Biotron Limited
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31 January 2023

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000 (3 pages by email)

Dear Madam

REPORT ON ACTIVITIES FOR THE QUARTER ENDED 31 DECEMBER 2022

Biotron Limited ('Biotron' or 'the Company') has achieved key outcomes including:

- Completed a rights issue plus a follow-on placement, raising $6 million before costs. Proceeds will be used to:
    - Undertake a Phase 2 COVID-19 clinical trial.
    - Complete non-clinical assays for the Company's two Phase 2 HIV-1 clinical trials.
    - Develop next generation drugs for HIV-1 and COVID-19 programs.
    - Advance the Hepatitis B virus program.
    - Advance commercialisation activities.
    - support working capital and costs of the offer.
- Received an R&D Tax Incentive rebate of $1,430,725 for the 2021/22 financial year.
- Continued dosing of enrolled patients in the two ongoing Phase 2 trials of BIT225 for treatment of HIV-1 infection that are underway at sites in Australia and Thailand.
- Continued the design, synthesis and testing of new compounds under the HIV-1 and Hepatitis B virus (HBV) programs, with the aim of identifying a next-generation lead anti-HIV-1 drug and a lead candidate for HBV.

HIV-1 Program

During the quarter ended 31 December 2022, Biotron continued dosing of patients enrolled into the two Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection that are underway at sites in Australia and Thailand. The trials had completed recruitment (as announced on 23 August 2022 and 4 October 2022) and completion of the clinical phase of the trial is expected shortly.

In 2021, 38.4 million people globally were living with HIV, with 1.5 million becoming newly infected with the virus and an estimated 650,000 people dying from AIDS-related illnesses. The global HIV drug market size in 2021 was estimated to be US$30 billion. The increased prevalence of HIV-1 infections, percentage of patients on treatment due to improved disease awareness and the need for treatments to improve quality of life are expected to drive market growth to over US$50 billion by 2030.

During the quarter under review, people enrolled in the trial continued to receive either BIT225 or placebo according to the clinical trial protocols. Once the clinical phases of the trials are complete, blood samples collected during the study will be analysed and once all analyses are complete, the trial database will be locked and the results subject to statistical evaluation. The study will then be unblinded and outcomes reported.

Other HIV-1 clinical-trial supporting activities undertaken during the quarter included preparation of laboratory protocols and finalising the selection of test sites for undertaking post-trial sample analyses. The assays to be run on blood samples collected during the trials are complex and have required careful consideration of detailed methodologies.

The clinical trial databases into which all trial data, including patient demographics, results of prescreening, screening and ongoing medical tests set out in the clinical trial protocols, as well as the results of all post-trial analyses, have been routinely monitored and checked for errors by external contractors.

Both trials are designed to generate data that extend the positive findings from previous clinical trials conducted by Biotron. The data will be central to demonstrating to potential pharmaceutical partners and regulatory authorities the safety and efficacy of BIT225 in patients with currently unmet medical needs.

Preliminary results from the trials are anticipated to be available in mid-2023.

SARS-CoV-2

During the quarter ended 31 December 2022, the Company identified suitable trial sites and finalised a new clinical trial protocol and other necessary documentation for a standalone Phase 2 trial of BIT225 as a potential treatment of COVID-19 based on guidance received during 2022 from the USA Food and Drug Administration (FDA). Documentation is progressing through relevant ethics and regulatory submissions at identified trial sites and, subject to approvals, the trial is expected to commence shortly.

The trial design has taken into consideration the continually changing landscape of COVID-19. The Company has consulted with international clinicians, clinical research organisations and other relevant experts to design a study aimed to be recruited quickly and generate meaningful data in a very tight timeframe.

As previously advised (14 September 2022), Biotron added a COVID-19 sub-study to one of the Phase 2 HIV-1 clinical trials of BIT225, with any eligible person enrolled in the HIV-1 trial who becomes infected with SARS-CoV-2 will be intensively monitored for SARS-CoV-2 viral load and clinical symptoms over a 28-day period. While the study is small and end points are exploratory, the sub-study provided an efficient, cost effective and timely opportunity to study BIT225 for this indication in an at-risk population. As discussed above, the HIV-1 clinical trials are in progress, with data for both HIV-1 trials as well as the COVID-19 sub-study expected in mid-2023.

Despite the availability of SARS-CoV-2 vaccines, there remains a need for oral drugs to treat the infection and prevent severe disease, especially in at-risk individuals.

BIT225 has an established human safety profile and has the potential to be an important first-in-class drug for COVID-19 treatment.

Hepatitis B Program

While the Company's main focus during the quarter has been its clinical programs for HIV-1 and COVID-19, the Hepatitis B virus (HBV) program continues to be an important preclinical program.

Biotron is working with other experienced groups to access key antiviral HBV assays and continues to make good progress. The aim is to identify a lead series to progress to preliminary safety studies and assessment in animal models of HBV infection.

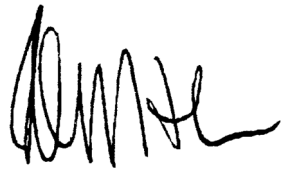
During the first quarter of 2023, focus will return to progressing the HBV preclinical program as well as advancing the identification of next-generation compounds for both HIV and SARS-CoV-2. During the quarter under review, detailed work plans were set up and studies initiated for each of these activities.

The current pandemic highlights the importance of novel approaches such as Biotron's viroporin compounds which have the potential to target a broad range of existing and emerging viruses.

Expenditures

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totalled $601,000 and $211,000 of related staff costs. As disclosed in the Company's Quarterly Cash Flow Report, payments to related parties and their associates during the quarter totalled $148,000 for director fees, salaries and superannuation payments.

By order of the Board



Peter J. Nightingale
Company Secretary

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