EDISON

Mesoblast

Financial update

An important next several months

Pharma & biotech

It is going to be a busy next several months for Mesoblast. The company recently completed filing the biologics license application (BLA) for Ryoncil (remestemcel-L) with the FDA for approval for the treatment of pediatric steroid-refractory acute graft versus host disease (aGvHD). Mesoblast should be notified by the end of March whether the BLA has been accepted and whether it will have a six-month priority review or a 10-month standard review. Additionally, data from the Revascor DREAM-HF1 Phase III trial in 566 advanced heart failure patients is expected by the middle of 2020. Data from the MPC-06-ID 404-patient trial in lower back pain is also expected around the middle of the year.

Year end	Revenue (US$m)	PBT* (US$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
06/18	17.0	(68.6)	(8.14)	0.0	N/A	N/A
06/19	16.0	(86.5)	(15.69)	0.0	N/A	N/A
06/20e	61.2	(37.2)	(5.49)	0.0	N/A	N/A
06/21e	48.5	(49.8)	(9.28)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Ryoncil aGvHD launch expected in 2020

Mesoblast completed its rolling BLA submission to the FDA on 31 January. Within 60 days of filing (which would be the end of March), the FDA should notify the company of its acceptance and whether it will have a six-month priority review or a 10-month standard review. We expect that it will receive a priority review due to the innovative nature of the therapy and the positive safety and efficacy data in an indication with unmet need.

Revascor Phase III in heart failure readout mid-2020

The company announced that the required accrual of primary endpoint events in its DREAM HF-1 Phase III trial in 566 advanced heart failure patients has occurred. The primary endpoint is a reduction in recurrent heart failure-related major adverse cardiac events such as heart-failure related hospitalization and cardiac death. Also, a protocol for a Phase III in LVAD patients has been agreed upon between Mesoblast and InCHOIR, in line with FDA guidance.

MPC-06-ID Phase III data mid-2020

The 404-patient Phase III in lower back pain has completed recruitment and final study visits have been initiated. Data is expected by the middle of the year. A confirmatory Phase III is currently being planned with partner Grünenthal in Europe.

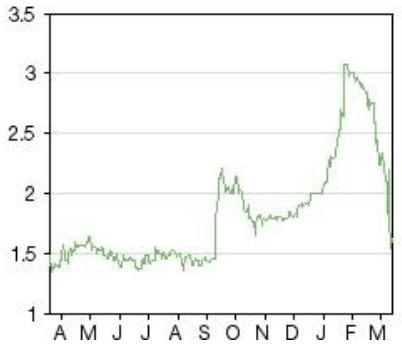
Valuation: A$4.2bn or A$7.89 per share

We have slightly adjusted our valuation to A$4.2bn or A$7.89 per share (A$7.51 per diluted share) from A$4.2bn or A$7.91 per share (A$7.53 per diluted share), mainly due to lower net cash. A number of key valuation inflection points are coming up for the company in the next 12 months including a potential FDA approval and data from two Phase III trials in large indications.

16 March 2020

Price	**A$1.62**
Market cap	**A$870m**
	US$0.66/A$
Net debt (A$m) at 31 December 2019	5.3
Shares in issue	537.1m
Free float	83.0%
Code	MSB
Primary exchange	ASX
Secondary exchange	Nasdaq

Share price performance



%	1m	3m	12m
Abs	(43.6)	(15.4)	36.1
Rel (local)	(27.3)	3.6	52.1
52-week high/low	A$3.07		A$1.20

Business description

Mesoblast is an Australia-based biotechnology company developing adult stem-cell therapies based on its proprietary MPC and MSC platforms. Its lead programs are in pediatric aGvHD, heart failure and lower back pain. Approval is expected in the US for Ryoncil for aGvHD in 2020.

Next events

Revascor Phase III data	Mid-2020
MPC-06-ID Phase III data	Mid-2020
Ryoncil FDA approval decision	H220

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Edison profile page

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Fiscal Q2 update

Mesoblast reported revenues of US$2.2m for the second quarter of FY20 (the period ending 31 December 2019), US$2.0m of which was related to royalties on Temcell sales in Japan (up 62% year over year). For the first half of the fiscal year, total revenues were US$19.2m (up 43% compared to fiscal H119), due to a US$15m upfront payment that was part of the Grünenthal licensing agreement for MPC-06-ID. The operating cash burn rate was US$16.9m for fiscal H120.

The company is awaiting a response from the FDA regarding its BLA application for Ryoncil for steroid-refractory aGvHD, which we expect by the end of March. At that point we will learn both whether the application was accepted for review and the expected length of the review. The company is seeking a six-month priority review and we expect it to receive it due to the innovative nature of the therapy and the positive safety and efficacy data in an indication with unmet need. A six-month review would mean the PDUFA date would be around the end of September this year.

Additionally, the company announced positive outcomes from an investigator trial of remestemcel-L (the same product as Ryoncil; the Ryoncil name will only be used for aGvHD) in chronic graft versus host disease (cGvHD) patients. All three patients (two children and one adult) had clinically meaningful outcomes within 28 days after just two infusions. This compares favorably to Imbruvica (from Johnson & Johnson and AbbVie), which needs to be taken orally on a daily basis and had a median time to response of 12.3 weeks in the pivotal trial. Mesoblast is now planning a pivotal trial of remestemcel-L in cGvHD. For reference, cGvHD has around 14,000 patients in the United States, with the average annual cost estimated to be US$291,357 per patient.[1]

Importantly, in March the company announced its intention to develop remestemcel-L for the treatment of acute respiratory distress syndrome (ARDS) due to coronavirus (COVID-19). In one study of 191 coronavirus patients in Wuhan, China, 31% had ARDS, including 93% of patients who would eventually not survive the infection.[2] With regards to efficacy, there are two particular studies that are encouraging. First, in an investigator sponsored trial in China in seven coronavirus patients (five of which were severe cases), treatment with allogeneic mesenchymal stem cell therapy (which is what remestemcel-L is) resulted in significantly improved pulmonary function in all seven patients within two days of treatment.[3] Additionally, in a post-hoc analysis of a trial of remestemcel-L in chronic obstructive pulmonary disease (COPD), remestemcel-L significantly reduced inflammatory biomarkers and improved pulmonary function in those patients with elevated inflammatory biomarkers. The company is currently in discussions with various governmental, medical and pharmaceutical organizations on the best way to proceed with development.

For Revascor, the necessary number of primary endpoint events has occurred in the DREAM HF-1 Phase III trial in 566 advanced heart failure patients and final study visits have been initiated. Study data is expected in mid-CY20. The primary endpoint is a reduction in recurrent heart failure-related major adverse cardiac events such as heart-failure related hospitalization and cardiac death. With regards to the use of Revascor to treat end-stage heart failure patients with a left ventricular assist device (LVAD), Mesoblast and the International Center for Health Outcomes and Innovation Research (InCHOIR) have agreed on a protocol for a confirmatory Phase III trial, which incorporates FDA guidance.

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1 Bachier et al. Epidemiology and Real-World Treatment of Chronic Graft-Versus-Host Disease Post Allogeneic Hematopoietic Cell Transplantation: A US Claims Analysis. *Blood* (2019) 134 (Supplement_1): 2109.

2 Zhou et al., Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *Lancet*. www.thelancet.com/pb-assets/Lancet/pdfs/S014067362305663.pdf

3 Leng Z, et al. Transplantation of ACE2- Mesenchymal Stem Cells Improves the Outcome of Patients with COVID-19 Pneumonia. *Aging and Disease.* Volume 11, Number 2; 216-228, April 2020

The MPC-06-ID Phase III trial is also on track to provide data by the middle of this year. It enrolled 404 patients with chronic low back pain due to degenerative disc disease and had a composite primary endpoint that included measures of pain and disability/function at 12 and 24 months. As with the DREAM HF-1 trial, final study visits have been initiated. Two Phase III trials will likely be necessary for approval in this indication and a confirmatory European Phase III is currently being planned with partner Grünenthal.

Valuation

We have slightly adjusted our valuation to A$4.2bn or A$7.89 per share (A$7.51 per diluted share) from A$4.2bn or A$7.91 per share (A$7.53 per diluted share), mainly due to lower net cash. A number of key valuation inflection points are coming up for the company in the next 12 months including a potential FDA approval and data from two Phase III trials in large indications.

Exhibit 1: Valuation of Mesoblast

Product	Indication	Probability of success (%)	Launch (FY)	Peak sales (US$m)	rNPV (A$m)
Active projects					
Ryoncil (remestemcel-L)	Acute graft versus host disease (GvHD)	Range 50–80%	2020	574	1,200.6
Revascor (MPC-150-IM)	Congestive heart failure (CHF) (includes use with LVAD)	50%	2023	3,208	1,926.1
MPC-06-ID	Intervertebral disc repair	50%	2022	3,302	1,634.0
On-hold projects					
MPC-300-IV	Diabetic nephropathy	5.0%	On hold	2,186	49.1
MPC-300-IV	Rheumatoid arthritis	5.0%	On hold	1,350	27.9
MPC-25-IC	Acute myocardial infarction (AMI)	5.0%	On hold	1,057	43.5
MPC-25-Osteo	Lumber fusion	5.0%	On hold	662	18.4
Total value					**4,899.7**
R&D expenses					(307.6)
Manufacturing expenses					(70.1)
G&A expenses					(122.9)
Net cash/(debt) (at 31 December 2019)					(5.3)
Non-dilutive funding interest and repayments					(153.9)
Total (A$)					**4,240**
Shares (m)					537.12
Value per share (A$)					**7.89**
Options outstanding (2019 onwards) (m)					27.17
Fully diluted shares in issue (m)					564.29
Fully diluted value per share (A$)					7.51

Source: Edison Investment Research

Financials

For the period ending 31 December 2019, Mesoblast reported cash and equivalents of US$81.3m with US$18.9m in current borrowings and an additional US$66.0m in long-term borrowings. We continue to forecast no additional financing requirement for FY20 and US$50m in FY21, which we record as illustrative debt.

Exhibit 2: Financial summary

US$000s	2018	2019	2020e	2021e
Year end 30 June	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	16,975	16,003	61,244	48,510
Cost of Sales	0	0	0	0
Gross Profit	16,975	16,003	61,244	48,510
R&D Expenses	(62,289)	(57,531)	(50,000)	(50,000)
Manufacturing & Commercialisation Expenses	(4,040)	(14,466)	(12,000)	(10,500)
SG&A Expenses	(18,165)	(18,293)	(15,920)	(18,745)
EBITDA	(66,207)	(75,373)	(23,849)	(37,751)
Operating Profit (before amort. and except.)	(67,116)	(75,935)	(24,099)	(38,001)
Intangible Amortisation	(1,741)	(1,577)	(1,750)	(1,750)
Exceptionals	10,541	(6,264)	(1,152)	0
Share-based payments	(6,198)	(4,368)	(5,330)	(5,330)
Operating Profit	(64,514)	(88,145)	(32,330)	(45,081)
Net Interest	(1,463)	(10,609)	(13,124)	(11,829)
Profit Before Tax (norm)	(68,579)	(86,544)	(37,223)	(49,830)
Profit Before Tax (FRS 3)	(65,977)	(98,754)	(45,454)	(56,910)
Tax	30,687	8,955	7,728	0
Profit After Tax (norm)	(37,892)	(77,589)	(29,495)	(49,830)
Profit After Tax (FRS 3)	(35,290)	(89,799)	(37,726)	(56,910)
Average Number of Shares Outstanding (m)	465.7	494.4	537.1	537.1
EPS - normalised fully diluted (c)	(8.14)	(15.69)	(5.49)	(9.28)
EPS - normalised (c)	(8.14)	(15.69)	(5.49)	(9.28)
EPS - (IFRS) (c)	(7.58)	(18.16)	(7.02)	(10.60)
Dividend per share (c)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	100.0	100.0
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	591,372	589,593	596,930	597,542
Intangible Assets	584,606	583,126	582,338	582,588
Tangible Assets	1,084	826	1,554	1,916
Investments	5,682	5,641	13,038	13,038
Current Assets	101,071	62,522	87,979	87,444
Stocks	0	0	0	0
Debtors	50,366	4,060	3,091	3,091
Cash	37,763	50,426	76,020	75,485
Other	12,942	8,036	8,868	8,868
Current Liabilities	(24,003)	(44,331)	(80,949)	(80,949)
Creditors	(18,921)	(13,060)	(19,241)	(19,241)
Deferred revenue	(5,082)	(17,264)	(42,780)	(42,780)
Short term borrowings	0	(14,007)	(18,928)	(18,928)
Long Term Liabilities	(122,432)	(126,732)	(112,476)	(143,548)
Long term borrowings	(59,397)	(67,279)	(65,996)	(97,068)
Deferred revenue	0	0	0	0
Other long term liabilities	(63,035)	(59,453)	(46,480)	(46,480)
Net Assets	546,008	481,052	491,484	460,489
CASH FLOW				
Operating Cash Flow	(74,563)	(54,572)	(8,937)	(19,681)
Net Interest	(449)	(3,217)	(12,952)	(11,390)
Tax	0	0	0	0
Capex	(201)	(279)	(612)	(612)
Acquisitions/disposals	(952)	0	0	0
Financing	40,566	30,258	51,053	0
Dividends	0	0	0	0
Other	(31,742)	21,203	0	0
Net Cash Flow	(67,341)	(6,608)	28,553	(31,684)
Opening net debt/(cash)	(45,761)	21,634	30,860	8,904
Loan movements	0	0	0	0
Other	(54)	(2,619)	(6,597)	77
Closing net debt/(cash)	21,634	30,860	8,904	40,511

Source: company reports, Edison Investment Research

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