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29 January 2021

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 2020

During the quarter ended 31 December 2020 Biotron Limited ('Biotron' or 'the Company') has achieved outcomes including:

- Publication of a peer-reviewed scientific paper on the Company's lead anti-HIV-1 drug BIT225 in a prestigious international scientific journal in October 2020.
- Continued the expanded screening program of Company compounds for activity against SARS-CoV-2, the causative agent of Covid-19.
- 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 Biotron continued testing of compounds against SARS-CoV-2 following the announcement in September 2020 of the first round of results from the testing program announced on 6 February 2020 to screen compounds from its proprietary small molecule compound library for antiviral activity against SARS-CoV-2, the causative agent of the Covid-19 outbreak. As explained at the time, Biotron has a number of compounds in its library that have previously shown good activity against a range of coronaviruses, dating back to studies undertaken at the time of outbreak of severe acute respiratory syndrome (SARS-1), a coronavirus, in 2002–2004 when several of Biotron's compounds showed antiviral activity against SARS-1.

The Company is now expanding its screening program to include a new series of recently designed and synthesised compounds. It is hoped that within these new compounds there will be potent, druggable compound(s) that can be progressed to testing in animal models of COVID-19 disease and ultimately clinical trials.

### **HIV-1 Program**

During the quarter ended 31 January 2021, Biotron has continued to undertake cell culture-based assays to further elucidate the mechanism of action of BIT225. This follows on from Biotron's demonstration that BIT225 directly modifies immune responses to HIV-1 infection.

In October 2020 a manuscript containing data from its Phase 2 trial of BIT225 in HIV-1-infected subjects was accepted for publication following peer-review in a prestigious international journal. The paper, entitled "Human immunodeficiency virus type-1 Vpu inhibitor, BIT225, in combination with 3-drug antiretroviral therapy modulates inflammation and immune cell function" has published in the Journal of Infectious Diseases.

The Company has also continued to design, synthesise and screen new chemical entities with the aim of identifying a follow-on, next-generation lead.

As previously advised to the market on 12 March 2020, the Phase 2 clinical trial demonstrated that BIT225 induced statistically significant changes to key immune cell populations. These changes had not previously been reported for any HIV-1 therapeutics. The results open the possibility that BIT225 may play a key role in restoring immune function, leading to improved health outcomes and elimination of residual virus.

Biotron is currently mapping out the next stage of clinical development of this important new anti-HIV class of compounds in consultation with the Company's Chief Medical Officer and international Scientific Advisory Board. The completion of long-term toxicology studies of BIT225 earlier in the year was an important milestone as they support long-term dosing of BIT225 in the next stage of clinical development and beyond.

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. 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.

#### **Hepatitis B Program**

Hepatitis B Virus (HBV) is another 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.

# **Expenditures**

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totalled \$697,000 and \$192,000 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 of \$5,150,000 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

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