Biotron Limited
A.B.N. 60 086 399 144

Level 2, 66 Hunter Street
Sydney NSW 2000
Tel: (61-2) 9300 3344
Fax: (61-2) 9221 6333
E-mail: pnightingale@biotron.com.au
Website: www.biotron.com.au

27 April 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 MARCH 2023

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

- Completed the two Phase 2 trials of BIT225 for treatment of HIV-1 infection that are underway at sites in Australia and Thailand.
- Progressed documentation for a Phase 2 trial of BIT225 for treatment of adults with COVID-19 through relevant ethics and regulatory authorities.
- Presented BIT225 COVID-19 data at an international conference.
- 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.

HIV-1 Program

During the quarter, Biotron completed the clinical phase of two Phase 2 clinical trials (BIT225-011 and BIT225-010) for treatment of HIV-1 infection that are underway at sites in Australia and Thailand, respectively.

The two trials were designed to generate data to 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 BIT225-011 Phase 2 HIV-1 trial that has been underway at sites in Sydney, Australia, including St Vincent's Hospital, Holdsworth House and East Sydney Doctors, is investigating the impact of BIT225 in HIV-infected people who have been taking approved anti-HIV-1 treatment ('ART') for an extended period with well-controlled HIV-1 infection but not achieved full immune reconstitution despite long term durably suppressive ART. This group, estimated to encompass more than one-third of the HIV treated population, is at an increased risk of clinical progression to AIDS and other morbidities and has higher rates of mortality than HIV infected patients who have attained full immune reconstitution.

BIT225 was added to this group's ART treatment for a period of three months. The endpoints for this trial include measurements of improved immune function and markers linked to immune reconstitution.

The BIT225-010 Phase 2 HIV-1 trial that was run at sites in Thailand included people newly diagnosed as being HIV-1 positive but not yet commenced ART with BIT225 treatment or placebo continuing for six months in combination with ART. This extended dosing period allows for a more detailed investigation of immune changes observed in previously completed HIV-1 clinical studies with BIT225. The endpoints for this trial include measurements of improved immune function and markers linked to immune reconstitution.

With the clinical phase completed, focus is now on undertaking detailed laboratory analyses of all the samples collected during the trials. The assays are complex and will take several months to complete. Once all the data is available, the study will be unblinded and the data subjected to statistical analyses.

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/COVID-19 Program

During the quarter, the Company progressed detailed documentation for a standalone Phase 2 trial of BIT225 through relevant ethics and regulatory submissions at identified trial sites and, subject to approvals, the trial is expected to commence shortly.

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.

In February 2023, the Company presented COVID-19 data from studies with its lead antiviral drug BIT225 at the 30th Conference on Retroviruses and Opportunistic Infections ('CROI') in Seattle, WA, USA. CROI is the pre-eminent international HIV research meeting and this year it also featured new findings on SARS-CoV-2 and the mpox virus.

Biotron's paper, entitled "SARS-CoV-2 E-Protein Viroporin Inhibitor BIT225 Active in hACE2 Transgenic Mice" presented data confirming that BIT225 targets the E protein of SARS-CoV-2. The E protein is central to initiating the SARS-CoV-2-induced adverse inflammatory cascade that leads to increases in proinflammatory cytokines that are associated with the oedema and acute respiratory distress syndrome (ARDS) observed with SARS-CoV-2 infection.

The paper also presented data from the study of BIT225 in the K18-hACE2 transgenic mouse model of COVID-19 disease, demonstrating that BIT225 protected mice from weight loss and death, inhibited virus replication and reduced inflammation. These effects were noted when treatment with BIT225 was initiated before or 24 to 48 hours after infection.

The data support the proposed clinical study of BIT225 in treatment of SARS-CoV-2 and validate SARS-CoV-2 E protein as a viable antiviral target.

Hepatitis B Program

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

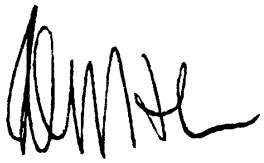
Biotron is working with other experienced groups to access key antiviral HBV assays and continues to make good progress. The aim is to identify a lead series to progress to preliminary safety studies and assessment in animal models of HBV infection.

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 $784,000 and $210,000 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.

By order of the Board



Peter J. Nightingale
Company Secretary

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