

28 October 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 SEPTEMBER 2021**

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

- Continued 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.
- Progressed submissions to relevant ethics and regulatory authorities for two clinical trials of the Company's lead antiviral drug, BIT225, for treatment of HIV-1 infection.
- 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 30 September 2021, the Company has continued the progression of 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 propriety 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.

Preliminary safety studies, including bioavailability studies in mice, have been completed. The data from these studies has been used to design and implement testing in a mouse model of COVID-19 infection. The animal studies are expected to conclude shortly.

## **HIV-1 Program**

During the quarter ended 30 September 2021, Biotron finalised protocols and supporting documentation for two clinical trials of its lead anti-HIV-1 drug, BIT225. The trials have been designed in consultation with the Company's Chief Medical Officer and international Scientific Advisory Board. The trials 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.

Documentation is now progressing through relevant ethics and regulatory authorities in Thailand and Australia where the trials will be conducted. The trials will commence on receipt of the necessary approvals and are expected to be completed by mid-2022, with data available in the second half of 2022.

During the quarter the Company 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.

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**

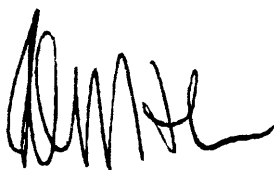
Hepatitis B Virus (HBV) is an important early-stage program for Biotron. The Company continues to design, synthesise and test new compounds with the aim of identifying a lead candidate. Biotron is working with other experienced groups to access key assays and continues to make good progress. The aim is to identify a lead series to progress to preliminary safety studies and assessment in animal models of HBV infection.

The current pandemic 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 \$396,000 and \$201,000 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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