instructions from us or its counsel in respect of any approval or license required for any currency conversion, transfer or distribution. The depositary shall not incur any liability for the content of any information submitted to it by us or on our behalf for distribution to ADR holders or for any inaccuracy of any translation thereof, for any investment risk associated with acquiring an interest in the deposited securities, for the validity or worth of the deposited securities, for the credit-worthiness of any third party, for allowing any rights to lapse upon the terms of the deposit agreement or for the failure or timeliness of any notice from us. The depositary shall not be liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary, provided that in connection with the issue out of which such potential liability arises the depositary performed its obligations without negligence while it acted as depositary. Neither us, nor the depositary nor any of their respective agents shall be liable to registered holders of ADRs or beneficial owners of interests in ADSs for any indirect, special, punitive or consequential damages or lost profits, in each case of any form incurred by any person or entity, whether or not foreseeable and regardless of the type of action in which such a claim may be brought.

In the deposit agreement each party thereto (including, for avoidance of doubt, each holder and beneficial owner and/or holder of interests in ADRs and/or ADSs irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us directly or indirectly arising out of or relating to the ordinary shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory).

The depositary and its agents may own and deal in any class of our securities and in ADSs.

Disclosure of Interest in ADSs

To the extent that the provisions of or governing any deposited securities may require disclosure of or impose limits on beneficial or other ownership of deposited securities, other ordinary shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof. We reserve the right to instruct you to deliver your ADSs for cancellation and withdrawal of the deposited securities so as to permit us to deal with you directly as a holder of ordinary shares and, by holding an ADS or an interest therein, you will be agreeing to comply with such instructions.

Books of Depositary

The depositary or its agent will maintain a register for the registration, registration of transfer, combination and split-up of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times for the purpose of communicating with other holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register may be closed from time to time, when deemed expedient by the depositary or, in the case of the issuance portion of the ADR Register, when reasonably requested by us to enable us to comply with applicable law.

The depositary will maintain facilities for the delivery and receipt of ADRs.

Pre-release of ADSs

In its capacity as depositary, the depositary shall not lend ordinary shares or ADSs; provided, however, that the depositary may (i) issue ADSs prior to the receipt of ordinary shares and (ii) deliver ordinary shares prior to the receipt of ADSs for withdrawal of deposited securities, including ADSs which were issued under (i) above but for which ordinary shares may not have been received (each such transaction a "pre-release"). The depositary

may receive ADSs in lieu of ordinary shares under (i) above (which ADSs will promptly be canceled by the depositary upon receipt by the depositary) and receive ordinary shares in lieu of ADSs under (ii) above. Each such pre-release will be subject to a written agreement whereby the person or entity (the "applicant") to whom ADSs or ordinary shares are to be delivered (a) represents that at the time of the pre-release the applicant or its customer owns the ordinary shares or ADSs that are to be delivered by the applicant under such pre-release, (b) agrees to indicate the depositary as owner of such ordinary shares or ADSs in its records and to hold such ordinary shares or ADSs in trust for the depositary until such ordinary shares or ADSs are delivered to the depositary or the custodian, (c) unconditionally guarantees to deliver to the depositary or the custodian, as applicable, such ordinary shares or ADSs, and (d) agrees to any additional restrictions or requirements that the depositary deems appropriate. Each such pre-release will be at all times fully collateralized with cash, U.S. government securities or such other collateral as the depositary deems appropriate, terminable by the depositary on not more than five (5) business days' notice and subject to such further indemnities and credit regulations as the depositary deems appropriate. The depositary will normally limit the number of ADSs and ordinary shares involved in such pre-release at any one time to thirty percent (30%) of the ADSs outstanding (without giving effect to ADSs outstanding under (i) above), provided, however, that the depositary reserves the right to change or disregard such limit from time to time as it deems appropriate. The depositary may also set limits with respect to the number of ADSs and ordinary shares involved in pre-release with any one person on a case-by-case basis as it deems appropriate. The depositary may retain for its own account any compensation received by it in conjunction with the foregoing. Collateral provided in connection with pre-release transactions, but not the earnings thereon, shall be held for the benefit of the ADR holders (other than the applicant).

Appointment

In the deposit agreement, each registered holder of ADRs and each person holding an interest in ADSs, upon acceptance of any ADSs (or any interest therein) issued in accordance with the terms and conditions of the deposit agreement will be deemed for all purposes to:

- be a party to and bound by the terms of the deposit agreement and the applicable ADR or ADRs, and
- appoint the depositary its attorney-in-fact, with full power to delegate, to act on its behalf and to take any and all actions contemplated in the deposit agreement and the applicable ADR or ADRs, to adopt any and all procedures necessary to comply with applicable laws and to take such action as the depositary in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR and ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof.

Governing Law

The deposit agreement and the ADRs shall be governed by and construed in accordance with the laws of the State of New York. In the deposit agreement, we have submitted to the jurisdiction of the courts of the State of New York and appointed an agent for service of process on our behalf. Notwithstanding the foregoing, any action based on the deposit agreement may be instituted by the depositary in any competent court in Australia and/or the United States.

By holding an ADS or an interest therein, registered holders of ADRs and owners of ADSs each irrevocably agree that any legal suit, action or proceeding against or involving us or the depositary, arising out of or based upon the deposit agreement or the transactions contemplated thereby, may only be instituted in a state or federal court in New York, New York, and each irrevocably waives any objection which it may have to the laying of venue of any such proceeding, and irrevocably submits to the exclusive jurisdiction of such courts in any such suit, action or proceeding.

SHARES AND ADSS ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have outstanding 7,753,214 ADSs representing 38,766,070 ordinary shares, or approximately 10.3% of our ordinary shares in issue assuming no exercise of the underwriters' option to purchase ADSs in this offering. In addition, we will have outstanding 336,052,647 ordinary shares not represented by ADSs. All outstanding ordinary shares and all of the ADSs sold in this offering will be freely transferable by persons other than our "affiliates" without restriction or further registration under the Securities Act. Sales of substantial amounts of our ADSs in the public market could have a material adverse effect on the prevailing market prices of our ADSs.

Our ordinary shares have been trading on the ASX since December 16, 2004. While we received approval to list our ADSs on the NASDAQ Global Select Market, we cannot assure you that an active trading market for our ADSs will develop.

Lock-up Agreements

Our directors, our chief executive officer and our chief financial officer have each entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC, (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs (including, without limitation, ordinary shares or such other securities which may be deemed to be beneficially owned by such directors, senior management, managers and members in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a share option or warrant) or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ordinary shares or ADSs or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ordinary shares or ADSs or such other securities, in cash or otherwise, or (3) make any demand for or exercise any right with respect to the registration of any ordinary shares or ADSs or any security convertible into or exercisable or exchangeable for ordinary shares or ADSs, subject to certain exceptions.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the date of this prospectus a person who has beneficially owned our "restricted securities" within the meaning of Rule 144 for at least six months is entitled to sell the restricted securities without registration under the Securities Act, subject to certain restrictions. Persons who are our affiliates may sell within any three-month period a number of restricted securities that does not exceed the greater of the following:

- 1% of the number of our ordinary shares then outstanding, in the form of ADSs or otherwise, which will equal approximately 3,748,187 ordinary shares immediately after this offering, or approximately 3,804,284 ordinary shares if the underwriters exercise their option to purchase additional ADSs in full; and
- The average weekly trading volume of our ADSs on the NASDAQ Global Select Market during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales under Rule 144 by persons who are deemed our affiliates are subject to manner-of-sale provisions, notice requirements and the availability of current public information about us. Persons who are not our affiliates and have beneficially owned our restricted securities for more than six months but not more than one year may sell the restricted securities without registration under the Securities Act, subject to the availability of current public information about us. Persons who are not our affiliates and have beneficially owned our restricted securities for more than one year may freely sell the restricted securities without registration under the Securities Act.

In addition, in each case, these shares would remain subject to lock-up arrangements and would only become eligible for sale when the lock-up period expires.

Rule 701

Beginning 90 days after the date of the prospectus, persons other than our affiliates who purchased ordinary shares under a written compensatory plan or contract may be entitled to sell such shares in the United States in reliance on Rule 701. Rule 701 permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. Rule 701 further provides that non-affiliates may sell these shares in reliance on Rule 144 subject only to its manner-of-sale requirements.

Share options

Shortly after the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all ordinary shares issuable under our equity-based compensation plan. See "Management—Remuneration—Non-CEO Executive Remuneration" for a description of such plan.

This Form S-8 registration statement is expected to become effective immediately upon filing, and ordinary shares (and the ADSs representing such ordinary shares) covered by that registration statement will then be eligible for sale in the public markets, subject to:

- The Rule 144 limitations applicable to affiliates;
- The expiration of the lock-up period; and
- Vesting restrictions imposed by us.

As of June 30, 2015, there were employee options outstanding to purchase 18,369,078 fully paid ordinary shares at a weighted average exercise price of A$5.25 per share and an aggregate of 3,500,000 shares at a weighted average exercise price of A$6.78 per share held in trust as part of our LFSP.

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 prospectus, 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 ordinary shares or ADSs acquired in this offering 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.

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 United States 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 noncorporate 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. We have received approval to list the ADSs on the NASDAQ Global Select Market. Provided that the listing is approved, U.S. Treasury Department guidance indicates that the 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 above, 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—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 believe we were not a PFIC for the taxable year ending June 30, 2015 and we do not expect to be a PFIC for the taxable year ending June 30, 2016. 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 this offering. 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 increases. 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, 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 in the third preceding paragraph 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 the PFIC 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 no later than 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.

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. This discussion represents the opinion of Minter Ellison, our Australian counsel. It is based upon existing Australian tax law as of the date of this prospectus, 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.

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 individuals on gains accrued after May 8, 2012. Companies are not entitled to a capital gains tax discount.

The previous Australian Government has announced that it would introduce a withholding regime which applies to the disposal by non-Australian residents of certain taxable Australian property which is subject to capital gains tax. Broadly, where a foreign resident disposes of certain taxable Australian property, the purchaser will be required to withhold and remit to the Australian Taxation Office, or ATO, 10% of the proceeds from the sale. No legislation has been introduced although the current Government has announced that it will proceed with this measure, which is proposed to apply from July 1, 2016.

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.

Non-Australian resident 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 non-Australian resident 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 proposed withholding regime which has been announced by the Australian Government to apply from July 1, 2016 is proposed to also apply where the disposal of the Australian real property asset by a foreign resident is likely to generate gains on revenue account, and therefore be taxable as ordinary income 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 on the issue, trading or surrender of the ADSs. Further, no Australian stamp duty is payable on the issue or trading of the underlying Mesoblast ordinary shares provided that all of our issued ordinary shares remain quoted on the ASX and no person commences to hold an associate inclusive interest of 90% or more in Mesoblast.

Goods and Services Tax

The issue or transfer of ordinary shares to a non-Australian resident investor will not incur Australian goods and services tax.

UNDERWRITING

We are offering the ADSs described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC are acting as joint book running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of ADSs listed next to its name in the following table:

Name	Number of ADSs
J.P. Morgan Securities LLC	3,665,012
Credit Suisse Securities (USA) LLC	2,991,847
Ladenburg Thalmann & Co. Inc.	411,379
Maxim Group LLC	411,379
Total	7,479,617

The underwriters are committed to purchase all the ADSs offered by us if they purchase any ADSs. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the ADSs directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of US$0.336 per ADS. After the initial public offering of the ADSs, the offering price and other selling terms may be changed by the underwriters. Sales of ADSs made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 1,121,942 additional ADSs from us to cover sales of ADSs by the underwriters which exceed the number of ADSs specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this over-allotment option. If any ADSs are purchased with this over-allotment option, the underwriters will purchase ADSs in approximately the same proportion as shown in the table above. If any additional ADSs are purchased, the underwriters will offer the additional ADSs on the same terms as those on which the ADSs are being offered.

The underwriting fee is equal to the public offering price per ADS less the amount paid by the underwriters to us per ADS. The underwriting fee is US$0.56 per ADS. The following table shows the per ADS and total underwriting discounts and commissions to be paid to the underwriters by us assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

Underwriting discounts and commissions	Without over-allotment exercise	With full over-allotment exercise
Per ADS	US$ 0.56	US$ 0.56
Total	US$4,188,586	US$4,816,873

We have also agreed to reimburse the underwriters for certain of their expenses, in an amount of up to $25,000, incurred in connection with review by the Financial Industry Regulatory Authority, Inc. of the terms of this offering, as set forth in the underwriting agreement.

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately US$4.7 million.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of ADSs to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or file with the SEC a registration statement under the Securities Act relating to, any ordinary shares or ADSs or securities convertible into or exchangeable or exercisable for any shares of our ordinary shares or ADSs, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any ordinary shares or ADSs or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of ordinary shares or ADSs or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC for a period of 180 days after the date of this prospectus, other than (A) the ADSs to be sold in this offering, (B) any ordinary shares or ADSs issued upon the exercise of options granted under our equity plans or warrants described as outstanding in this prospectus, (C) any options and other awards granted under our equity plans described in this prospectus, (D) our filing of any registration statement on Form S-8 or a successor form thereto relating to our equity plans described in this prospectus, (E) the sale or issuance of ordinary shares or ADSs to Osiris Therapeutics, Inc., or the Osiris Shares, pursuant to the Purchase Agreement, dated October 11, 2013, as amended, by and between Mesoblast International Sarl and Osiris Therapeutics, Inc., or the Osiris Agreement; provided that any Osiris Shares issued pursuant to this clause (E) will be subject to a one-year lock-up pursuant to the Osiris Agreement and such lock-up period shall not be shortened or waived by us or through amendment of the Osiris Agreement, and (F) the sale or issuance of or entry into an agreement to sell or issue ordinary shares, ADSs, or securities convertible into or exercisable or exchangeable for ordinary shares in connection with any (1) mergers, (2) acquisitions of securities, businesses, property or other assets, (3) joint ventures, (4) strategic alliances, collaboration agreements or intellectual property license agreements, (5) partnerships with experts or other talent or (6) marketing or distribution arrangements; provided that the aggregate number of ordinary shares, ADSs, or securities convertible or exchangeable for ordinary shares pursuant to this clause (F) shall not exceed ten percent (10%) of the total number of outstanding ordinary shares immediately following the issuance and sale of the ADSs in this offering, unless the ordinary shares, ADSs, or securities convertible or exchangeable for ordinary shares issued pursuant to this clause (F) are required by applicable law or the ASX to be, and have been, approved by a vote of our shareholders; provided further that the recipient(s) of the ordinary shares, ADSs or securities convertible into or exercisable for ordinary shares pursuant to this clause (F) shall agree in writing to be bound by the terms of the lock-up.

Our directors, our chief executive officer, our chief financial officer and Cephalon, Inc. have each entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC and Credit Suisse Securities (USA) LLC , (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any ordinary shares or ADSs or any securities convertible into or exercisable or exchangeable for our ordinary shares or ADSs (including, without limitation, ordinary shares or such other securities which may be deemed to be beneficially owned by such directors, senior management, and shareholder in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a share option or warrant) or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ordinary shares or ADSs or such other securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of ordinary shares or ADSs or such other securities, in cash or otherwise, or (3) make any demand for or exercise any right with respect to the registration of any ordinary shares or ADSs or any security convertible into or exercisable or exchangeable for ordinary shares or ADSs; provided that (1) our chief executive officer and Cephalon, Inc. may take part in a full or proportionate takeover bid as defined in the Corporations Act 2001 (Australia) and (2) our directors and our chief financial officer may take part in a takeover bid where the holders of at least 50% of our ordinary shares that are not subject to any lock-up agreements have accepted the takeover bid.

The lock-up agreements entered into with our directors, chief executive officer and our chief financial officer, are initially enforceable by Mesoblast Limited until notice is received from the Treasurer of the Commonwealth of Australia that there are no objections under the Australian government's foreign investment policy. Once such notice is obtained, the lock-up agreements will then become enforceable by the underwriters.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We have received approval to list our ADSs on the NASDAQ Global Select Market under the symbol "MESO."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling ADSs in the open market for the purpose of preventing or retarding a decline in the market price of the ADSs while this offering is in progress. These stabilizing transactions may include making short sales of the ADSs, which involves the sale by the underwriters of a greater number of ADSs than they are required to purchase in this offering, and purchasing ADSs on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' over-allotment option referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their over-allotment option, in whole or in part, or by purchasing ADSs in the open market. In making this determination, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market compared to the price at which the underwriters may purchase ADSs through the over-allotment option. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase ADSs in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, as amended they may also engage in other activities that stabilize, maintain or otherwise affect the price of the ADSs, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase ADSs in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those ADSs as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of our ordinary shares and the ADSs or preventing or retarding a decline in the market price of the ADSs, and, as a result, the price of the ADSs may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time.

Prior to this offering, our ADSs have been quoted on the over-the-counter markets under the symbol "MBLTY." Our ordinary shares have been trading on the ASX since December 2004 under the symbol "MSB." The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded ADSs of generally comparable companies;
- the trading price of our ordinary shares on the ASX; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our ADSs, or that the ADSs will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to Canadian Residents

Resale Restrictions

The distribution of securities offered by this prospectus in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the securities in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

Representations of Canadian Purchasers

By purchasing securities offered by this prospectus in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the securities without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106 –*Prospectus Exemptions*,
- the purchaser is a "permitted client" as defined in National Instrument 31-103—*Registration Requirements, Exemptions and Ongoing Registrant Obligations*,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

Conflicts of Interest

Canadian purchasers are hereby notified that the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 –*Underwriting Conflicts* from having to provide certain conflict of interest disclosure in this document.

Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the offering memorandum (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Taxation and Eligibility for Investment

Canadian purchasers of securities offered by this prospectus should consult their own legal and tax advisors with respect to the tax consequences of an investment in the securities in their particular circumstances and about the eligibility of the securities for investment by the purchaser under relevant Canadian legislation.

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom or (ii) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling with Article 49(2)(a) to (d) of the Order, all such persons together being referred to as "relevant persons". The securities are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such securities will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, or each, a Relevant Member State, from and including the date on which the European Union Prospectus Directive, or the EU Prospectus Directive, was implemented in that Relevant Member State, or the Relevant Implementation Date, an offer of securities described in this prospectus may not be made to the public in that Relevant Member State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the EU Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of securities described in this prospectus may be made to the public in that Relevant Member State at any time:

- to any legal entity which is a qualified investor as defined under the EU Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the EU Prospectus Directive); or
- in any other circumstances falling within Article 3(2) of the EU Prospectus Directive, provided that no such offer of securities described in this prospectus shall result in a requirement for the publication by us of a prospectus pursuant to Article 3 of the EU Prospectus Directive.

For the purposes of this provision, the expression an "offer of securities to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the EU Prospectus Directive in that Member State. The expression "EU Prospectus Directive" means Directive 2003/71/EC (and any amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

This document is not intended to constitute an offer or solicitation to purchase or invest in the shares described herein. The shares may not be publicly offered, sold or advertised, directly or indirectly, in, into or from Switzerland and will not be listed on the SIX Swiss Exchange or on any other exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares

constitutes a prospectus as such term is understood pursuant to article 652a or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or any other regulated trading facility in Switzerland, and neither this document nor any other offering or marketing material relating to the shares may be publicly distributed or otherwise made publicly available in Switzerland. Neither this document nor any other offering or marketing material relating to the offering, nor the Company nor the shares have been or will be filed with or approved by any Swiss regulatory authority. The shares are not subject to the supervision by any Swiss regulatory authority, e.g., the Swiss Financial Markets Supervisory Authority FINMA (FINMA), and investors in the shares will not benefit from protection or supervision by such authority.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

EXPENSES RELATING TO THIS OFFERING

The following table sets forth the estimated costs and expenses, other than the underwriting discounts and commissions, payable by us in connection with the offering (all amounts are estimated except the SEC registration fee and the FINRA filing fee):

SEC registration fee	US$	9,657
FINRA filing fee		31,300
Listing fee		71,967
Printing expenses		902,353
Legal fees and expenses		2,909,605
Accounting fees and expenses		787,934
Miscellaneous		10,000
Total		4,722,816

LEGAL MATTERS

Certain legal matters as to United States federal and New York law in connection with this offering will be passed upon for us by Wilson Sonsini Goodrich & Rosati, P.C., Palo Alto, California. Certain legal matters as to Australian law in connection with this offering will be passed upon for us by Minter Ellison. Wilson Sonsini Goodrich & Rosati, P.C., may rely upon Minter Ellison with respect to matters governed by Australian law. Certain legal matters as to United States federal and New York law in connection with the offering will be passed upon for the underwriters by Skadden, Arps, Slate, Meagher & Flom LLP.

EXPERTS

Our consolidated financial statements as of June 30, 2015 and 2014 and for each of the three years in the period ended June 30, 2015 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The offices of PricewaterhouseCoopers are located at Freshwater Place, 2 Southbank Boulevard, Southbank, VIC 3006, Australia.

ENFORCEMENT OF CIVIL LIABILITIES

We are a public limited company incorporated under the laws of Australia. Certain of our directors are non-residents of the United States and all or substantially all of their assets are located outside the United States. As a result, it may not be possible for you to:

- effect service of process within the United States upon our non-U.S. resident directors or on us;
- enforce in U.S. courts judgments obtained against our non-U.S. resident directors or us in the U.S. courts in any action, including actions under the civil liability provisions of U.S. securities laws;
- enforce in U.S. courts judgments obtained against our non-U.S. resident directors or us in courts of jurisdictions outside the United States in any action, including actions under the civil liability provisions of U.S. securities laws; or
- bring an original action in an Australian court to enforce liabilities against our non-U.S. resident directors or us based solely upon U.S. securities laws.

You may also have difficulties enforcing in courts outside the United States judgments that are obtained in U.S. courts against any of our non-U.S. resident directors or us, including actions under the civil liability provisions of the U.S. securities laws.

With that noted, there are no treaties between Australia and the United States that would affect the recognition or enforcement of foreign judgments in Australia. We also note that investors may be able to bring an original action in an Australian court against us to enforce liabilities based in part upon U.S. federal securities laws.

We have appointed Mesoblast, Inc., as our agent to receive service of process with respect to any action brought against us in the U.S. District Court for the Southern District of New York under the federal securities laws of the United States or any action brought against us in the Supreme Court of the State of New York in the County of New York under the securities laws of the State of New York.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act with respect to the underlying ordinary shares represented by the ADSs to be sold in this offering. This prospectus, which forms a part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. You should refer to the registration statement for further information.

Statements contained in this prospectus as to the content of any contract or other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or document. We intend to file a registration statement on Form F-6 to register the issuance of the ADSs offered hereby.

Upon declaration by the SEC of the effectiveness of the registration statement, we will become subject to the periodic reporting and other informational requirements of the Exchange Act applicable to a foreign private issuer. Under the Exchange Act, we will be required to file reports, including annual reports on Form 20-F, and other information with the SEC. All information filed with the SEC can be inspected and copied at the public reference facilities maintained by the SEC at Room 1580, 100 F Street, N.E., Washington, D.C. 20549. You can request copies of these documents, upon payment of a duplicating fee, by writing to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. You may also obtain additional information over the Internet at the SEC's website at *www.sec.gov*.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. Our consolidated financial statements will be prepared in IFRS and certified by an independent public accounting firm. If we make any written communications generally available to holders of our ordinary shares, and we furnish copies thereof (or English translations of summaries) to the depositary, it will distribute the same to registered ADR holders.

Mesoblast Limited

Index to Financial Statements

Report of Independent Registered Public Accounting Firm

To the 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, 2015 and June 30, 2014, and the results of their operations and their cash flows for each of the three years in the period ended June 30, 2015 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers

Melbourne, Australia
September 21, 2015

Mesoblast Limited

Consolidated Income Statements

(in thousands, except per share amounts)	Note	Year Ended June 30, 2015	2014	2013
Revenue from continuing operations	3(a)	19,761	23,390	29,301
Other income	3(b)	15,399	10,119	5,495
		35,160	**33,509**	**34,796**
Expenses from continuing operations	3(c)			
Research and development		(62,649)	(50,929)	(48,513)
Manufacturing commercialization		(23,783)	(25,434)	(23,082)
Management and administration		(29,636)	(24,403)	(22,899)
Finance costs		(8,506)	(4,078)	—
Other expenses		(6,830)	(4,195)	(952)
		(131,404)	**(109,039)**	**(95,446)**
Loss before income tax		**(96,244)**	**(75,530)**	**(60,650)**
Income tax expense	4	—	(4)	(1,470)
Loss attributable to the owners of Mesoblast Limited		**(96,244)**	**(75,534)**	**(62,120)**
		Cents	**Cents**	**Cents**
Losses per share from continuing operations attributable to the ordinary equity holders of the Group:				
Basic — losses per share	20	(29.99)	(23.65)	(21.02)
Diluted — losses per share	20	(29.99)	(23.65)	(21.02)

The above consolidated income statement should be read in conjunction with the accompanying Notes.

Mesoblast Limited

Consolidated Statement of Comprehensive Income

(in thousands)	Note	Year Ended June 30, 2015	2014	2013
Loss for the year		**(96,244)**	**(75,534)**	**(62,120)**
Other comprehensive income/(loss)				
Items that may be reclassified to profit and loss				
Exchange differences on translation of foreign operations	7(b)	(25,783)	3,371	(27,642)
Income tax relating to these items		—	—	—
Other comprehensive income /(loss) for the period, net of tax		**(25,783)**	**3,371**	**(27,642)**
Total comprehensive loss attributable to the owners of Mesoblast Limited		**(122,027)**	**(72,163)**	**(89,762)**

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 thousands)	Note	Issued Capital	Share Option Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total
Balance as of July 1, 2012		**467,760**	**38,256**	**12,070**	**(30,062)**	**488,024**
Loss for the year		—	—	—	(62,120)	(62,120)
Other comprehensive income		—	—	(27,642)	—	(27,642)
Total comprehensive profit/(loss) for the period		**—**	**—**	**(27,642)**	**(62,120)**	**(89,762)**
Transactions with owners in their capacity as owners:						
Contributions of equity net of transaction costs		173,923	—	—	—	173,923
	7(a)	**173,923**	**—**	**—**	**—**	**173,923**
Tax effect of options deductible for tax		—	—	—	—	—
Transfer exercised options		695	(695)	—	—	—
Fair value of share-based payments	18	—	12,407	—	—	12,407
Balance as of June 30, 2013		**642,378**	**49,968**	**(15,572)**	**(92,182)**	**584,592**
Loss for the year		—	—	—	(75,534)	(75,534)
Other comprehensive loss		—	—	3,371	—	3,371
Total comprehensive loss for the year		**—**	**—**	**3,371**	**(75,534)**	**(72,163)**
Transactions with owners in their capacity as owners:						
Contributions of equity net of transaction costs		17,502	—	—	—	17,502
	7(a)	**17,502**	**—**	**—**	**—**	**17,502**
Transfer exercised options		2,842	(2,842)	—	—	—
Fair value of share-based payments	18	—	8,628	—	—	8,628
Balance as of June 30, 2014		**662,722**	**55,754**	**(12,201)**	**(167,716)**	**538,559**
Loss for the year		—	—	—	(96,244)	(96,244)
Other comprehensive income		—	—	(25,783)	—	(25,783)
Total comprehensive income/(loss) for the year		**—**	**—**	**(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	18	—	6,976	—	—	6,976
Reclassification of modified options to liability		—	(1,394)	—	—	(1,394)
Balance as of June 30, 2015		**709,191**	**60,740**	**(37,984)**	**(263,960)**	**467,987**

The above consolidated statement of changes in equity should be read in conjunction with the accompanying Notes.

Mesoblast Limited

Consolidated Balance Sheet

(in thousands)	Note	As of June 30, 2015	2014
Assets			
Current assets			
Cash and cash equivalents	5(a)	110,701	185,003
Trade and other receivables	5(b)	3,972	5,744
Prepayments	5(b)	7,787	1,184
Total current assets		**122,460**	**191,931**
Non-current assets			
Property, plant and equipment	6(a)	4,398	4,411
Available-for-sale financial assets	5(c)	2,300	—
Other non-current assets	5(d)	2,367	2,806
Intangible assets	6(b)	650,241	648,005
Total non-current assets		**659,306**	**655,222**
Total assets		**781,766**	**847,153**
Liabilities			
Current liabilities			
Trade and other payables	5(e)	28,242	19,521
Deferred revenue	6(c)	15,004	15,004
Derivative financial instruments	10(a)	—	317
Provisions	6(d)	5,161	5,357
Total current liabilities		**48,407**	**40,199**
Non-current liabilities			
Deferred revenue	6(c)	22,505	37,508
Deferred tax liability	6(e)	149,387	149,387
Provisions	6(d)	93,480	81,500
Total non-current liabilities		**265,372**	**268,395**
Total liabilities		**313,779**	**308,594**
Net assets		**467,987**	**538,559**
Equity			
Issued capital	7(a)	709,191	662,722
Reserves	7(b)	22,756	43,553
Accumulated losses		(263,960)	(167,716)
Total equity		**467,987**	**538,559**

The above consolidated balance sheet should be read in conjunction with the accompanying Notes.

Mesoblast Limited

Consolidated Statement of Cash Flows

(in thousands)	Note	Year Ended June 30, 2015	2014	2013
Cash flows from operating activities				
Milestone payment received		2,000	—	—
Research and development tax incentive received		4,456	8,709	—
Payments to suppliers and employees (inclusive of goods and services tax)		(106,817)	(97,438)	(69,786)
Payments for fair value adjustments to contingent consideration subsequent to the business combination measurement period		(4,112)	—	—
Interest received		3,043	11,609	10,608
Rent received		57	—	—
Other income received		405	—	—
Income taxes (paid)/refunded		(68)	2,214	3,432
Net cash (outflows) in operating activities	8(b)	**(101,036)**	**(74,906)**	**(55,746)**
Cash flows from investing activities				
Payments for financial derivatives		(851)	(1,383)	(1,955)
Payments for business combination	12(c)	(2,086)	(33,370)	(1,581)
Payments for licenses		(195)	(426)	—
Proceeds/(payments) for rental deposits		272	(1,609)	—
Investment in fixed assets		(2,204)	(1,712)	(1,265)
Receipts from repayments of loans from employees		—	298	—
Net cash (outflows) in investing activities		**(5,064)**	**(38,202)**	**(4,801)**
Cash flows from financing activities				
Proceeds from issue of shares		46,291	2,237	180,179
Payments for share issue costs		(439)	(41)	(5,764)
Net cash inflows by financing activities		**45,852**	**2,196**	**174,415**
Net (decrease)/increase in cash and cash equivalents		(60,248)	(110,912)	113,868
Cash and cash equivalents at beginning of year		185,003	292,449	209,518
FX (losses)/gains on the translation of foreign bank accounts		(14,054)	3,466	(30,937)
Cash and cash equivalents at end of year	8(a)	**110,701**	**185,003**	**292,449**

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 Company's primary proprietary regenerative medicine technology platform is based on specialised 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.

These financial statements are presented in thousands of U.S. dollars ("$" or "USD"), unless otherwise noted, including certain amounts that are presented in thousands of Australian dollars ("AUD").

1. Significant changes in the current reporting period

The financial position and performance of the Group was not particularly affected by any significant changes in the year ended June 30, 2015.

The financial position and performance of the Group was particularly affected by the following transaction during the year ended June 30, 2014:

- The acquisition of the entire culture-expanded mesenchymal stem cell ("MSC") business of Osiris Therapeutics, Inc. on October 11, 2013 ("Osiris") (see Note 12) which resulted in a recognition of in-process research and development acquired and goodwill (see Note 6(b)).

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. Revenue and expenses from continuing operations

(in thousands)	Note	Year Ended June 30, 2015	2014	2013
(a) Revenue from continuing operations				
Commercialization revenue[1]	6(c)	15,004	15,004	18,685
Milestone revenue[2]		2,000	—	—
Interest revenue		2,757	8,386	10,616
		19,761	**23,390**	**29,301**
(b) Other income				
Foreign exchange gains (net of losses)		10,478	—	—
Research and development tax incentive[3]		4,418	7,775	5,495
Other revenue		407	—	—
Rental income		96	—	—
Release of excess provision for services	6(d)	—	2,344	—
		15,399	**10,119**	**5,495**

3. Revenue and expenses from continuing operations (continued)

(in thousands)	Note	Year Ended June 30, 2015	2014	2013
(c) Expenses from continuing operations				
Clinical trial research and development		**33,877**	**19,245**	**20,013**
Manufacturing production and development		**16,965**	**21,127**	**20,258**
Employee benefits				
Salaries and employee benefits		30,945	26,590	20,225
Defined contribution superannuation expenses		441	376	316
Share-based payment transactions[4]		6,976	8,628	12,409
Total employee benefits		**38,362**	**35,594**	**32,950**
Depreciation and amortization of non-current assets				
Plant and equipment depreciation	6(a)	1,474	892	683
Intellectual property amortization	6(b)	127	132	104
Total depreciation and amortization of non-current assets		**1,601**	**1,024**	**787**
Other management and administration expenses				
Overheads and administration		10,683	9,798	8,788
Consultancy		5,857	6,279	5,260
Legal, patent and other professional fees		6,294	5,093	5,500
Intellectual property expenses (excluding the amount amortized above)		2,429	2,606	938
Total other management and administration expenses		**25,263**	**23,776**	**20,486**
Other expenses				
Foreign exchange losses (net of gains)		—	3,946	952
Remeasurement of contingent consideration		6,830	249	—
Total other expenses		**6,830**	**4,195**	**952**
Finance costs				
Provisions: unwinding of discount	6(d)(ii)	8,506	4,078	—
Total finance costs		**8,506**	**4,078**	**—**
Total expenses from continuing operations		**131,404**	**109,039**	**95,446**

(1) Commercialization revenue

In November 2010, the Group signed a development and commercialization agreement with Cephalon Inc., a major global biopharmaceutical company.

The total upfront cash received under the development and commercialization agreement was $130,000. For the years ended June 30, 2015, 2014 and 2013, the Group has recognized revenue of $15,004, $15,004 and $18,685, respectively, for this payment on the basis that the revenue will be earned through-out the life of the development of those products pertaining to that payment. The Group continuously monitors and reviews the development timelines of the products with no changes being made in the current year.

(2) Milestone revenue

For the year ended June 30, 2015, the Group recognized milestone revenue of $2,000. This revenue was recognized on achievement of a substantive milestone being the filing for marketing approval (Japan) for MSC product TEMCELL. No further performance obligations are required of the Group in relation to this revenue.

3. Revenue and expenses from continuing operations (continued)

(3) 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. This estimate is also reviewed by external tax advisors. For the years ended June 30, 2015, 2014 and 2013, the Group has recognized income of $4,418, $7,775 and $5,495, respectively. See Note 21(e)(iii).

Of the $4,418 research and development tax incentive recorded in other income for the year ended June 30, 2015, $474 relates to a favourable 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.

Of the $7,775 research and development tax incentive recorded in other income for the year ended June 30, 2014, $3,415 relates to research and development tax incentive income the Group received from the Australian Government for the year ended June 30, 2013 following a favourable change in the original estimate. The change in estimate was due to the fact that research and development tax incentives were dependent upon the level of qualifying research and development expenditure and as such we estimated amounts we deemed probable of collection in the year ended June 30, 2013, until we had better information related to the implementation of the relevant regulations with the assistance of our tax advisors.

(4) Share-based payment transactions

For the years ended June 30, 2015, 2014 and 2013, share-based payment transactions have been reflected in the consolidated Income Statement functional expense categories as follows: research and development $3,023, $4,650 and $7,964, respectively, manufacturing commercialization $718, $792 and $504, respectively, and management and administration $3,235, $3,186 and $3,941, respectively.

4. Income tax expense

(in thousands)	Year Ended June 30, 2015	2014	2013
(a) Reconciliation of income tax to prima facie tax payable			
Loss from continuing operations before income tax	(96,244)	(75,530)	(60,650)
Tax benefit at the Australian tax rate of 30% (2014: 30%)	(28,873)	(22,659)	(18,195)
Tax effect of amounts which are not deductible/(exempt) in calculating taxable income:			
Share-based payments expense	2,048	2,590	3,642
Research and development tax concessions	1,343	3,518	(211)
Contingent consideration	4,439	—	—
Other sundry items	1,299	4,415	(824)
Current year tax benefit	**(19,744)**	**(12,136)**	**(15,588)**
Adjustments for current tax of prior periods	3,633	2,319	4,087
Differences in overseas tax rates	11,528	(1,389)	(2,252)
Tax benefit not recognized	4,583	11,205	13,633
Alternative minimum tax charge (USA)	—	—	1,593
USA City and State tax benefit/(charge)	(323)	(2,646)	1,589
USA City and State tax benefit — not recognized	323	2,651	(1,592)
Income tax expense attributable to loss before income tax	**—**	**4**	**1,470**
(b) Income tax expense			
Current tax	—	4	1,470
Deferred tax	—	—	—
	—	**4**	**1,470**
(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 bought to account)	(137)	(148)	1,433
Deferred tax recorded in equity (if bought to account)	516	430	452
	379	**282**	**1,885**

(in thousands)	As of June 30, 2015	2014	2013
(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	—	—	—
(e) Deferred tax assets not brought to account			
Unused tax losses			
Potential tax benefit at local tax rates	69,929	57,019	42,125
Other temporary differences			
Potential tax benefit at local tax rates	16,507	25,145	28,229
Total potential tax benefit at local tax rates	**86,436**	**82,164**	**70,354**

4. Income tax expense (continued)

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

a. Significant estimates

The Group is subject to income taxes in Australia, Singapore, Switzerland, the United Kingdom and the United States of America. Significant judgment is required in determining the worldwide provision for income taxes. There are certain transactions and calculations undertaken during the ordinary course of business for which the ultimate tax determination is uncertain. The Group consulted professional tax advisers to estimate its tax liabilities based on the Group's understanding of the tax law. Where the final outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred income tax assets and liabilities in the period in which such determination is made.

The Group has recognized deferred tax assets to the extent that it is probable that the asset will be utilized either through the application of carry back rules or the utilization of taxable temporary differences (deferred tax liabilities) relating to the same taxation authority and the same subsidiary against which the unused tax losses can be utilized. As of June 30, 2015 and 2014, the Group has recorded deferred tax assets of $Nil due to the Company's plans to consolidate certain intellectual property assets and therefore taxable temporary differences will not be available to offset deferred tax assets in the same jurisdictions.

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 thousands)	Notes	Assets at FVOCI[1]	Assets at FVTPL[2]	Assets at amortized cost	Total
As of June 30, 2015					
Cash and cash equivalents	5(a)	—	—	110,701	110,701
Trade and other receivables	5(b)	—	—	3,972	3,972
Available-for-sale financial assets	5(c)	2,300	—	—	2,300
Other non-current assets	5(d)	—	—	2,367	2,367
		2,300	**—**	**117,040**	**119,340**
As of June 30, 2014					
Cash and cash equivalents	5(a)	—	—	185,003	185,003
Trade and other receivables	5(b)	—	—	5,744	5,744
Other non-current assets	5(d)	—	—	2,806	2,806
		—	**—**	**193,553**	**193,553**

(1) Fair value through other comprehensive income

(2) Fair value through profit or loss

5. Financial assets and liabilities (continued)

Financial liabilities (in thousands)	Notes	Liabilities at FVOCI[1]	Liabilities at FVTPL[2]	Liabilities at amortized cost	Total
As of June 30, 2015					
Trade and other payables	5(e)	—	—	28,242	28,242
Contingent consideration	5(f)	—	91,890	—	91,890
Derivative financial instruments	10(a)	—	—	—	—
		—	**91,890**	**28,242**	**120,132**
As of June 30, 2014					
Trade and other payables	5(e)	—	—	19,521	19,521
Contingent consideration	5(f)	—	81,247	—	81,247
Derivative financial instruments	10(a)	—	317	—	317
		—	**81,564**	**19,521**	**101,085**

(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 thousands)	As of June 30, 2015	2014
Cash at bank	21,126	3,605
Deposits at call[1]	89,575	181,398
	110,701	**185,003**

(1) As of June 30, 2015 and 2014, interest-bearing deposits at call include an amount of $5,742 (2014: $5,832) held as security against future foreign exchange deals and is 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 and are repayable with 24 hours' notice with no loss in interest. See Note 21(k) for the Group's other accounting policies on cash and cash equivalents.

5. Financial assets and liabilities (continued)

b. Trade and other receivables and prepayments

(in thousands)	As of June 30, 2015	2014
Income tax and tax incentives recoverable	3,696	4,949
Sundry debtors	136	11
Interest receivables	84	279
Other recoverable taxes (goods and services tax and value-added tax)	56	124
Other receivables	—	381
Trade and other receivables	**3,972**	**5,744**
Clinical trial research and development expenditure	3,475	502
Prepaid insurance and subscriptions	635	416
Other prepayments	3,677	266
Prepayments	**7,787**	**1,184**

(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 at both June 30, 2015 and June 30, 2014. The Group's impairment and other accounting policies for trade and other receivables are outlined in Notes 10(c) and 22(l) respectively.

(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 thousands)	As of June 30, 2015	2014
Unlisted securities:		
Equity securities	2,300	—
	2,300	**—**

(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.

5. Financial assets and liabilities (continued)

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, 2015 and 2014, there were no gains/(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) below. 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

	As of June 30,	
(in thousands)	**2015**	**2014**
Bank guarantee	737	904
Letter of credit	1,630	1,902
	2,367	**2,806**

(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 are held in an account named Mesoblast, Inc. at the Bank of America according to the terms of two irrevocable standby letters of credit which are security for the sublease agreement for our occupancy of 505 Fifth Avenue, New York, New York, United States of America. The letters of credit are security for the full and faithful performance and observance by the subtenant of the terms, covenants and conditions of the sublease. The letters of credit are 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 ($1,186) and May 30, 2021 ($443).

(ii) Impairment and risk exposure

No other non-current assets are either past due or impaired.

5. Financial assets and liabilities (continued)

e. Trade and other payables

(in thousands)	As of June 30, 2015	2014
Trade payables and other payables	28,242	19,521
	28,242	**19,521**

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, 2015 and June 30, 2014 on a recurring basis, categorized by level according to the significance of the inputs used in making the measurements:

As of June 30, 2015

(in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial assets					
Available-for-sale financial assets					
Equity securities — biotech sector		—	—	2,300	2,300
Total financial assets	5(c)	**—**	**—**	**2,300**	**2,300**
Financial liabilities					
Financial liabilities at fair value through profit or loss					
Derivative financial instruments	10(a)	—	—	—	—
Contingent consideration	6(d)	—	—	91,890	91,890
Total financial liabilities		**—**	**—**	**91,890**	**91,890**

As of June 30, 2014

(in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial liabilities					
Financial liabilities at fair value through profit or loss					
Derivative financial instruments	10(a)	—	317	—	317
Contingent consideration	6(d)	—	—	81,247	81,247
Total financial liabilities		**—**	**317**	**81,247**	**81,564**

There were no transfers between any of the levels for recurring fair value measurements during the year.

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.

5. Financial assets and liabilities (continued)

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 following techniques to determine the fair value measurements:

- Level 2: The fair value of forward foreign exchange contracts is determined using forward exchange rates at the balance sheet date.
- Level 3: The fair value is determined using discounted cash flow analysis.

(iii) Fair value measurements using significant unobservable inputs (level 3)

The following table presents the changes in level 3 instruments for the year ended June 30, 2015 and June 30, 2014:

	Notes	Contingent consideration provision
Opening balance — July 1, 2013		—
Initial recognition	12(b)	77,169
Charged/(credited) to consolidated income statement		
Unwinding of discount[1]		4,078
Closing balance — June 30, 2014		**81,247**
Opening balance — July 1, 2014		81,247
Amount used during the year		(6,779)
Allocated to goodwill		
Remeasurement[2][3]		2,086
Charged/(credited) to consolidated income statement		
Unwinding of discount[1]		8,506
Remeasurement[3]		6,830
Closing balance — June 30, 2015		**91,890**

(1) The unwinding of the risk adjusted discount as the time period shortens between the valuation date and the potential settlement date of the contingent consideration.

(2) $2,086 out of period adjustment to goodwill was recognized on finalisation of the MSC business combination of Osiris.

(3) The total amount of remeasurement of contingent consideration pertaining to the acquired MSC assets of Osiris was $8,916.

5. Financial assets and liabilities (continued)

(iv) Valuation inputs and relationship to fair value

The following table summarises the quantitative information about the significant unobservable inputs used in level 3 fair value measurements:

Description	Fair value as of June 30, 2015	Fair value as of June 30, 2014	Valuation technique	Unobservable Inputs*	Range of inputs (weighted average) for the year ended June 30, 2015	Range of inputs (weighted average) for the year ended June 30, 2014	Relationship of unobservable inputs to fair value
Contingent consideration provision	91,890	81,247	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	2015: A change in the discount rate by 0.5% would increase/decrease the fair value by 3% 2014: A change in the discount rate by 0.5% would increase/decrease the fair value by 3%
				Expected unit revenues	n/a	n/a	2015: A 10% increase in the price assumptions adopted would increase the fair value by 8% 2014: A 10% increase in the price assumptions adopted would increase the fair value by 5%

* 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 June 30, 2015, 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 market population, market penetration, product pricing and development timelines.

For the year ended June 30, 2014, an independent valuation was undertaken. The CFO and the internal valuation team reviewed the independent valuation and determined there was no material change to the inputs supporting the fair value that was recorded at the acquisition date. A key reason for this determination is that the independent valuation was completed during the financial year ended June 30, 2014 and no significant events have occurred since it was completed that would lead to the valuation changing.

5. Financial assets and liabilities (continued)

The fair value of contingent consideration

(in thousands)	As of June 30, 2015	As of June 30, 2014
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets	23,883	23,580
Fair value of royalty payments from commercialization of the intellectual property acquired	68,007	57,667
	91,890	**81,247**

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.
Expected unit revenues:	Expected market sale price based on independent expert's review of the most comparable products currently available in the market place.

6. Non-financial assets and liabilities

This Note provides information about the Group's non-financial assets and liabilities, including:

- specific information about each type of non-financial asset and non-financial liability
  - property, plant and equipment (Note 6(a));
  - intangible assets (Note 6(b));
  - deferred revenue (Note 6(c));
  - provisions (Note 6(d));
  - deferred tax liability (Note 6(e));
- accounting policies; and
- information about determining the fair value of the instruments, including judgments and estimation uncertainty involved.

6. Non-financial assets and liabilities (continued)

a. Property, plant and equipment

(in thousands)	Plant and equipment	Office furniture and equipment	Computer hardware and software	Total
Year Ended June 30, 2014				
Opening net book amount	889	816	852	2,557
Additions	1,964	203	597	2,764
Exchange differences	15	(2)	(31)	(18)
Depreciation charge	(295)	(117)	(480)	(892)
Closing net book value	2,573	900	938	4,411
As of June 30, 2014				
Cost or fair value	3,085	1,209	2,318	6,612
Accumulated depreciation	(512)	(309)	(1,380)	(2,201)
Net book value	2,573	900	938	4,411
Year Ended June 30, 2015				
Opening net book amount	2,573	900	938	4,411
Additions	871	50	351	1,272
Exchange differences	—	23	166	189
Depreciation charge	(798)	(148)	(528)	(1,474)
Closing net book value	2,646	825	927	4,398
As of June 30, 2015				
Cost or fair value	3,956	1,259	2,669	7,884
Accumulated depreciation	(1,310)	(434)	(1,742)	(3,486)
Net book value	2,646	825	927	4,398

(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 the other accounting policies relevant to property, plant and equipment.

6. Non-financial assets and liabilities (continued)

b. Intangible assets

(in thousands)	Goodwill	Acquired licenses to patents	In-process research and development acquired	Total
Year ended June 30, 2014				
Opening net book value	118,431	1,205	388,497	508,133
Additions[1]	13,936	868	125,200	140,004
Exchange differences	—	—	—	—
Amortization charge	—	(132)	—	(132)
Impairment charge	—	—	—	—
Closing net book value	132,367	1,941	513,697	648,005
As of June 30, 2014				
Cost	132,367	2,512	513,697	648,576
Accumulated amortization	—	(571)	—	(571)
Accumulated impairment	—	—	—	—
Net book amount	132,367	1,941	513,697	648,005
Year ended June 30, 2015				
Opening net book value	132,367	1,941	513,697	648,005
Additions[2]	2,086	201	—	2,287
Exchange differences	—	76	—	76
Amortization charge	—	(127)	—	(127)
Impairment charge	—	—	—	—
Closing net book value	134,453	2,091	513,697	650,241
As of June 30, 2015				
Cost	134,453	2,713	513,697	650,863
Accumulated amortization	—	(622)	—	(622)
Accumulated impairment	—	—	—	—
Net book amount	134,453	2,091	513,697	650,241

(1) The total additions of In-process research and development recorded in Note 12 is $126,697 which represents the total for the years ended June 30, 2014 and 2013.

(2) An immaterial out of period adjustment to goodwill was recognized on finalization of the MSC business combination of Osiris.

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

(in thousands)	As of June 30, 2015	2014
Cardiovascular products	254,351	254,351
Intravenous products for metabolic diseases and inflammatory/immunologic conditions	70,730	70,730
Ophthalmic product	31,090	31,090
Bone marrow transplantation	30,829	30,829
Mesenchymal stem cells (MSC)	126,697	126,697
	513,697	**513,697**

6. Non-financial assets and liabilities (continued)

For all products the above balances, underlying currency of the item recorded is USD.

(ii) Amortization methods and useful lives

The Group amortizes intangible assets with a limited useful life using the straight-line method over the following periods:

- Acquired licenses to patents 7-16 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 an 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 carrying value of in-process research and development ($513,697) 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 May 31, 2015 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:

- the valuation of the Company that was applicable to the recent (April 12, 2015) equity placement undertaken with Celgene Corporation (NASDAQ: CELG) through issuing of the Company's securities on the Australian Securities Exchange;
- the market capitalisation of the Company on the ASX (ASX:MSB) on the impairment testing date of May 31, 2015;
- the valuation of the Company that was applicable to the March 25, 2013 capital raising undertaken through issuing of the Company's securities to investors on the Australian Securities Exchange;
- the amount of time that has elapsed since the goodwill acquisition of MSC assets from Osiris in October 2013 and of certain other products from Angioblast in December 2010;
- discounted expected future cash flows of programs; and

6. Non-financial assets and liabilities (continued)

- the scientific results and progress of the trials since acquisition.

Costs of disposal were assumed to be immaterial.

Discounted cash-flows used a real pre-tax discount rate range of 15.4% to 17.4%, 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. The assessment showed the recoverable amount of goodwill and in-process research and development exceeds the carrying amounts, and therefore there is no impairment.

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 in-process research and development, 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

Due to the significant excess value of the recoverable amount over the carrying value, a reasonably possible change in the key assumptions would not cause the carrying amount of the segment to exceed its recoverable amount.

Whilst we note there is no impairment the key sensitivities in the valuation remain the continued successful development of our technology platform.

c. Deferred revenue

	Year Ended June 30,	
	2015	**2014**
Opening balance	52,513	67,515
Amount recognized as revenue in the year	(15,004)	(15,004)
Foreign exchange difference	—	1
Balance as of the end of the year	**37,509**	**52,512**
- To be recognized in the next twelve months (current deferred revenue)	15,004	15,004
- To be recognized beyond twelve months (non-current deferred revenue)	22,505	37,508
Balance as of the end of the year	**37,509**	**52,512**

6. Non-financial assets and liabilities (continued)

d. Provisions

(in thousands)	Year ended June 30,					
	2015			2014		
	Current	Non-current	Total	Current	Non-current	Total
Contingent consideration	—	91,890	91,890	—	81,247	81,247
Employee benefits	5,161	1,590	6,751	4,607	253	4,860
Other	—	—	—	750	—	750
	5,161	**93,480**	**98,641**	**5,357**	**81,500**	**86,857**

(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 Therapeutics Inc. Further disclosures can be found in Note 12 and Note 6(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, 2015 and 2014, the entire amount of the accrual was $545 and $559, 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.

Other

During the ordinary course of business the Group occasionally has disputes with service providers. This provision allows for those disputes in the event the disputed amounts may become due and payable. Further disclosure is considered to be prejudicial to the Group.

6. Non-financial assets and liabilities (continued)

(ii) Movements

Movements in each class of provision during the financial year, other than employee benefits, are set out below:

(in thousands)	Note	Contingent consideration	Other	Total
Carrying amount at start of the year – July 1, 2013		—	8,594	8,594
Initial recognition on business combination	12(b)	77,169	—	77,169
Amount used during the year		—	(5,500)	(5,500)
Charged/(credited) to consolidated income statement				
Unwinding of discount[1]		4,078	—	4,078
Unused amount reversed		—	(2,344)	(2,344)
Carrying amount as of June 30, 2014		**81,247**	**750**	**81,997**
Carrying amount at start of period – July 1, 2014		81,247	750	81,997
Amount used during the year		(6,779)	(750)	(7,529)
Allocated to goodwill				
Remeasurement[2][3]	5(f)(iii)	2,086	—	2,086
Charged/(credited) to consolidated income statement				
Unwinding of discount[1]		8,506	—	8,506
Remeasurement[1]		6,830	—	6,830
Carrying amount as of June 30, 2015		**91,890**	**—**	**91,890**

(1) The unwinding of the risk adjusted discount as the time period shortens between the valuation date and the potential settlement date of the contingent consideration.

(2) $2,086 out of period adjustment to goodwill was recognized on finalization of the MSC business combination of Osiris.

(3) The total amount of remeasurement of contingent consideration pertaining to the acquired MSC assets of Osiris was $8,916.

e. Deferred tax balances

(in thousands)	As of June 30, 2015	As of June 30, 2014
(i) Deferred tax liabilities		
The balance comprises temporary differences attributable to:		
Deferred tax liabilities related to intangible assets	149,387	149,387
Deferred tax liabilities expected to be settled within 12 months	—	—
Deferred tax liabilities expected to be settled after 12 months	149,387	149,387

Movements

(in thousands)	Intellectual Property	Total
As of June 30, 2013	135,450	135,450
Foreign exchange difference	—	—
Acquisition of in-process research and development	13,937	13,937
As of June 30, 2014	**149,387**	**149,387**
Foreign exchange difference	—	—
As of June 30, 2015	**149,387**	**149,387**

7. Equity

a. Contributed equity

(dollars in thousands)	As of June 30,					
	2015 Shares No.	2014 Shares No.	2013 Shares No.	2015	2014	2013
Contributed equity						
(i) Share capital						
Ordinary shares	336,997,729	321,640,094	316,468,901	709,191	662,722	642,378
Less: Treasury Shares	(3,500,000)	(4,485,000)	(3,320,000)	—	—	—
Total Contributed Equity	**333,497,729**	**317,155,094**	**313,148,901**	**709,191**	**662,722**	**642,378**

(ii) Movements in ordinary share capital

	Shares No.	Issue price	Dollars in thousands
Opening Balance as of July 1, 2012	285,835,106		467,760
Exercise of share options	150,000	$ 0.31	46
Exercise of share options	255,913	$ 0.34	87
Exercise of share options	255,913	$ 0.47	121
Exercise of share options	80,000	A$0.96	80
Exercise of share options	646,000	A$1.00	612
Exercise of share options	300,000	A$1.58	490
Exercise of share options	72,000	A$2.00	148
Exercise of share options	40,000	A$2.64	108
Exercise of share options	475,600	A$3.48	1,727
Exercise of share options	277,390	A$3.78	1,096
Share issue to institutions and sophisticated investors	26,970,979	A$6.30	175,185
Placement of shares under LSFP(1)	50,000	A$6.29	—
Placement of shares under LSFP(1)	235,000	A$6.36	—
Placement of shares under LSFP(1)	50,000	A$6.69	—
Placement of shares under LSFP(1)	775,000	A$6.70	—
	30,633,795		179,700
Transaction costs arising on share issues			(5,777)
Contribution of equity (net of transaction costs)			173,923
Share options reserve transferred to equity on exercise of options			695
Movement for the year			174,618
Balance as of June 30, 2013	**316,468,901**		**642,378**
Exercise of share options	230,000	A$1.58	332
Exercise of share options	150,000	A$1.73	232
Exercise of share options	310,000	A$2.64	733
Exercise of share options	297,300	A$3.48	940
Consideration for In-process research and development acquired (Note 12)	2,948,729	A$5.69	14,926
Consideration for Acquired licenses to patents	70,164	A$5.96	380
Placement of shares under LSFP(1)	900,000	A$5.92	—
Placement of shares under LSFP(1)	100,000	A$6.28	—
Placement of shares under LSFP(1)	165,000	A$6.70	—
	5,171,193		17,543
Transaction costs arising on share issues			(41)
Contribution of equity (net of transaction costs)			17,502
Share options reserve transferred to equity on exercise of options			2,842
Movement for the year			20,344
Balance as of June 30, 2014	**321,640,094**		**662,722**

7. Equity (continued)

	Shares No.	Issue price	Dollars in thousands
Opening balance as of July 1, 2014	321,640,094		662,722
Exercise of share options	41,935	$ 0.31	13
Exercise of share options	255,913	$ 0.34	87
Exercise of share options	480,000	A$1.58	663
Exercise of share options	150,000	A$1.73	226
Exercise of share options	115,950	A$3.48	323
Placement of shares under LSFP(1)	600,000	A$4.46	—
Placement of shares under LSFP(1)	25,000	A$4.54	—
Placement of shares under LSFP(1)	150,000	A$4.66	—
Placement of shares under LSFP(1)	1,225,000	A$4.71	—
Placement of shares under a share placement agreement (2)	15,298,837	A$3.82	45,000
Share buy-back of LFSP(3)	(600,000)	A$4.46	—
Share buy-back of LFSP(3)	(700,000)	A$4.71	—
Share buy-back of LFSP(3)	(500,000)	A$5.92	—
Share buy-back of LFSP(3)	(135,000)	A$6.36	—
Share buy-back of LFSP(3)	(400,000)	A$6.70	—
Share buy-back of LFSP(3)	(650,000)	A$7.99	—
	15,357,635		46,312
Transaction costs arising on share issues			(439)
Contribution of equity (net of transaction costs)			45,873
Share options reserve transferred to equity on exercise of options			596
Movement for the year			46,469
Balance as of June 30, 2015	**336,997,729**		**709,191**

(1) 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 Loan Funded Share Plan ("LFSP") a dollar movement will be recorded at that date.

(2) These shares were issued to Celgene Corporation (NASDAQ: CELG) under a placement agreement pursuant to which Celgene purchased Mesoblast Limited securities and received a six-month right of refusal to certain disease fields.

(3) Repurchase of shares held in trust under LFSP by the Company. Therefore there is no dollar movement recorded in ordinary share capital.

(iii) Ordinary shares

Ordinary shares participate in dividends and the proceeds on winding up of the Group in equal proportion to the number of shares held. At shareholders meetings each ordinary share is entitled to one vote when a poll is called, otherwise each shareholder has one vote on a show of hands. Ordinary shares have no par value and the Company does not have a limited amount of authorized capital.

(iv) Employee share options

Information relating the Group's employee share option plan, including details of shares issued under the scheme, is set out in Note 18.

7. Equity (continued)

b. Reserves

(in thousands)	As of June 30,		
	2015	2014	2013
(i) Reserves			
Share-based payments reserve	60,740	55,754	49,968
Foreign currency translation reserve	(37,984)	(12,201)	(15,572)
	22,756	**43,553**	**34,396**
(ii) Reconciliation of reserves			
Share-based payments reserve			
Opening balance	55,754	49,968	38,256
Transfer to ordinary shares on exercise of options	(596)	(2,842)	(695)
Fair value of share-based payments	6,976	8,628	12,407
Reclassification of modified options to liability	(1,394)	—	—
Closing balance	**60,740**	**55,754**	**49,968**
Foreign currency translation reserve			
Opening balance	(12,201)	(15,572)	12,070
Currency (loss)/gain on translation of foreign operation's net assets	(25,783)	3,371	(27,642)
Closing balance	**(37,984)**	**(12,201)**	**(15,572)**

(iii) Nature and purpose of reserves

Share-based payment reserve

The share-based payments reserve is used to recognize:

- the grant date fair value of options issued but not exercised; and
- the grant date fair value of deferred shares granted but not yet vested.

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 thousands)	Year Ended June 30,		
	2015	2014	2013
(a) Reconciliation of cash and cash equivalents			
Cash at bank	21,126	3,605	11,820
Deposit at call	89,575	181,398	280,629
	110,701	**185,003**	**292,449**

8. Cash flow information (continued)

(in thousands)	Year Ended June 30,		
	2015	2014	2013
(b) Reconciliation of net cash flows used in operations with loss after income tax			
Loss for the year	(96,244)	(75,534)	(62,120)
Add/(deduct) net loss for non-cash items as follows:			
Commercialization revenue	(15,004)	(15,004)	(18,685)
Depreciation and amortization	1,601	1,024	787
Foreign exchange (gains)/losses	(9,729)	4,075	1,581
Finance costs	8,506	4,078	—
Remeasurement of contingent consideration	2,164	—	—
Release of excess provision for services	—	(2,344)	—
Equity settled share-based payment	6,976	8,628	12,409
Change in operating assets and liabilities:			
Decrease in trade and other receivables	697	3,086	2,795
(Increase) in prepayments	(7,439)	(189)	(590)
Decrease/(increase) in tax assets	38	3,153	(1,925)
(Decrease)/increase in trade creditors and accruals	7,721	(1,331)	8,669
(Decrease)/increase in provisions	(323)	(4,548)	1,333
Net cash outflows used in operations	**(101,036)**	**(74,906)**	**(55,746)**

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.

a. 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 asset (Note 6(b));
- estimates of tax payable and current tax expense (Note 4(b));
- accrued research and development and manufacturing commercialization expenses (Note 5(e));

9. Significant estimates, judgments and errors (continued)

- fair value of share-based payments (Note 18); and
- fair value of available-for-sale financial assets (Note 5(f)).

Estimates and judgments are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

10. Financial risk management

This note explains the Group's exposure to financial risks and how these risks could affect the Group's future financial performance. Current year profit and loss information has been included where relevant to add further context.

Risk	Exposure arising from	Measurement	Management
Market risk — currency risk	Future commercial transactions Recognized financial assets and liabilities not denominated in the functional currency of each entity within the Group	Cash flow forecasting Sensitivity analysis	The future cash flows of each currency are forecast and the quantum of cash reserves held for each currency are managed in line with future forecasted requirements. Cross currency swaps are undertaken as required.
Market risk — interest rate risk	Term deposits at fixed rates	Sensitivity analysis	Vary length of term deposits
Credit risk	Cash and cash equivalents, trade receivables and derivative financial instruments	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. Derivatives

Derivatives are only used for economic hedging purposes and not as trading or speculative instruments. The Group has the following derivative financial instruments:

(in thousands)	As of June 30	
	2015	2014
Current liabilities		
Forward foreign exchange contracts – held for trading	—	317
	—	**317**

10. Financial risk management (continued)

(i) *Classification of derivatives*

Derivatives are classified as held for trading and accounted for at fair value through profit or loss. They are presented as current assets or liabilities if they are expected to be settled within 12 months after the end of the reporting period.

(ii) *Change in accounting policy*

The Group has applied the new standard on IFRS 13 *Fair Value Measurement* from July 1, 2013.The adoption of the standard has not affected the measurement of the fair value of certain derivative liabilities.

(iii) *Fair value measurement*

For information about the methods and assumptions used in determining the fair value of derivatives please refer to Note 5(f).

b. 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. The Group engages professional advice when considering forward foreign exchange contracts.

As of June 30, 2015, the Group held 64% of its cash in USD, and 36% in AUD. As of June 30, 2015, the Group did not hold any financial derivative contracts.

As of June 30, 2014, the Group held 45% of its cash in USD, and 55% in AUD. 12% of the AUD balance is subject to forward contracts to purchase USD at a predetermined rate in the future. After allowing for financial derivative contracts, the Group held 51% USD and 49% AUD. The Group utilized financial derivative contracts to take advantage of enhanced interest rates yields available on AUD deposits when compared to USD deposits. The Group sells USD and buys AUD from the bank at a pre-agreed FX rate and agrees to then sell those AUD and buy USD from the bank on maturity also at a pre-agreed rate. As these FX rates are known at the outset there is no currency risk. It should be noted that trading in speculative derivatives is strictly prohibited in accordance with the Group's treasury and financial risk management policy.

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, 2015 and 2014 would have had on the Group's reported net profits/(losses) and/or equity balance.

10. Financial risk management (continued)

The Group's exposure to foreign currency risk at the end of the reporting period was as follows:

As of June 30, 2015 (in thousands)	Foreign currency balance held	+20% Profit/(loss) USD	-20% Profit/(loss) USD
Bank accounts	USD 70,599	(12,353)	18,529
Bank accounts	CHF 158	(30)	44
Bank accounts	SGD 12	(2)	2
Trade and other receivables — CHF	CHF 117	(22)	33
Trade payables & accruals — USD	(USD 22,899)	4,006	(6,010)
Trade payables & accruals — AUD	(AUD 149)	14	(21)
Trade payables & accruals — SGD	(SGD 208)	27	(40)
Trade payables & accruals — GBP	(GBP 60)	16	(25)
Trade payables & accruals — EUR	(EUR 184)	36	(54)
Trade payables & accruals — CHF	(CHF 111)	22	(32)
Provisions — USD	(USD 2,814)	493	(739)
Provisions — SGD	(SGD 55)	7	(10)
		(7,786)	**11,677**

As of June 30, 2014 (in thousands)	Foreign currency balance held	+20% Profit/(loss) USD	-20% Profit/(loss) USD
Bank accounts	USD 82,853	(13,677)	20,516
Bank accounts	CHF 632	(117)	175
Forward exchange contracts			
Buy foreign currency (Note 10(a))	USD76,000	(12,546)	18,819
Trade and other receivables — USD	USD 990	(163)	245
Trade and other receivables — CHF	CHF 3	(1)	1
Trade payables & accruals — USD	(USD 16,788)	2,771	(4,156)
Trade payables & accruals — AUD	(AUD 222)	33	(49)
Trade payables & accruals — SGD	(SGD 722)	95	(143)
Trade payables & accruals — GBP	(GBP 27)	7	(11)
Trade payables & accruals — EUR	(EUR 86)	20	(29)
Trade payables & accruals — CHF	(CHF 12)	2	(4)
Trade payables & accruals — DKK	(DKK 2)	—	—
Provisions — USD	(USD 3,144)	519	(778)
Provisions — SGD	(SGD 34)	5	(7)
		(23,052)	**34,579**

(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 cash flow requirements of the Group.

10. Financial risk management (continued)

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, 2015. The effect on profit is shown if interest rates change by 10%, in either direction, is as follows:

(in thousands, except percent data)	June 30, 2015			June 30, 2014		
USD	**Low**	**High**	**USD**	**Low**	**High**	**USD**
Funds invested	0.30%	0.30%	55,636	0.04%	0.27%	81,000
Rate increase by 10%	0.33%	0.33%	17	0.04%	0.30%	3
Rate decrease by 10%	0.27%	0.27%	(17)	0.04%	0.24%	(3)
AUD	**Low**	**High**	**AUD**	**Low**	**High**	**AUD**
Funds invested	2.85%	2.92%	44,191	3.41%	3.60%	107,540
Rate increase by 10%	3.14%	3.21%	129	3.75%	3.96%	374
Rate decrease by 10%	2.57%	2.63%	(129)	3.07%	3.24%	(374)

(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.

c. 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. As the Group is non–revenue generating it generally does not have trade receivables. The Group's receivables are tabled below.

(in thousands)	As of June 30, 2015	2014
Cash and cash equivalents		
Cash and cash equivalents (Note 5(a)) — minimum A rated	110,701	185,003
Trade and other receivables		
Receivable from the Australian Government (Goods and Services Tax)	54	120
Receivable from the Australian Government (Income Tax)	3,625	4,879
Receivable from the United States Government (Income Tax)	71	70
Receivable from the Swiss Government (Value-Added Tax)	2	4
Receivable from minimum A rated bank deposits (interest)	84	279
Receivable from other parties (non-rated)	136	392

d. Liquidity risk

Liquidity risk is the risk that the Group will not be able to pay its debts as and when they fall due.

For the years ended June 30, 2015, 2014 and 2013 the Group has incurred a total comprehensive loss after income tax of $122,027, $72,163 and $89,762, respectively, and net cash outflows from operations of $101,036, $74,906 and $55,746 respectively. As at June 30, 2015, the Group held total cash and cash equivalents of $110,701. The Group is a development stage biotechnology company and as such expects to be utilizing cash reserves until its research activities are commercialized. The Group has historically funded its research activities through raising capital from shareholders and entering into licensing and partnership agreements, it is expected that similar funding will be obtained to provide working capital as and when required.

10. Financial risk management (continued)

The directors are satisfied that there is sufficient working capital to support the committed research activities over the coming 12 months and the Group has the ability to realize its assets and pay its liabilities and commitments in the normal course of business. Accordingly, the directors have prepared the financial report on a going concern basis.

All financial liabilities, excluding contingent consideration, held by the Group as of June 30, 2015 and June 30, 2014 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. Business combination

a. Summary of acquisition

On October 11, 2013, the Group acquired the culture-expanded mesenchymal stem cell ("MSC") business of Osiris Therapeutics Inc.

The acquisition is complementary in its nature with many commercial and strategic benefits. The potential benefits derived from acquiring the late-phase MSC products include:

- near term market launch of a mesenchymal lineage product in major jurisdictions;
- broadened late-phase clinical programs in strategic areas of focus;
- leveraged roll out of infrastructure, skills and expertise needed to commercialize mesenchymal precursor cell products;
- ownership of extensive long-term clinical data from over 1,000 patients treated with culture-expanded mesenchymal stem cells, including safety, efficacy and repeat dosing data; and
- acquisition of new intellectual property which is highly complementary to the Group's existing patent estate.

Details of the purchase consideration, the net assets acquired and goodwill are as follows:

Purchase consideration at fair value

(in thousands)	Fair value at October 11, 2013
Cash paid on closing	20,000
Cash payment made on the six month anniversary of the agreement (Fair Value)	14,751
Securities allotment (2,948,729 shares were allotted)(1)	15,000
Contingent consideration (Note 6(d)(ii))(2)	77,169
Total purchase consideration	**126,920**

12. Business combination (continued)

Net assets acquired at fair value

(in thousands)	Fair value at October 11, 2013
Property, plant and equipment	223
Intangible assets: in-process research and development	126,697
Deferred tax liability on intangible assets	(13,937)
Net identifiable assets acquired	**112,983**
add: Goodwill	13,937
Net assets acquired	**126,920**

(1) The Company's securities (ASX: MSB) were issued as consideration upon the transfer of assets on December 18, 2013, which had a value of $15,000 (AUD 16,717) on that date.

(2) At acquisition date contingent consideration of $77,169 was recorded as tabled above. Please refer to Note 6(d)(ii) for the reconciliation of the subsequent movements of this contingent consideration provision.

All assets acquired and purchase consideration amounts are denominated in USD. The goodwill is attributable to the deferred tax liability that is required to be recognized on the difference between the intangible asset's book value compared to its tax value.

No amount of goodwill is expected to be deducted for tax purposes.

The tax base of the asset assumes that the asset is held for use and is therefore $Nil resulting in a deferred tax liability calculated at the tax rate of the jurisdiction where the underlying intangible assets are held.

Refer also to Note 6(b) for an immaterial out of period adjustment to goodwill on finalization of the business combination.

b. Contingent consideration

In the event that certain pre-determined milestones and royalties are achieved additional consideration is payable. The fair value of the contingent consideration is set out in the table below. The fair value estimates have been calculated on the basis of fair value less cost to sell by using the income approach, with reference to both the excess earnings and relief from royalty methods as set out below:

The fair value of contingent consideration (in thousands)	Fair value at October 11, 2013
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets(1)	23,159
Fair value of royalty payments from commercialization of the intellectual property acquired(2)	54,010
	77,169

(1) The contingent consideration payable for each milestone is a fixed dollar amount and can be paid either in cash or through the allotment of Mesoblast Ltd securities at the date of payment, at the discretion of the Mesoblast Group. The potential undiscounted amount of the contingent consideration for milestones is a minimum of $Nil and a maximum of $50,000.

12. Business combination (continued)

(2) The amount of the contingent consideration payable as royalties paid on sales achieved is variable. The contingent consideration paid could range from zero dollars if no sale of product occurs, up to a maximum that is unlimited. This maximum is calculated at a commercial arm's length percentage of net sales. Royalty payments will cease after a 10 year commercial sales period. Royalties are payable in cash after the conclusion of the period in which the sales were made.

c. Purchase consideration — cash outflow

(in thousands)	Year Ended June 30, 2015	2014
Cash consideration (fair value) owed pursuant to the asset purchase agreement	33,370	34,951
Securities allotment consideration owed (fair value) pursuant to the asset purchase agreement	2,086	—
less: amount paid during the prior full year ended	(33,370)	(1,581)
Cash outflow reported for the current reporting period(1)	**2,086**	**33,370**

(1) Included within cash flows from investing activities within the statements of cash flows.

d. Revenue and profit contribution

The acquired business contributed revenues of $Nil and net loss of $5,465 to the Group for the period October 11, 2013 to June 30, 2014.

If the acquisition had occurred on July 1, 2013, consolidated revenue and loss for the year ended June 30, 2014 would have been $23,863 and $75,607 respectively. These amounts have been calculated using the Osiris audited financial statements segment information. This has been calculated based on expenditure incurred with external providers to develop programs acquired from Osiris. There were no allocations of internal labour or other internal cost bases.

e. Acquisition-related costs

Directly attributable acquisition-related costs of approximately $876 are included in management and administration expenses in the consolidated income statement, and in the operating cash flows section in the consolidated statement of cash flows, for the full-year ended June 30, 2014.

13. Interests in other entities

a. Material subsidiaries

The Group's principal subsidiaries as of June 30, 2015 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.

Name of entity	Country of incorporation	Class of shares	Equity holding June 30, 2015	Equity holding June 30, 2014
			%	%
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 Limited	United Kingdom	Ordinary	100	100

14. Contingent assets and contingent liabilities

a. Contingent assets

The Group did not have any contingent assets outstanding as of June 30, 2015 and 2014.

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 $250 on completion of Phase 3 clinical trials and $350 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.

Additionally, in regards to certain intellectual property assets originally assigned to Mesoblast Inc., the Group may be required to pay consideration to CALHNI depending on the achievement of future milestones. They represent payments on successful completion of subsequent clinical milestones in fields other than orthopaedic. If all milestones were to be reached these payments total $1,850. In addition it stipulates the requirement for royalty payments as a percentage of sales of product in fields other than orthopaedic at a commercial arm's length rate as well as minimum annual royalties after commercial sale of product scaling up from $100 to $500 over 5 years.

Across all fields, if all milestones were reached, milestone payments would total $2,450.

(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. At this time the Group has assessed these contingent liabilities to be remote and specific disclosure is not required.

15. Commitments

a. Capital commitments

The Group did not have any commitments for future capital expenditure outstanding as of June 30, 2015 and 2014.

b. Lease commitments: Group as lessee

i. Non-cancellable operating leases

The Group leases various offices under non-cancellable operating leases expiring within 1 to 6 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	14,116	2,592	7,448	4,076	—
Total commitments	14,116	2,592	7,448	4,076	—

15. Commitments (continued)

Lease commitments include amounts in AUD and Singapore dollars which have been translated to USD as of June 30, 2015 foreign exchange rates published by the Reserve Bank of Australia.

ii. Sub-lease payments

Future minimum lease payments expected to be received in relation to non-cancellable sub-leases 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	711	161	483	67	—
Total commitments	711	161	483	67	—

c. Purchase commitments

The Group has established a strategic alliance for clinical and long-term commercial production of Mesoblast's off-the-shelf (allogeneic) adult stem cell products with Lonza Group (SWS: LONN).

As part of this agreement, Mesoblast has an option to trigger a process requiring Lonza Group to construct a purpose-built manufacturing facility exclusively for Mesoblast's marketed products. In return, Mesoblast will purchase agreed quantities of marketed products from the facility.

The Group has a purchase commitment of $4,416 to Lonza Group.

16. Events occurring after the reporting period

There are no events that have occurred after June 30, 2015 and prior to the signing of this financial report that would likely have a material impact on the financial results presented.

17. 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 13 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:

	Year Ended June 30,		
(in dollars)	2015	2014	2013
Short-term employee benefits	2,975,780	2,579,498	2,511,857
Long-term employee benefits	16,287	21,296	23,290
Post-employment benefits	77,083	60,028	59,744
Share-based payments	282,138	—	5,047
	3,351,288	**2,660,822**	**2,599,938**

17. Related party transactions (continued)

d. Transactions with other related parties

Accounts receivable from, accounts payable to 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.

18. 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.

Grant policy

In accordance with the Company's current 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, the grant made on July 10, 2015 was issued with a seven year term. 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 for options 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 grant date. In the case of options issued to staff (performance based) the board of directors add a 10% premium, options issued to directors, which are not performance based, are issued with no premium. A one off issue of options to non-Australian based directors was made 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 [CO 14/1000].

In addition the LFSP 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.

18. Share-based payments (continued)

a. Reconciliation of outstanding share based payments

Year ended June 30, 2015

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)
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)	—	1453,350	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	09/07/2012	08/07/2018	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	24/01/2018-28/01/2008	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	03/09/2013	30/06/2018	AUD 5.92	3,290,000	—	—	(548,333)	2,741,667	1,206,671
22/LF8	04/09/2013	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)	—	—
LF9.4	11/12/2013	30/06/2017	AUD 6.70	165,000	—	—	(165,000)	—	—
LF9.7	03/09/2013	30/06/2018	AUD 5.92	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	09/02/2019	AUD 6.41	100,000	—	—	(100,000)	—	—
24a (ii)	17/02/2014	16/02/2019	AUD 6.33	25,000	—	—	(25,000)	—	—
25	15/07/2014	06/04/2019	AUD 5.80	—	15,000	—	—	15,000	5,000
25a (i&ii)	01/01/2014	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	02/09/2014	AUD 5.43	—	60,000	—	(60,000)	—	—
26/LF11	24/07/2014	23/07/2019	AUD 4.71	—	575,000	—	(360,000)	215,000	—
27/LF12	05/09/2014	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)	04/08/2014	03/08/2019	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	05/09/2014	30/06/2019	AUD 4.46	—	600,000	—	(600,000)	—	—
28/LF13	09/10/2014	08/10/2019	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	—
INC	7/12/2010	7/07/2015	$ 0.046	287,903	—	—	—	287,903	287,903
INC	7/12/2010	26/10/2018	$ 0.305	195,999	—	(41,935)	—	154,064	154,064
INC	7/12/2010	26/10/2019	$ 0.340	703,761	—	(255,913)	—	447,848	447,848
INC	7/12/2010	25/04/2017	$ 0.444	127,956	—	—	—	127,956	127,956
INC	7/12/2010	2/05/2017	$ 0.444	127,956	—	—	—	127,956	127,956
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 5.82	AUD 4.69	AUD 1.49	AUD 5.91	AUD 5.49	AUD 5.78

18. Share-based payments (continued)

(1) 30a to 30i were granted as a remuneration for the repurchase and cancellation of 2,985,000 LFSP during the year ended June 30, 2015 (see Note 18(b)).

Year ended June 30, 2014

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)
8	7/07/2008	30/06/2013	AUD 1.00	180,000	—	—	(180,000)	—	—
10	30/11/2009	30/11/2014	AUD 1.73	300,000	—	(150,000)	—	150,000	150,000
11	30/11/2009	30/11/2014	AUD 1.58	710,000	—	(230,000)	—	480,000	480,000
13	22/09/2010	21/09/2015	AUD 2.64	445,000	—	(310,000)	—	135,000	135,000
14	29/11/2010	29/11/2015	AUD 3.48	1,866,600	—	(297,300)	—	1,569,300	1,569,300
15/LF1	22/12/2011	30/06/2016	AUD 7.99	4,560,000(1)	—	—	(316,666)	4,243,334	3,543,339
16/LF2	24/02/2012	23/02/2017	AUD 8.48	340,000	—	—	—	340,000	226,668
17/LF3	9/07/2012	8/07/2018	AUD 6.69	250,000	—	—	—	250,000	83,331
18/LF4	21/09/2012-29/10/2012	30/06/2017	AUD 6.70	2,915,000(1)	—	—	(261,667)	2,653,333	1,275,002
19/LF5	25/01/2013-29/01/2013	24/01/2018-28/01/2008	AUD 6.29	100,000	—	—	—	100,000	33,334
20/LF6	24/05/2013	23/05/2018	AUD 6.36	1,000,000	—	—	—	1,000,000	378,338
21/LF7	3/09/2013	30/06/2018	AUD 5.92	—	3,490,000	—	(200,000)	3,290,000	325,001
22/LF8	4/09/2013	27/08/2018	AUD 6.28	—	325,000	—	—	325,000	—
23a	26/11/2013	10/10/2018	AUD 6.20	—	50,000	—	—	50,000	—
23b	30/11/2013	29/11/2018	AUD 6.79	—	200,000	—	—	200,000	—
24	17/12/2013	16/12/2018	AUD 6.25	—	190,000	—	(10,000)	180,000	—
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	—
25a (i&ii)	1/01/2014	31/12/2018	AUD 6.38	—	650,000	—	—	650,000	—
LF9.4	11/12/2013	30/06/2017	AUD 6.70	—	165,000	—	—	165,000	110,000
LF9.7	3/09/2013	30/06/2018	AUD 5.92	—	200,000	—	—	200,000	66,667
INC	7/12/2010	7/07/2015	$ 0.046	287,903	—	—	—	287,903	287,903
INC	7/12/2010	26/10/2018	$ 0.305	195,999	—	—	—	195,999	195,999
INC	7/12/2010	26/10/2019	$ 0.340	703,761	—	—	—	703,761	703,761
INC	7/12/2010	25/04/2017	$ 0.444	127,956	—	—	—	127,956	127,956
INC	7/12/2010	2/05/2017	$ 0.444	127,956	—	—	—	127,956	127,956
June 30, 2014				**14,110,175**	**5,395,000**	**(987,300)**	**(968,333)**	**17,549,242**	**9,819,555**
Weighted average share purchase price				AUD 5.46	AUD 6.08	AUD 2.51	AUD 5.90	AUD 5.82	AUD 5.32

(1) The opening balance for 15/LF1 and 18/LF4 has been restated to increase the balance by 100,000 and 45,000 loan funded shares respectively. These shares were forfeited by participants in accordance with the terms of the loan funded share plan and are now the property of the Employee Share Trust.

18. Share-based payments (continued)

Year ended June 30, 2013

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)
8	07/07/08	30/06/13	AUD 1.00	826,000	—	(646,000)	—	180,000	180,000
9	19/01/09	18/01/14	AUD 0.96	80,000	—	(80,000)	—	—	—
10	30/11/09	30/11/14	AUD 1.73	300,000	—	—	—	300,000	300,000
11	30/11/09	30/11/14	AUD 1.58	1,010,000	—	(300,000)	—	710,000	710,000
12	26/02/10	26/02/15	AUD 2.00	72,000	—	(72,000)	—	—	—
13	22/09/10	21/09/15	AUD 2.64	485,000	—	(40,000)	—	445,000	270,000
14	29/11/10	29/11/15	AUD 3.48	2,365,600	—	(475,600)	(23,400)	1,866,600	983,000
15/LF1	22/12/11	30/06/16	AUD 7.99	4,770,000	—	—	(310,000)	4,460,000	2,566,673
16/LF2	24/02/12	23/02/17	AUD 8.48	440,000	—	—	(100,000)	340,000	113,334
17/LF3	09/07/12	08/07/18	AUD 6.69	—	250,000	—	—	250,000	—
18/LF4	21/09/2012-29/10/2012	30/06/17	AUD 6.70	—	2,995,000	—	(125,000)	2,870,000	456,667
19/LF5	25/01/13	24/01/18	AUD 6.29	—	100,000	—	—	100,000	—
20/LF6	24/05/13	23/05/18	AUD 6.36	—	1,000,000	—	—	1,000,000	—
INC	07/12/10	07/07/15	$ 0.046	287,903	—	—	—	287,903	287,903
INC	07/12/10	26/10/18	$ 0.305	345,999	—	(150,000)	—	195,999	195,999
INC	07/12/10	07/12/14	$ 0.340	255,913	—	(255,913)	—	—	—
INC	07/12/10	26/10/19	$ 0.340	703,761	—	—	—	703,761	703,761
INC	07/12/10	25/04/17	$ 0.444	127,956	—	—	—	127,956	127,956
INC	07/12/10	02/05/17	$ 0.444	127,956	—	—	—	127,956	127,956
INC	07/12/10	07/12/14	$ 0.474	255,913	—	(255,913)	—	—	—
Conv	07/12/10	07/12/12	AUD3.78	277,390	—	(277,390)	—	—	—
June 30, 2013				**12,731,391**	**4,345,000**	**(2,552,816)**	**(558,400)**	**13,965,175**	**7,023,249**
Weighted average exercise price				AUD 4.42	AUD 6.61	AUD 1.72	AUD 6.33	AUD 5.46	AUD 4.40

The weighted average share price at the date of exercise of options exercised during the year ended June 30, 2015, 2014 and 2013 was AUD 4.06, AUD 5.83 and AUD 5.94, respectively.

The weighted average remaining contractual life of share options and loan funded shares outstanding as of June 30, 2015, 2014 and 2013 was 2.43 years, 2.96 years and 3.38 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 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, the grant made on July 10, 2015 was issued with a seven year term. Vesting occurs 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

18. Share-based payments (continued)

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 enrolment 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 year.

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.

Modifications to share-based payment arrangements

During the year ended June 30, 2015, the Company repurchased an aggregate amount of $13,908 (AUD 17,665) 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 $606.

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, 2015, 2014 and 2013 was AUD 1.22, AUD 1.71 and AUD 2.69, respectively.

18. Share-based payments (continued)

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 grant date

The share price underpinning the exercise price has been used as the share price at grant date for valuation purposes. This price is generally the volume weighted average share price for the 5 trading days leading up to grant 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.

Share price date from January 1, 2012 through to the end of each applicable financial year has been used to calculate share price 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 issued during the year ended June 30, 2015 are as follows:

Series	Financial year of grant	Exercise/Loan Price per share AUD	Share price at grant date AUD	Expected share price volatility	Life	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%

18. Share-based payments (continued)

Series	Financial year of grant	Exercise/Loan Price per share AUD	Share price at grant date AUD	Expected share price volatility	Life	Dividend yield	Risk-free interest rate
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%

The closing share market price of an ordinary share of Mesoblast Limited on the Australian Securities Exchange as of June 30, 2015 was AUD 3.76.

The model inputs for the valuations of options approved and issued during the year ended June 30, 2014 are as follows:

Series	Financial year of grant	Exercise/Loan Price per share AUD	Share price at grant date AUD	Expected share price volatility	Life	Dividend yield	Risk-free interest rate
15/LF1	2014	7.99	7.00-7.48	51.48%	0.6-4.5yrs	0%	3.18%
18/LF4	2014	6.70	5.83-7.14	48.49%	4.75 yrs	0%	2.78%
21/LF7	2014	5.92	5.56	38.80%	3.6 yrs	0%	3.31%
22	2014	6.28	5.49	38.79%	3.7 yrs	0%	3.37%
LF8	2014	5.92	6.28	38.79%	3.7 yrs	0%	3.37%
LF9.4	2014	6.70	5.88	38.79%	2.6 yrs	0%	3.47%
LF9.7	2014	5.92	5.88	38.79%	3.4 yrs	0%	3.47%
23a	2014	6.20	6.04	38.74%	3.6 yrs	0%	3.45%
23b	2014	6.20	6.79	38.73%	3.7 yrs	0%	3.44%
24	2014	6.25	5.58	38.80%	3.7 yrs	0%	3.38%
24a.(i)	2014	6.41	5.75	38.37%	3.7 yrs	0%	3.44%
24a.(ii)	2014	6.33	5.76	38.20%	3.7 yrs	0%	3.45%
25a.(i)	2014	6.38	5.84	38.04%	3.6 yrs	0%	3.43%
25a.(ii)	2014	6.38	5.84	38.04%	4.9 yrs	0%	3.43%

The closing share market price of an ordinary share of Mesoblast Limited on the Australian Securities Exchange as of June 30, 2014 was AUD 4.47.

18. Share-based payments (continued)

The model inputs for the valuations of options approved and issued during the year ended June 30, 2013 are as follows:

Series	Financial year of grant	Exercise/Loan Price per share AUD	Share price at grant date AUD	Expected share price volatility	Life	Dividend yield	Risk-free interest rate
17/LF3	2013	6.69	6.00	49.61%	5 yrs	0%	2.73%
18/LF4	2013	6.70	5.83-7.14	48.49%	4.75 yrs	0%	2.78%
19/LF5	2013	6.29	5.56-5.61	40.10%	5 yrs	0%	3.09%
20/LF6	2013	6.36	6.01	40.96%	5 yrs	0%	2.84%

The closing share market price of an ordinary share of Mesoblast Limited on the Australian Securities Exchange as of June 30, 2013 was AUD 5.30.

19. 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:

	Year Ended June 30,		
	2015	2014	2013
a. PricewaterhouseCoopers Australia			
(i) Audit and other assurance services			
Audit and review of financial reports	271,926	264,575	172,966
Audit and review of financial reports and registration statements for United States Initial Public Offering purposes	1,003,706	—	—
Total remuneration of PricewaterhouseCoopers Australia	1,275,632	264,575	172,966
b. Network firms of PricewaterhouseCoopers Australia			
(i) Audit and other assurance services			
Audit and review of financial reports	90,991	115,435	55,288
Total remuneration of Network firms of PricewaterhouseCoopers Australia	90,991	115,435	55,288
Total auditors' remuneration	**1,366,623**	**380,010**	**228,254**

20. Losses per share

	Year Ended June 30,		
	2015 Cents	2014 Cents	2013 Cents
a. Basic losses per share			
From continuing operations attributable to the ordinary equity holders of the Company	(29.99)	(23.65)	(21.02)
Total basic losses per share attributable to the ordinary equity holders of the Company	**(29.99)**	**(23.65)**	**(21.02)**
b. Diluted losses per share			
From continuing operations attributable to the ordinary equity holders of the Company	(29.99)	(23.65)	(21.02)
Total basic losses per share attributable to the ordinary equity holders of the Company	**(29.99)**	**(23.65)**	**(21.02)**

20. Losses per share (continued)

	Year Ended June 30,		
	2015 Cents	2014 Cents	2013 Cents
c. Reconciliation of losses used in calculating earnings per share (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	(96,244)	(75,535)	(62,120)
Diluted losses per share			
Losses from continuing operations attributable to the ordinary equity holders of the Company:			
Used in calculating basic losses per share	(96,244)	(75,535)	(62,120)
Losses attributable to the ordinary equity holders of the Company used in calculating diluted losses per share	(96,244)	(75,535)	(62,120)

	Year Ended June 30,		
	2015 Number	2014 Number	2013 Number
Weighted average number of ordinary shares used as the denominator in calculating basic losses per share	320,867,433	319,450,496	295,529,473
Weighted average number of ordinary shares and potential ordinary shares used in calculating diluted losses per share	320,867,433	319,450,496	295,529,473

Options granted to employees (see Note 18) 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, 2015, 2014 and 2013. Shares that may be paid as contingent consideration (see Note 12(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, 2015, 2014 and 2013.

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 ("IFRS"). 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.

21. Summary of significant accounting policies (continued)

ii. Change in reporting currency

Mesoblast Limited has changed its reporting currency from Australian dollars to U.S. dollars and has recast its consolidated financial statements for all periods presented. The reporting currency was changed to align with the expectations of the users of the financial statements.

iii. New and amended standards adopted by the Group

The Group has applied the following standards and amendments for first time for their annual reporting period commencing July 1, 2014.

The adoption of the below standards, amendments and interpretation did not result in any changes in accounting policies or adjustments to the amounts recognized in the financial statements. They also do not significantly affect the disclosures in the Notes to the financial statements.

Title	Key requirements	Effective Date
Amendment to IAS 32 *Financial Instruments: Presentation*	The amendments clarify the offsetting rules in the application guidance in IAS 32 *Financial Instruments: Presentation* and explain when offsetting can be applied. In particular, they clarify that the right of set-off must be available today (i.e. not contingent on a future event) and must be legally enforceable in the normal course of business as well as in the event of default, insolvency or bankruptcy.	Annual reporting periods commencing on or after January 1, 2014
Amendment to IAS 36 *Recoverable Amount Disclosures for Non-Financial Assets*	Amendments to the disclosures required by IAS *36 Impairment of Assets* which: • remove the requirement to disclose the recoverable amount of all cash generating units (CGU) that contain goodwill or identifiable assets with indefinite lives if there has been no impairment. • require disclosure of the recoverable amount of an asset or CGU when an impairment loss has been recognized or reversed. • require detailed disclosure of how the fair value less costs of disposal has been measured when an impairment loss has been recognized or reversed.	Annual reporting periods commencing on or after January 1, 2014
Annual improvements 2010-2012 and 2011-2013 cycles	These annual improvements amend standards from the 2010 — 2012 and 2011 — 2013 reporting cycles: • IFRS 2 *Share based payments* — clarifies the definition of 'vesting condition' and now distinguishes between 'performance condition' and 'service condition' • IFRS 3 *Business combinations* — clarifies that an obligation to pay contingent consideration is classified as financial liability or equity under the principles in IAS 32 and that all non-equity contingent consideration (financial and non-financial) is measured at fair value at each reporting date.	Annual reporting periods commencing on or after July 1, 2014

21. Summary of significant accounting policies (continued)

Title	Key requirements	Effective Date
	• IFRS 8 *Operating segments* — requires disclosure of the judgments made by management in aggregating operating segments and clarifies that a reconciliation of segment assets must only be disclosed if segment assets are reported. • IFRS 13 *Fair value* — confirms that short-term receivables and payables can continue to be measured at invoice amounts if the impact of discounting is immaterial. • IFRS 13 *Fair value* — clarifies that the portfolio exception in IFRS 13 (measuring the fair value of a group of financial assets and financial liabilities on a net basis) applies to all contracts within the scope of IAS 39 *Financial instruments: recognition and measurement* or IFRS 9 *Financial instruments*.	

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, 2015 reporting period. The Group has not elected to apply any pronouncements before their operative date in the annual reporting period beginning July 1, 2014.

Initial application of the following Standard is not expected to affect any of the amounts recognized or disclosures made in the current financial report, but may have a material impact on future transactions made in relation to the Group. The Group is assessing the impact of the new standard on its revenue recognition policy. The Group intends to apply the new standard from July 1, 2018.

Title	Key requirements	Effective Date
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 Earlier application is permitted.

21. Summary of significant accounting policies (continued)

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, 2015 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

21. Summary of significant accounting policies (continued)

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 sol 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 revenue

Development and commercialization 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. Development and commercialization revenue was $15,004, $15,004 and $18,685 for the years ended June 30, 2015, 2014 and 2013, respectively.

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

21. Summary of significant accounting policies (continued)

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 the Group, 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, current portion. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, non-current portion.

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 allows 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 $130,000 as a non-refundable up-front payment.

Further payments up to $1,700,000 may be received on achievement of certain regulatory milestones with respect to each product Teva may choose to capitalize. The milestones are based on approvals in specific indications of product candidates in certain major jurisdictions. The Group would also be entitled to receive future royalty payments for supply of commercialized product as escalating double digit percentage of net sales of certain product candidates. No such payments have been received.

The Group analyzed the arrangement to determine whether the components which include a license, participation in a joint steering committee, a development program, and manufacturing and supply services, can be separated or must be treated as a single transaction in assessing revenue recognition criteria.

As the Group's obligations in relation to the steering committee and the development program are substantive and cannot be readily separated from the initial license transfer, the Group has not accounted for the license as a separate component. As the Group cannot readily estimate the costs required to complete the development program, due to significant uncertainties as development is the joint responsibility of the Group and Teva, revenue has been recognized on a straight line basis over the estimated development term of the main product, being MPC-150-IM. If the Group shortens or lengthens the development period then the amount of revenues recognized would change.

For the years ended June 30, 2015, 2014 and 2013, the Group recognized $15,004, $15,004 and $18,685 of revenue respectively being the amortization of the initial payment over the estimated development program term. The Group has a policy of reviewing the estimated development program term on a quarterly basis. The estimated development program term is refined with reference to the Joint Steering Committee's expectation of the timeline to complete development. The Group extended the estimated development program timeline in the year ended June 30, 2013 following the Joint Steering Committee's approval of the program protocol and associated development timelines. No revenue has been recognized for any future development milestones or royalties specified in the DCA as we cannot reliably estimate whether we would become entitled to such payments.

21. Summary of significant accounting policies (continued)

JCR arrangement

In October 2013, the Group acquired all of Osiris' business and assets. These assets included assumption of a collaboration agreement with JCR, a research and development oriented pharmaceutical company 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, 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, the Group is entitled to a double digit profit share. Revenue recognized under this model is limited to the amount of cash received or for which the Group is entitled, as JCR has the right to terminate the agreement at any time. Royalty revenue is recognized upon the sale of the related products provided the Group has no remaining performance obligations under the arrangement.

For the years ended June 30, 2015, 2014 and 2013, the Group recognized $2,000, $Nil and $Nil of commercialization revenue, respectively. This revenue was recognized on achievement of a substantive milestone being the filing for marketing approval in Japan for MSC product TEMCELL. 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 20,000. Eligible companies can receive a refundable tax offset of 45% of their research and development spending. Up to June 30, 2013 the rate of the refundable tax offset is 45%, after that date the rate is 43.5%.

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.

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 labour 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

21. Summary of significant accounting policies (continued)

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 15). 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.

21. Summary of significant accounting policies (continued)

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

21. Summary of significant accounting policies (continued)

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.

21. Summary of significant accounting policies (continued)

(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 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.

21. Summary of significant accounting policies (continued)

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.

(i) 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.

21. Summary of significant accounting policies (continued)

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 at 31 May 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.

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.

21. Summary of significant accounting policies (continued)

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 grant 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 behavioural 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 18.

The fair value determined at the grant 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.

21. Summary of significant accounting policies (continued)

u. Contributed equity

Ordinary shares are classified as equity.

Transaction costs arising on the issue of equity instruments are recognized directly in equity as a reduction of the proceeds of the equity instruments to which the costs relate. 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. Comparative figures

Comparatives have been reclassified where necessary so as to be consistent with the figures presented in the current year.

y. Rounding of amounts

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

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7,479,617 American Depositary Shares representing 37,398,085 ordinary shares

mesoblast
the regenerative medicine company

Mesoblast Limited

Prospectus

Joint Bookrunners

J.P. Morgan **Credit Suisse**

Co-managers

Ladenburg Thalmann **Maxim Group LLC**

November 12, 2015

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information that is different from that contained in this prospectus. We are offering to sell, and seeking offers to buy, ADSs only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our ADSs.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the ADSs or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable that jurisdiction.

Until December 7, 2015, (the 25th day after the date of this prospectus) all dealers that buy, sell or trade in our ADSs, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.