Biotron Limited
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28 January 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 31 DECEMBER 2021

During the quarter ended 31 December 2021 Biotron Limited ('Biotron' or 'the Company') achieved key outcomes including:

- Commenced two Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection following receipt of relevant ethics and regulatory approvals at sites in Australia and Thailand.
- Reported that Biotron's lead antiviral drug BIT225 demonstrated substantial and clinically meaningful efficacy against SARS-CoV-2 in a series of animal and cell-based studies.
- Continued the design, synthesis and testing of new compounds under its HIV-1 program, with the aim of identifying a next-generation lead anti-HIV-1 drug.
- Continued the design, synthesis and testing of new compounds under its Hepatitis B program.

SARS-CoV-2

During the quarter ended 31 December 2021, the Company announced 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.

The drug protected animals infected with the virus from developing severe disease.

BIT225 belongs to a new class of antiviral drugs, known as viroporin inhibitors, targeting key viral-encoded proteins known as viroporins 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, small molecule antiviral drug. It is an oral drug, suitable for once-a-day dosing and has a well characterised safety profile. The drug 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). Formal pre-clinical studies have assessed safety over 24 weeks of dosing.

The emergence of new SARS-CoV-2 variants such as Omicron highlights the urgent 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.

The Company is currently mapping out a clinical and regulatory pathway for treatment of COVID-19 with BIT225 in consultation with its USA-based advisors and consultants. Designing a suitable trial in the current fluid environment of the pandemic requires careful consideration of the clinical, regulatory and epidemiologic features of the SARS-CoV-2 virus. This process involves coordination between the Company, international medical experts in the treatment of COVID-19 and clinical trial design, regulatory authorities and funding agencies.

The U.S.A. Food and Drug Administration ('FDA') has created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program ('CTAP'). The program uses every available method to move new treatments to patients as quickly as possible. Biotron is preparing a detailed briefing package to submit to the FDA during the first quarter of 2022.

Guidance from the FDA will inform the final design of a suitable international trial and will be a key component of outreach to potential partners.

HIV-1 Program

During the quarter ended 31 December 2021, Biotron commenced two Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection.

Previous clinical trials have shown that BIT225, an oral, first-in-class anti-viral drug in capsule form, induces important immune system changes that indicate improved health outcomes in HIV-positive people commencing antiretroviral treatment for the first time.

One of the new trials (BIT225-011) will further investigate the impact of BIT225 in 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 new 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.

The two HIV-1 trials are expected to conclude in mid-2022 and data to be made available during the second half of 2022.

During the quarter, the Company also progressed its program to design, synthesise and screen new chemical entities with the aim of identifying a follow-on, next-generation lead. The aim is to identify a lead candidate to progress to formal safety studies. Key lead candidates are currently being assessed for safety and favourable drug-like properties in animal studies.

Hepatitis B Program

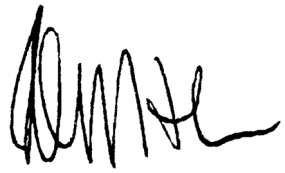
Company continuesto design, synthesise and test new compounds with the aim of identifying a lead candidate for Hepatitis B virus ('HBV'). Biotronis working with other experienced groups to access key assays and continues to make good progress. The aim is to identify a lead series to progress to preliminary 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 $748,000 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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