

Mesoblast

Waiting for readouts

Mesoblast is entering a period of top-line readouts. This note focuses on two possible value events in 2018 in graft vs host disease and in Class IV heart failure. In addition, the critical [Phase III](#) heart failure (HF) trial could complete enrolment in H218; the trial readout depends on the number and timing of clinical events but will probably not be before H219. The [lower back pain](#) trial plans to complete enrolment by the end of 2017 with a two-year endpoint. Mesoblast had effective cash of US\$84.0m on 30 June.

Year end	Revenue (US\$m)	PBT* (US\$m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
06/16	44.2	(87.4)	(0.2)	0.0	N/A	N/A
06/17	3.4	(84.9)	(18.1)	0.0	N/A	N/A
06/18e	6.7	(85.0)	(18.9)	0.0	N/A	N/A
06/19e	9.0	(88.7)	(18.9)	0.0	N/A	N/A

Note: *PBT and EPS (fully diluted) are normalised, excluding exceptional items and share-based payments.

MSC-100-IV: Paediatric graft vs host disease (GvHD)

The trial ([NCT02652130](#)) is in steroid refractory GvHD, that is patients had a blood cancer and to cure them had a transplanted allogeneic immune system. This is now attacking their healthy tissues. The trial could enrol up to 60 young patients treated with Remestemcel-L (2 x 10⁶ MSC/kg) with a 100-day endpoint of complete or partial GvHD remission. Data is due from December 2017; this could be in Q118 as recruitment is apparently ongoing. There are about 4,000 paediatric stem cell US and EU transplants a year according to Mesoblast. We estimate 15% might be steroid refractory. This is a high value application sold in Japan for US\$195,000.

MPC-150-IM: LVAD and heart failure

Class IV heart failure patients are incapacitated. Implanting an LVAD heart pump can restore some function; transplants are rare. Remestemcel-L (150m cells injected into the heart) is being tested vs a sham comparator in 159 LVAD patients to test if it improves heart function measured by short-term weaning off the LVAD. The trial ([NCT02362646](#)) is funded by the US National Heart, Lung, and Blood Institute, which will disclose data. The six-month LVAD weaning primary endpoint completes in Q118; co-primary endpoint adverse event data will be in Q318. The LVAD market, about 3,500 per year in the US, is small but valuable. The trial may act as an indicator for the 600-patient Class II/III heart failure study ([NCT02032004](#)).

Further cash or deals needed, valuation unchanged

FY17 (Japanese) royalties were US\$1.4m with US\$1m other income. The FY17 cash outflow was US\$95.5m with year-end effective cash of US\$84.0m implying further funding needs in H1 CY18; Edison projects a US\$90m funding need to June 2019. Mallinckrodt did not use its exclusive option in Q3 CY17 but may still do a deal, although Mesoblast could now partner with another company as it still intends to partner a core (Tier One) project for cash. Mesoblast still has a two-year US\$90m equity facility with Kentgrove Capital. Edison has retained the current indicative value of A\$1.72bn (A\$4.02 /share) pending trial data and possible corporate transactions, which could offset any future potential dilution.

Trial timing and FY17 results

Pharma & biotech

7 November 2017

Price **A\$1.32**

Market cap **A\$565m**

US\$0.76/A\$

Cash (US\$m) at 30 June 2017 (including US\$40m capital raise in Q118) 84.0

Shares in issue 427.9m

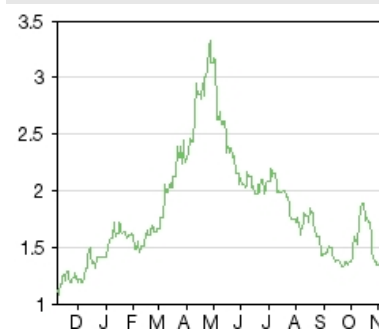
Free float 66.1%

Code MSB

Primary exchange ASX

Secondary exchange NASDAQ

Share price performance



% 1m 3m 12m

Abs (7.1) (22.8) 17.6

Rel (local) (11.2) (25.9) 3.4

52-week high/low A\$3.3 A\$1.1

Business description

Mesoblast is developing adult stem-cell therapies based on its proprietary MPC and culture-expanded MSC platforms. The key trial is a 600-patient Phase III in heart failure. Other indications are in back pain and paediatric GvHD. There is an NIH Class IV heart failure study.

Next events

Top-line data GvHD Phase III Q417

Fully enrol MPC-06-ID back pain Phase III Q417

LVAD HF Phase IIb weaning endpoint H118

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[Edison profile page](#)

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Exhibit 1: Financial summary

	US\$000s	2016	2017	2018e	2019e
Year end 30 June		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		44,183	3,433	6,740	8,980
Cost of Sales		0	0	(1,207)	(2,382)
Gross Profit		44,183	3,433	5,533	6,598
R&D Expenses		(50,013)	(58,914)	(60,092)	(62,496)
Manufacturing & Commercialisation Expenses		(29,763)	(12,065)	(12,186)	(12,551)
SG&A Expenses		(22,500)	(23,007)	(22,895)	(23,582)
EBITDA		(86,319)	(82,350)	(83,154)	(85,384)
Operating Profit (before amort and except)		(88,511)	(85,407)	(86,364)	(88,755)
Intangible Amortisation		0	0	0	0
Exceptionals		0	0	0	0
Share-based payments		(3,389)	(5,276)	(5,276)	(5,276)
Operating Profit		(91,900)	(90,683)	(91,640)	(94,031)
Net Interest		1,079	468	1,373	56
Profit Before Tax (norm)		(87,432)	(84,939)	(84,991)	(88,698)
Profit Before Tax (FRS 3)		(90,821)	(90,215)	(90,267)	(93,974)
Tax		86,694	13,400	0	0
Profit After Tax (norm)		(738)	(71,539)	(84,991)	(88,698)
Profit After Tax (FRS 3)		(4,127)	(76,815)	(90,267)	(93,974)
Average Number of Shares Outstanding (m)		360.8	395.3	449.3	470.4
EPS - normalised fully diluted (c)		(0.20)	(18.10)	(18.92)	(18.85)
EPS - normalised (c)		(0.20)	(18.10)	(18.92)	(18.85)
EPS - (IFRS) (c)		(1.14)	(19.43)	(20.09)	(19.98)
Dividend per share (c)		0.0	0.0	0.0	0.0
Gross Margin (%)		100.0	100.0	82.1	73.5
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		595,195	592,077	589,178	586,118
Intangible Assets		587,823	586,350	586,350	586,350
Tangible Assets		3,063	1,814	(1,085)	(4,145)
Investments		4,309	3,913	3,913	3,913
Current Assets		88,823	63,609	19,717	24,079
Stocks		0	0	0	0
Debtors		4,054	3,743	3,743	3,743
Cash		80,937	45,761	1,869	6,231
Other		3,832	14,105	14,105	14,105
Current Liabilities		(29,415)	(36,670)	(36,670)	(36,670)
Creditors		(27,155)	(21,805)	(21,805)	(21,805)
Deferred revenue		(2,260)	(14,865)	(14,865)	(14,865)
Short term borrowings		0	0	0	0
Long Term Liabilities		(126,442)	(102,250)	(102,250)	(192,250)
Long term borrowings		0	0	0	(90,000)
Deferred revenue		0	0	0	0
Other long term liabilities		(126,442)	(102,250)	(102,250)	(102,250)
Net Assets		528,161	516,766	469,975	381,277
CASH FLOW					
Operating Cash Flow		(89,125)	(95,954)	(83,154)	(85,384)
Net Interest		1,129	483	1,373	56
Tax		0	(1)	0	0
Capex		(922)	(311)	(311)	(311)
Acquisitions/disposals		(805)	453	0	0
Financing		62,066	60,005	38,200	0
Dividends		0	0	0	0
Other		0	0	0	0
Net Cash Flow		(27,657)	(35,324)	(43,892)	(85,639)
Opening net debt/(cash)		(110,701)	(80,937)	(45,761)	(1,869)
HP finance leases initiated		0	0	0	0
Other		(2,107)	148	0	0
Closing net debt/(cash)		(80,937)	(45,761)	(1,869)	83,769

Source: Mesoblast accounts, Edison Investment Research. Note: Mesoblast's reporting currency is US dollars.

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