



Will it beat the FDA?

Company/ASX Code	Mesoblast
AGM date	24th November 2020
Time and location	11:00am - Virtually through https://agmlive.link/MSB20
Registry	LINK Market Services
Webcast	Yes
Poll or show of hands	Poll on all items
Monitor	Stewart Burn assisted by Steve van Emmerik
Pre AGM Meeting?	Yes - with Director Donal O'Dwyer and Secretary Charlie Harrison

Stewart Burn (or their associates) involved in the preparation of this voting intention has a shareholding in this company.

Item 1	Consideration of accounts and reports
ASA Vote	No vote required

Summary of ASA Position

Mesoblast is a stem cell development company listed on the ASX in 2004 and on the NASDAQ in 2015, which has developed mesenchymal lineage cells for the treatment of severe inflammation. Mesenchymal lineage cells have the ability to be activated and then counter severe inflammation at various disease sites in the body. Unlike stem cells taken from individuals for their own treatment these ones are suitable for all, providing a major advantage in scale-up.

Mesoblast is developing Remestemcel products to address the issues of acute graft versus host disease (aGVHD), Acute Respiratory Distress Syndrome (ARDS), Crohn's disease and more recently COVID-19. Its also developing Rexlemestocel products for the treatment of heart failure and lower back pain.

The relationship with JCR pharmaceuticals in Japan for its commercial steroid refractory product "TEMCELL" continues to grow, with sales increasing 32% from US\$5.0m to US\$6.6m. TEMCELL is an aGVHD product which counters the after-effects of transplants where the body's antibodies reject the 'invading' graft.

The agreement with Tasly Pharmaceutical group, continues with a US\$10.0 million milestone payment received for the development, and manufacture of MPC-150-IM and MPC-25-IC for the treatment of advanced heart failure.

In 2017, Mesoblast granted TiGenix, now a wholly owned subsidiary of Takeda, exclusive access to certain of its patents to support global commercialization of Alofisel®, previously known as Cx601, the first allogeneic MSC therapy to receive central marketing authorization approval from the European Commission. Mesoblast receives royalty income on Takeda's worldwide sales of

Alofisel® in the local treatment of perianal fistulae, to date sales of this product have not been significant.

In September it entered a strategic relationship with Grunenthal for the development and commercialisation in Europe and Latin America, of MPC-06-ID an allogeneic cell therapy (allogenic, meaning not derived from a single genetic source donor) for chronic low back pain associated with degenerative disc disease. This agreement resulted in an upfront payment of US\$15m and if successful will lead to a significant income stream

In October Mesoblast entered into an agreement with LONZA for the commercial manufacture of RYONCIL (remestemcel-L) for pediatric steroid-refractory acute graft versus host disease ahead of the planned USA market launch of RYONCIL.

The original indication for which remestemcel-L was developed, pediatric steroid-refractory acute graft versus host disease (SR-aGVHD), has a shared mechanism of action with COVID-19 ARDS. Consequently, in April, a Phase 3 randomized, placebo-controlled trial was initiated to confirm whether remestemcel-L provides a survival benefit in patients with moderate/severe ARDS due to COVID-19 commenced with enrolment of up to 300 patients. This followed a study at Mt Sinai hospital where 75% of patients came off ventilators within 10 days of treatment. To date RYONCIL for steroid-refractory acute graft versus host disease (SR-aGVHD) has not been approved by the United States Food and Drug Administration (USFDA), although the Oncologic Drugs Advisory Committee (ODAC) voted overwhelmingly in favour that available data support the efficacy of RYONCIL

Mesoblast continues to burn cash, spending US\$56m in operating this year, although with the recent capital raisings of US\$137m it has enough funds left to sustain about 1.4 more years. After that, it may need to raise funds into the future to meet its projected spend rate, we have raised the issue of retail shareholder dilution with the company and how these shareholders were loyal in its early stage and should be considered in any future raisings, but so far our requests have not been fruitful, despite the company saying it will address this at the last AGM. Mesoblast also pays its chairman at a higher rate than comparable companies, however not as excessively as it did in 2019, due to the significant increase in market capitalisation. It has also changed its policy with regards to rewarding its CEO and directors with free options, which is counter to ASA recommended practices, now valuing them at the 5 day VWAP prior to issue.

Mesoblast now has one female director who was appointed in July 2018, this is still less than that suggested by the ASA, this was raised at last year's AGM. The reasonable response is that the pool of women with direct pre-commercialisation experience in new pharma in the USA is rather shallow. We will continue to raise this as an issue.

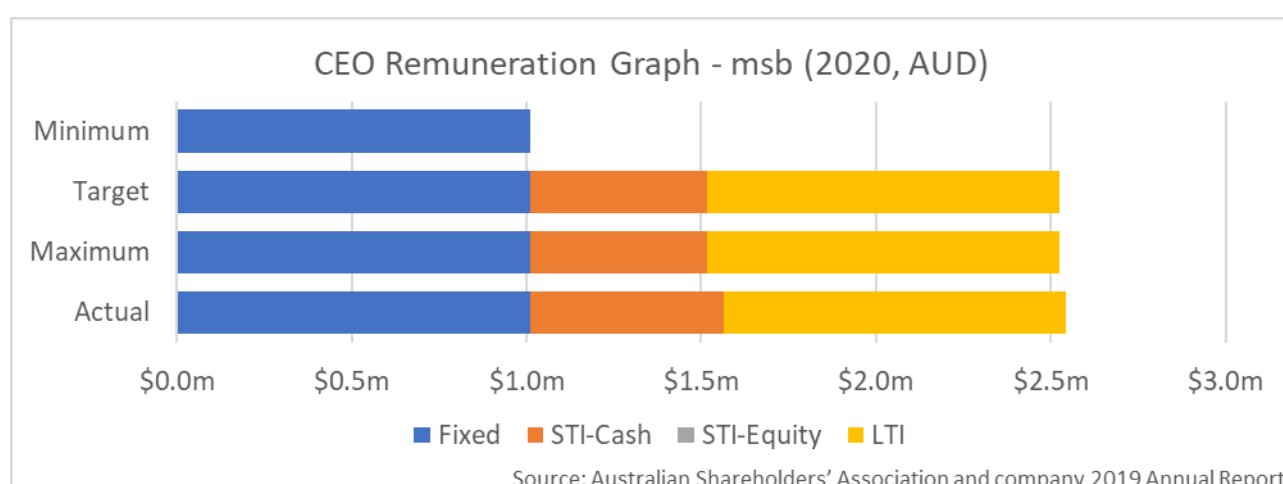
(As at FYE)	2020	2019	2018	2017	2016	2015
NPAT (\$m)	-126	-128	-48	-100	-78	-119
UPAT (\$m)	-113	-128	-48	-100	-5.6	-119
Share price (\$)	3.25	1.48	1.48	2.08	1.08	3.75
Dividend (cents)	0	0	0	0	0	0
TSR (%)	120	0	-28	92	-72	-15
EPS (cents)	-21.4	-25.9	-10.2	-25	21.3	-36.8
CEO total remuneration, actual (\$m)	2.65	1.927	2.034	1.85	1.134	1.921

Based on an exchange rate of A\$1 =US\$0.69 on July 1

For 2019, the CEO's total actual remuneration was **28.8 times** the Australian Full time Adult Average Weekly Total Earnings (based on May 2020 data from the Australian Bureau of Statistics).

Item 2	Adoption of Remuneration Report
ASA Vote	For

Summary of ASA Position



This year has seen the implementation of changes to the remuneration framework in response to feedback from proxy advisers and investors. Many of the changes now align their remuneration policy with ASA guidelines, although the company still does not supply an actual remuneration table.

These changes include setting the CEO’s fixed remuneration to 40% of total remuneration (down from 50%), the setting of STI at 20% of total remuneration. The STI is now fully cash and is 50% of the fixed remuneration down from 100% in 2019, this is contrary to ASA policy where 50% of STIs should be equity based. We appreciate the changes that have occurred and will continue to raise this as an issue.

The STIs focus on KPIs (such as clinical, financial and partnering strategy, manufacturing, commercial, or organizational structure and development). In FY19/20 110% of the STI was paid, which included a special payment of 11% for outstanding leadership during the pandemic. We consider that some of the performance hurdles are light, especially for the clinical programs. For example, present GvHD data at an international conference and 3 articles published in international journals and some programs such as the CLBP program are automatic and ongoing. This issue was raised with the company and they stated that some of the performance hurdles were historic.

A long-term incentive (LTI) has been introduced and is set at 100% of fixed remuneration to be paid in options over ordinary shares, with a 7-year expiry date with vesting to occur over a 3 year period. The option exercise price is based on the 5-day VWAP prior to grant date and for 2019 this appears to have been \$0.935, with an exercise price of \$1.83 compared with the share price at that date of \$1.48. Additionally, there does not appear to be a total shareholder return (TSR) component in the LTI. The 1,200,000 options for 2020 are to be issued at a VWAP of \$3.41 with the same vesting price.

In 2019 the CEO remuneration was significantly higher than for an ASX-listed company of similar market capitalization, since then the market value has substantially increased, and the CEO’s remuneration is now comparable to that of similar sized ASX listed companies. The remuneration of the Chairman is, however, still significantly higher than comparable companies. The company claims that ASX-listed companies are not the primary benchmark that should be used in determining remuneration, as most employees are based in the USA, and most have skills in-demand globally, rather than locally, which may have some relevance. Unfortunately, options are still issued to NEDs, generally at the start of their tenure, these options vest, one third each after one, two and three years. We discussed this issue with Mesoblast last year and they stated that there is no intention of making options an annual or regular part of NED remuneration. They stated that no options have been issued this year.

Considering these issues, and the fact that Mesoblast have made significant changes since last year, we have decided to vote in favour of the remuneration report this year, but we will take a firmer stance next year, especially on the issue of options which we believe dilutes the shareholdings of retail investors.

Item 3	Re-election of Donal O’Dwyer as a Director
ASA Vote	For

Summary of ASA Position

Mr O’Dwyer has served on our board of directors since 2004, consequently he does not meet the ASA guidelines to be classified as an independent director. The boards opinion regarding Mr O’Dwyer is contrary to that of the ASA, as they consider him independent as he continues to bring

valuable expertise, independent judgement and has not formed associations with management or others that might compromise his ability to fulfil his role as an independent Director. To a certain extent we agree with the board as Mr O’Dwyer certain acts like an independent director. We have raised this issue with the board and at the moment it would be against the best interests of the company to vote against Mr O’Dwyer with respect to this issue. As the majority of the board is classified as independent as well as the chair the ASA would support his re-election. Mr O’Dwyer holds 1,234,392 shares in the company and his experience is certainly valuable to the company, having over 35 years of experience as a senior executive and director in the global cardiovascular and medical devices industries. He is on the board of directors of several companies including Fisher & Paykel Healthcare Ltd, NIB Holdings Ltd and Cochlear Limited (although he retired in October this year). This year the ASA has a policy of opposing incumbent directors seeking re-election where unfair capital raisings have occurred. We have discussed this issue with the company and will continue to do so, but at this stage of the company’s development, we believe that little will be gained by voting against Mr O’Dwyer this year. The ASA thus supports his re-election.

Item 4	Approval of Proposed Issue of Options to Chief Executive, Dr Silviu Itescu, in Connection with his Remuneration for the 2020/2021 Financial Year
ASA Vote	For

Summary of ASA Position

For the 2019/20 financial year the board implemented several changes to the remuneration framework based on feedback. The CEO’s cash short term incentive (STI) award has been reduced to 50% of his fixed remuneration, down from 100% and is now to be paid fully in cash rather than a mixture of cash and options. The long-term incentive (LTI) component of his remuneration comprises the issue of 1,200,000 options issued at a 5 days VWAP of \$3.41 and due to vest over 3 years. The options to be issued to Dr Itescu are split evenly between clinical/commercialisation and financial/business KPI’s. The notice of meeting asks for approval of 600,000 LTI options against Clinical/Commercialisation KPIs and 600,000 options against Financial/Business KPIs. At the moment we consider the LTI hurdles to be weak with respect to TSR and we have raised this issue with the company. As they are not currently cash flow positive, they recognise that including a TSR component is difficult as their share price fluctuates significantly.

This issue of 1,200,000 options this year compares to the issue of 1,346,667 options in 2019 for the granting of a PDUFA date and USFDA approval of remestencel-L, 50% of which were achieved and 50% are pending and from the annual report have a value of A\$978,232.

Whilst the ASA would prefer to see the CEO receive performance-based shares rather than options we recognise that this is an issue for companies in the early stages of commercialisation. As this issue was raised with the company last year and the situation has not changed, we will continue to monitor the situation and for this year we support this resolution.

Item 5	Ratification of shares to Existing and New Institutional Investors
ASA Vote	Against

Summary of ASA Position

At this stage in its life the raising of capital is critical for Mesoblast, however, the company still continues to favour institutional and sophisticated investors over retail investors. We understand the reasons for this, but retail investors still continue to be diluted by this preferred capital raisings. We will, continue to press for retail shareholders to be offered a significant quantity of shares at a value equivalent to those issued to institutional shareholders. We have raised the issue of retail shareholder dilution with the company on several occasions and how these shareholders were loyal in its early stage and should be considered in any future raisings, but so far our requests have not been fruitful, despite the company saying it will address this issue at the last AGM.

Net cash inflows for financing activities were US\$137.0 million for the year ended June 30, 2020, Comprised of US\$50.6 million received from share placements to existing and new Australian and global institutional investors in October 2019, and proceeds of US\$88.8 million from share placements to existing and new institutional investors in May 2020. In both of these cases retail investors were ignored. The ASA supports retail investors and recommends that they be included in any capital raising visa the placement of pro-rata renounceable share issues. Consequently, we recommend voting against the ratification of these shares.

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