

30 July 2021

The Manager Companies  
ASX Limited  
20 Bridge Street  
Sydney NSW 2000

(2 pages by email)

Dear Madam

### **REPORT ON ACTIVITIES FOR THE QUARTER ENDED 30 JUNE 2021**

During the quarter ended 30 June 2021, Biotron Limited ('Biotron' or 'the Company') has achieved outcomes including:

- Progressed testing a series of compounds with promising activity against SARS-CoV-2, the causative agent of Covid-19, in preliminary safety studies and animal models of disease.
- Finalised the designs of two clinical trials of the Company's lead antiviral drug, BIT225, and progressed documentation for ethics and regulatory approvals.
- 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.
- Received an R&D Tax Incentive refund of \$1,411,944 for the 2019/20 financial year.

#### **SARS-CoV-2**

During the quarter ended 30 June 2021, the Company progressed a lead series of compounds to preliminary safety studies and animal models of COVID-19 disease. The series, comprising the three most active compounds tested by the Company in a series of cell culture-based assays against SARS-CoV-2, was identified following an extensive campaign to screen proprietary compounds designed specifically to target the virus (announced 11 March 2021). The compounds were selected on the basis of inhibiting SARS-CoV-2 replication in three different cell culture models of SARS-CoV-2 virus infection. The assays were performed by collaborators at the Scripps Research Institute, La Jolla, California, USA.

The preliminary safety studies include bioavailability studies in mice and will provide key data to support their progression to testing in animal model(s) of COVID-19 infection. The animal studies are expected to be completed during the third quarter of 2021.

## **HIV-1 Program**

During the quarter ended 30 June 2021, Biotron finalised the design of two clinical trials of its lead anti-HIV-1 drug, BIT225, in consultation with the Company's Chief Medical Officer and international Scientific Advisory Board. The trials, to be done in HIV-positive populations, will be undertaken in Thailand and Australia. They build on the positive results from the completed BIT225-009 Phase 2 trial and 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.

Currently, protocols for these two trials are being finalised and progressing through relevant ethics and regulatory processes. Subject to receipt of the necessary approvals, recruitment is expected to commence in the third quarter of 2021 and be complete by mid-2022, with data available in 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 compound to progress to formal safety studies.

The Company is focused on achieving a commercial outcome for its promising antiviral programs whilst continuing to progress its clinical HIV-1 program to prepare for more advanced clinical trials, including Phase 3 studies.

## **Hepatitis B Program**

Hepatitis B Virus (HBV) is an important early-stage program for Biotron. The Company continues to design, synthesise and test new compounds with the aim of identifying a lead candidate. 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, which may impact on the timing of the Company's programs, 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 \$673,000 and \$191,000 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. Biotron's cash position at 30 June 2021 of \$4,211,000 includes receipt in April 2021 of an R&D Tax Incentive refund of \$1,411,944 for the 2019/20 financial year which places the Company in a sound financial position as it focuses on achieving commercial outcomes for its programs.

By order of the Board



Peter J. Nightingale  
Company Secretary

pjn10898