Biotron Limited
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30 January 2024

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 2023

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

- Continued detailed post-clinical phase analyses of samples collected during the completed Phase trial of BIT225 for treatment of adults with COVID-19 (BIT225-012).
- Continued detailed post-clinical phase analyses of samples collected during the two completed Phase 2 trials of BIT225 for treatment of HIV-1 infection (BIT225-010 and BIT225-011).
- Continued post-clinical phase activities for all three Phase 2 trials including site monitoring and close-out, and finalising statistical analyses plans ahead of locking of trial databases and unblinding of data.
- Continued the design, synthesis and testing of new compounds with the aim of identifying next-generation lead anti-HIV-1 and anti-SARS-CoV-2 drugs and a lead candidate for HBV.

SARS-CoV-2/COVID-19 and HIV-1 Clinical Programs

During the second half quarter of 2023 the Company completed a Phase 2 clinical trial (BIT225-012) with its lead antiviral drug BIT225 for treatment of COVID-19 at sites in Thailand.

The trial commenced in May 2023, and was very quickly fully enrolled with dosing completed in August.

During the quarter ended 31 December 2023 the Company has been focused on post-trial activities that are essential parts of the clinical assessment of new drugs. There is a major workload associated with monitoring of all aspects of the completed trial to ensure that all information within patient master files, and subsequently in trial databases, is correct and compliant with international regulatory guidelines.

The double blind, placebo-controlled trial aims to determine if 7 days of treatment with BIT225 commenced within 3 days of onset of COVID-19 symptoms results in reduction in SARS-CoV-2

blood viral load, clinically favourable changes in viral, inflammatory and immune activation markers, as well as improvement in clinical symptoms of COVID-19.

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 the potential to be an important first in class drug for COVID-19 treatment.

During the quarter post-trial activities have also continued for the two HIV-1 Phase 2 clinical trials (BIT225-010 and -011). These important trials have been designed to generate data that extend the positive findings from previous clinical trials conducted by Biotron in which BIT225 was shown to have positive effects on key immunologic markers of improved health outcomes. 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.

End of trial activities for all three clinical trials are primarily in the hands of external Contract Research Organisations (CROs) that are responsible for independent management and oversight of all data generated throughout clinical trials. Once all post-trial activities are completed, the trial database will be locked, the data unblinded and statistical analyses of the data can be completed.

As outlined in a market update on 14 December 2023 external factors beyond the Company's control that have impacted on timelines of data release. Firstly, the workload associated with completing three very complex, data-heavy Phase 2 trials. Secondly, the quantity of data that has been generated from trials involving up to 6 months of treatment plus several weeks follow-up post-dosing. And thirdly, in the aftermath of the COVID-19 pandemic, which caused significant delays across all aspects of clinical studies undertaken globally, many clinical studies in Australia are now in the same post-clinical stage and this is creating backlogs and delays with the CROs involved in the studies. The Company continues to work closely with the CROs involved with the trials to facilitate completion of all essential post-trial activities. Release of headline results is expected in coming weeks.

Hepatitis B Program

While the clinical programs for HIV-1 and COVID-19 continue to be the Company's main focus, its 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.

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 totaled $1,524,000 and $212,000 of related staff costs. As disclosed in the Company's Quarterly Cash Flow Report, payments to related parties and their associates during the quarter totaled $149,000 for director fees, salaries and superannuation payments.

In late 2023 an R&D Tax Incentive Registration was filed for eligible activities undertaken during the 2022/23 financial year. The Company expects to shortly receive a cash rebate of approximately $1.6 million from AusIndustry under the scheme.

By order of the Board

Peter J. Nightingale
Company Secretary

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