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mesoblast

CHAIRMAN'S ADDRESS TO SHAREHOLDERS
2022 MESOBLAST ANNUAL GENERAL MEETING

I am pleased to be with you today at this exciting time for Mesoblast.

Today we announced long-term survival results for our lead product remestemcel-L in children with severe steroid-refractory acute graft-versus-host disease (SR-aGVHD), a devastating disease with high mortality. The results showed durable survival through 4 years of follow-up reaffirming the potential significance of remestemcel-L as new life-saving treatment for children with SR-aGVHD where to date there are no other approved therapies. These new long-term survival data are a key component of the Company's BLA resubmission to the United States Food and Drug Administration (FDA).

These long-term survival results follow our filing with FDA in October of substantial new information on clinical and potency assay items which they requested in their Complete Response Letter from 2020, and will be formally submitted to FDA.

We would hope to see a successful regulatory outcome for remestemcel-L during the first half of the upcoming calendar year.

As I told shareholders in the Annual Report, this approval would be the most transformative event in Mesoblast's history – hence why I believe these are exciting times for our company.

In addition to preparing for the remestemcel-L BLA resubmission, we have been in regular contact with the FDA over the past year across our broad portfolio of products. Specifically, we have focused on pathways to market approval for rexlemestrocel-L in the treatment of chronic low back pain associated with degenerative disc disease and for heart failure with reduced ejection fraction.
In today's quarterly financial report we show that the company is in strong financial shape to meet our commitments to bring our products to market. Management has continued to maintain reduced operating expenses year-on-year, strengthened the balance sheet, and successfully restructured long-term debt.

I'm pleased to say we welcomed two new Board members in the past year as we continued our program of Board renewal and enhancing Board diversity. The appointment of Dr Philip Krause and Ms Jane Bell have greatly added to our company's expertise, especially as we move towards potential regulatory approval and commercialization of our lead asset as well as our follow-on products in Phase 3.

Let me thank the whole Board for their efforts in 2022 to continue to chart a course which we know is in the best interests of all shareholders.

I'd like to leave you with a simple message. Mesoblast will enter 2023 in a very strong position to take advantage of years of hard work and significant investment to develop our world-leading technologies.

I would like to thank the efforts of our Chief Executive Dr Silviu Itescu and his talented team. We know each stage of our development requires countless hours of dedicated effort and commitment. We can all see the finish line, in terms of a potential first US regulatory approval for one of our products, and we would not have got to where we are without the hard work of our management team.

Lastly, shareholders on behalf of your Board of Directors, I would like to take this opportunity to express our deep gratitude for your ongoing support and confidence in our technology.

About Mesoblast

Mesoblast is a world leader in developing allogeneic (off-the-shelf) cellular medicines for the treatment of severe and life-threatening inflammatory conditions. The Company has leveraged its proprietary mesenchymal lineage cell therapy technology platform to establish a broad portfolio of late-stage product candidates which respond to severe inflammation by releasing anti-inflammatory factors that counter and modulate multiple effector arms of the immune system, resulting in significant reduction of the damaging inflammatory process.

Mesoblast has a strong and extensive global intellectual property portfolio with protection extending through to at least 2041 in all major markets. The Company's proprietary manufacturing processes yield industrial-scale, cryopreserved, off-the-shelf, cellular medicines. These cell therapies, with defined pharmaceutical release criteria, are planned to be readily available to patients worldwide.

Mesoblast is developing product candidates for distinct indications based on its remestemcel-L and rexlemestrocel-L allogeneic stromal cell technology platforms. Remestemcel-L is being developed for inflammatory diseases in children and adults including steroid refractory acute graft versus host disease, biologic-resistant inflammatory bowel disease, and acute respiratory distress syndrome. Rexlemestrocel-L is in development for advanced chronic heart failure and chronic low back pain. Two products have been commercialized in Japan and Europe by Mesoblast's licensees, and the Company has established commercial partnerships in Europe and China for certain Phase 3 assets.

Mesoblast has locations in Australia, the United States and Singapore and is listed on the Australian Securities Exchange (MSB) and on the Nasdaq (MESO). For more information, please see www.mesoblast.com, LinkedIn: Mesoblast Limited and Twitter: @Mesoblast

Forward-Looking Statements

This press release includes forward-looking statements that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements should not be read as a guarantee of future performance or results, and actual results may differ from the results anticipated in these forward-looking statements, and the differences may be material and adverse. Forward-looking statements include, but are not limited to, statements about: the initiation, timing, progress and results of Mesoblast's preclinical and clinical studies, and Mesoblast's research and development programs; Mesoblast's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; Mesoblast's ability to advance its manufacturing capabilities; the timing or likelihood of regulatory filings and approvals (including BLA resubmission), manufacturing activities and product marketing activities, if any; the commercialization of Mesoblast's product candidates, if approved; regulatory or public perceptions and market acceptance surrounding the use of stem-cell based therapies; the potential for Mesoblast's product candidates, if any are approved, to be withdrawn from the market due to patient adverse events or deaths; the potential benefits of strategic collaboration agreements and Mesoblast's ability to enter into and maintain established strategic collaborations; Mesoblast's ability to establish and maintain intellectual property on its product candidates and Mesoblast's ability to successfully defend these in cases of alleged infringement; the scope of protection Mesoblast is able to establish and maintain for intellectual property rights covering its product candidates and technology; estimates of Mesoblast's expenses, future revenues, capital requirements and its needs for additional financing; Mesoblast's financial performance; developments relating to Mesoblast's competitors and industry; and the pricing and reimbursement of Mesoblast's product candidates, if approved. You should read this press release together with our risk factors, in our most recently filed reports with the SEC or on our website. Uncertainties and risks that may cause Mesoblast's actual results, performance or achievements to be materially different from those which may be expressed or implied by such statements, and accordingly, you should not place undue reliance on these forward-looking statements. We do not undertake any obligations to publicly update or revise any forward-looking statements, whether as a result of new information, future developments or otherwise.

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