

# Mesoblast

Q317 results

Confident management

Pharma & biotech

**Mesoblast has raised cash and cleared an interim futility analysis of its Phase III heart failure (HF) trial, will complete enrolment in H218 vs H217. In 2017, Mesoblast expects data from a Phase III trial in paediatric graft vs host disease (GvHD) by H217. An NIH-funded Phase IIb in end-stage HF may be reported by NIH in Q417. Mallinckrodt has an option until the end of Q3 to in-license the GvHD and the Phase III in chronic low-back pain (full enrolment expected in H217). Our indicative valuation is unchanged at A\$1.72bn (A\$4.02 per share) as we await these potential catalysts.**

| Year end | Revenue (US\$m) | PBT* (US\$m) | EPS* (c) | DPS (c) | P/E (x) | Yield (%) |
|----------|-----------------|--------------|----------|---------|---------|-----------|
| 06/15    | 32.4            | (96.2)       | (30.0)   | 0.0     | N/A     | N/A       |
| 06/16    | 44.2            | (87.4)       | (0.2)    | 0.0     | N/A     | N/A       |
| 06/17e   | 5.8             | (82.0)       | (20.6)   | 0.0     | N/A     | N/A       |
| 06/18e   | 9.0             | (81.0)       | (18.9)   | 0.0     | N/A     | N/A       |

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

## HF Phase III clears futility; end-stage IIb HF data Q4

The Phase III trial of MPC-150-IM in HF cleared the April interim futility analysis in the first 270 of 600 planned subjects with Class II / Class III HF. The trial will report once 540 non-fatal HF-related major adverse cardiac events have occurred. Mesoblast, FDA and investigators remain blinded to the numerical results of the analysis. An NIH-funded 159-patient Phase IIb in end-stage HF is expected to be fully enrolled soon and the NIH may report data in Q417. Positive results might lead to an application for accelerated approval under the 21<sup>st</sup> Century Cures Act.

## HF Phase III half enrolled, European sites planned

On the Q3 quarterly call, management said that the HF Phase III had recruited substantially above half the target of 600 patients and is currently on track to complete recruitment in H2 CY18 vs our prior target of H217. Most enrolled patients are Class III, so events are more likely. MSB is at an advanced stage of planning for additional recruitment sites in Europe.

## Mallinckrodt option could drive partnering news

A paediatric GvHD Phase III is expected to complete enrolment and read out top-line data in H217. The chronic low-back pain Phase III is on track to complete recruitment in H217. Mallinckrodt Pharmaceuticals has an exclusive negotiation period that runs until September 2017, covering these two programmes.

## Valuation unchanged, cash runway to Q417

Although the Phase III HF trial end has potentially slipped by 12 months, we have left our valuation unchanged for now at A\$1.72bn (A\$4.02/share), as there is potential for accelerated approval under the under the 21<sup>st</sup> Century Cures Act. Operating cash burn for the first nine months of FY17 was US\$73m. Edison estimates that cash of US\$69m on 31 March could fund operations into Q4 CY17. Additional funds may come from partnering agreements or from the US\$90m discretionary equity facility with Kentgrove Capital.

7 June 2017

**Price** **A\$2.03**

**Market cap** **A\$869m**

US\$0.76/A\$

Cash (US\$m) at 31 March 2017 69.1

Shares in issue 427.9m

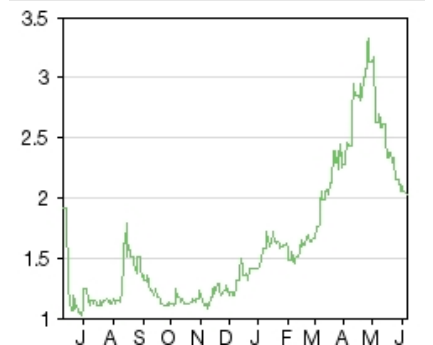
Free float 66.1%

Code MSB

Primary exchange ASX

Secondary exchange NASDAQ

### Share price performance



% 1m 3m 12m

Abs (22.8) 14.7 5.7

Rel (local) (20.7) 16.3 0.6

52-week high/low A\$3.3 A\$1.0

### Business description

Mesoblast is developing adult stem-cell therapies based on its proprietary MPC and culture-expanded MSC platforms. It has multiple late-stage clinical trials across four areas: immunologic/inflammatory (Phase III), spine disease (Phase III), cardiovascular (Phase III) and cancer (Phase III).

### Next events

Top-line data GvHD Phase III H217

Top-line data NIH end-stage HF Phase IIb Q417

Fully enrol MPC-06-ID back pain Phase III H217

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**Exhibit 1: Financial summary**

|   | US\$'000s | 2015      | 2016      | 2017e     | 2018e     | 2019e     |
|---|-----------|-----------|-----------|-----------|-----------|-----------|
| 30-June                                     |           | IFRS      | IFRS      | IFRS      | IFRS      | IFRS      |
| <b>PROFIT &amp; LOSS</b>                    |           |           |           |           |           |           |
| Revenue                                     |           | 32,403    | 44,183    | 5,825     | 9,048     | 11,288    |
| Cost of Sales                               |           | 0         | 0         | 0         | (1,207)   | (2,382)   |
| Gross Profit                                |           | 32,403    | 44,183    | 5,825     | 7,841     | 8,906     |
| R&D Expenses                                |           | (62,649)  | (50,013)  | (50,013)  | (51,013)  | (53,054)  |
| Manufacturing & Commercialisation Expenses  |           | (23,783)  | (29,763)  | (22,025)  | (22,245)  | (22,912)  |
| SG&A Expenses                               |           | (29,636)  | (22,500)  | (17,881)  | (17,820)  | (18,355)  |
| EBITDA                                      |           | (97,977)  | (86,319)  | (81,292)  | (80,320)  | (82,377)  |
| Operating Profit (before amort and except)  |           | (99,001)  | (88,511)  | (83,594)  | (82,737)  | (84,914)  |
| Intangible Amortisation                     |           | 0         | 0         | 0         | 0         | 0         |
| Exceptionals                                |           | 0         | 0         | 0         | 0         | 0         |
| Share-based payments                        |           | 0         | (3,389)   | (2,500)   | (2,500)   | (2,500)   |
| Operating Profit                            |           | (99,001)  | (91,900)  | (86,094)  | (85,237)  | (87,414)  |
| Net Interest                                |           | 2,757     | 1,079     | 1,619     | 1,767     | 101       |
| Profit Before Tax (norm)                    |           | (96,244)  | (87,432)  | (81,975)  | (80,970)  | (84,814)  |
| Profit Before Tax (FRS 3)                   |           | (96,244)  | (90,821)  | (84,475)  | (83,470)  | (87,314)  |
| Tax   |           | 0         | 86,694    | 0         | 0         | 0         |
| Profit After Tax (norm)                     |           | (96,244)  | (738)     | (81,975)  | (80,970)  | (84,814)  |
| Profit After Tax (FRS 3)                    |           | (96,244)  | (4,127)   | (84,475)  | (83,470)  | (87,314)  |
| Average Number of Shares Outstanding (m)    |           | 320.9     | 360.8     | 398.2     | 441.1     | 467.3     |
| EPS - normalised fully diluted (c)          |           | (29.99)   | (0.20)    | (20.59)   | (18.92)   | (19.82)   |
| EPS - normalised (c)                        |           | (29.99)   | (0.20)    | (20.59)   | (18.92)   | (19.82)   |
| EPS - (IFRS) (c)                            |           | (29.99)   | (1.14)    | (21.22)   | (19.50)   | (20.40)   |
| Dividend per share (c)                      |           | 0.0       | 0.0       | 0.0       | 0.0       | 0.0       |
| Gross Margin (%)                            |           | 100.0     | 100.0     | 100.0     | 86.7      | 78.9      |
| EBITDA Margin (%)                           |           | N/A       | N/A       | N/A       | N/A       | N/A       |
| Operating Margin (before GW and except) (%) |           | N/A       | N/A       | N/A       | N/A       | N/A       |
| <b>BALANCE SHEET</b>                        |           |           |           |           |           |           |
| Fixed Assets                                |           | 659,306   | 595,195   | 594,893   | 594,477   | 593,939   |
| Intangible Assets                           |           | 650,241   | 587,823   | 587,823   | 587,823   | 587,823   |
| Tangible Assets                             |           | 4,398     | 3,063     | 2,761     | 2,345     | 1,807     |
| Investments                                 |           | 4,667     | 4,309     | 4,309     | 4,309     | 4,309     |
| Current Assets                              |           | 122,460   | 88,823    | 66,789    | 11,236    | 51,960    |
| Stocks                                      |           | 0         | 0         | 0         | 0         | 0         |
| Debtors                                     |           | 3,972     | 4,054     | 4,054     | 4,054     | 4,054     |
| Cash  |           | 110,701   | 80,937    | 58,903    | 3,350     | 44,074    |
| Other                                       |           | 7,787     | 3,832     | 3,832     | 3,832     | 3,832     |
| Current Liabilities                         |           | (48,407)  | (29,415)  | (29,415)  | (29,415)  | (29,415)  |
| Creditors                                   |           | (43,246)  | (27,155)  | (27,155)  | (27,155)  | (27,155)  |
| Deferred revenue                            |           | (5,161)   | (2,260)   | (2,260)   | (2,260)   | (2,260)   |
| Short term borrowings                       |           | 0         | 0         | 0         | 0         | 0         |
| Long Term Liabilities                       |           | (265,372) | (126,442) | (126,442) | (151,442) | (276,442) |
| Long term borrowings                        |           | 0         | 0         | 0         | (25,000)  | (150,000) |
| Deferred revenue                            |           | (22,505)  | 0         | 0         | 0         | 0         |
| Other long term liabilities                 |           | (242,867) | (126,442) | (126,442) | (126,442) | (126,442) |
| Net Assets                                  |           | 467,987   | 528,161   | 505,826   | 424,856   | 340,042   |
| <b>CASH FLOW</b>                            |           |           |           |           |           |           |
| Operating Cash Flow                         |           | (104,079) | (89,125)  | (81,292)  | (80,320)  | (82,377)  |
| Net Interest                                |           | 3,043     | 1,129     | 1,619     | 1,767     | 101       |
| Tax   |           | 0         | 0         | 0         | 0         | 0         |
| Capex                                       |           | (2,204)   | (922)     | (2,000)   | (2,000)   | (2,000)   |
| Acquisitions/disposals                      |           | 0         | (805)     | 0         | 0         | 0         |
| Financing                                   |           | 45,852    | 62,066    | 59,640    | 0         | 0         |
| Dividends                                   |           | 0         | 0         | 0         | 0         | 0         |
| Other                                       |           | (2,860)   | 0         | 0         | 0         | 0         |
| Net Cash Flow                               |           | (60,248)  | (27,657)  | (22,034)  | (80,553)  | (84,276)  |
| Opening net debt/(cash)                     |           | (185,003) | (110,701) | (80,937)  | (58,903)  | 21,650    |
| HP finance leases initiated                 |           | 0         | 0         | 0         | 0         | 0         |
| Other                                       |           | (14,054)  | (2,107)   | 0         | 0         | 0         |
| Closing net debt/(cash)                     |           | (110,701) | (80,937)  | (58,903)  | 21,650    | 105,926   |

Source: Mesoblast accounts, Edison Investment Research. Note: Mesoblast has changed its reporting currency to US dollars.

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