

27 September 2013

SHAREHOLDER UPDATE

Dear Shareholder

We are writing to provide you with an update on our progress as well as outlining some of our plans for the future.

The Company's strategy of developing an inhaled follistatin biotherapeutic for respiratory diseases with cystic fibrosis as our lead indication remains unchanged. The Board and management believe this focus remains appropriate in light of our latest preclinical results, the granting of a European patent, and encouraging feedback received during a recent meeting with senior representatives from Cystic Fibrosis Australia and the US Cystic Fibrosis Federation in Auckland.

We are pleased to advise that solid progress has been made across a number of important areas since our last formal update to shareholders in November 2012:

- Excellent results have been obtained in a large preclinical study undertaken by Professor Robyn O'Hehir and her research group which evaluated different doses of follistatin in a transgenic mouse model of cystic fibrosis. We are currently assessing the patentability of results from the study and therefore we are unable to disclose details at this time. Suffice to say the results build upon the Company's previous studies and have highlighted the potential therapeutic value of follistatin for treating cystic fibrosis as well as a range of other respiratory diseases. The study has also provided important dose-response data which has enabled the design of our preclinical toxicology program.
- The development of follistatin manufacturing processes is well advanced at DSM Biologics. Since commencing activities in October 2012, a number of unforeseen

and complex technical issues have been encountered. We are pleased to advise that most of the issues have been successfully addressed. Upstream (bioreactor) processes have been developed to a stage where they are suitable for scale-up although the development of downstream (purification) processes is still ongoing. Design of the front half of the downstream process has been finalised and we are confident the most vexing of technical issues are now behind us. Demonstration of the entire manufacturing process at pilot scale is expected to occur in December 2013. This is a prerequisite for the Company to commit to the manufacture of a large scale batch which will be required to provide follistatin for use in our preclinical toxicology program.

- The design of the Company's preclinical safety and toxicology program to support a first-in-human clinical trial of an inhaled follistatin biotherapeutic has been drafted. Proposals will be sought from suitably qualified contract research organisations to undertake these studies over the coming weeks with the aim of finalising contracts by early January. This will enable the Company to commence preclinical toxicology studies in the first quarter of 2014. On a related matter, we have completed studies at Prince Henry's Institute which confirmed the bioactivity of follistatin is retained following nebulization into an aerosol suitable for inhalation.
- The Company has continued to strengthen its IP portfolio with the allowance of two new patents; one in Europe relating to airway inflammation, and one in Canada relating to liver fibrosis. Several new Australian and international patent applications were also filed. Of particular note, the Company engaged Professor Frank Rosenfeldt and his surgical research team at The Alfred Hospital to undertake a small study to investigate the use of follistatin in a canine model of lung transplantation. Results exceeded our most optimistic expectations with follistatin treatment producing significant beneficial effects in the treated dogs. An extension to the study is currently under consideration, and it is our view this IP may provide the Company with a valuable licensing opportunity in the future.

As mentioned above, the development of manufacturing processes has been considerably slower and more expensive than expected through a combination of technical and non-technical issues. As a risk mitigation strategy, the Company has investigated alter-

native options regarding follistatin manufacture. A viable option has been identified and this provides the Company with flexibility on how we choose to proceed with scale-up.

Given the issues encountered in the development of manufacturing processes, the Company does not expect to commence preclinical toxicology studies until the first quarter of 2014 and additional funds will be required before the Company can commit to a clinical trial. The Company is continuing to work on a range of strategies relating to funding and these can be discussed at the forthcoming Annual General Meeting of Shareholders which is scheduled for:

11:00am – 1:00pm Monday 25 November 2013
The Auditorium
Melbourne Institute of Plastic Surgery
253 Wattletree Road
Malvern, VIC

A separate Notice of AGM and copy of the Company's 2013 annual report will be distributed to shareholders approximately one month before the AGM.

To conclude, the Board and management are enthusiastic regarding the potential therapeutic value of follistatin, and this enthusiasm is shared by our clinical collaborators. The Company remains focussed on the current strategy and our immediate priority is to enter preclinical toxicology as soon as possible. We look forward to seeing you at the AGM and, in the interim, please contact either of the undersigned if you require additional information.

Kind regards,

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