BELL POTTER

28 February 2019

Speculative
See Key risks on Page 8 & Biotechnology Risk Warning on Page 10
Speculative securities may not be suitable for Retail clients

Analyst
Tanushree Jain 612 8224 2849

Authorisation
TS Lim 612 8224 2810

Mesoblast (MSB)

Phase 3 assets approaching inflexion point

Recommendation
Buy (unchanged)
Price
$1.235
Valuation
$3.97 (previously $4.03)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**221.5%**
Dividend yield	**0.0%**
Total expected return	**221.5%**
Company Data & Ratios	
Enterprise value	**$596.8m**
Market cap	**$615.8m**
Issued capital	**498.63m**
Free float	**70.5%**
Avg. daily val. (52wk)	**$2.30m**
12 month price range	**$1.015- $2.47**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	1.34	1.34	1.58
Absolute (%)	-6.34	-5.99	-20.32
Rel market (%)	-11.27	-14.01	-23.48

1H19 impacted by deferring revenue and higher opex

Underlying Net loss of US$47.7m was higher than BPe of US$34.5m and was impacted by MSB deferring revenue of US$10m from Tasly and higher manufacturing commercialisation expense in preparation for BLA filing for its GvHD product in the US. Pleasingly Temcell royalties grew 43% over pcp. MSB reduced its operating cash flows by 50% in 1H19 vs. pcp. Proforma cash of US$92m provides runway into 4QCY19, with another US$35m available through existing financing agreements. MSB is building a targeted sales force (~12) to launch GvHD in US and in China with Tasly will meet with regulators to clarify path forward for CHF which could include a global trial (China, US and EU sites), designed similarly to the Phase 3 US trial.

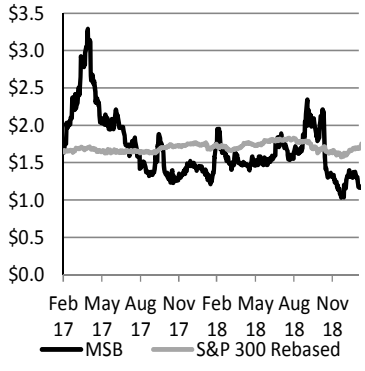
Strong outlook for CY19

With 3 late stage assets approaching key inflexion points and a strong balance sheet, we believe CY19 could be a transformational year for MSB. Key catalysts: a) Initiation of BLA submission for MSC-100-IV for GvHD, following scheduled FDA meeting in April, with potential approval by end CY19; b) FDA meeting in 1HCY19 to discuss an accelerated pathway under the RMAT designation for MPC-150-IM for reducing GI bleeding in LVAD patients with end stage CHF; c) Top line results from MPC-150-IM Phase 3 trial in advanced CHF patients in 1HCY20 (endpoint events to accrue within 12 months) and d) potential interim look from MSB's back pain trial in 2HCY19 (all patients to complete 12 month assessment in 1HCY19). A partnering deal over the next 6-12 months (MSB is focused on CHF or back pain, following completion of enrolment in Phase 3 trials for both) could act as a significant re-rating catalyst.

Retain Buy (spec) with Valuation largely unchanged at $3.97

Following changes to our model, the net result is an increase in our net loss forecasts for FY19, FY20 and FY21 forecasts by 19%, 12% and 7%. FY20 and FY21 revisions were driven by an increase in our opex forecasts. For FY19 it was driven by both reduced revenue (owing to US$10m from Tasly being treated as deferred consideration on balance sheet) and an increase in our opex forecasts. The short term NPAT adjustments were partially offset by rolling forward of our DCF model. Our valuation for MSB is largely unchanged at A$3.97/sh (was A$4.03/sh).

Absolute Price



SOURCE: IRESS

Earnings Forecast

Year end 30th June	2017A	2018A	2019E	2020E	2021E
Sales (US$m)	3.5	18.8	15.8	69.1	40.2
EBITDA (US$m)	-87.5	-71.9	-92.8	-42.5	-76.7
NPAT (reported) (US$m)	-76.8	-35.3	-102.8	-54.5	-89.0
NPAT (adjusted) (US$m)	-90.2	-66.0	-106.4	-54.5	-89.0
EPS (reported) (cps)	-19.2	-7.6	-21.0	-10.9	-17.1
EPS (adjusted) (cps)	-22.6	-14.2	-21.7	-10.9	-17.1
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
PER (x)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA (x)	-4.9	-5.9	-4.6	-10.0	-5.6
Dividend (¢ps)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
ROE (%)	-17.5%	-12.1%	-22.6%	-12.8%	-19.5%

Note: Revenue includes R&D tax incentive, commercial milestone and royalty revenue from launch of TEMCELL GvHD product in Japan, revenue from launch of GvHD and CHF in US and potential upfront and milestone from CLBP deal.SOURCE: BELL POTTER SECURITIES ESTIMATES

1H19 – Results Summary

A summary of the reported 1H19 result is shown in the Table below:

Table 1 – 1H19 result summary

	Result vs PCP			Result vs Forecast		Comments
	1H18A	1H19A	% change	1H19E	Variance (%)	
Revenues	**15.3**	**13.2**	-14%	**23.2**	**-43%**	Revenue lower by $10m. This is related to treatment of $10m from Tasly upfront as deferred consideration vs. us recognising it as milestone revenue
R&D including manufacturing commercialization	32.5	42.9	32%	40.0	7%	Higher than our forecast due to higher manufacturing commercialisation expense
G&A	10.2	10.4	3%	11.2	-7%	G&A lower than expected
Operating costs	42.7	53.3	25%	51.2	4%	Opex higher than our forecast with higher manufacturing commercialisation expense partially offset by lower G&A
EBITDA	**-27.4**	**-40.1**	**46%**	**-28.3**	**42%**	EBITDA loss higher than forecast driven by lower revenue and higher opex
Depreciation and Amortisation	-1.2	-1.1	-11%	-1.2	-10%	D&A lower than forecast due to lower depreciation
EBIT	**-28.6**	**-41.2**	**44%**	**-29.5**	**40%**	Higher EBIT loss with variance reduced from EBITDA due to lower D&A
Net Interest Income/(expense)	0.2	-4.9	NM	-4.2	14%	Higher interest expense than forecast
Other Income/(expense)	8.9	-1.6	NM	-0.8	109%	Higher non-cash expense. Includes Fx loss of $0.2m, $0.1m of foreign withholding tax, $0.8m loss on remeasurement of borrowing arrangements and ~$0.6m loss related to remeasurement of contingent consideration payable to Osiris
Pretax Income (Loss)	-19.6	-47.7	144%	-34.5	38%	
Net Income (Loss) after tax - normalised	**-19.6**	**-47.7**	**144%**	**-34.5**	**38%**	Higher than expected loss with variance increasing from EBIT due to higher interest expense and non cash other expense adjustments
Diluted EPS/Share (cps)	**-4.27**	**-9.82**	**130%**	**-7.03**	**40%**	
Abnormal items	*26.2*	*3.6*	-86%	*-0.7*	*NM*	*Relates to non-cash income tax benefit related to net change in recognised deferred tax asset and liabilities*
Reported Net Income (Loss) after tax	*6.7*	*-44.1*	-760%	*-35.2*	*25%*	*Higher reported net loss than forecast, with variance reducing from normalised NPAT due to non-cash tax benefit*
Diluted Reported EPS (cps)	***1.46***	***-9.08***	***-723%***	***-7.18***	***27%***	

ALL AMOUNTS IN USD EXCEPT EPS. SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Key result highlights

- **Revenue lower by US$10m:** Revenue (including commercialization revenue and R&D tax incentive) of US$13.2m (down 14% over pcp) was US$10m lower than our forecast (BPe US$23.2m) and was driven by the difference in treatment of the upfront payment received from Tasly. We recorded the entire US$20m as revenue, whereas MSB has recorded US$10m of it as deferred consideration on the balance sheet. The variance from pcp was due to lower milestone revenue (US$11.8m received from Takeda/Tigenix in pcp vs. US$10m in 1H19 from Tasly) and R&D tax incentive (nil vs. US$0.9m in pcp), partially offset by higher royalty revenue from Temcell (GvHD product partnered with JCR for Japan) which grew 43% over pcp (US$2.2m vs. US$1.6m in pcp).
- **Operating costs were higher than expected:** Opex (including R&D plus manufacturing commercialization expenses and G&A) of US$53.3m (up 25% y/y) were ~4% higher than our forecast (BPe US$51.2m), driven primarily by higher manufacturing commercialisation expense, partially offset by lower G&A. Manufacturing commercialization expense increased by US$8m over pcp due to an increase in process validation activities required ahead of the BLA filing of MSC-100-IV for steroid refractory GvHD in children to the US FDA. We expect manufacturing expense will increase moving forward as MSB gets closer to commercial launch of its GvHD product and undertakes further manufacturing readiness and inventory build-up activities. R&D costs were higher over pcp primarily due to increased clinical cost related to MSB's Tier 1 products and increased salaries driven by an increase in headcount (46.6 FTE down from 43.4 in 1H18), partially offset by a US$1.2m decrease in share based payment expense. G&A costs were mostly flat over pcp (+3% over pcp).
- **Lower than expected D&A:** D&A was US$1.1m (down 11% over pcp) and 10% below our forecast (BPe US$1.2m) as a result of lower depreciation expense. Amortisation expense was in-line with our forecasts.

- **EBIT loss higher than our forecast:** EBIT loss of US$41.2m (up 44% over pcp) was 40% higher than our forecast of US$29.5m, driven primarily by lower revenue (US$10m deferred from Tasly) and higher opex, partially offset by lower depreciation.
- **Higher interest and other expense:** Interest expense was higher than our forecast. Non-cash other expense was also higher than our forecast. It consisted of non-cash Fx loss of US$0.2m, US$0.1m of foreign withholding tax, US$0.8m loss on re-measurement of NovaQuest borrowing arrangements and a loss of US$0.6m related to re-measurement of contingent consideration payable to Osiris (vs. the gain reported for pcp).
- **Underlying Net loss and reported net loss higher than our forecasts:** Underlying Net loss of US$47.7m (up 144% y/y) was higher than our forecast of US$34.5m. In absolute terms the variance from our numbers was higher than the EBIT line, due to non-cash adjustments. The variance in reported net loss of US$44.1m and our numbers (BPe net loss of US$35.2m), reduced due to non-cash income tax benefit of US$3.6m related to net change in recognised deferred tax asset and liabilities.
- **Cash at end of 1H19 provides runway into 4QCY19:** MSB reported cash of US$77.0m, slightly below our forecasts (BPe US$78.1m). The company reduced its net operating cash flows by 50% or US$17.7m in 1H19 vs. pcp. This was driven by increased inflows from milestones from Tasly and higher revenue from Temcell, partially offset by an increase of US$5.4m in payments to suppliers and employees.

  Its current cash position on a proforma basis is US$92.0m (US$77.0m end of 1HFY19 and US$15m additional drawdown from Hercules Capital in Jan'19). We estimate that MSB has cash runway into 4QCY19. It also has access to another US$35m through existing financing agreements.

  MSB also has the ability to raise up to US$90m through the Kentgrove equity financing facility, for the next 6 months.

Earnings and Valuation Changes

We have revisited our assumptions for Mesoblast and made adjustments to our forecasts based on the 1H19 results and comments from the management on the investor call, which have impacted earnings and valuation.

Key assumption changes

- In 1H19, MSB recorded US$10m upfront from Tasly as milestone revenue and the balance US$10m as a deferred consideration on the balance sheet. MSB expects to recognise the deferred consideration in revenue when and if control transfers to Tasly related to this portion of their agreement. We had initially recorded the entire US$20m as FY19 revenue, and therefore have now reduced our FY19 revenue forecasts by US$10m. We have also recorded US$10m as deferred consideration on the balance sheet for FY19 and onwards.
- We have modestly increased our royalty revenue estimate from JCR for FY19 (US$4.8m vs. US$4.6m earlier). Our forward forecasts remain unchanged.
- We have increased our manufacturing commercialisation expense forecast for FY19-FY21 by ~US$6.5m and reduced our G&A forecasts for FY19-20 by ~3-6%.
- We have incorporated the US$3.6m deferred tax benefit in our FY19 numbers.
- We have also reduced our depreciation forward forecasts based on 1H19 numbers.
- We have reduced our capex forecasts for FY19-FY21 based on the lower than expected spend in 1H19.
- We have increased the interest rate on the Hercules Loan to 10.45%, which has led to an increase in our interest expense forecasts.
- Other changes in working capital include an increase in payables, offset by an increase in prepayments.
- We have updated our model with revised BPe USD/AUD currency assumptions for FY19 to 0.732 (was 0.75)
- We have rolled forward our DCF model.

Following the above changes, the net result is an increase in our net loss forecasts for FY19, FY20 and FY21 forecasts by 19%, 12% and 7%. FY20 and FY21 revisions were driven by an increase in our opex forecasts. For FY19 revision was driven by both reduced revenue (owing to US$10m from Tasly being treated as deferred consideration on balance sheet) and an increase in our opex forecasts. The short term NPAT adjustments were partially offset by rolling forward of our DCF model. Our valuation for MSB is largely unchanged at A$3.97/sh (was A$4.03/sh). **We retain our Buy (speculative) recommendation.**

Table 2 - Key Changes to our last published FY19-21 Forecasts

	FY2019E			FY2020E			FY2021E		
	Old	New	Change (%)	Old	New	Change (%)	Old	New	Change (%)
Revenues	25.6	15.8	-38%	69.1	69.1	0%	40.2	40.2	0%
Interest Income	0.3	0.5	49%	0.3	0.3	-17%	0.2	0.2	-13%
Interest Expense	-8.8	-10.0	13%	-9.8	-9.8	0%	-10.2	-10.0	-2%
Opex	102.8	107.9	5%	104.2	109.9	5%	105.5	111.9	6%
EBITDA	-77.9	-92.8	19%	-36.8	-42.5	15%	-70.3	-76.7	9%
EBIT	-80.3	-95.3	19%	-39.3	-45.0	14%	-72.8	-79.1	9%
NPAT (adjusted)	-89.6	-106.4	19%	-48.9	-54.5	12%	-82.8	-89.0	7%
Adjusted Diluted EPS (cents)	-18.3	-21.7	19%	-9.8	-10.9	12%	-16.0	-17.1	7%

ALL AMOUNTS IN USD IN MILLIONS EXCEPT EPS. SOURCE: BELL POTTER SECURITIES ESTIMATES

Our DCF valuation model is based on a WACC of 21% and a terminal growth rate of 1%.

Table 3 - Summary of Revised Valuation

Forecasts	Base case (US$m)	Base case (A$m)
Enterprise Value from DCF	1594.1	2061.8
Add: Cash at end 1HFY19	77.0	105.2
Add: additional drawdown from Hercules	15.0	20.5
Less: Debt (including US$15m Hercules drawdown)	-78.5	-107.2
Equity Value	1607.6	2080.3
Total diluted shares (million)	524.1	524.1
Value per share (US$/A$)	**$3.07**	**$3.97**
Current Share price (A$)		$1.24
Expected Capital Growth		221.5%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Table 4 - MSB- Probability-Weighted Sum-of parts Valuation Summary

Asset	Identifier	Stage	Partnering Status	First Fiscal Year of sales (Est.)	Peak Market share	Peak Sales Global (US$m)	Probability of success	Probability adjusted NPV (US$m)	Value per share (US$)	% Mix
SR Acute GvHD (Japan)	TEMCELL	Approved	JCR Pharma	2016	50.0%	$79	100.0%	$42	**$0.08**	2.6%
Steroid Refractory Acute GvHD (Pediatric) -Ex-Japan	MSC-100-IV	Phase III	Will launch directly in US. Not likely to partner	2020 (US); 2021 (ROW)	50.0%	$224	85% (US), (54% ROW)	$148	**$0.28**	9.2%
Revascor - End Stage CHF with LVAD (US)	MPC-150-IM	Phase IIb	NIH Funding Trial, will look to partner	2021	85.0%	$350	33.0%	$30	**$0.06**	1.9%
Chronic Discogenic lower back pain (CLDBP)	MPC-06-ID	Phase III	In negotiations with potential partners	2023	10.0%	$4,362	44.0%	$394	**$0.75**	24.5%
Revascor - Congestive Heart Failure (CHF)	MPC-150-IM	Phase III	Will look to partner	2022	15.0%	$7,375	60.0%	$1,048	**$2.00**	65.2%
Diabetic Nephropathy	MPC-300-IV	Phase II	Will look to partner	2024	10.0%	$1,378	14.5%	$55	**$0.11**	3.4%
Rheumatoid Arthritis (RA)	MPC-300-IV	Phase II	Will look to partner	2024	10.0%	$1,597	20.0%	$139	**$0.27**	8.7%
Other Pipeline/Non-allocated		NA	NA	NA	NA	NA	NA	($262)	**-$0.50**	-16.3%
Cash		NA	NA	NA	NA	NA	NA	$92	**$0.18**	5.7%
Debt		NA	NA	NA	NA	NA	NA	($78)	**-$0.15**	-4.9%
Equity Value								**$1,608**	**$3.07**	**100%**

ALL ASSETS ABOVE SHADED IN GREY ARE TIER 1 PRODUCTS AND THE KEY FOCUS FOR MSB. GLOBAL PEAK SALES ARE PRE-RISK ADJUSTMENT AND ROYALTIES.

SOURCE: BELL POTTER SECURITIES ESTIMATES

Upside risk to our valuation

- Under the Tasly deal on MSB's cardiovascular products for China, MSB also stands to receive US$25 million on each achievement of product regulatory approvals in China for both MPC-150-IM and MPC-25-IC, double-digit escalating royalties on net product sales and six additional undisclosed escalating milestone payments upon the product candidates reaching certain sales thresholds. At this stage we do not model royalties or the US$50m in product approval milestones or the undisclosed 6 sales milestones attached to the deal. We intend to model royalties and approval and sales milestones once we get greater clarity on the timelines and regulatory path forward for China, which represents a potential upside to our estimates.
- At this stage we only model MSC-100-IV for Steroid refractory acute GvHD in children for both US and EU. We do not include any value for the MSC-100-IV for the expanded indication into high risk adults (those with gut and liver involvement). It is MSB's intention to pursue a trial in this high risk adult GvHD population in the future to expand the label for MSC-100-IV. We also do not include any value at this stage for potential off-label usage in adults following the approval of the product for children. We also expect the FDA would require commitment from MSB to run a trial in the adults' population given the potential for off label use as a condition for marketing approval in the paediatric indication. Once MSB initiates clinical trials in the high risk adult population, it would be a source of considerable upside to our valuation, given the adult opportunity is expected to be 3x times that of the paediatric opportunity.
- MSB has recently expanded its relationship with partner JCR pharmaceuticals in Japan for Temcell to include now a second indication for wound healing in patients with Epidermolysis Bullosa (EB). EB is an orphan disease for which JCR has already

obtained an orphan drug designation for Temcell in Japan. JCR intends to pursue label expansion for Temcell by obtaining approval for EB in future (Temcell is already approved and marketed for GvHD in Japan). MSB is eligible to receive undisclosed royalties on sales of Temcell for EB in Japan. They could also potentially use all data generated in Japan to pursue the EB indication for MSC-100-IV in other markets including US. At this stage we include no value from EB for Temcell in Japan or in other markets and hence this opportunity represents a source of upside to our valuation in future.

- Under MSB's December 2017 patent license agreement with Tigenix (now a wholly owned subsidiary of Takeda), apart from the initial €10m that we modelled, MSB also stands to receive an additional €10.0m when Takeda reaches certain product regulatory milestones and single digit royalties on net sales of Alofisel. Alofisel was approved in Europe in March 2018 for the treatment of complex perianal fistulas in adult patients with nonactive/mildly active luminal Crohn's disease, when fistulas have shown an inadequate response to at least one conventional or biologic therapy. We understand Takeda is currently involved with the NICE and other regulatory authorities on pricing and reimbursement for the product and in the meanwhile in the last few months of CY18, has been allowing access to the product under an EAP (expanded access program). A US launch is expected for the product subject to trial results in 2021. As per EvaluatePharma in 2024, worldwide consensus sales for Alofisel are forecast to reach US$521 million. At this stage we do not model the regulatory milestones (€10.0m) or royalties from Alofisel, which represents a potential upside to our valuation.

Key Near-term Catalysts

- **BLA filing for paediatric GvHD for MSC-100-IV in 1HCY19-** MSB plans to file the BLA for use of MSC-100-IV to treat children with steroid refractory aGvHD in 1HCY19, following their pre-BLA scheduled meeting with the FDA in April. This follows on from its two successful end-of Phase 3 meetings, in which MSB gained agreement from the FDA on its proposed chemistry and manufacturing. FDA has also provided guidance to MSB on the manner of presenting its clinical data from the recently completed Phase 3 trial and the Expanded Access program under which the product has been available for compassionate use. Recall, MSC-100-IV successfully met its Day 28 primary endpoint showing improved overall response (69% vs. 45% historical controls, p=0.0003) and continued to show safety and improved overall survival at both Day 100 (75%, with 87% survival in Day 28 responders) and Day 180 (Overall Survival 69%, with 79% survival in Day 28 responders) in the recently completed Phase 3 paediatric GvHD trial in the US. It has a Fast Track designation which will allow for rolling submission as well as priority review. We expect approval by end CY19. MSB will be launching this product commercially in the US itself by establishing a small sales force (~12 sales reps).
- **FDA meeting to discuss potential BLA filing under RMAT designation for MPC-150-IM in end stage Heart Failure patients requiring LVAD:** MSB intends to meet with the FDA to provide full study data from recently completed Phase 2B trial and discuss potential pathway for approval for MPC-150-IM (Revascor) for reduction of GI bleeding in LVAD patients with end stage heart failure in 1HCY19. We note that the trial successfully achieved the FDA identified clinically meaningful and approvable endpoint of reduction in incidence of GI bleeding and related hospitalisation, a serious and common complication of LVAD with high morbidity associated with it. We note that the product has an RMAT (Regenerative Medicine Advanced Therapy) designation.
- **Potential global partnering deal for MSB's congestive heart failure product in CY19:** Enrollment has now been completed in MSB's Phase 3 congestive heart failure (CHF) trial with Revascor (MPC-150-IM). The double-blind, placebo controlled trial has enrolled 566 moderate to advanced CHF patients (class II/III), across 55 sites in North America. Although Top-line results from this events driven trial (with 12 months follow up) are not expected till end CY19/early CY20, we believe the completion of enrollment will now assist MSB in its ongoing partnering negotiations for the product. A partnering deal over the next 12 months could act as a significant re-rating catalyst for the stock.
- **Increase in royalties from TEMCELL in Japan:** JCR Pharmaceuticals launched its acute Graft versus Host Disease (GvHD) product TEMCELL on 24th Feb' 16. MSB has received in 4QCY15 US$3.5m in pre-commercial milestones triggered by the approval of TEMCELL. Under the deal sales milestones (BPe ~US$3m) as well as royalties in the mid 20% range are also payable by JCR. MSB recorded US$1.4m in royalty revenues and sales milestone revenue of US$0.5m in FY17. Royalties increased by 152% in FY18 to US$3.6m and MSB also received another US$1.5m sales milestone. MSB also received another US$1m sales milestone in 1HFY19, while royalty in 1HFY19 grew 43% over pcp. We assume that at peak penetration (peak sales of US$79m); MSB will receive ~US$20m in annual royalty revenues from TEMCELL.
- **Potential global or regional partnering deal for MSB's chronic discogenic lower back pain (CLBP) product in FY20:** MSB is in active discussions with several potential strategic partners for its CLBP product. The company finished enrolment in the first Phase 3 trial for this product in 1QCY18. There is possibility to get an interim look in 2HCY19 as all patients would have finished their 12 month assessment for safety and efficacy in 1HCY19. We assume that a deal for CLBP is inked in 1HFY20 and model a US$60m upfront in our forecasts.

Mesoblast (ASX: MSB, NASDAQ:MESO)

MSB has 3 late stage Tier 1 products

COMPANY DESCRIPTION

The Melbourne-based Mesoblast (MSB) is a biotechnology company commercialising the therapeutic use of mesenchymal lineage cells (MPCs and MSCs) – a kind of adult stem cell. MSB's MPC technology allows these cells to be extracted from the bone marrow of donors, grown into therapeutic quantities and administered 'allogeneically' – ie, to patients that are not related to the donor. It has one of the most diversified pipelines, with 3 Tier 1 products in late stage. The first commercial for GvHD launched in Japan in 1QCY16. Substantial shareholders include CEO Silviu Itescu, M&G, Thorney and Capital Group.

INVESTMENT STRATEGY

MSB is the leading allogeneic stem cell player with several late-stage clinical assets in multiple therapeutic indications. We expect progress of the Tier 1 products towards commercial launch and monetisation to be the key value driver for MSB. In recent months MSB has organised non-dilutive financing both through debt facility agreements and its strategic licensing agreement with Tasly for China. It has also completed enrolment in 2 phase 3 trials (back pain and CHF) and reported clinically meaningful results from a Phase 2b trial in end stage CHF patients with LVAD. The company has ~9 months of cash runway. MSB's strengthened balance sheet allows it to focus on its BLA submission for its GvHD product in children in 1HCY19, which could become the first allogeneic stem cell product to be approved in the US (BPe end CY19). MSB will also meet with the FDA for the MPC-150-IM product in LVAD patients with end stage CHF in 1HCY19 to discuss an accelerated pathway under the RMAT designation. The company's first marketed product Temcell for GvHD in Japan is also doing well, with both royalties and sales milestones increasing in 1HFY19. A partnership deal in 2019 for the back pain or CHF products could result in substantial cash injection, extend MSB's cash runway and trigger a re-rating.

KEY RISKS

We see the following key stock specific risks to our investment thesis on Mesoblast:

- **Clinical risk:** There is a risk that MSB's clinical trials fail to reach their endpoints. Failure of a Phase III trial may significantly impact markets confidence on Mesoblast's technology and in case of an un-partnered product will reduce its partnering prospects.
- **Commercialisation risk:** MSB needs a partner to undertake commercialization for its pipeline products. The ability of MSB's products to finally reach the market will depend on them doing a partnering deal. We currently assume the back pain asset is partnered in FY20. Delays or failure in attracting a suitable partner at terms as we have postulated will negatively impact our forecasts.
- **Manufacturing risk:** The key success of Mesoblast's business model is dependent on its ability to manufacture its stem cells on commercial scale as well as at a cost-effective price. Mesoblast has partnered with Lonza to manufacture its stem cells. Our underlying assumption is that together the companies will be able to drive down the COGS by driving efficiencies in the manufacturing process. Failure to cost-effectively manufacture would impact our valuation.
- **Regulatory risk:** Successful commercialisation of MSB's products is ultimately dependent on getting approval from the regulatory authorities to commercially launch the product. Failure to satisfy regulatory requirements could mean that the product will fail to reach the market.
- **Funding risk:** MSB has cash runway into 4QCY19, with further extension expected through additional drawdown on its existing debt facilities and partnering deals. Failure to attract a partner is likely to impact MSB's ability to service its debt and would require MSB to raise additional capital. There is no guarantee that such funds will be available or at suitable terms.

Mesoblast
as at 28 February 2019

Recommendation	Buy, Speculative
Price	$1.235
Valuation	$3.97

Table 5 - Financial summary

Mesoblast (MSB) — **Share price (A$)** **$1.235**
As at 28 February 2019 — **Market cap (A$m)** **615.8**

Profit and Loss

Y/e June 30 (US$m)	2017A	2018A	2019E	2020E	2021E
Revenue	3.5	18.8	15.8	69.1	40.2
Gross profit (loss)	3.5	18.8	15.0	67.3	35.2
Total Operating costs	-90.9	-90.7	-107.9	-109.9	-111.9
EBITDA	**-87.5**	**-71.9**	**-92.8**	**-42.5**	**-76.7**
Depreciation & Amortisation	-3.1	-2.7	-2.4	-2.5	-2.5
EBIT	**-90.5**	**-74.6**	**-95.3**	**-45.0**	**-79.1**
Net interest & Other Income/(expense)	0.3	8.6	-11.1	-9.5	-9.8
Pre-tax profit (loss)	-90.2	-66.0	-106.4	-54.5	-89.0
Tax	0.0	0.0	0.0	0.0	0.0
Adjusted Net Profit (Loss)	-90.2	-66.0	-106.4	-54.5	-89.0
Less minority interests	0.0	0.0	0.0	0.0	0.0
Net profit (loss) to shareholders	**-90.2**	**-66.0**	**-106.4**	**-54.5**	**-89.0**
Reported net profit (loss) to shareholders	-76.8	-35.3	-102.8	-54.5	-89.0

Cashflow

Y/e June 30 (US$m)	2017A	2018A	2019E	2020E	2021E
Reported NPAT	-76.8	-35.3	-102.8	-54.5	-89.0
Non-cash items	-4.9	-30.8	16.1	8.4	8.4
Working capital	-13.8	-8.9	12.5	-3.2	-4.9
Other operating cash flow	0.0	0.0	0.0	0.0	0.0
Operating cashflow	**-95.5**	**-75.0**	**-74.2**	**-49.3**	**-85.5**
Capex	-0.3	-0.2	-0.4	-0.4	-0.4
Investments	0.0	0.0	0.0	0.0	0.0
Other investing cash flow	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**-0.3**	**-0.2**	**-0.4**	**-0.4**	**-0.4**
Change in borrowings	0.0	31.3	42.4	35.0	-36.2
Equity issued	60.0	37.3	29.1	3.4	114.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other financing cash flow	0.0	0.0	0.0	0.0	0.0
Financing cashflow	**60.0**	**68.6**	**71.5**	**38.4**	**77.8**
Net change in cash	**-35.8**	**-6.6**	**-3.1**	**-11.3**	**-8.0**
Cash at end of period*	45.8	37.8	34.5	23.2	15.2
* Includes effect of exchange rate fluctuations on cash balance					
Free cash flow	**-95.8**	**-75.2**	**-74.6**	**-49.7**	**-85.9**

Balance sheet

Y/e June 30 (US$m)	2017A	2018A	2019E	2020E	2021E
Cash	45.8	37.8	34.5	23.2	15.2
Current receivables	3.7	50.4	4.7	5.3	6.3
Inventories	0.0	0.0	0.0	0.6	1.6
Other current assets	14.1	12.9	16.8	16.8	16.8
Current assets	**63.6**	**101.1**	**56.1**	**46.0**	**39.9**
PPE	1.8	1.1	0.8	0.5	0.1
Non-current receivables	0.0	0.0	0.0	0.0	0.0
Intangible assets	586.4	584.6	582.9	581.1	579.4
Other non-current assets	3.9	5.7	5.8	5.8	5.8
Non-current assets	**592.1**	**591.4**	**589.5**	**587.4**	**585.4**
Total assets	**655.7**	**692.4**	**645.6**	**633.4**	**625.2**
Payables	21.8	18.9	21.1	19.1	16.1
Debt	0.0	59.4	78.5	113.5	77.3
Provisions	67.8	48.0	48.7	48.7	48.7
Other liabilities	49.3	20.1	26.5	26.5	26.5
Total liabilities	**138.9**	**146.4**	**174.8**	**207.8**	**168.6**
Shareholders' equity	516.8	546.0	470.8	425.6	456.6
Minorities	0.0	0.0	0.0	0.0	0.0
Total shareholders funds	**516.8**	**546.0**	**470.8**	**425.6**	**456.6**
Total funds employed	**655.7**	**692.4**	**645.6**	**633.4**	**625.2**
W/A shares on issue	399.0	465.7	490.6	499.5	520.4

Valuation data

Y/e June 30	2017A	2018A	2019E	2020E	2021E
Net profit (US$m)	-90.2	-66.0	-106.4	-54.5	-89.0
adjusted EPS (c)	-22.6	-14.2	-21.7	-10.9	-17.1
EPS growth (%)	N/A	N/A	N/A	N/A	N/A
P/E ratio (x)	N/A	N/A	N/A	N/A	N/A
CFPS (c)	-23.9	-16.1	-15.1	-9.9	-16.4
Price/CF (x)	-5.2	-7.7	-8.2	-12.5	-7.5
DPS (c)	0.0	0.0	0.0	0.0	0.0
Yield (%)	0.0%	0.0%	0.0%	0.0%	0.0%
Franking (%)	N/A	N/A	N/A	N/A	N/A
EV/EBITDA	-4.9	-5.9	-4.6	-10.0	-5.6
EV/EBIT	-4.7	-5.7	-4.5	-9.5	-5.4

Share price now (A$)	$1.24
Valuation: (A$)	$3.97
Premium (discount) to price	221.5%
Recommendation:	Buy
Risk Rating	Speculative

Profitability ratios

Y/e June 30	2017A	2018A	2019E	2020E	2021E
EBITDA/revenue (%)	N/A	N/A	N/A	N/A	N/A
EBIT/revenue (%)	N/A	N/A	N/A	N/A	N/A
Return on assets (%)	-13.8%	-9.5%	-16.5%	-8.6%	-14.2%
Return on equity (%)	-17.5%	-12.1%	-22.6%	-12.8%	-19.5%
Return on funds empl'd (%)	-17.5%	-10.9%	-19.4%	-10.1%	-16.7%
Dividend cover (x)	N/A	N/A	N/A	N/A	N/A
Effective tax rate (%)	0.0%	0.0%	0.0%	0.0%	0.0%

Liquidity and leverage ratios

Y/e June 30	2017A	2018A	2019E	2020E	2021E
Net cash (debt) (US$m)	45.8	-21.6	-43.9	-90.3	-62.1
Net debt/equity (%)	N/A	-4.0%	-9.3%	-21.2%	-13.6%
Net interest cover (x)	N/A	N/A	N/A	N/A	N/A
Current ratio (x)	1.7	4.2	1.7	0.8	0.7

Interims

Y/e June 30 (US$m)	2H17A	1H18A	2H18A	1H19A	2H19E
Revenue	2.0	15.3	3.5	13.2	2.6
EBITDA	-44.0	-27.4	-44.5	-40.1	-52.7
Depreciation & Amortisation	-1.5	-1.2	-1.4	-1.1	-1.3
EBIT	-45.5	-28.6	-45.9	-41.2	-54.0
Net interest & Other Income/(expense)	1.4	9.1	-0.5	-6.5	-4.6
Pre-tax profit (loss)	-44.1	-19.6	-46.4	-47.7	-58.7
Tax	0.0	0.0	0.0	0.0	0.0
Adjusted Net Profit (loss)	-44.1	-19.6	-46.4	-47.7	-58.7
Less minority interests	0.0	0.0	0.0	0.0	0.0
Net profit (loss) to shareholders	-44.1	-19.6	-46.4	-47.7	-58.7
Reported net profit (loss) to shareholders	-37.0	6.7	-42.0	-44.1	-58.7

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

Research Team

Staff Member	Title/Sector	Phone	@bellpotter.com.au
TS Lim	Head of Research	612 8224 2810	tslim
Industrials			
Sam Haddad	Industrials	612 8224 2819	shaddad
Chris Savage	Industrials	612 8224 2835	csavage
Jonathan Snape	Industrials	613 9235 1601	jsnape
John Hester	Healthcare	612 8224 2871	jhester
Tanushree Jain	Healthcare/Biotech	612 8224 2849	tnjain
Financials			
TS Lim	Banks/Regionals	612 8224 2810	tslim
Lafitani Sotiriou	Diversified Financials/Fintech	613 9235 1668	lsotiriou
Resources			
Peter Arden	Resources	613 9235 1833	parden
David Coates	Resources	612 8224 2887	dcoates
Stuart Howe	Resources	613 9235 1856	showe
Analysts			
James Filius	Analyst	613 9235 1612	jfilius
Alexander McLean	Analyst	612 8224 2886	amclean
Damien Williamson	Analyst	613 9235 1958	dwilliamson

Bell Potter Securities Limited
ABN 25 006 390 7721
Level 38, Aurora Place
88 Phillip Street, Sydney 2000
Telephone +61 2 9255 7200
www.bellpotter.com.au