Biotron

Biotron Limited ABN 60 086 399 144

BITNews

December 2018

Dear Shareholder,

This last quarter of 2018 has been profound for Biotron. The announcement in late September of positive headline data from its pivotal Phase 2 clinical trial for the treatment of HIV-1 provided a major inflection point for your Company.

The clinical trial was built on a scientifically sound, solid foundation of laboratory studies. Based on research originating at the John Curtin School of Medical Research at the Australian National University, the Company's scientists designed and developed BIT225. Many years have been spent characterising how the drug works on HIV-1, making step-wise progress along a well-considered development pathway, culminating in human clinical trials. All of these steps have led to the recently successful Phase 2 trial, BIT225-009.

Scientific evidence from laboratory and clinical studies has demonstrated that BIT225 attacks HIV-1 in macrophage cells. Current drugs do an excellent job of taking HIV-1 in the blood to undetectable levels but do not clear virus in macrophages. These cells, which reside in the body's tissues, produce low levels of HIV-1, even in patients taking antiretroviral drugs. This means that the infection persists. Patients cannot stop taking antiretroviral drugs. If they do, the virus quickly rebounds to high, potentially life-threatening, levels.

Drug development is inherently risky, and many drugs fail before or during Phase 2 trials. The positive data from the BIT225-009 Phase 2 HIV-1 clinical trial are important as they provide evidence of your Company's drug having an effect in patients that is quite distinct from the antiviral effect of current antiretroviral drugs.

In late November, the Company presented data from the BIT225-009 trial at the HIV DART and Emerging Viruses 2018 conference in Miami, Florida USA. The conference, which focused on the latest developments in HIV therapeutics, management and cure, provided the first opportunity for us to share the scientific data from the trial.

The data was well received, and as validation of the robustness and integrity of the data from the trial, the presenting author, Biotron's Head of Research and Development, Dr Carolyn Luscombe, received the conference's 2018 HIV DART Poster Award.

Ongoing analyses of BIT225-009 samples and data are in progress to further characterise the observed unique effects of BIT225 in patients. Work is also underway to refine the regulatory and developmental pathway to Phase 3 and beyond.

The sharing of data with the scientific community is an important step towards commercialising your Company's antiviral platform. Briefing potential partners in the pharmaceutical industry on the trial outcomes is another key step. These meetings with potential partners are not single events, but involve multiple meetings, spread several months. We believe that the successful results from this study will facilitate commercialisation negotiations with these parties.

In parallel with progressing the HIV-1 program towards a commercial outcome, we continue to evaluate the activity of Biotron compounds for activity against Hepatitis B virus (HBV). The HBV therapeutic space is currently very active within the pharmaceutical industry, with significant investor interest in the search for and development of effective HBV treatments. While the HBV program is preclinical, it may provide the Company with an early stage development opportunity with an appropriate partner.

As advised to the market in early December, exercise of the 30 November 2018 options has raised a total of $4.7 million, to bring our current cash balance to $7.1 million. With the positive data from the Phase 2 HIV-1 clinical trial in hand and a sound financial position resulting from this significant injection of funds, the Company ends 2018 in an robust position.

We'd like to wish shareholders and their families best wishes for the holiday season. We look forward to 2019 with confidence.

Regards,

Michelle Miller
CEO & Managing Director

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