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

28 July 2022

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

Dear Madam

REPORT ON ACTIVITIES FOR THE QUARTER ENDED 30 JUNE 2022

During the quarter ended 30 June 2022 Biotron Limited ('Biotron' or 'the Company') achieved key outcomes including:

- Extended the previous findings on the effectiveness of Biotron's lead antiviral drug BIT225 by demonstrating the ability of the drug to protect against severe disease in established SARS-CoV-2 infection in an animal model of human COVID-19.
- Received guidance from the USA Food and Drug Administration (FDA) relating to the proposed clinical development of BIT225 for the treatment of COVID-19.
- Continued the recruitment for two Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection at sites in Australia and Thailand.
- Continued the design, synthesis and testing of new compounds under its 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.

SARS-CoV-2

During the quarter ended 30 June 2022, the Company announced new data that confirms and extends previous findings that BIT225 had demonstrated substantial and clinically meaningful efficacy against SARS-CoV-2 in a series of animal and cell-based studies performed at The SCRIPPS Research Institute, La Jolla, CA, USA.

Previous data demonstrated that BIT225 protected against COVID related death in K18 transgenic mice (a strain generated to be infectable with SARS-CoV-2, resulting in severe COVID) that were infected with a lethal dose of the virus. The latest data, announced on 2 May 2022, demonstrated that BIT225 was equally effective whether given before infection or 48 hours after an infection had been established.

The latest results indicate that BIT225 can both prevent and treat SARS-CoV-2 disease in this internationally recognised model of COVID-19.

BIT225 belongs to a new class of antiviral drugs known as viroporin inhibitors. Viroporins are virus-encoded proteins that are central to establishing and maintaining infections through modulation of the body's immune system. BIT225 is Biotron's lead antiviral clinical-stage, investigational, orally-dosed small molecule antiviral drug that has been evaluated in nine clinical trials involving healthy volunteers, patients with HIV-1 infection, patients co-infected with Hepatitis C virus (HCV) and HIV-1 and patients with HCV (as monotherapy and in combination with pegylated interferon-alfa and ribavirin).

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.

As announced on 30 May 2022, Biotron has received guidance from the USA Food and Drug Administration (FDA) for development of BIT225 as a potential treatment of COVID-19. The guidance provides clarity on the design of a Phase 2 trial including end points for such a study in the evolving COVID treatment landscape.

The Company is now consulting with clinical research organisations to identify potential trial sites and work through the logistics and costs of undertaking a COVID-19 treatment trial.

HIV-1 Program

During the quarter ended 30 June 2022, Biotron continued recruitment of the two previously announced Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection. As stated in the Report on Activities released on 26 April 2022 patient recruitment had been adversely impacted by the wave of the Omicron variant of SARS-CoV-2 during the first quarter of 2022, resulting in lower than anticipated recruitment rates. However, in recent weeks recruitment rates have increased, and the trials are expected to be fully recruited early in the 3Q2022.

Preliminary results for the BIT225-011 trial are still anticipated to be available in late 2022, with preliminary results for the BIT225-010 trial expected in early 2023.

One of the trials (BIT225-011) will investigate 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. The trial is in progress at sites in Sydney, Australia including St Vincent's Hospital and Holdsworth House.

The second trial (BIT225-010) is underway at sites in Thailand. This study includes people newly diagnosed as being HIV-1 positive but not yet commenced ART with BIT225 treatment or placebo continuing for 6 months in combination with ART.

The trials are designed to generate data that will be central to demonstrating to potential pharmaceutical partners and regulatory authorities how BIT225 can be used to improve patient outcomes and address currently unmet medical needs.

Hepatitis B Program

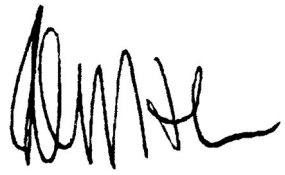
Biotron continues to design, synthesise and test new compounds with the aim of identifying a lead candidate for Hepatitis B virus (HBV). Biotron is working with other experienced groups to access key assays and continues to make good progress. The aim is to identify a lead series to progress to preliminary 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 totalled $670,000 and $206,000 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 $144,000 for director fees, salaries and superannuation payments.

By order of the Board



Peter J. Nightingale
Company Secretary

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