Table of Contents

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

Form 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934

For the month of February 2016

Commission File Number 001-37626

Mesoblast Limited
(Exact name of Registrant as specified in its charter)

Not Applicable
(Translation of Registrant's name into English)

Australia
(Jurisdiction of incorporation or organization)

Silviu Itescu
Chief Executive Officer and Executive Director
Level 38
55 Collins Street
Melbourne 3000
Australia
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes ☐ No ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes ☐ No ☐

TABLE OF CONTENTS

QUARTERLY REPORT ON FORM 6-K
(INCORPORATING THE HALF-YEAR REPORT)
FOR THE THREE AND SIX MONTHS ENDED DECEMBER 31, 2015

Foreword

The Board of Directors of Mesoblast Limited (ABN 68 109 431 870) has resolved to submit the following report of Mesoblast Limited and its subsidiaries for the three and six months ended December 31, 2015 in compliance with the provisions of the *Corporations Act 2001*.

Directors of Mesoblast Limited in office at any time during or since the end of the six months ended December 31, 2015 were:

Name	Position
Silviu Itescu	Executive Director
Brian Jamieson	Chairman
Donal O'Dwyer	Non-executive Director, Chair of Nomination and Remuneration Committee
Eric Rose	Non-executive Director, Chair of Science and Technology Committee
Michael Spooner	Non-executive Director, Chair of Audit and Risk Committee
William M Burns	Non-executive Director
Ben-Zion Weiner	Non-executive Director

Currency of Presentation and Certain Defined Terms

In this Quarterly Report on Form 6-K, references to "U.S." or "United States" are to the United States of America, its territories and its possessions. References to "US$" or "dollars" or "U.S. dollars" are to the legal currency of the United States and references to "A$" or "Australian Dollars" are to the legal currency of Australia. Our financial statements are presented in U.S. dollars and are prepared in accordance with the International Financial Reporting Standards as issued by the International Accounting Standards Board, or IFRS. References to a particular "fiscal" year are to our fiscal year ended June 30 of such year.

All references to "we", "us', "our", "Mesoblast", "Mesoblast Group" or the "company" shall mean Mesoblast Limited, and, unless specifically indicated otherwise or the context indicates otherwise, our consolidated subsidiaries. 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 Quarterly Report are the property of their respective owners.

Forward-Looking Statements

This Quarterly Report on Form 6K 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. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 6-K are forward-looking statements. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "could," and similar expressions or phrases identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. Forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical and clinical studies, and our research and development programs;
- our ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials;
- our ability to advance our manufacturing capabilities;
- the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any;
- the commercialization of our product candidates, if approved;
- regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies;
- the potential for our product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths;
- the potential benefits of strategic collaboration agreements and our ability to enter into and maintain established strategic collaborations;
- our ability to establish and maintain intellectual property on our product candidates and our ability to successfully defend these in cases of alleged infringement;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our financial performance;
- developments relating to our competitors and our industry;
- the pricing and reimbursement of our product candidates, if approved; and
- other risks and uncertainties, including those listed under the caption “Risk Factors” included elsewhere in this Quarterly Report on Form 6-K.

You should read thoroughly this Quarterly Report on Form 6-K 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 Quarterly Report on Form 6-K 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.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements made in this Quarterly Report on Form 6-K relate only to events or information as of the date on which the statements are made in this Quarterly Report on Form 6-K. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Consolidated Income Statement
(unaudited)

(in thousands, except per share amounts)	Note	Three Months Ended December 31, 2015	Three Months Ended December 31, 2014	Six Months Ended December 31, 2015	Six Months Ended December 31, 2014
Revenue	3	4,014	4,377	11,527	11,344
Research and development		(12,515)	(17,839)	(23,604)	(30,732)
Manufacturing commercialization		(8,118)	(5,551)	(14,321)	(11,450)
Management and administration		(5,716)	(7,546)	(11,251)	(14,486)
Fair value remeasurement of contingent consideration		541	(2,834)	4,271	(4,482)
Other operating income and expenses		1,495	4,173	2,343	10,978
Finance costs		(2,026)	(2,662)	(4,450)	(4,597)
Loss before income tax	3	**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**
Income tax expense	4	—	—	—	—
Loss attributable to the owners of Mesoblast Limited		**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**
Losses per share attributable to the ordinary equity holders of the Group:		**Cents**	**Cents**	**Cents**	**Cents**
Basic – losses per share		(6.29)	(8.78)	(10.31)	(13.68)
Diluted – losses per share		(6.29)	(8.78)	(10.31)	(13.68)

The above consolidated income statement should be read in conjunction with the accompanying Notes.

Consolidated Statement of Comprehensive Income
(unaudited)

(in thousands)	Note	Three Months Ended December 31, 2015	Three Months Ended December 31, 2014	Six Months Ended December 31, 2015	Six Months Ended December 31, 2014
Loss for the period		**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**
Other comprehensive income/(loss)					
Items that may be reclassified to profit and loss					
Changes in the fair value of available-for-sale financial assets		(185)	—	(185)	—
Exchange differences on translation of foreign operations		1,742	(8,310)	(1,851)	(19,624)
Income tax relating to these items		—	—	—	—
Other comprehensive income /(loss) for the period, net of tax		**1,557**	**(8,310)**	**(2,036)**	**(19,624)**
Total comprehensive loss attributable to the owners of Mesoblast Limited		**(20,768)**	**(36,192)**	**(37,521)**	**(63,049)**

The above consolidated statement of comprehensive income should be read in conjunction with the accompanying Notes.

Consolidated Statement of Changes in Equity
(unaudited)

(in thousands)	Note	*Issued Capital*	Share Option Reserve	Investment Revaluation Reserve	Foreign Currency Translation Reserve	Retained Earnings	Total
Balance as of June 30, 2014		**662,722**	**55,754**	**—**	**(12,201)**	**(167,716)**	**538,559**
Loss for the period		—	—	—	—	(43,425)	(43,425)
Other comprehensive income		—	—	—	(19,624)	—	(19,624)
Total comprehensive income/(loss) for the period		**—**	**—**	**—**	**(19,624)**	**(43,425)**	**(63,049)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		955	—	—	—	—	955
	8	**955**	**—**	**—**	**—**	**—**	**955**
Transfer exercised options		42	(42)	—	—	—	—
Fair value of share-based payments		—	3,250	—	—	—	3,250
Balance as of December 31, 2014		**663,719**	**58,962**	**—**	**(31,825)**	**(211,141)**	**479,715**
Balance as of June 30, 2015		**709,191**	**60,740**	**—**	**(37,984)**	**(263,960)**	**467,987**
Loss for the period		—	—	—	—	(35,485)	(35,485)
Other comprehensive income		—	—	(185)	(1,851)	—	(2,036)
Total comprehensive income/(loss) for the period		**—**	**—**	**(185)**	**(1,851)**	**(35,485)**	**(37,521)**
Transactions with owners in their capacity as owners:							
Contributions of equity net of transaction costs		59,507	—	—	—	—	59,507
	8	**59,507**	**—**	**—**	**—**	**—**	**59,907**
Transfer exercised options		134	(134)	—	—	—	—
Fair value of share-based payments		—	1,676	—	—	—	1,676
Reclassification of modified options to liability		—	1,105	—	—	—	1,105
Balance as of December 31, 2015		**768,832**	**63,387**	**(185)**	**(39,835)**	**(299,445)**	**492,754**

The above consolidated statement of changes in equity should be read in conjunction with the accompanying Notes.

Consolidated Balance Sheet
(unaudited)

(in thousands)	Note	As of December 31, 2015	As of June 30, 2015
Assets			
Current assets			
Cash and cash equivalents	5(a)	120,783	110,701
Trade and other receivables	5(b)	7,833	3,972
Prepayments	5(b)	3,903	7,787
Total current assets		**132,519**	**122,460**
Non-current assets			
Property, plant and equipment		3,742	4,398
Available-for-sale financial assets	5(d)	2,115	2,300
Other non-current assets		2,331	2,367
Intangible assets	6	650,246	650,241
Total non-current assets		**658,434**	**659,306**
Total assets		**790,953**	**781,766**
Liabilities			
Current liabilities			
Trade and other payables	5(c)	23,980	28,242
Deferred revenue		15,004	15,004
Provisions		2,695	5,161
Total current liabilities		**41,679**	**48,407**
Non-current liabilities			
Deferred revenue		15,003	22,505
Deferred tax liability		149,387	149,387
Provisions		92,130	93,480
Total non-current liabilities		**256,520**	**265,372**
Total liabilities		**298,199**	**313,779**
Net assets		**492,754**	**467,987**
Equity			
Issued capital	8	768,832	709,191
Reserves		23,367	22,756
Accumulated losses		(299,445)	(263,960)
Total equity		**492,754**	**467,987**

The above consolidated balance sheet should be read in conjunction with the accompanying Notes.

Consolidated Statement of Cash Flows
(unaudited)

(in thousands)	Note	Six months Ended December 31, 2015	2014
Cash flows from operating activities			
Milestone payment received		3,500	2,000
Research and development tax incentive received		—	1
Payments to suppliers and employees (inclusive of goods and services tax)		(51,881)	(54,849)
Interest received		508	2,163
Income taxes (paid)/refunded		—	(67)
Net cash (outflows) in operating activities	7(b)	**(47,873)**	**(50,752)**
Cash flows from investing activities			
Payments for financial derivatives		—	(851)
Payments for investments		(805)	—
Payments for licenses		(200)	(70)
Investment in fixed assets		(613)	(1,730)
Net cash (outflows) in investing activities		**(1,618)**	**(2,651)**
Cash flows from financing activities			
Proceeds from issue of shares		68,549	990
Payments for share issue costs	8	(6,618)	—
Net cash inflows by financing activities		**61,931**	**990**
Net (decrease)/increase in cash and cash equivalents		12,440	(52,413)
Cash and cash equivalents at beginning of period		110,701	185,003
FX (losses)/gains on the translation of foreign bank accounts		(2,358)	(10,220)
Cash and cash equivalents at end of period	7(a)	**120,783**	**122,370**

The above consolidated statement of cash flows should be read in conjunction with the accompanying Notes.

Notes to Consolidated Financial Statements
(unaudited)

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 specialized cells known as mesenchymal lineage adult stem cells. The Company was formed in 2004 as an Australian company and has been listed on the Australian Securities Exchange (the "ASX") since 2004. On November 18, 2015, the Company listed in the United States of America ("U.S.") on the NASDAQ Global Select Market ("NASDAQ") and from this date has been dual-listed in Australia and the U.S.

These financial statements 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 three and six month periods ended December 31, 2015.

2. Segment information

Operating segments are identified on the basis of whether the allocation of resources and/or the assessment of performance of a particular component of the Company's activities are regularly reviewed by the Company's chief operating decision maker as a separate operating segment. By these criteria, the activities of the Company are considered to be one segment being the development of adult stem cell technology platform for commercialization, and the segmental analysis is the same as the analysis for the Company as a whole. The chief operating decision maker (Chief Executive Officer) reviews the consolidated income statement, balance sheet, and statement of cash flows regularly to make decisions about the Company's resources and to assess overall performance.

3. Loss before income tax

(in thousands)	Note	Three Months Ended December 31, 2015	Three Months Ended December 31, 2014	Six Months Ended December 31, 2015	Six Months Ended December 31, 2014
Revenue					
Commercialization revenue[1]		3,751	3,751	7,502	7,502
Milestone revenue[2]		—	—	3,500	2,000
Interest revenue		263	626	525	1,842
		4,014	**4,377**	**11,527**	**11,344**
Clinical trial research and development		**(8,430)**	**(10,494)**	**(13,393)**	**(15,742)**
Manufacturing production and development		**(5,530)**	**(3,223)**	**(10,078)**	**(8,020)**
Employee benefits					
Salaries and employee benefits		(6,284)	(8,126)	(13,475)	(16,091)
Defined contribution superannuation expenses		(121)	(94)	(205)	(227)
Share-based payment transactions[3]		(675)	(2,231)	(1,676)	(3,250)
Total employee benefits		**(7,080)**	**(10,451)**	**(15,356)**	**(19,568)**
Depreciation and amortization of non-current assets					
Plant and equipment depreciation		(410)	(303)	(817)	(697)
Intellectual property amortization		(31)	(32)	(61)	(65)
Total depreciation and amortization of non-current assets		**(441)**	**(335)**	**(878)**	**(762)**
Other management and administration expenses					
Overheads and administration		(2,449)	(2,445)	(4,596)	(5,173)
Consultancy		(863)	(1,395)	(2,046)	(3,088)
Legal, patent and other professional fees		(1,051)	(1,840)	(1,819)	(3,080)
Intellectual property expenses (excluding the amount amortized above)		(505)	(753)	(1,010)	(1,235)
Total other management and administration expenses		**(4,868)**	**(6,433)**	**(9,471)**	**(12,576)**
Fair value remeasurement of contingent consideration					
Remeasurement of contingent consideration	5(d)(iii)	541	(2,834)	4,271	(4,482)
Total fair value remeasurement of contingent consideration		**541**	**(2,834)**	**4,271**	**(4,482)**
Other operating income and expenses					
Research & development tax incentive[4]		1,504	825	2,609	2,998
Foreign exchange gains/(losses)		(9)	3,348	(266)	7,980
Total other operating income and expenses		**1,495**	**4,173**	**2,343**	**10,978**
Finance costs					
Provisions: unwinding of discount	5(d)(iii)	(2,026)	(2,662)	(4,450)	(4,597)
Total finance costs		**(2,026)**	**(2,662)**	**(4,450)**	**(4,597)**
Total loss before income tax		**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**

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 three months ended December 31, 2015 and 2014, and the six months ended December 31, 2015 and 2014, the Group has recognized revenue of $3,751, $3,751, $7,502 and $7,502, respectively, for this payment on the basis that revenue will be earned over 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 period.

2) Milestone revenue

For the three months ended December 31, 2015 and 2014, the Group recognized $Nil milestone revenue.

For the six months ended December 31, 2015, the Group recognized milestone revenue of $3,500. This revenue was recognized on receipt of the full regulatory approval in Japan for the Group's licensee, JCR's, MSC product TEMCELL®, which was a substantive milestone. No further performance obligations are required of the Group in relation to this revenue.

For the six months ended December 31, 2014, the Group recognized milestone revenue of $2,000. This revenue was recognized on filing for marketing approval in Japan for the Group's licensee, JCR's, MSC product TEMCELL®, which was a substantive milestone. No further performance obligations are required of the Group in relation to this revenue.

3) Share-based payment transactions

For the three months ended December 31, 2015 and 2014, and the six months ended December 31, 2015 and 2014, share-based payment transactions have been reflected in the consolidated Income Statement functional expense categories as follows: research and development $584, $1,043, $1,237 and $1,529, respectively, manufacturing commercialization $180, $234, $326 and $361, respectively, and management and administration $(89), $954, $113 and $1,360, respectively.

4) Research and development tax incentive

The Group's research and development activities are eligible under an Australian Government tax incentive for eligible expenditures from July 1, 2011. Management has assessed these activities and expenditures to determine which are likely to be eligible under the incentive scheme. At each period end management estimates the refundable tax offset available to the Group based on available information at the time. The Group employs independent tax specialists to review, on an annual basis, the quantum of our previous research and development tax claim and our on-going eligibility to claim this tax incentive in Australia. For the three months ended December 31, 2015 and 2014, and the six months ended December 31, 2015 and 2014, the Group has recognized income of $1,504, $825, $2,609 and $2,998, respectively.

Of the $1,504 and $2,609 research and development tax incentive recorded in other income for the three and six months ended December 31, 2015, respectively, $1,019 relates to a change in the original estimate of the research and development tax incentive income the Group estimated it would receive from the Australian Government for the year ended June 30, 2015.

Of the $825 and $2,998 research and development tax incentive recorded in other income for the three and six months ended December 31, 2014, $87 and $483, respectively, relates to a change in the original estimate of the research and development tax incentive income the Group estimated it would receive from the Australian Government for the year ended June 30, 2014.

4. Income tax expense

(in thousands)	As of December 31, 2015	As of June 30, 2015
Deferred tax assets not brought to account		
Unused tax losses		
Potential tax benefit at local tax rates	77,382	69,929
Other temporary differences		
Potential tax benefit at local tax rates	15,032	16,507
Total potential tax benefit at local tax rates	**92,413**	**86,436**

Temporary differences have been brought to account only to the extent that it is foreseeable that they are recoverable against future tax liabilities. As of December 31, 2015 and June 30, 2015, 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 jurisdiction. The Company continues to assess the consolidation of intellectual property assets. Should there be a change in the Company's plans, there may be greater certainty surrounding the availability of temporary differences such that offsetting deferred tax assets in the same jurisdictions can be recorded.

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 December 31, 2015					
Cash and cash equivalents	5(a)	—	—	120,783	120,783
Trade and other receivables	5(b)	—	—	7,833	7,833
Available-for-sale financial assets		2,115	—	—	2,115
Other non-current assets		—	—	2,331	2,331
		2,115	**—**	**130,947**	**133,062**
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		2,300	—	—	2,300
Other non-current assets		—	—	2,367	2,367
		2,300	**—**	**117,040**	**119,340**

(1) Fair value through other comprehensive income
(2) Fair value through profit or loss

Financial liabilities (in thousands)	Notes	Liabilities at FVOCI(1)	Liabilities at FVTPL(2)	Liabilities at amortized cost	Total
As of December 31, 2015					
Trade and other payables	5(c)	—	—	23,980	23,980
Contingent consideration	5(d)	—	92,069	—	92,069
		—	**92,069**	**23,980**	**116,049**
As of June 30, 2015:					
Trade and other payables	5(c)	—	—	28,242	28,242
Contingent consideration	5(d)	—	91,890	—	91,890
		—	**91,890**	**28,242**	**120,132**

(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 this Note. 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 December 31, 2015	As of June 30, 2015
Cash at bank	8,432	21,126
Deposits at call(1)	112,351	89,575
	120,783	**110,701**

(1) As of December 31, 2015 and June 30, 2015, interest-bearing deposits at call include amounts of $4,523 and $4,755, respectively, held as security against future foreign exchange deals and are restricted for use.

(i) Classification as cash equivalents

Term deposits are presented as cash equivalents if they have a maturity of three months or less from the date of acquisition.

(ii) Market risk – interest rate risk

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 December 31, 2015 and June 30, 2015.

(in thousands, except percent data)	December 31, 2015			June 30, 2015		
	Low	High		Low	High	
Funds invested—USD	0.30%	0.70%	89,562	0.30%	0.30%	55,636
Funds invested—AUD	2.89%	2.96%	31,191	2.85%	2.92%	44,191

(iii) Market risk – currency risk

The Group has foreign currency amounts owing primarily in USD in Mesoblast Limited (AUD functional currency) relating to clinical, regulatory and overhead activities. The Group also has foreign currency amounts owing in various other non-USD currencies in USD functional currency entities in the Group relating to clinical, regulatory and overhead activities. These foreign currency balances give rise to a currency risk, which is the risk of the exchange rate moving, in either direction, and the impact it may have on the Group's financial performance.

Currency risk is minimized by ensuring the proportion of cash reserves held in each currency matches the expected rate of spend of each currency.

(iv) Liquidity risk

Liquidity risk is the risk that the Group will not be able to pay its debts as and when they become due.

For the six months ended December 31, 2015 and 2014, the Group has incurred a total comprehensive loss after income tax of $37,521 and $63,049, respectively, and net cash outflows from operations of $47,873 and $50,752, respectively. As at December 31, 2015, the Group held total cash and cash equivalents of $120,783. 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 by issuing securities in the Company and entering into licensing and partnership agreements, it is expected that similar funding will be obtained to provide working capital as and when required. If the Group is unable to raise capital in the future, the Group may need to curtail expenditure by scaling back certain research and development programs.

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 December 31, 2015 and as of June 30, 2015 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.

b. Trade and other receivables and prepayments

(in thousands)	As of December 31, 2015	As of June 30, 2015
Income tax and tax incentives recoverable	6,175	3,696
Sundry debtors	173	136
Interest receivables	93	84
Other recoverable taxes (goods and services tax and value-added tax)	47	56
Other receivables	1,345	—
Trade and other receivables	**7,833**	**3,972**
Clinical trial research and development expenditure	2,213	3,475
Prepaid insurance and subscriptions	1,199	635
Other prepayments	491	3,677
Prepayments	**3,903**	**7,787**

(i) Classification as trade and other receivables

Interest receivables are amounts due at maturity of term deposits. All trade and other receivable balances are within their due dates and none are considered to be impaired as of December 31, 2015 and June 30, 2015.

(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.

c. Trade and other payables

(in thousands)	As of December 31, 2015	As of June 30, 2015
Trade payables and other payables	23,980	28,242
	23,980	**28,242**

The carrying amounts of trade and other payables are assumed to be the same as their fair values, due to their short-term nature.

d. 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 December 31, 2015 and June 30, 2015 on a recurring basis, categorized by level according to the significance of the inputs used in making the measurements:

As of December 31, 2015 (in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial assets					
Available-for-sale financial assets					
Equity securities – biotechnology sector		—	—	2,115	2,115
Total financial assets		**—**	**—**	**2,115**	**2,115**
Financial liabilities					
Financial liabilities at fair value through profit or loss					
Contingent consideration	5(d)(iii)	—	—	92,069	92,069
Total financial liabilities		**—**	**—**	**92,069**	**92,069**

As of June 30, 2015 (in thousands)	Notes	Level 1	Level 2	Level 3	Total
Financial assets					
Available-for-sale financial assets					
Equity securities – biotechnology sector		—	—	2,300	2,300
Total financial assets		**—**	**—**	**2,300**	**2,300**
Financial liabilities					
Financial liabilities at fair value through profit or loss					
Contingent consideration	5(d)(iii)	—	—	91,890	91,890
Total financial liabilities		**—**	**—**	**91,890**	**91,890**

There were no transfers between any of the levels for recurring fair value measurements during the period.

The Group's policy is to recognize transfers into and transfers out of fair value hierarchy levels as at the end of the reporting period.

Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, and trading and available-for-sale securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by the Group is the current bid price. These instruments are included in level 1.

Level 2: The fair value of financial instruments that are not traded in an active market (for example, foreign exchange contracts) is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3. This is the case for provisions (contingent consideration) and equity securities (unlisted).

(ii) Valuation techniques used.

The Group used the following techniques to determine the fair value measurements:

- 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 six months ended December 31, 2015 and the year ended June 30, 2015:

(in thousands)	Notes	Contingent consideration provision
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**
Opening balance – July 1, 2015		91,890
Charged/(credited) to consolidated income statement		
Unwinding of discount[1]		4,450
Remeasurement		(4,271)
Closing balance – December 31, 2015		**92,069**

(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 Therapeutics, Inc. (“Osiris”).
(3) The total amount of remeasurement of contingent consideration pertaining to the acquired MSC assets of Osiris was $8,916 in the year ended June 30, 2015.

(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:

(in thousands, except percent data)

Description	Fair value as of		Valuation technique	Unobservable Inputs*	Range of inputs (weighted average) for		Relationship of unobservable inputs to fair value
	December 31, 2015	June 30, 2015			Six months Ended December 31, 2015	Year ended June 30, 2015	
Contingent consideration provision	92,069	91,890	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11% - 13% (12.5%)	Six months ended December 31, 2015: A change in the discount rate by 0.5% would increase/decrease the fair value by 3% Year ended June 30, 2015: A change in the discount rate by 0.5% would increase/decrease the fair value by 3%
				Expected unit revenues	n/a	n/a	Six months ended December 31, 2015: A 10% increase in the price assumptions adopted would increase the fair value by 8% Year ended June 30, 2015: A 10% increase in the price assumptions adopted would increase the fair value by 8%

* *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 six months ended December 31, 2015 and 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.

The fair value of contingent consideration

(in thousands)	As of December 31, 2015	As of June 30, 2015
Fair value of cash or stock payable, dependent on achievement of future late-stage clinical or regulatory targets	24,171	23,883
Fair value of royalty payments from commercialization of the intellectual property acquired	67,898	68,007
	92,069	**91,890**

The main level 3 inputs used by the Group are evaluated as follows:

Risk adjusted discount rate:	The discount rate used in the valuation has been determined based on required rates of returns of listed companies in the biotechnology industry (having regards to their stage of development, their size and number of projects) and the indicative rates of return required by suppliers of venture capital for investments with similar technical and commercial risks. This assumption is reviewed as part of the valuation process outlined above.
Expected unit revenues:	Expected market sale price of the most comparable products currently available in the market place. This assumption is reviewed as part of the valuation process outlined above.

6. Intangible assets

(in thousands)	Goodwill	Acquired licenses to patents	In-process research and development acquired	Total
Year ended June 30, 2015				
Opening net book value	132,367	1,941	513,697	648,005
Additions(1)	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
Six months ended December 31, 2015				
Opening net book value	134,453	2,091	513,697	650,241
Additions	—	75	—	75
Exchange differences	—	(9)	—	(9)
Amortization charge	—	(61)	—	(61)
Impairment charge	—	—	—	—
Closing net book value	134,453	2,096	513,697	650,246
As of December 31, 2015				
Cost	134,453	2,762	513,697	650,912
Accumulated amortization	—	(666)	—	(666)
Accumulated impairment	—	—	—	—
Net book amount	134,453	2,096	513,697	650,246

(1) An immaterial out of period adjustment to goodwill was recognized on finalization of the MSC business combination of Osiris.

7. Cash flow information

(in thousands)	Six months Ended December 31, 2015	Six months Ended December 31, 2014
(a) Reconciliation of cash and cash equivalents		
Cash at bank	8,432	9,378
Deposit at call	112,351	112,992
	120,783	**122,370**
(b) Reconciliation of net cash flows used in operations with loss after income tax		
Loss for the period	(35,485)	(43,425)
Add/(deduct) net loss for non-cash items as follows:		
Commercialization revenue	(7,502)	(7,502)
Depreciation and amortization	878	761
Foreign exchange (gains)/losses	206	(8,265)
Finance costs	4,449	4,569
Remeasurement of contingent consideration	(4,271)	4,482
Equity settled share-based payment	1,676	3,250
Change in operating assets and liabilities:		
(Increase)/Decrease in trade and other receivables	(97)	68
Decrease/(Increase) in prepayments	385	(2,913)
(Increase)/Decrease in tax assets	(2,609)	(2,998)
(Decrease)/increase in trade creditors and accruals	(2,688)	3,451
(Decrease)/increase in provisions	(2,815)	(2,230)
Net cash outflows used in operations	**(47,873)**(1)	**(50,752)**(2)

(1) Within operating cash flows are share issue costs of $315 associated with the November 2015 NASDAQ IPO equity raising incurred during the three months ended September 30, 2015.

(2) Within operating cash flows are share issue costs of $285 associated with the November 2015 NASDAQ IPO equity raising incurred during the six months ended December 31, 2014.

8. Issued capital

	As of December 31, 2015 Shares No.	2014 Shares No.	As of December 31, 2015 (in thousands)	2014 (in thousands)
Opening balance	336,997,729	321,640,094	709,191	662,722
Issues of ordinary shares during the period				
Exercise of share options(1)	422,903	710,935	268	955
Placement of shares under LFSP(2)	—	1,850,000	—	—
Share issue for NASDAQ IPO	42,675,295	—	68,280	—
Transaction costs arising on share issue(3)			(9,041)	—
	43,098,198	**2,560,935**	**59,507**	**955**
Share options reserve transferred to equity on exercise of options			134	42
Ending balance	**380,095,927**	**324,201,029**	**768,832**	**663,719**

(1) Options are issued to employees, directors and consultants in accordance with the Mesoblast Employee Share Options Plan (“ESOP”). The shares issued and share capital received on the exercise of options are recorded above.

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

(3) Payments for share issue costs in the three months ended December 31, 2015 were $6,618. In addition to these share issue costs paid, the transaction costs arising on share issue of $9,041 include amounts of $2,748 paid in prior periods offset by $325 of non-cash items recognised as transaction costs on the balance sheet in association with the November 2015 NASDAQ IPO equity raising.

9. Events occurring after the reporting period

There are no events that have occurred after December 31, 2015 and prior to the signing of this financial report that would likely have a material impact on the financial results presented.

10. Basis of preparation

Mesoblast Limited is a for-profit entity for the purpose of preparing the financial statements. The general purpose interim financial statements of Mesoblast Limited and its subsidiaries have been prepared in accordance with Australian Accounting Standard 134 *Interim Financial Reporting*, as issued by the Australian Accounting Standards Board ("AASB"), and the *Corporations Act 2001,* which ensures compliance with International Accounting Standard IAS 34 *Interim Financial Reporting*, as issued by the International Accounting Standards Board ("IASB"), and are unaudited. In the opinion of management, the interim financial data includes all adjustments, consisting only of normal recurring adjustments, necessary to a fair statement of the results for the interim periods. These interim financial statements follow the same accounting policies as compared to the June 30, 2015 consolidated financial statements and related notes as filed with the Australian Securities Exchange and the Securities and Exchange Commission.

Preparation of interim financial statements for users in multiple jurisdictions

The Company has prepared the interim financial statements to conform to the requirements and needs of users of the financial statements located in both Australia and the U.S..

U.S. users: The Company has prepared the interim financial statements to conform to the requirements of IAS 34 *Interim Financial Reporting*. Consistent with U.S. domestic registrants, the Company has labelled the interim financial information "unaudited" because the interim financial information is not subject to an audit by our independent registered public accounting firm. The auditor's independence declaration and independent auditor's review report are included within this filing to meet the requirements of Australian laws and regulations and are furnished, not filed, for the purposes of incorporation of the related financial statements in any U.S. registration document.

Australian users: The Company has prepared the interim financial statements to conform to the requirements of the *Corporations Act 2001* and AASB 134 *Interim Financial Financial Reporting*. A review of the interim financial information has been performed by the Company's independent auditors to meet the requirements of Australian Auditing Standard on Review Engagements ASRE2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity* and users should refer to the auditor's independence declaration and independent auditor's review report included within this filing.

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 period ended December 31 2014. The reporting currency was changed to align with the expectations of the users of the financial statements.

Changes to comparative figures

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

Recent developments in the business, including listing on the NASDAQ and changing our presentation currency from AUD to USD, triggered a wider review on the presentation of our financial results which was recently completed. The Company therefore performed a benchmarking study against other seasoned filers to understand best practice in presenting financial information to the users of the financial statements.

The impact of this analysis was to collapse Other Income with Other Expenses into one line item 'Other operating income and expenses' and present all fair value remeasurements of contingent consideration within one line item 'Fair value remeasurement of contingent consideration' within the Consolidated Income Statement.

The changes to comparative figures provide users of the financial statements financial information that is more reliable and more relevant than the previous classification adopted by the Company. The impact of the reclassification of the prior period financial statements is summarized below:

	Six Months Ended December 31, 2014		
(in thousands)	Previously reported	Reclassified	Effect of change
Other income	10,978	—	(10,978)
Fair value remeasurement of contingent consideration	—	(4,482)	(4,482)
Other operating income and expenses	—	10,978	10,978
Other expenses	(4,482)	—	4,482

As it relates to the consolidated financial statements that were filed with the Australian Securities Exchange and the Securities and Exchange Commission for each of the three years ended June 30, 2015, the changes to the comparative figures are:

- Other income was previously reported as 2015: $15,399, 2014: $10,119 and 2013: $5,495 and is now revised to 2015: $Nil, 2014: $Nil and 2013: $Nil.
- Fair value remeasurement was previously reported as 2015: $Nil, 2014: $Nil and 2013: $Nil and is now revised to 2015: $(6,830), 2014: $(249) and 2013: $Nil.
- Other operating income and expenses was previously reported as 2015: $Nil, 2014: $Nil and 2013: $Nil and is now revised to 2015: $15,303, 2014: $6,173 and 2013: $4,543.
- Other expenses was previously reported as 2015: $(6,830), 2014: $(4,195) and 2013: $(952) and is now revised to 2015: $Nil, 2014: $Nil and 2013: $Nil.

Directors' Declaration

In accordance with a resolution of directors of Mesoblast Group,

In the opinion of the directors:

a) the financial statements and notes set out on pages 5 to 24 are in accordance with the *Corporations Act 2001,* including:

   i) complying with Accounting Standards, the *Corporations Regulations 2001* and other mandatory professional reporting requirements, and

   ii) giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and of its performance for the three and six months ended on that date, and

b) there are reasonable grounds to believe that Mesoblast Group will be able to pay its debts as and when they become due and payable.

This declaration is made in accordance with a resolution of the directors.

Mr Brian Jamieson
Director

Dr Silviu Itescu
Chief Executive Officer

February 16, 2016
Melbourne

Independent auditor's review report to the members of Mesoblast Limited

Report on the Half-Year Financial Report

We have reviewed the accompanying half-year financial report of Mesoblast Limited (the company), which comprises the consolidated balance sheet as at 31 December 2015, the consolidated income statement and consolidated statement of comprehensive income for the three and six months ended on that date, consolidated statement of changes in equity and consolidated statement of cash flows for the six months ended on that date, selected explanatory notes and the directors' declaration for Mesoblast Limited Group (the consolidated entity). The consolidated entity comprises the company and the entities it controlled during the six months ended 31 December 2015.

Directors' responsibility for the half-year financial report

The directors of the company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards (including the Australian Accounting Interpretations) and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that is free from material misstatement whether due to fraud or error.

Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Australian Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and its performance for the three and six months ended on that date; and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*. As the auditor of Mesoblast Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Independence

In conducting our review, we have complied with the independence requirements of the *Corporations Act 2001.*

Conclusion

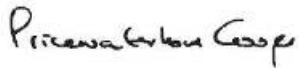
Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Mesoblast Limited is not in accordance with the *Corporations Act 2001* including:

PricewaterhouseCoopers, ABN 52 780 433 757
Freshwater Place, 2 Southbank Boulevard, SOUTHBANK VIC 3006, GPO Box 1331, MELBOURNE VIC 3001
T: 61 3 8603 1000, F: 61 3 8603 1999, www.pwc.com.au

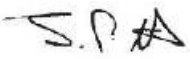
Liability limited by a scheme approved under Professional Standards Legislation.

a) giving a true and fair view of the consolidated entity's financial position as at 31 December 2015 and of its performance for the three and six months ended on that date;

b) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001.*



PricewaterhouseCoopers



Jon Roberts
Partner

Melbourne
16 February 2016

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 our consolidated financial statements included in this Quarterly Report on Form 6-K. 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 in our Rule 424(b)(4) prospectus (the "Prospectus"), filed with the Securities and Exchange Commission on November 13, 2015, for more information.

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.

Overview

We are a world leader in innovative cellular medicine. We have leveraged our proprietary technology platform, which is based on specialized cells known as mesenchymal lineage adult stem cells (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. 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. Recruitment of our three Tier 1 Phase 3 clinical trials is progressing well in the United States, including MPC-150-IM for chronic heart failure (CHF), MPC-06-ID for chronic low back pain, and MSC-100-IV for acute graft versus host disease (aGVHD) in children.

On September 18, 2015, our licensee, JCR Pharmaceuticals Co. Ltd. (JCR), received full approval for the first "allogeneic" cell-based product in Japan, meaning a product containing cells from a single donor was expanded and used in many unrelated patients. Furthermore on November 26, 2015, JCR received notification that the Japanese Government's National Health Insurance (NHI) body has formally set a price for the mesenchymal stem cell product TEMCELL® HS Inj. at ¥868,680 (US$7,200) for 72 million cells. A four-week, multi-dose treatment course of TEMCELL® HS Inj. for an average adult is expected to be reimbursed at ¥13,898,880 (US$115,000), or at ¥20,848,320 (US$172,000) if symptoms persist and additional dosing is required. We are entitled to receive royalties and other payments at pre-defined thresholds of net sales. JCR are expected to launch TEMCELL® HS Inj. in Japan for adult and pediatric aGVHD in the first quarter of the 2016 calendar year.

On January 11, 2016, we announced that the size of the ongoing Phase 3 trial in chronic heart failure (CHF) for our proprietary cell-based medicine MPC-150-IM is planned to be substantially reduced. This announcement followed communications between Mesoblast's development and commercial partner, Teva Pharmaceutical Industries Ltd., and the United States Food and Drug Administration (FDA).

The ongoing Phase 3 program is planned to be optimized as follows:

- the FDA has agreed to a reduction in the current Phase 3 trial size from 1,165 to approximately 600 patients due to a proposed change in the primary endpoint;
- the revised primary endpoint will be a comparison of recurrent heart failure-related major adverse cardiovascular events (HF-MACE) between patients treated with MPC-150-IM and controls;
- the proposed use of recurrent HF-MACE as a primary endpoint in the Phase 3 trial is based on the fact that a single injection of MPC-150-IM successfully prevented recurrent HF-MACE over three years in the Phase 2 trial; and
- a second confirmatory study will be conducted in parallel in an identical patient population of approximately 600 subjects using the same primary endpoint.

On February 16, 2016, we announced results from the first cohort of our ongoing Phase 2 trial in rheumatoid arthritis (RA) patients who have previously failed one or more biologic agents. Top line results showed that a single intravenous infusion of the lower dose of our proprietary Mesenchymal Precursor Cell (MPC) product candidate, MPC-300-IV, was safe and resulted in early and sustained clinical responses. The lower MPC dose (1 million MPCs/kg) was evaluated in the first cohort of 24 patients, of whom 16 had failed 1-2 biologics. The second cohort of 24 patients, evaluating the higher dose of MPCs (2 million MPCs/kg), is actively recruiting. Trial results for both cohorts are expected to be reported in the third quarter of the 2016 calendar year. The trial's primary endpoint is safety, with pre-specified efficacy endpoints at 12 weeks including the American College of Rheumatology (ACR) 20%, 50% and 70% response criteria (ACR20/50/70). Key top line results for cohort 1 were:

- cell infusions were well tolerated with no cell-related adverse events;
- the trial's 12 week, pre-specified ACR20 efficacy endpoint was achieved by 47% of all MPC-treated patients and by 60% of MPC-treated patients who failed 1-2 biologics, vs 25% and 17%, respectively, of matched placebo-treated controls;
- 71% of MPC-treated patients who achieved ACR20 responses did so as early as week 1;
- at week 12, 27% of MPC-treated patients, but no placebo-treated controls, achieved ACR50 or ACR70 responses;
- remission at week 12, as defined by Disease Activity Score (DAS28/CRP) < 2.6, was seen in 20% of MPC-treated patients but in no controls.

On July 15, 2015, we announced that Phase 2 trial results of our cell therapy product candidate for the treatment of CHF have been published in the latest edition of *Circulation Research*, the peer-reviewed journal of the American Heart Association. On July 23, 2015, we announced that results of the Phase 2 trial of our cell therapy product candidate for the treatment of type 2 diabetes have been published in *Diabetes Care*, the peer-reviewed journal of the American Diabetes Association.

We have incurred net losses during most of our fiscal periods since our inception. For the three months ended December 31, 2015, we had a loss after tax of $22.3 million.

Mergers and Acquisitions

We had no mergers and acquisitions during the three months ended December 31, 2015.

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

We expect that our research and development as well as management and administration expenses will decrease in the short term. Subject to us achieving successful regulatory approval, we expect an increase in our total expenses driven by an increase in our selling, general and administrative expenses as we move towards commercialization. Therefore we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for our product candidates.

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

In the three months ended December 31, 2015 and 2014 we recognized milestone revenue of $Nil.

In the six months ended December 31, 2015, we recognized $3.5 million in milestone revenue from JCR for the receipt of full regulatory approval of TEMCELL® in Japan, which is a substantive milestone under our agreement with JCR. In the six months ended December 31, 2014, we recognized $2.0 million in milestone revenue from JCR for the completion of another substantive milestone pertaining to the filing of TEMCELL® for regulatory approval in Japan. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

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

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.

Research and Development. Research and development expenditure is recognized as an expense as incurred. Our research and development expenses consist primarily of:

- third party costs comprising all external expenditure on our research and development programs such as fees paid to Contract Research Organizations, ("CROs"), and consultants who perform research on our behalf and under our direction, rent and utility costs for our research and development facilities, and database analysis fees;
- product support costs consisting primarily of salaries and related overhead expenses for personnel in research and development functions (for example wages, salaries and associated on costs such as superannuation, share-based incentives and payroll taxes, plus travel costs and recruitment fees for new hires); and
- intellectual property support costs comprising payments to our patent attorneys to progress patent applications and all costs of renewing of our granted patents.

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

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

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

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

Fair Value Remeasurement of Contingent Consideration. Remeasurement of contingent consideration pertains to the acquisition of assets from Osiris Therapeutics, Inc. ("Osiris"). The fair value remeasurement of contingent consideration is recognized as a result of changes to the key assumptions of the contingent consideration valuation such as market population, market penetration, product pricing and developmental timelines. As the net result of changes to the key assumptions in the valuation of contingent consideration payable to Osiris on royalties from sales and on the achievement of certain pre-determined milestones, we recognized $0.5 million gains and $2.8 million losses for the three months ended December 31, 2015 and 2014, respectively. We recognized $4.3 million gains and $4.5 million losses for the six months ended December 31, 2015 and 2014, respectively.

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

Tax incentives comprise payments from the Australian government's Innovation Australia Research and Development Tax Incentive 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. The rate of the refundable tax offset is 45%. We recognized income of $1.5 million and $0.8 million, respectively, from research and development tax incentives in the three months ended December 31, 2015 and 2014. We recognized income of $2.6 million and $3.0 million, respectively, from research and development tax incentives in the six months ended December 31, 2015 and 2014.

Foreign exchange gains and losses relate to unrealized foreign exchange gains and losses on our U.S. dollar deposits plus realized gains and losses on any foreign currency payments to our suppliers due to movements in exchange rates. We recognized $Nil foreign exchange losses in the three months ended December 31, 2015 and a foreign exchange gain of $3.3 million in the three months ended December 31, 2014.

We recognized $0.3 million foreign exchange losses in the six months ended December 31, 2015 and a foreign exchange gain of $8.0 million in the six months ended December 31, 2014.

Finance Costs. Finance costs relate to the unwinding of contingent consideration items pertaining to the Mesenchymal Stem Cells ("MSC") assets of Osiris. We did not have any borrowings outstanding as of December 31, 2015 and 2014.

Results of Operations:

Comparison of Our Results for the Three Months Ended December 31, 2015 with the Three Months Ended December 31, 2014

The following table summarizes our results of operations for the three months ended December 31, 2015 and 2014, together with the changes in those items in dollars and as a percentage.

(in thousands except per share information)	Three months ended December 31, 2015	2014	$ Change	% Change
Consolidated Income Statement data:				
Revenue:				
Commercialization revenue	$ 3,751	$ 3,751	—	0%
Interest revenue	263	626	(363)	(58%)
Total revenue	4,014	4,377	(363)	(8%)
Research and development	(12,515)	(17,839)	5,324	(30%)
Manufacturing commercialization	(8,118)	(5,551)	(2,567)	46%
Management and administration	(5,716)	(7,546)	1,830	(24%)
Fair value remeasurement of contingent consideration	541	(2,834)	3,375	(119%)
Other operating income and expenses	1,495	4,173	(2,678)	(64%)
Finance costs	(2,026)	(2,662)	636	(24%)
Loss before income tax	(22,325)	(27,882)	5,557	(20%)
Income tax expense	—	—	—	—
Loss attributable to the owners of Mesoblast Limited	$(22,325)	$(27,882)	5,557	(20%)

Losses per share attributable to our ordinary equity holders:	Cents	Cents	Cents change	% Change
Basic - losses per share	(6.29)	(8.78)	2.49	(28%)
Diluted - losses per share	(6.29)	(8.78)	2.49	(28%)

Revenue

Revenues were $4.0 million for the three months ended December 31, 2015, compared with $4.4 million for the three months ended December 31, 2014, a decrease of $0.4 million. The following table shows the movement within revenues for the three months ended December 31, 2015 and 2014, together with the changes in those items.

(in thousands)	Three months ended December 31, 2015	2014	$ Change	% Change
Revenue:				
Commercialization revenue	$ 3,751	$ 3,751	—	0%
Interest revenue	263	626	(363)	(58%)
Revenue	$ 4,014	$ 4,377	(363)	(8%)

There was no change in commercialization revenue in the three months ended December 31, 2015 when compared with the three months ended December 31, 2014.

The $0.4 million decrease in interest revenue in the three months ended December 31, 2015 compared with the three months ended December 31, 2014 was primarily driven by us retaining a higher proportion of cash reserves in US$ instead of with A$ in the three months ended December 31, 2015, when compared with the three months ended December 31, 2014. This change in cash reserve holdings decreased revenue as yields on US$ cash deposits are lower than yields on A$ cash deposits. We increased the proportion of cash reserves held in US$ to reduce currency risk. Currency risk is minimized by ensuring the proportion of cash reserves held in each currency matches the expected rate of spend of each currency.

Research and development

Research and development expenses were $12.5 million in the three months ended December 31, 2015, a decrease of $5.3 million as compared with $17.8 million in the three months ended December 31, 2014. The $5.3 million net decrease in research and development expenses primarily reflects a reduction in expenditures of our Tier 2 products and product support costs as management reduced costs in line with our corporate strategy.

(in thousands)	Three months ended December 31, 2015	2014	$ Change	% Change
Research and development:				
Third party costs	$ 6,852	$ 9,106	(2,254)	(25%)
Product support costs	5,115	7,948	(2,833)	(36%)
Intellectual property support costs	548	785	(237)	(30%)
Research and development	$12,515	$17,839	(5,324)	(30%)

Third party costs, which consist of all external expenditure on our research and development programs, decreased by $2.3 million in the three months ended December 31, 2015 compared with the three months ended December 31, 2014. The $6.9 million in third party costs for the three month period ended December 31, 2015 primarily consisted of $5.2 million in third party costs on our MPC-06-ID, MSC-100-IV, and MPC-150-IM Tier 1 products as well our MPC-300-IV product that was promoted from Tier 2 to Tier 1 on June 30, 2015. The $2.3 million decrease in third party costs primarily consisted of a $2.1 million decrease in third party costs for our Tier 2 and pipeline products for the three months ended December 31, 2015 compared with the three months ended December 31, 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 decreased by $2.8 million for the three months ended December 31, 2015 compared with the three months ended December 31, 2014. A cost saving of $1.2 million was realized in salaries and $0.8 million was realized in share based payments primarily due to vacated positions remaining unfilled. In the three months ended December 31, 2015, full time equivalents decreased by 8.8 from 85.4 for the three months ended December 31, 2014 to 76.6 for the three months ended December 31, 2015. Additionally, consultancy expenses and travel expenses were reduced by $0.6 million and $0.2 million, respectively, for the three months ended December 31, 2015 compared to the three months ended December 31, 2014 due to management’s cost reduction efforts.

Also included in research and development expenses are intellectual property support costs, which consist of payments to our patent attorneys to progress patent applications and all costs of renewing our granted patents. These costs have fallen by $0.2 million in the three months ended December 31, 2015 compared with the three months ended December 31, 2014 due to efficiencies in cost management.

Manufacturing commercialization

Manufacturing commercialization expenses, which consist of fees paid to our contract manufacturing organizations and laboratory supplies used in the manufacturing commercialization of our MPC and MSC based products, increased by $2.6 million in the three months ended December 31, 2015 compared to the three months ended December 31, 2014 primarily due to an increase in the number of production runs completed in the three months ended December 31, 2015 compared to the three months ended December 31, 2014 to meet the clinical supply demands of our Tier 1 products.

	Three months ended December 31,			
(in thousands)	2015	2014	$ Change	% Change
Manufacturing commercialization:				
MSC-based manufacturing commercialization	$ 5,024	$ 2,351	2,673	114%
MPC-based manufacturing commercialization	2,099	2,259	(160)	(7%)
Manufacturing commercialization support expenses	995	941	54	6%
Manufacturing commercialization	$ 8,118	$ 5,551	2,567	46%

The MSC-based manufacturing commercialization expenses increased by $2.7 million in the three months ended December 31, 2015 compared to the three months ended December 31, 2014 as 100% of the production runs in the three months ended December 31, 2015 were for MSC-based clinical supply whereas only 67% of production runs in the three months ended December 31, 2014 were for MSC-based clinical supply. The expenditure incurred for MSC-based manufacturing commercialization in the three months ended December 31, 2014 was for process development activities.

The MPC-based manufacturing commercialization expenses decreased by $0.2 million in the three months ended December 31, 2015 compared to the three months ended December 31, 2014 as no MPC-based production was undertaken in the three months ended December 31, 2015 whereas 33% of the production was for MPC-based clinical supply in the three months ended December 31, 2014. The balance of expenditure incurred in both the three month periods ended December 31, 2015 and 2014 was for process development activities.

Manufacturing commercialization support expenses, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, increased by $0.1 million for the three months ended December 31, 2015 compared with the three months ended December 31, 2014 as full time equivalents increased by 0.6 from 11.0 for the three months ended December 31, 2014 to 11.6 for the three months ended December 31, 2015.

Management and administration

Management and administration expenses were $5.7 million for the three months ended December 31, 2015, compared with $7.5 million for the three months ended December 31, 2014, a decrease of $1.8 million. This decrease was primarily due to lower share based payment expenses because of lower valuations and favorable exchange rate fluctuations as the US$ strengthened against the A$ given that the majority of management and administration expenses are incurred in A$ by our headquarter office located in Australia.

(in thousands)	Three months ended December 31, 2015	2014	$ Change	% Change
Management and administration:				
Labor and associated expenses	$ 2,307	$ 3,620	(1,313)	(36%)
Corporate overheads	2,578	2,236	342	15%
Legal and professional fees	831	1,690	(859)	(51%)
Management and administration	$ 5,716	$ 7,546	(1,830)	(24%)

Labor and associated expenses decreased by $1.3 million from $3.6 million for the three months ended December 31, 2014 to $2.3 million for the three months ended December 31, 2015. Within the $1.3 million decrease share based payment expenses was reduced by $0.7 million due to a reduction in the valuation of equity settled share based payments resulting from changes in the key assumptions such as share price and risk free rate and consultancy expenses were reduced by $0.1 million. The remaining decrease of $0.5 million related to salaries as we benefited from the impact of exchange rate fluctuations and full time equivalents reduced by 0.6 from 27.8 for the three months ended December 31, 2014 to 27.2 for the three months ended December 31, 2015.

Corporate overhead expenses increased by $0.3 million from $2.2 million for the three months ended December 31, 2014 to $2.6 million due to depreciation charges and a one off cost related to office space.

Legal and professional fees decreased by $0.9 million from $1.7 million for the three months ended December 31, 2014 to $0.8 million for the three months ended December 31, 2015 due to reductions on intellectual property management and associated legal, taxation and accounting compliance advice. We also benefited from exchange rate fluctuations as indicated above.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration was a $0.5 million gain for the three months ended December 31, 2015 compared with $2.8 million loss for the three months ended December 31, 2014, an increase of $3.3 million. The $0.5 million gain recognized in the three months ended December 31, 2015 is due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This gain is as a result of changes to a key assumption of the contingent consideration valuation relating to product pricing. The net result of changes to the key assumption was a decrease in the valuation of contingent consideration payable to Osiris on royalties from sales and on the achievement of certain pre-determined milestones.

The $2.8 million loss for the three months ended December 31, 2014 was due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This remeasurement loss is also as a result of changes to the key assumptions of the contingent consideration valuation such as product pricing, market population, 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.

Other operating income and expenses

Other operating income and expenses were $1.5 million for the three months ended December 31, 2015, compared with $4.2 million for the three months ended December 31, 2014, a decrease of $2.7 million. The following table shows movements within other operating income and expenses for the three months ended December 31, 2015 and 2014, together with the changes in those items:

(in thousands)	Three months ended December 31, 2015	2014	$ Change	% Change
Other operating income and expenses:				
Research & development tax incentive income	$1,504	$ 825	679	82%
Foreign exchange (losses)/gains—net	(9)	3,348	(3,357)	(100%)
Other operating income and expenses	$1,495	$ 4,173	(2,678)	(64%)

Research and development tax incentive income increased by $0.7 million from $0.8 million for the three months ended December 31, 2014 to $1.5 million for the three months ended December 31, 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 incentive available to us based on available information at the time. We employ independent tax specialists to review, on an annual basis, the quantum of our previous research and development tax claim and our on-going eligibility to claim the research and development tax incentive in Australia.

Of the $1.5 million research and development tax incentive recorded in other income for the three months ended December 31, 2015, $1.0 million relates to a change in the original estimate of the research and development tax incentive income that we would receive from the Australian government for the year ended June 30, 2015.

Of the $0.8 million research and development tax incentive recorded in other income for the three months ended December 31, 2014, $0.1 million relates to a change in the original estimate of the Research and development tax incentive income we estimated we would receive from the Australian government for the year ended June 30, 2014.

For the three months ended December 31, 2014, we recognized a net foreign exchange gain of $3.3 million due to movements in exchange rates as the US$ appreciated against the A$. Within Mesoblast Limited (exclusive of its consolidated subsidiaries), we held certain cash and term deposit balances in US$, resulting in foreign exchange gains on the revaluation of foreign currency denominated monetary assets and liabilities into our functional currency of A$.

In July 2015, we transferred all US$ deposits to a wholly owned subsidiary of Mesoblast Limited that has a US$ functional currency. Therefore in the three months ended December 31, 2015 no major foreign exchange impacts were recognized.

Finance costs

Finance costs decreased by $0.7 million from $2.7 million for the three months ended December 31, 2014 to $2.0 million for the three months ended December 31, 2015. The Finance costs of $2.0 million in the three months ended December 31, 2015 represent the unwinding of the risk adjusted discount as the time period shortens between the valuation date and the potential settlement dates of contingent consideration of the acquired MSC assets of Osiris. 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.

Loss after income tax

(in thousands)	Three months ended December 31, 2015	2014	$ Change	% Change
Loss before income tax	$(22,325)	$(27,882)	5,557	(20%)
Income tax expense	—	—	—	—
Loss after income tax	**$(22,325)**	**$(27,882)**	**5,557**	**(20%)**

Loss after income tax was $22.3 million for the three months ended December 31, 2015 compared with $27.9 million for the three months ended December 31, 2014, a decrease of $5.6 million. This decrease is the net effect of the changes in revenues and expenses which have been fully discussed above.

Comparison of Our Results for the Six Months Ended December 31, 2015 with the Six Months Ended December 31, 2014

The following table summarizes our results of operations for the six months ended December 31, 2015 and 2014, together with the changes in those items in dollars and as a percentage.

(in thousands except per share information)	Six months ended December 31, 2015	2014	$ Change	% Change
Consolidated Income Statement data:				
Revenue:				
Commercialization revenue	$ 7,502	$ 7,502	—	—
Milestone revenue	3,500	2,000	1,500	75%
Interest revenue	525	1,842	(1,317)	(71%)
Total revenue	11,527	11,344	183	2%
Research and development	(23,604)	(30,732)	7,128	(23%)
Manufacturing commercialization	(14,321)	(11,450)	(2,871)	25%
Management and administration	(11,251)	(14,486)	3,235	(22%)
Fair value remeasurement of contingent consideration	4,271	(4,482)	8,753	(195%)
Other operating income and expenses	2,343	10,978	(8,635)	(79%)
Finance costs	(4,450)	(4,597)	147	(3%)
Loss before income tax	(35,485)	(43,425)	7,940	(18%)
Income tax expense	—	—	—	—
Loss attributable to the owners of Mesoblast Limited	$(35,485)	$(43,425)	7,940	(18%)
Losses per share attributable to our ordinary equity holders:	**Cents**	**Cents**	**Cents change**	**% Change**
Basic - losses per share	(10.31)	(13.68)	3.37	(25%)
Diluted - losses per share	(10.31)	(13.68)	3.37	(25%)

Revenue

Revenues were $11.5 million for the six months ended December 31, 2015, compared with $11.3 million for the six months ended December 31, 2014, an increase of $0.2 million. The following table shows the movement within revenue for the six months ended December 31, 2015 and 2014, together with the changes in those items.

(in thousands)	Six months ended December 31, 2015	2014	$ Change	% Change
Revenue:				
Commercialization revenue	$ 7,502	$ 7,502	—	0%
Milestone revenue	3,500	2,000	1,500	75%
Interest revenue	525	1,842	(1,317)	(71%)
Revenue	$11,527	$11,344	183	2%

There was no change in commercialization revenue in the six months ended December 31, 2015 when compared with the six months ended December 31, 2014.

We recognized $3.5 million in milestone revenue in the six months ended December 31, 2015 upon our partner, JCR, receiving full regulatory approval of MSC product TEMCELL® in Japan, which is a substantive milestone under our agreement with JCR. In the six months ended December 31, 2014 we recognized milestone revenue of $2.0 million as JCR filed for marketing approval for TEMCELL® in Japan which constitutes a substantive milestone under our agreement with JCR.

The $1.3 million decrease in interest revenue from the six months ended December 31, 2015 compared with December 31, 2014 was primarily driven by us retaining a higher proportion of cash reserves in US$ instead of A$ in the six months ended December 31, 2015, when compared with the six months ended December 31, 2014. This change in cash reserve holdings decreased revenue as yields on US$ cash deposits are lower than yields on A$ cash deposits. We increased the proportion of cash reserves held in US$ to reduce currency risk. Currency risk is minimized by ensuring the proportion of cash reserves held in each currency matches the expected rate of spend of each currency.

Research and development

Research and development expenses were $23.6 million for the six months ended December 31, 2015, compared with $30.7 million for the six months ended December 31, 2014, a decrease of $7.1 million. The $7.1 million net decrease in research and development expenses reflects a reduction in expenditures of our Tier 2 products and product support costs.

(in thousands)	Six months ended December 31, 2015	2014	$ Change	% Change
Research and development:				
Third party costs	$11,012	$14,095	(3,083)	(22%)
Product support costs	11,518	15,286	(3,768)	(25%)
Intellectual property support costs	1,074	1,351	(277)	(21%)
Research and development	$23,604	$30,732	(7,128)	(23%)

Third party costs, which consist of all external expenditure on our research and development programs, decreased by $3.1 million in the six months ended December 31, 2015 compared with the six months ended December 31, 2014.

Within this $3.1 million decrease, there was a $0.8 million increase in third party costs for the advancement of our Tier 1 products due to clinical advancement during the period for the six months ended December 31, 2015 compared with the six months ended December 31, 2014. In the six months ended December 31, 2015 we incurred costs on our MPC-06-ID, MSC-100-IV, and MPC-150-IM Tier 1 products as well our MPC-300-IV product which was promoted from Tier 2 to Tier 1 on June 30, 2015. This increase in Tier 1 costs was offset by a $3.9 million decrease in third party costs for our Tier 2 and pipeline products for the six months ended December 31, 2015, compared with the six months ended December 31, 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 decreased by $3.8 million for the six months ended December 31, 2015 compared with the six months ended December 31, 2014. A cost saving of $1.7 million was realized in salaries and $0.7 million was realized in share based payments primarily due to vacated positions remaining unfilled. In the six months ended December 31, 2015, full time equivalents decreased by 6.3 from 83.1 for the six months ended December 31, 2014 to 76.8 for the six months ended December 31, 2015. Additionally, consultancy expenses and travel expenses decreased by $1.0 million and $0.4 million, respectively, for the six months ended December 31, 2015 compared to the six months ended December 31, 2014 due to management’s cost reduction efforts.

Also included in research and development expenses are intellectual property support costs, which consist of payments to our patent attorneys to progress patent applications and all costs of renewing our granted patents. These costs fell by $0.3 million in the six months ended December 31, 2015 compared with the six months ended December 31, 2014 due to efficiencies in cost management.

Manufacturing commercialization

Manufacturing commercialization expenses, which consist of fees paid to our contract manufacturing organizations and laboratory supplies used in manufacturing commercialization of our MPC and MSC based products, increased by $2.9 million for the six months ended December 31, 2015 compared to the six months ended December 31, 2014. This increase was due to 106% growth in the number of production runs completed in the six months ended December 31, 2015 compared to the six months ended December 31, 2014 to meet the clinical supply demands of our Tier 1 products.

(in thousands)	Six months ended December 31, 2015	2014	$ Change	% Change
Manufacturing commercialization:				
MSC-based manufacturing commercialization	$ 9,566	$ 4,396	5,170	118%
MPC-based manufacturing commercialization	2,892	5,270	(2,378)	(45%)
Manufacturing commercialization support expenses	1,863	1,784	79	4%
Manufacturing commercialization	$14,321	$11,450	2,871	25%

The MSC-based manufacturing commercialization expenses increased by $5.2 million in the six months ended December 31, 2015 compared to the six months ended December 31, 2014 as 100% of the production runs in the six months ended December 31, 2015 were for MSC-based clinical supply whereas the expenditure incurred for MSC-based manufacturing commercialization in the six months ended December 31, 2014 was primarily for process development activities.

The MPC-based manufacturing commercialization expenses decreased by $2.4 million in the six months ended December 31, 2015 compared to the six months ended December 31, 2014 as no MPC-based production was undertaken in the six months ended December 31, 2015 whereas 25% of production was for MPC-based clinical supply in the six months ended December 31, 2014. The balance of expenditure incurred in both the six month periods ended December 31, 2015 and 2014 was for process development activities.

Manufacturing commercialization support expenses, which consist primarily of salaries and related overhead expenses for personnel in manufacturing commercialization functions, increased by $0.1 million for the six months ended December 31, 2015 compared with the six months ended December 31, 2014. Within this $0.1 million cost increase, there was a $0.2 million increase in consultancy expenses and a $0.1 million reduction in salary costs as full time equivalents decreased by 0.3 from 11.2 for the six months ended December 31, 2014 to 10.9 for the six months ended December 31, 2015.

Management and administration

Management and administration expenses were $11.3 million for the six months ended December 31, 2015, compared with $14.5 million for the six months ended December 31, 2014, a decrease of $3.2 million. This decrease was primarily due to lower share based payment expenses because of lower valuations and favorable exchange rate fluctuations as the US$ strengthened against the A$ given that the majority of management and administration expenses are incurred in A$ by our headquarter office located in Australia.

	Six months ended December 31,			
(in thousands)	2015	2014	$ Change	% Change
Management and administration:				
Labor and associated expenses	$ 5,043	$ 7,129	(2,086)	(29%)
Corporate overheads	4,738	4,702	36	1%
Legal and professional fees	1,470	2,655	(1,185)	(45%)
Management and administration	$11,251	$14,486	(3,235)	(22%)

Labor and associated expenses decreased by $2.1 million from $7.1 million for the six months ended December 31, 2014 to $5.0 million for the six months ended December 31, 2015. Within the $2.1 million decrease share based payment expenses were reduced by $0.9 million due to a reduction in the valuation of equity settled share based payments resulting from changes in the key assumptions such as the share price and risk free rate and consultancy and recruitment expenses were reduced by $0.6 million due to management's cost reduction efforts. The remaining decrease of $0.6 million related to salaries as we benefited from the impact of exchange rate fluctuations.

Corporate overhead expenses increased by 1% for the six months ended December 31, 2015 compared with the six months ended December 31, 2014. Within this 1% increase, a $0.4 million was due to increase in non-cash depreciation charges and a one off cost related to office space. This is offset by a $0.4 million decrease in other overhead expense categories.

Legal and professional fees decreased by $1.2 million from $2.7 million for the six months ended December 31, 2014 to $1.5 million for the six months ended December 31, 2015 due to reductions on intellectual property management and associated legal, taxation and accounting compliance advice. We also benefited from exchange rate fluctuations as indicated above.

Fair value remeasurement of contingent consideration

Fair value remeasurement of contingent consideration was a $4.3 million gain for the six months ended December 31, 2015 compared with a $4.5 million loss for the six months ended December 31, 2014, an increase of $8.8 million. The $4.3 million gain recognized in the six months ended December 31, 2015 is due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This gain is as a result of changes to the key assumptions of the contingent consideration valuation such as product pricing, market population, and developmental timelines. The net result of changes to the key assumptions was a decrease in the valuation of contingent consideration payable to Osiris on royalties from sales and on the achievement of certain pre-determined milestones.

The $4.5 million expense for the six months ended December 31, 2014 is due to the remeasurement of contingent consideration pertaining to the acquisition of assets from Osiris. This remeasurement expense is also as a result of changes to the key assumptions of the contingent consideration valuation such as product pricing market population, 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.

Other operating income and expenses

Other operating income and expenses were $2.3 million for the six months ended December 31, 2015, compared with $11.0 million for the six months ended December 31, 2014, a decrease of $8.6 million. The following table shows movements within other operating income and expenses for the six months ended December 31, 2015 and 2014, together with the changes in those items:

	Six months ended December 31,			
(in thousands)	2015	2014	$ Change	% Change
Other operating income and expenses:				
Research & development tax incentive income	$2,609	$ 2,998	(389)	(13%)
Foreign exchange (losses)/gains - net	(266)	7,980	(8,246)	(103%)
Other operating income and expenses	$2,343	$10,978	(8,635)	(79%)

Research and development tax incentive income decreased by $0.4 million from $3.0 million for the six months ended December 31, 2014 to $2.6 million for the six months ended December 31, 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 incentive available to us based on available information at the time. We employ independent tax specialists to review, on an annual basis, the quantum of our previous research and development tax claim and our on-going eligibility to claim the research and development tax incentive in Australia.

Of the $2.6 million research and development tax incentive recorded in other income for the six months ended December 31, 2015, $1.0 million relates to a change in the original estimate of the research and development tax incentive income we estimated we would receive from the Australian government for the year ended June 30, 2015.

Of the $3.0 million research and development tax incentive recorded in other income for the six months ended December 31, 2014, $0.5 million relates to a change in the original estimate of the research and development tax incentive income that we would receive from the Australian Government for the year ended June 30, 2014.

For the six months ended December 31, 2015 we recognized a net foreign exchange loss of $0.3 million due to the movement of the A$ to US$ exchange rates within the period.

For the six months ended December 31, 2014, we recognized a net foreign exchange gain of $8.0 million due to movements in exchange rates as the US$ appreciated against the A$. Within Mesoblast Limited (exclusive of its consolidated subsidiaries), we held certain cash and term deposit balances in US$, resulting in foreign exchange gains on the revaluation of foreign currency denominated monetary assets and liabilities into our functional currency of A$.

Finance costs

Finance costs decreased by $0.1 million from $4.6 million for the six months ended December 31, 2014 to $4.5 million for the six months ended December 31, 2015. The Finance costs of $4.5 million in the six months ended December 31, 2015 represent the unwinding of the risk adjusted discount as the time period shortens between the valuation date and the potential settlement dates of contingent consideration of the acquired MSC assets of Osiris. 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.

Loss after income tax

(in thousands)	Six months ended December 31, 2015	2014	$ Change	% Change
Loss before income tax	$(35,485)	$(43,425)	7,940	(18%)
Income tax expense	—	—	—	—
Loss after income tax	$(35,485)	$(43,425)	7,940	(18%)

Loss after income tax was $35.5 million for the six months ended December 31, 2015 compared with $43.4 million for the six months ended December 31, 2014, a decrease of $7.9 million. This decrease is the net effect of the changes in revenues and expenses which have been fully discussed above.

Liquidity and Capital Resources

Sources of liquidity

We have incurred losses from operations since our inception in 2004 and as of December 31, 2015, we had an accumulated deficit of $299.4 million. During the three months ended December 31, 2015, we raised net proceeds of approximately $59.2 million from the initial public offering (“IPO”) on the NASDAQ Global Select Market which closed on November 18, 2015, after deducting underwriting discounts and commissions and estimated expenses of the IPO. We expect that our cash and cash equivalents as at December 31, 2015 of $120.8 million will be sufficient to fund our current operations through at least the next twelve months.

Cash flows

(in thousands)	Six months ended December 31, 2015	2014	$ Change	% Change
Cash Flow Data:				
Net cash (outflows) in operating activities	$(47,873)	$(50,752)	2,879	(6%)
Net cash (outflows) in investing activities	(1,618)	(2,651)	1,033	(39%)
Net cash inflows in financing activities	61,931	990	60,941	NM*
Net (decrease) in cash and cash equivalents	$ 12,440	$(52,413)	64,853	NM*

* NM = not meaningful.

Net cash outflows in operating activities

Net cash outflows for operating activities were $47.9 million for the six months ended December 31, 2015, compared with $50.8 million for the six months ended December 31, 2014, a decrease of $2.9 million. Outflows decreased by $3.0 million due to a decrease in payments to suppliers in relation to research and development costs, primarily for our Tier 2 products, and a decrease in management and administration costs as well as payments to employees. Inflows decreased as interest receipts reduced by $1.7 million as we held a higher proportion of cash reserves in US$ compared with A$ in the six months ended December 31, 2015, when compared with the six months ended December 31, 2014. This was offset by a $1.5 million increase in milestone payments received after our partner, JCR, received full regulatory approval of MSC product TEMCELL® in Japan during the six months ended December 31, 2015 which entitled us to a milestone payment. Outflows for income tax paid decreased by $0.1 million to $Nil in the six months ended December 31, 2015 from $0.1 million in the six months ended December 31, 2014.

Net cash outflows in investing activities

Net cash outflows for investing activities were $1.6 million for the six months ended December 31, 2015, compared with $2.7 million for the six months ended December 31, 2014, a decrease of $1.1 million. This decrease was primarily due to a $1.2 million decrease related to lower payments for fixed assets, such as plant and equipment for our clinical trials as well as office and computer equipment for our staff and a $0.8 million decrease due to a 0.8 million decrease in payments for financial derivatives. This was offset by a $0.8 million increase in payments for investments and a $0.1 million increase in payments for licenses in the six months ended December 31, 2015.

Net cash inflows in financing activities

Net cash inflows for financing activities were $61.9 million for the six months ended December 31, 2015, compared with $1.0 million for the six months ended December 31, 2014, an increase of $60.9 million. This increase was primarily due to $68.3 million increase related to the gross proceeds from the IPO which were offset by $6.6 million in payments for share issue costs and a $0.8 million decrease related to a decrease in receipts from the exercise of the employee share options.

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. 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 as well as management and administration expenses will decrease in the short term. Subject to us achieving successful regulatory approval we expect an increase in our total expenses driven by an increase in our selling, general and administrative expenses as we move towards commercialization. Therefore we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of 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 and sub-lease commitments

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. There have been no material updates to our lease commitments disclosure included in the Prospectus.

Contingent liabilities

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

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

We have entered into a number of agreements with other third parties pertaining to intellectual property. Contingent liabilities may arise in the future if certain events or developments occur in relation to these agreements. As of December 31, 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 December 31, 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 in our 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. Our strategy of entering into new deposits as old deposits mature and reinvesting surplus funds ensures that we spread the timing of new deposits which assists us to achieve the average interest rates available in the market throughout the year. We also ensure that sufficient funds are available, in at-call accounts, to meet our cash flow requirements.

Foreign currency exchange risk

We have foreign currency amounts owing primarily in our Australian parent entity, whose functional currency is the A$, relating to clinical, regulatory and overhead activities. These foreign currency balances give rise to a currency risk, which is the risk of the exchange rate moving, in either direction, and the impact it may have on our financial performance.

We manage the currency risk by evaluating levels to hold in each currency by assessing our future activities which will likely be incurred in those currencies.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with IFRS. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in our consolidated financial statements included in the 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 and milestone revenue

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

Where such arrangements can be divided into separately identifiable components (each component constituting a separate earnings process), the arrangement consideration is allocated to the different components based on their relative fair values and recognized over the respective performance period in accordance with IAS 18 Revenue. Where the components of the arrangement cannot be divided into separate units, the individual deliverables are combined as a single unit of accounting and the total arrangement consideration is recognized over the estimated collaboration period. Such analysis requires considerable estimates and judgments to be made by us, including the relative fair values of the various elements included in such agreements and the estimated length of the respective performance periods.

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

Cephalon arrangement

In December 2010, we entered into a development and commercialization agreement ("DCA"), with Cephalon, Inc., now a wholly-owned subsidiary of Teva, which 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 $130 million as a non-refundable up-front payment.

Further payments of up to $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 three months ended December 31, 2015 and 2014, we recognized $3.8 million and $3.8 million of revenue, respectively, being the amortization of the initial payment over the estimated development program term.

For the six months ended December 31, 2015 and 2014, we recognized $7.5 million and $7.5 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 will become entitled to such payments.

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.

In the three months ended December 31, 2015 and 2014, we recognized milestone revenue of nil.

In the six months ended December 31, 2015, we recognized $3.5 million in milestone revenue from JCR for the receipt of full regulatory approval of TEMCELL® in Japan, which is a substantive milestone under our agreement with JCR. In the six months ended December 31, 2014, we recognized $2.0 million in milestone revenue from JCR for the completion of another substantive milestone pertaining to the filing of TEMCELL® for regulatory approval in Japan. These amounts were recorded in revenue as there are no further performance obligations required in regards to these items.

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 allows a refundable tax offset 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 at the rate of 45%. We have assessed our research and development activities and expenditure to determine which of these spending are likely to be eligible under the incentive scheme. At each period end, we estimate and recognize the refundable tax offset available to us based on available information at the time.

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

Goodwill

We have recognized goodwill as a result of two separate acquisitions. Goodwill of $118.4 million was recognized on acquisition of Angioblast Systems Inc. in 2010 and $13.9 million was recognized on the acquisition of assets from Osiris in 2013. In the year ended June 30, 2015, there was a $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 in the 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 $387.0 million was recognized on the acquisition of Angioblast Systems Inc. in 2010 and $126.7 million was recognized on the acquisition of assets from Osiris in 2013.

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 in the 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 valuations 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); and
- It must be subject to insignificant risk of change of value.

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

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

As at December 31, 2015 and 2014, we did not hold any deposits with maturity dates between 3 months and 12 months and therefore we did not hold any deposits classified as short term investments.

Fair Value Measurements

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

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

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 December 31, 2015. There were no level 3 assets as of December 31, 2014.

Our level 3 liabilities consist of a contingent consideration provision related to the acquisition of Osiris' MSC business. Level 3 liabilities were 100% of total liabilities measured at fair value as of December 31, 2015 and 2014. 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 December 31, 2015	Fair value as of June 30, 2015	Valuation technique	Unobservable Inputs*	Range of inputs (weighted average) for Three Months Ended December 31, 2015	Range of inputs (weighted average) for Year ended June 30, 2015	Relationship of unobservable inputs to fair value
Contingent consideration provision	92,069	91,890	Discounted cash flows	Risk adjusted discount rate	11%-13% (12.5%)	11%-13% (12.5%)	Six months ended December 31, 2015: A change in the discount rate by 0.5% would increase/decrease the fair value by 3% Year ended June 30, 2015: A change in the discount rate by 0.5% would increase/decrease the fair value by 3%
				Expected unit revenues	n/a	n/a	Three months ended December 31, 2015: A 10% increase in the price assumptions adopted would increase the fair value by 8% Year ended June 30, 2015: A 10% increase in the price assumptions adopted would increase the fair value by 8%

* 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 reorganization 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.

Events subsequent to balance date

There have not been any events subsequent to the balance date, not otherwise disclosed in this report, which significantly affected or may significantly affect our operations, our results of our operations or our state of affairs in subsequent financial periods.

Auditor’s independence declaration

A copy of the auditor’s declaration as required under Section 307C of the Corporations Act 2001 is included on page 54 of this report.

Rounding of amounts

The company is of a kind referred to in Class Order 98/100, issued by the Australian Securities and Investments Commission, relating to the ‘rounding off’ of amounts in this report. Amounts in this report have been rounded off in accordance with that Class Order to the nearest thousand dollars, or in certain cases to the nearest dollar.

Directors’ resolution

This report is made in accordance with a resolution of the directors.

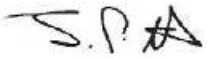
Auditor's Independence Declaration

As lead auditor for the review of Mesoblast Limited for the half-year ended 31 December 2015, I declare that to the best of my knowledge and belief, there have been:

a) no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and

b) no contraventions of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Mesoblast Limited and the entities it controlled during the period.



Jon Roberts
Partner
PricewaterhouseCoopers

Melbourne
16 February 2016

RISK FACTORS

You should carefully consider the risks described below and all other information contained in this Quarterly Report on Form 6-K 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 Quarterly Report on Form 6-K 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 Quarterly Report on Form 6-K.

Risks Related to Our Financial Position and Capital Requirements

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

We are a clinical-stage biotechnology company and we have not yet generated significant revenues. We have incurred net losses during most of our fiscal periods since our inception. For the three months ended December 31, 2015, we had a comprehensive loss of $20.8 million. For the six months ended December 31, 2015, we had a comprehensive loss of $37.5 million. Our net loss for the three months ended December 31, 2015 was $22.3 million and our net loss for the six months ended December 31, 2015 was $35.5 million. As of December 31, 2015, we have an accumulated deficit of $299.4 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.

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

Our operations have consumed substantial amounts of cash since inception. As of December 31, 2015, our cash and cash equivalents were $120.8 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future in connection with our planned research, development and product commercialization efforts. In addition, we will require additional financing to achieve our goals and our failure to do so could adversely affect our commercialization efforts. We anticipate that our expenses will increase if and as we:

- continue the research and clinical development of our product candidates, including MPC-150-IM (Class II-IV 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 our expected clinical milestones. A failure can occur at any stage of testing. Events that may prevent successful or timely commencement, enrollment or completion of clinical development include:

- 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. (now 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 $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, 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, 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 the United States, breach of insider trading laws. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

We have in the past and may in the future seek to acquire businesses, products or technologies that we believe could complement or expand our product offerings, enhance our technical capabilities or otherwise offer growth opportunities. For example, we acquired MSC-assets from Osiris 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 December 31, 2015, our cumulative operating losses have a potential tax benefit of $77.4 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 and Our Trading Markets

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. 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.

We list our ADSs in the United States on the NASDAQ under the symbol "MESO." However, we cannot assure you that an active public market in the United States for the ADSs will develop on that exchange, or if developed, that this market will be sustained. In the past, following periods of volatility in the market price of a company's securities, shareholders often instituted securities class action litigation against that company. If we were involved in a class action suit, it could divert the attention of senior management and, if adversely determined, could have a material adverse effect on our results of operations and financial condition.

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

Our ADSs are listed on the NASDAQ and our ordinary shares are listed on the ASX. We cannot predict the effect of this dual listing on the value of our ordinary shares and ADSs. However, the dual listing of our ordinary shares and ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for the ADSs in the United States. The price of the ADSs could also be adversely affected by trading in our ordinary shares on the ASX.

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 79% of our cash and cash equivalents as of December 31, 2015 were denominated in U.S. dollars and 21% were denominated in Australian dollars. Because we have multiple functional currencies across different jurisdictions, changes in the exchange rate between these currencies and the foreign currencies of the transactions recorded in our accounts could materially impact our reported results of operations and distort period-to-period comparisons. For example, a portion of our research and clinical trials are undertaken in Australia. As such, payment will be made in Australian dollar currency, and may exceed the budgeted expenditure if there are adverse currency fluctuations against the U.S. dollar.

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

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

As of December 31, 2015, we have 380,095,927 ordinary shares outstanding, including the shares underlying the ADSs listed on the NASDAQ. 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 our initial public offering in November 2015, 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.

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

As a company whose ADSs have recently begun to be publicly traded in the United States, we have incurred and will continue to incur significant legal, accounting, insurance and other expenses that we did not previously incur. In addition, the Sarbanes-Oxley Act, Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the SEC and NASDAQ, have imposed various requirements on public companies including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives, and we will need to add additional personnel and build our internal compliance infrastructure. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our senior management. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially civil litigation.

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

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

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

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

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

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. 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.

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 in the future.

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.

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.

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

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

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

As a result, our public shareholders 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.

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.

Furnished as Exhibit 99.1 to this Report on Form 6-K is an Appendix 4D of Mesoblast Limited ("the Company") for the half-year report for the six months ended December 31, 2015.

Furnished as Exhibit 99.2 to this Report on Form 6-K is the press release of the Company dated February 16, 2016, announcing the Company's unaudited consolidated financial results for the three and six months ended December 31, 2015.

Furnished as Exhibit 99.3 of this Report on Form 6-K is an investor presentation of the Company dated February 16, 2016.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Mesoblast Limited

Date: February 16, 2016

By: /S/ Silviu Itescu
Name: Silviu Itescu
Title: Chief Executive Officer

Mesoblast Limited
ABN 68 109 431 870
and Controlled Entities (Mesoblast Group)

HALF-YEAR INFORMATION
FOR THE SIX MONTHS ENDED 31 DECEMBER 2015

PROVIDED TO THE ASX UNDER LISTING RULE 4.2A

This half-year financial report is to be read in conjunction with the financial report for the period ended 30 June 2015.

APPENDIX 4D

Half-Year Report for the six months to 31 December 2015

Name of entity

MESOBLAST LIMITED
ABN 68 109 431 870

1. Reporting period

Report for the half-year ended	31 December 2015
Previous corresponding period is the financial year ended and half-year ended	30 June 2015 31 December 2014

2. Results for announcement to the market

This report has been prepared in U.S. dollars (US$) being the legal currency of the United States of America. All amounts are presented in US$ in thousands unless stated otherwise.

	Up/down	% change		Amount reported for the half-year ended 31 December 2015 (US$ in thousands)
Revenues *(item 2.1)*	Up	2%	to	11,527
Loss from ordinary activities after tax attributable to members *(item 2.2)*	Down*	18%	to	35,485
Net loss for the period attributable to members *(item 2.3)*	Down*	18%	to	35,485

**decrease in loss*

There are no dividends being proposed or declared for the period *(item 2.4)*

Date for determining entitlements to the dividends: N/A *(item 2.5)*

Brief explanation of any of the figures reported above necessary to enable the figures to be understood *(item 2.6)*:

Please refer to the Directors' Report (please see the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations on page 28 of the attached Form 6-K) and the accompanying press release.

3. Net tangible assets per security *(item 3)*

Net tangible (liability) / asset backing per ordinary security

31 December 2015	31 December 2014
(2.13) cents	(6.47) cents

A large proportion of the company's assets are intangible in nature, consisting of intellectual property and goodwill relating to the acquisition of Mesoblast, Inc and the Mesenchymal Stem Cells (MSCs) technology. These assets are excluded from the calculation of net tangible assets per security. Our total deferred tax liability has also been excluded from the calculation to the extent it relates to future tax obligations as a result of the intellectual property assets deriving revenue at some point in the future. This deferred tax liability has arisen as a direct result of the intellectual property being acquired.

4. Half-Year Financial Statements and Directors' Report

The financial information provided in the Appendix 4D should be read in conjunction with the Quarterly Report on Form 6-K (incorporating the Half-Year Report) for the three and six months ended December 31, 2015 (attached) which has been prepared in accordance with Australian Accounting Standards.

Directors' Report - please refer to the section titled Management's Discussion and Analysis of Financial Condition and Results of Operations on page 28 of the attached Form 6-K.

Half-Year Financial Statement – please refer to the Financial Statements on page 5 of the attached Form 6-K.

5. Independent review of the financial report (item 9)

The financial report has been independently reviewed. The financial report is not subject to a qualified independent review statement. The independent audit review report is attached to the financial statements.

asx announcement

mesoblast
the regenerative medicine company

MESOBLAST REPORTS ON FIRST HALF AND SECOND QUARTER FINANCIAL RESULTS

Melbourne, Australia (17 February 2016); and New York, USA (16 February 2016): Mesoblast Limited (ASX: MSB; Nasdaq: MESO) today reported financial results and operational highlights for the 1H/2Q ended 31 December 2015.

Financial Highlights (USD)

At 31 December 2015, the Company had cash reserves of $120.8 million.

Operating cash outflow for the second quarter of 2016 was US$19.8 million, a reduction of over 25% in comparison to the first quarter of 2016 (US$28.1 million) and the fourth quarter of 2015 (US$27.3 million). This reduction was implemented in line with previous guidance regarding fiscal control measures designed to reduce quarterly cash burn by approximately 20-25%.

For the six months ended 31 December 2015, the Company's loss before income tax improved by 18% ($7.9 million) as compared to the comparative period in FY2015. This improvement was principally due to a 23% reduction in research and development expenditure and a 22% reduction in management and administration expenditure.

Operational Highlights

- Recruitment of all three Tier 1 Phase 3 Clinical trials is progressing well across sites in the United States, including MPC-150-IM for Chronic Heart Failure (CHF), MPC-06-ID for Chronic Low Back Pain (CLBP), and MSC-100-IV for Acute Graft Versus Host Disease (aGVHD) in children.
- MPC-150-IM: Phase 3 trial size was significantly reduced from 1,165 to approximately 600 subjects following communications between our commercial partner, Teva Pharmaceutical Industries Ltd., and the United States Food and Drug Administration (FDA).
    - Phase 3 trial is targeting patients with advanced heart failure and high rates of hospitalization or death, a significant unmet need
    - Updated timelines for this trial will be provided in conjunction with Teva
- Mesoblast's licensee in Japan, JCR Pharmaceuticals Co. Ltd., received full approval for the first allogeneic regenerative medicine in Japan, TEMCELL® HS Inj. for aGVHD in children and adults.
    - Licensee JCR Pharmaceuticals Co. expected to launch TEMCELL® HS Inj. in Japan in the first quarter of the 2016 calendar year.
    - Japan's National Health Insurance (NHI) has set reimbursement for TEMCELL® HS Inj. at ¥868,680 (US$7,200) for 72 million cells.
    - A four-week, multi-dose treatment course of TEMCELL for an average adult is expected to be reimbursed at ¥13,898,880 (US$115,000), or at ¥20,848,320 (US$172,000) if symptoms persist and additional dosing is required.

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668
T +65 6570 0635
F +65 6570 0176

- Mesoblast is entitled to receive royalties and other payments at pre-defined thresholds of net sales.

- MPC-300-IV: top-line results released from the first cohort of Phase 2 trial in rheumatoid arthritis (RA) patients who have previously failed one or more biologic agents. Results show that a single intravenous infusion of the lower dose of MPC-300-IV was safe and resulted in early and sustained clinical responses.
- Phase 2 trial results in CHF and Type 2 Diabetes published in leading peer reviewed journals, Circulation Research and Diabetes Care, respectively.

Financial Results for the three months ended 31 December 2015 (the second quarter) (USD)

- **Revenue:** Revenue was $4.0 million for the second quarter of 2016 compared with $4.4 million for the second quarter of 2015, a decrease of $0.4 million. This decrease was primarily due to a decrease in interest income as the result of increased proportion of cash reserves held in U.S. dollars in line with our needs ensuring currency risk is mitigated.
- **Research and Development:** Research and development (R&D) expenses were $12.5 million for the second quarter of 2016 compared with $17.8 million for the second quarter of 2015, a decrease of $5.3 million. This decrease primarily reflects a reduction in expenditures of our Tier 2 products and product support costs as management reduced costs in line with our corporate strategy.
- **Manufacturing Commercialization:** Manufacturing commercialization expenses were $8.1 million for the second quarter of 2016 compared with $5.6 million for the second quarter of 2015, an increase of $2.5 million. This increase was primarily driven by increased Phase 3 clinical supply demands.
- **Management and Administration:** Management and administration expenses were $5.7 million for the second quarter of 2016 compared with $7.5 million for the second quarter of 2015, a decrease of $1.8 million. This decrease was primarily due to lower share based payment expenses and favourable exchange rate movements as the U.S. dollar strengthened against the Australian dollar. The majority of management and administration expenses were incurred in Australian dollars.
- **Net Loss:** Loss attributable to ordinary shareholders was $22.3 million, or 6.29 cents per share, for the second quarter of 2016, compared with $27.9 million, or 8.78 cents per share, for the second quarter of 2015.

Financial Results for the six months ended 31 December 2015 (the half-year) (USD)

- **Revenue:** Revenue was $11.5 million for the half-year of 2016 compared with $11.3 million for the half-year of 2015, an increase of $0.2 million. This increase was due to increased milestone revenue recognised in the half-year as a $3.5 million milestone revenue was recognised in the half-year of 2016 for the regulatory approval of MSC product TEMCELL® in Japan, compared to a $2.0 million milestone revenue being recognised in the half-year 2015 for marketing approval for TEMCELL® in Japan.
- **Research and Development:** Research and development (R&D) expenses were $23.6 million for the half-year of 2016 compared with $30.7 million for the half-year of 2015, a decrease of $7.1 million. This decrease primarily reflects a reduction in expenditures of our Tier 2 products and product support costs as management reduced costs in line with our corporate strategy.

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668
T +65 6570 0635
F +65 6570 0176

- **Manufacturing Commercialization:** Manufacturing commercialization expenses were $14.3 million for the half-year of 2016 compared with $11.4 million for the half-year of 2015, an increase of $2.9 million. This increase was primarily driven by increased Phase 3 clinical supply demands.
- **Management and Administration:** Management and administration expenses were $11.3 million for the half-year of 2016 compared with $14.5 million for the half-year of 2015, a decrease of $3.2 million. This decrease was primarily due to lower share based payment expenses and favourable exchange rate movements as the U.S. dollar strengthened against the Australian dollar. The majority of management and administration expenses were incurred in Australian dollars.
- **Net Loss:** Loss attributable to ordinary shareholders was $35.5 million, or 10.31 cents per share, for the half-year of 2016, compared with $43.4 million, or 13.68 cents per share, for the half-year of 2015.

2016 Financial Guidance

Mesoblast maintains last quarter's guidance, namely that quarterly operating cash burn will reduce by approximately 20-25% in comparison with Q1 FY2016 / Q4 FY2015 while still achieving timelines for important value inflexion points for our heart failure, back pain and rheumatoid arthritis programs, and to file with the FDA for approval of our pediatric graft versus host disease product candidate.

Conference Call Details

Australia: 9:00 am AEDT on Wednesday, 17 February 2016 1800-005-989 (toll-free Australia)

USA: 5:00 pm ET on Tuesday, 16 February 2016 877-456-0438 (toll-free US)

Ex USA and Australia: +1 262-558-6163

Passcode: 49888069

The live webcast can be accessed by clicking here, or by clicking here.

The archived webcast will be available in the Events and Presentations section of the Investor page on the Mesoblast website http://investorsmedia.mesoblast.com/phoenix.zhtml?c=187006&p=irol-calendar

About Mesoblast

Mesoblast Limited (ASX: MSB; Nasdaq: MESO) is a world leader in developing innovative cellular medicines. We have established what we believe is the industry's most clinically advanced and diverse portfolio of cell-based products with five programs, two of which are partnered, in active Phase 3 clinical studies or Phase 3-ready, and four programs in Phase 2. All our clinical programs target significant, under-served therapeutic areas including cardiac diseases, spine orthopedic disorders, oncology and hematology diseases, and immune-mediated and inflammatory conditions.

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668
T +65 6570 0635
F +65 6570 0176

Forward Looking Statements

This press release contains forward-looking statements which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on estimates and information available to us at the time of this press release and are not guarantees of future performance. Statements in this release involve risks, uncertainties and assumptions. If the risks or uncertainties ever materialize or the assumptions prove incorrect, our results may differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact could be deemed forward-looking statements, including, but not limited to: the initiation, timing, progress and results of our preclinical and clinical studies, and our research and development programs; our ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; our ability to advance our manufacturing capabilities; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities, if any; the commercialization of our product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for our product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and our ability to enter into and maintain established strategic collaborations; our ability to establish and maintain intellectual property on our product candidates and our ability to successfully defend these in cases of alleged infringement; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; estimates of our expenses, future revenues, capital requirements and our needs for additional financing; our financial performance; developments relating to our competitors and our industry; and the pricing and reimbursement of our product candidates, if approved.

Additional risks and uncertainties that could affect Mesoblast's financial results are included under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in the Mesoblast's most recent filings with the SEC, which are available on Mesoblast's website at http://www.mesoblast.com in the Investors and Media section and on the SEC's website at www.sec.gov. Additional information will also be set forth in other filings that the Company makes with the SEC from time to time. All forward-looking statements in this press release are based on information available to the Company as of the date hereof, and Mesoblast does not assume any obligation to update the forward-looking statements provided to reflect events that occur or circumstances that exist after the date on which they were made.

For further information, please contact:

Michael Schuster
Head, Investor Relations
Mesoblast Limited
T: +1 212-993-7910
E: michael.schuster@mesoblast.com

Julie Meldrum
Global Head of Corporate Communications
Mesoblast Limited
T: +61 3 9639 6036
E: julie.meldrum@mesoblast.com

Consolidated Income Statement
(unaudited)

(US dollars in thousands, except per share amounts)	Three Months Ended 31 December		Six Months Ended 31 December	
	2015	2014	2015	2014
Revenue	**4,014**	**4,377**	**11,527**	**11,344**
Research and development	(12,515)	(17,839)	(23,604)	(30,732)
Manufacturing commercialization	(8,118)	(5,551)	(14,321)	(11,450)
Management and administration	(5,716)	(7,546)	(11,251)	(14,486)
Fair value remeasurement of contingent consideration	541	(2,834)	4,271	(4,482)
Other operating income and expenses	1,495	4,173	2,343	10,978
Finance costs	(2,026)	(2,662)	(4,450)	(4,597)
Loss before income tax	**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**
Income tax expense	—	—	—	—
Loss attributable to the owners of Mesoblast Limited	**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**
	Cents	Cents	Cents	Cents
Losses per share attributable to the ordinary equity holders of the Group:				
Basic – losses per share	(6.29)	(8.78)	(10.31)	(13.68)
Diluted – losses per share	(6.29)	(8.78)	(10.31)	(13.68)

Consolidated Statement of Comprehensive Income
(unaudited)

(in thousands)	Three Months Ended 31 December		Six Months Ended 31 December	
	2015	2014	2015	2014
Loss for the period	**(22,325)**	**(27,882)**	**(35,485)**	**(43,425)**
Other comprehensive income/(loss)				
Items that may be reclassified to profit and loss				
Changes in the fair value of available-for-sale financial assets	(185)	—	(185)	—
Exchange differences on translation of foreign operations	1,742	(8,310)	(1,851)	(19,624)
Income tax relating to these items	—	—	—	—
Other comprehensive income /(loss) for the period, net of tax	**1,557**	**(8,310)**	**(2,036)**	**(19,624)**
Total comprehensive loss attributable to the owners of Mesoblast Limited	**(20,768)**	**(36,192)**	**(37,521)**	**(63,049)**

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668
T +65 6570 0635
F +65 6570 0176

Consolidated Balance Sheet
(unaudited)

(US dollars - in thousands)	As of 31 December 2015	As of 30 June 2015
Assets		
Current assets		
Cash and cash equivalents	120,783	110,701
Trade and other receivables	7,833	3,972
Prepayments	3,903	7,787
Total current assets	**132,519**	**122,460**
Non-current assets		
Property, plant and equipment	3,742	4,398
Available-for-sale financial assets	2,115	2,300
Other non-current assets	2,331	2,367
Intangible assets	650,246	650,241
Total non-current assets	**658,434**	**659,306**
Total assets	**790,953**	**781,766**
Liabilities		
Current liabilities		
Trade and other payables	23,980	28,242
Deferred revenue	15,004	15,004
Provisions	2,695	5,161
Total current liabilities	**41,679**	**48,407**
Non-current liabilities		
Deferred revenue	15,003	22,505
Deferred tax liability	149,387	149,387
Provisions	92,130	93,480
Total non-current liabilities	**256,520**	**265,372**
Total liabilities	**298,199**	**313,779**
Net assets	**492,754**	**467,987**
Equity		
Issued capital	768,832	709,191
Reserves	23,367	22,756
Accumulated losses	(299,445)	(263,960)
Total equity	**492,754**	**467,987**

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668
T +65 6570 0635
F +65 6570 0176

Consolidated Statement of Cash Flows
(unaudited)

(in thousands)	Six months Ended 31 December 2015	2014
Cash flows from operating activities		
Milestone payment received	3,500	2,000
Research and development tax incentive received	—	1
Payments to suppliers and employees (inclusive of goods and services tax)	(51,881)	(54,849)
Interest received	508	2,163
Income taxes (paid)/refunded	—	(67)
Net cash (outflows) in operating activities	**(47,873)**	**(50,752)**
Cash flows from investing activities		
Payments for financial derivatives	—	(851)
Payments for investments	(805)	—
Payments for licenses	(200)	(70)
Investment in fixed assets	(613)	(1,730)
Net cash (outflows) in investing activities	**(1,618)**	**(2,651)**
Cash flows from financing activities		
Proceeds from issue of shares	68,549	990
Payments for share issue costs	(6,618)	—
Net cash inflows by financing activities	**61,931**	**990**
Net (decrease)/increase in cash and cash equivalents	12,440	(52,413)
Cash and cash equivalents at beginning of period	110,701	185,003
FX (losses)/gains on the translation of foreign bank accounts	(2,358)	(10,220)
Cash and cash equivalents at end of period	**120,783**	**122,370**

Mesoblast Limited
ABN 68 109 431 870
www.mesoblast.com

Corporate Headquarters
Level 38
55 Collins Street
Melbourne 3000
Victoria Australia
T +61 3 9639 6036
F +61 3 9639 6030

United States Operations
505 Fifth Avenue
Third Floor
New York, NY 10017
USA
T +1 212 880 2060
F +1 212 880 2061

Asia
20 Biopolis Way
#05-01 Centros
Biopreneur 3
SINGAPORE 138668
T +65 6570 0635
F +65 6570 0176

mesoblast
the regenerative medicine company

Financial Results for the First Half And Second Quarter Ended 31 December 2015

February 2016

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation 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. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this presentation are 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. These statements may relate to, but are not limited to: expectations regarding the safety or efficacy of, or potential applications for, Mesoblast's adult stem cell technologies; expectations regarding the strength of Mesoblast's intellectual property, the timeline for Mesoblast's regulatory approval process, and the scalability and efficiency of manufacturing processes; expectations about Mesoblast's ability to grow its business and statements regarding its relationships with Teva Pharmaceutical Industries Ltd, JCR Pharmaceuticals Co., Ltd, and Lonza and future benefits of those relationships; statements concerning Mesoblast's share price or potential market capitalization; and statements concerning Mesoblast's capital requirements and ability to raise future capital, among others. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. You should read this presentation together with our financial statements and the notes related thereto, as well as the risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, include, without limitation: risks inherent in the development and commercialization of potential products; uncertainty of clinical trial results or regulatory approvals or clearances; government regulation; the need for future capital; dependence upon collaborators; and protection of our intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

Agenda

FINANCIAL RESULTS OVERVIEW

REVIEW OF OPERATIONS

OUR FOCUS, OUR COMMITMENT

mesoblast

Agenda

FINANCIAL RESULTS OVERVIEW

Financial Highlights for the Six Months Ended 31 December 2015 US$m

- Cash on hand at 31 December 2015 - $120.8 million
- Q2 FY2016 Cash outflow ($19.8) reduced by >25% in comparison to Q1 FY2016 ($28.1) and Q4 FY2015 ($27.3)
- For the six months ended 31 December 2015, loss before income tax improved by 18% ($7.9) vs comparative period in FY15 principally due to:
  - R&D expenses 23% lower
  - Management & Admin costs 22% lower
- Cash managed to extend runway and achieve Tier 1 value inflexion points

Profit and Loss - Expenditure Reduced Over Prior Period US$m

	6 months ending 31 Dec 2015	6 months ending 31 Dec 2014	$ Change	%
Revenue	**11.5**	**11.3**	**0.2**	**2%**
Loss Before Income Tax	**(35.5)**	**(43.4)**	**7.9**	**18%**

Revenue increased by 2% ($0.2) vs comparative period in FY15:

- Milestone revenue of $3.5 recognized on approval of TEMCELL® Hs. Inj., compared with $2.0 in FY15
- Interest is $1.3 lower due to rate as we held more of our cash in USD deposits in line with our needs

Loss before income tax improved by 18% ($7.9) vs comparative period in FY15:

- **R&D expenses 23% lower ($7.1)** - Reduced expenditure on Tier 2 programs and labour costs
- **Management & Admin costs 22% lower ($3.2)** - Savings on labour cost, currency impacts and IP
- **Manufacturing Commercialization 25% higher ($2.9)** – Increased Phase 3 clinical supply demands

mesoblast

Cash Management

US$m

	Q2 FY2016 3 months ended 31 Dec 2015	Q1 FY2016 3 months ended 30 Sep 2015	Q4 FY2015 3 months ended 30 Jun 2015
Net Cash Outflows in Operating Activities	**(19.8)**	**(28.1)**	**(27.3)**
Cash at the end of the period	**120.8**	**77.8**	**110.7**

Strengthened cash position

- US IPO completed in November 2015
- Significantly augmented existing cash reserves to $120.8 at 31 December 2015

Operating cash burn reduced

- In line with previous guidance, Q2 FY2016 Cash outflow ($19.8) reduced by >25% in comparison to Q1 FY2016 ($28.1) and Q4 FY2015 ($27.3)
- Cash being managed to extend runway and achieve Tier 1 program value inflexion points including in the P3 heart failure program, the P3 chronic back pain program and the P2 rheumatoid arthritis program, and to file with the FDA for approval of our pediatric graft versus host disease product candidate

mesoblast

Agenda

REVIEW OF OPERATIONS

Operational highlights for the six months ended 31 December 2015

- Recruitment of all three Tier 1 Phase 3 Clinical trials progressing well in the US, including MPC-150-IM for Chronic Heart Failure (CHF), MPC-06-ID for Chronic Low Back Pain (CLBP), and MSC-100-IV for Acute Graft Versus Host Disease (aGVHD) in children

- MPC-150-IM:
  - Phase 3 trial size significantly reduced from 1,165 to approximately 600 subjects following discussions between our commercial partner, Teva Pharmaceutical Industries Ltd, and the FDA
  - Trial is targeting patients with advanced heart failure and high rates of hospitalization or death, a significant unmet medical need
  - Updated timelines for this trial will be provided in conjunction with Teva

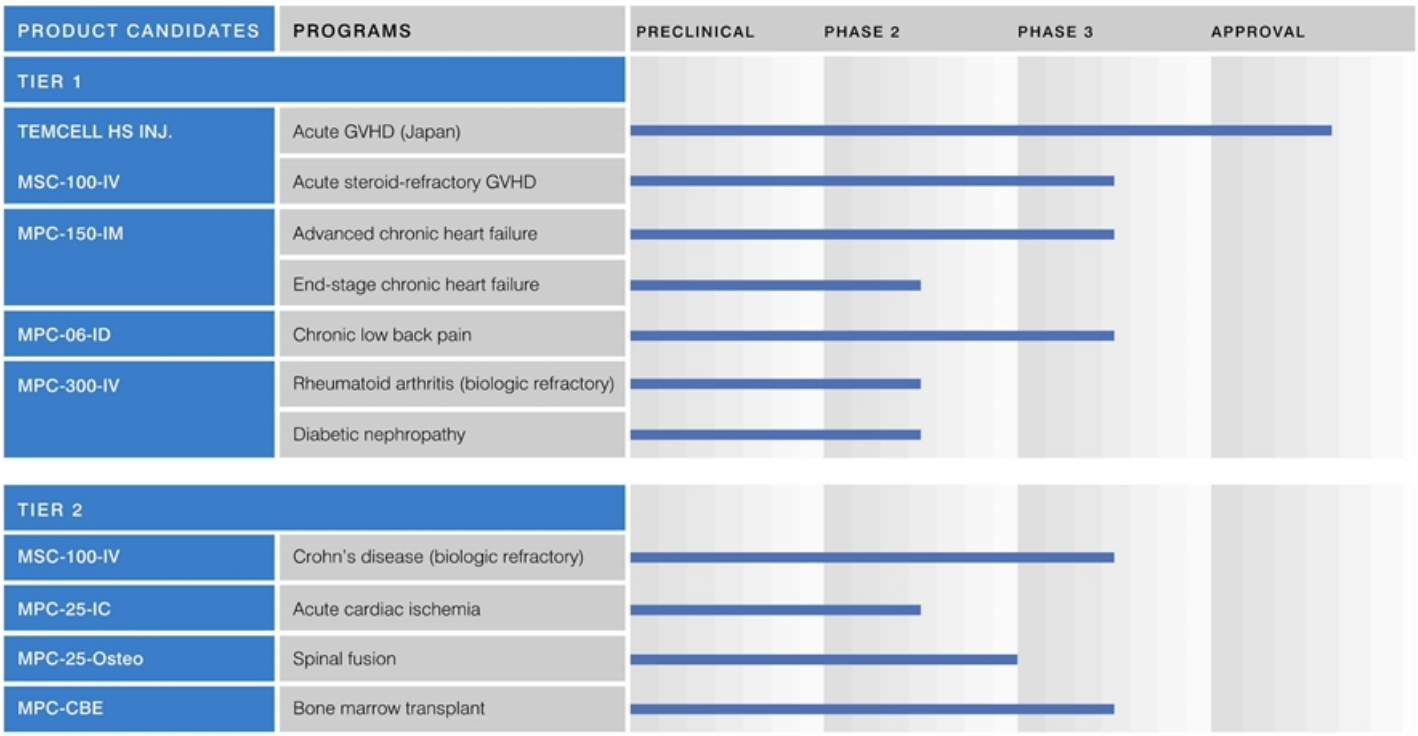
- TEMCELL® HS Inj. In Japan
  - Licensee JCR Pharmaceuticals Co. (JCR) received unconditional approval and reimbursement in Japan for adult and pediatric aGVHD
  - JCR expected to launch TEMCELL® HS Inj. in Japan for adult and pediatric aGVHD in Q1 CY 2016
  - Average reimbursement for 4 week multi-dose treatment is expected to be US$115k and will increase to US$172k if additional dosing is required
  - Mesoblast to receive royalties and other payments at pre-defined thresholds of net sales

- MPC-300-IV: Top line results from the biologic refractory rheumatoid arthritis Phase 2 trial, first dose cohort, show that a single intravenous infusion of the lower dose of MPC-300-IV was safe and resulted in early and sustained clinical responses

- Phase 2 trial results in CHF and Type 2 Diabetes published in leading peer reviewed journals, Circulation Research and Diabetes Care, respectively

Product Candidates in Major Markets with High Unmet Need

First Product on market - Three Tier 1 Product Candidates in Phase 3 Programs



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.

mesoblast

MPC-150-IM: Phase 3 Trial Recruiting Well and Targets Advanced Heart Failure where Medical Need is Greatest

- Patients with large baseline Left Ventricular End Systolic Volumes (LVESV) and advanced heart failure are at highest risk of recurrent Heart Failure - Related Major Adverse Cardiac Events (HF-MACE) including hospitalizations and death
- For these patients existing therapies are inadequate and economic burden is greatest
- Phase 2 results showed that MPC-150-IM prevented HF-MACE over 36 months in patients with advanced heart failure
- The ongoing Phase 3 trial is designed to enrich for patients with Advanced Heart Failure and high risk of HF-MACE in order to confirm therapeutic benefit of a single injection of MPC-150-IM

MPC-150-IM: Phase 3 Heart Failure Program Trial Size Reduced

Following our commercial partner's discussions with FDA, the ongoing Phase 3 program in patients with advanced heart failure, and a high risk of recurrent HF-MACE, is planned to be optimized as follows:

- Revised primary endpoint to a comparison of recurrent HF-MACE between MPC treated patients and controls
- Reduction in current Phase 3 trial size from 1,165 to 600 subjects
- Broaden enrollment centres to Europe
- Initiate a second confirmatory study, conducted in parallel in an identical patient population of up to 600 patients using the same primary endpoint

In Q2 CY 2016 Teva and Mesoblast to provide updated timelines for completion of current reduced Phase 3 Trial, regulatory submissions, and overall program completion

mesoblast

MPC-300-IV: Biologic Refractory Rheumatoid Arthritis (RA) – Market Opportunity

Ongoing randomized, controlled Phase 2 Trial in 48 patients with biologic refractory rheumatoid arthritis, comparing two doses of MPC-300-IV against placebo

Market opportunity

- There are 5.3 million prevalent cases in the US, Japan, and EU5, of which there were 2.4 million in the US alone in 2014[1]
- Incidence increases with age – 8.7 per 100,000 for ages 18-34 vs. 89 per 100,000 for ages 65-74[2]
- Aging population and early diagnosis and treatment will drive expanding RA prevalence
- Targeting active RA patients who have failed a previous biologic therapy – growing target patient group

Gap in treatment options

- One third of RA patients do not respond or cannot tolerate current biologic therapies
  - Sustained remission defined by ACR 70 only occurs in 5-15% of patients on biologics[3]
  - Biologics are associated with increased incidence of opportunistic infections and malignancies
- Biologics only target single cytokine pathways even though RA involves multiple signals / pathways
- Need for disease-modifying therapies with greater safety and efficacy that induce remission in a greater percentage of patients (ACR 70) as early as possible in the disease management

Rationale for Targeting Biologic Refractory RA population

MPCs have receptors that respond to inflammatory signals, resulting in anti-inflammatory mediators

MPC-300-IV targets multiple pathways associated with treatment resistant diseases, whereas existing biologics target a single pathway

1. Decision Resources Rheumatoid Arthritis Dec 2015
2. GlobalData©: Rheumatoid Arthritis Therapeutic – Pipeline Oct 2011
3. Alivernini, S et. al. Arthritis Research & Therapy 2009, 11:R163

mesoblast

MPC-300-IV: Biologic Refractory Rheumatoid Arthritis (RA) Trial Design

- Double-blind, randomized, placebo-controlled, two-dose escalating trial in the US
- Designed to evaluate safety and explore efficacy of MPC treatment in 48 patients with active RA randomized 2:1 to either placebo or a single intravenous infusion of 1 million or 2 million MPCs/kg
- Patients on stable regimen of methotrexate and have previously failed or had an adverse or inadequate clinical response to at least one biologic agent
- Lower MPC dose was evaluated in the first cohort of 24 patients, of whom 16 had failed 1-2 biologics
- Second cohort of 24 patients, evaluating higher dose of MPCs, actively recruiting
- Primary endpoint is safety, with pre-specified efficacy endpoints at 12 weeks including the American College of Rheumatology (ACR) 20%, 50% and 70% response criteria (ACR20/50/70) [1]

1: ACR20 is a key validated primary endpoint in clinical trials which is accepted by the United States Food and Drug Administration for product approval in RA

mesoblast

MPC-300-IV: Biologic Refractory Rheumatoid Arthritis (RA) - First Cohort Results

- Cell infusions were well tolerated with no cell-related adverse events
- The trial's 12 week, pre-specified ACR20 efficacy endpoint was achieved by 47% of all MPC-treated patients and by 60% of MPC-treated patients who failed 1-2 biologics, vs 25% and 17%, respectively, of matched placebo-treated controls
- 71% of MPC-treated patients who achieved ACR20 responses did so as early as week 1
- At week 12, 27% of MPC-treated patients, but no placebo-treated controls, achieved ACR50 or ACR70 responses
- Remission at week 12, as defined by Disease Activity Score (DAS28/CRP) <2.6, was seen in 20% of MPC-treated patients but in no controls

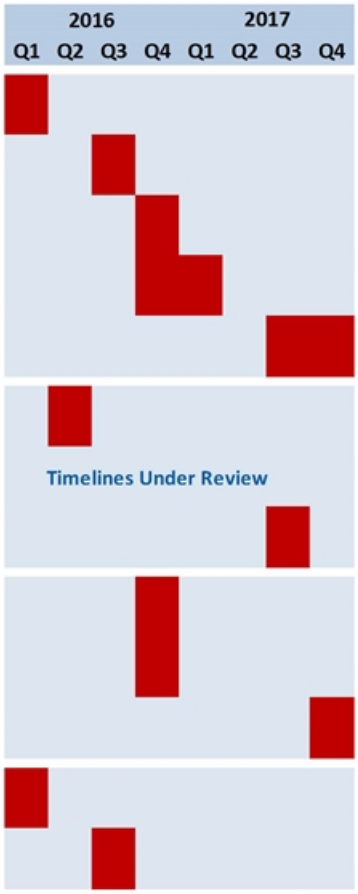
12-week trial results for both cohorts will be reported in Q3 CY 2016

Agenda

OUR FOCUS, OUR COMMITMENT

Tier 1 Product Candidate Deliverables (Calendar Year)

Product Candidate	Programs	Anticipated Milestones
MSC-100-IV / Temcell® HS Inj.	Acute Graft Versus Host Disease	Temcell® HS Inj. Launch in Japan US Pediatric Phase 3 Interim Analysis (IA) Top Line Results Phase 3 program complete, Top Line Results US Pediatric BLA Filing US Pediatric Approval
MPC-150-IM	Class II and III Heart Failure Class IV Heart Failure Requiring LVAD	Phase 3 1st IA results Phase 3 2nd IA (futility & efficacy analysis) Phase 2 trial results
MPC-06-ID	Chronic Low Back Pain Due to Degenerative Disc Disease	Phase 3 enrollment complete Trial 1 Phase 3 First IA results Trial 1 Phase 3 Second IA results Trial 1
MPC-300-IV	Rheumatoid Arthritis (Biologic Refractory)	Top line data first cohort released Full trial Results



mesoblast

Corporate Deliverables

- First royalties from TEMCELL product sales in Japan expected in Q1 CY 2016
- Complete Tier 1 Phase 3 programs on schedule
- Deliver commercial manufacturing in support of product candidate launches
- Deliver on commercial partnerships
- Continued focus on cash management