

Level 2, 66 Hunter Street  
Sydney NSW 2000  
Tel: (61-2) 9300 3344  
Fax: (61-2) 9221 6333  
E-mail: [pnightingale@biotron.com.au](mailto:pnightingale@biotron.com.au)  
Website: [www.biotron.com.au](http://www.biotron.com.au)

29 October 2020

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 SEPTEMBER 2020**

During the quarter ended 30 September 2020, Biotron Limited ('Biotron' or 'the Company') has achieved outcomes including:

- Reported the identification of compounds in Biotron's proprietary library of small molecule drugs with *in vitro* activity against SARS-CoV-2, the causative agent of Covid-19.
- Expanded the 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.
- Publication of a peer-reviewed scientific paper on its lead anti-HIV-1 drug BIT225 in a prestigious international scientific journal.
- Continued the design, synthesis and testing of new compounds under its Hepatitis B program.

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

During the quarter Biotron announced 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.

As reported on 7 September 2020, several compounds have been shown in laboratory cell-culture studies to have antiviral activity against SARSCoV-2. The assays were run under contract by an Australian NATA accredited clinical trial speciality laboratory, 360biolabs, based in Melbourne, Victoria.

The Company is now expanding its screening program to include a new series of recently designed and synthesised compounds. Screening of these additional new compounds is expected to conclude before the end of 2020. 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**

As advised in the update of activities for the quarter ended 30 June 2020, released on 29 July 2020, Biotron presented new data on its lead anti-HIV-1 drug BIT225 at the 23rd International AIDS Conference (AIDS 2020) on 6 July 2020. The data demonstrate how BIT225 directly modifies immune responses to HIV-1 infection and helps explain the positive immune changes that were reported in the Phase 2 clinical trial. The new data support and further extend Biotron's previous report that BIT225 "unmasks" HIV-infected cells and promotes immune recognition of the virus.

During the quarter ended 30 September 2020, Biotron has continued to undertake cell culture-based assays on trial samples to further elucidate the mechanism of action of BIT225. The Company has also continued to design, synthesise and screen new chemical entities with the aim of identifying a follow-on, next-generation lead.

Subsequent to the end of the period in review, on 15 October 2020, Biotron announced the publication of a manuscript containing data from its Phase 2 trial of BIT225 in HIV-1-infected subjects in a prestigious international journal. The peer-reviewed paper, entitled "Human immunodeficiency virus type-1 Vpu inhibitor, BIT225, in combination with 3-drug antiretroviral therapy modulates inflammation and immune cell function" was published online as advance access in the Journal of Infectious Diseases.

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.

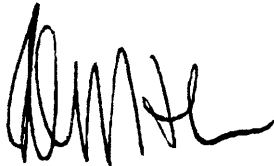
## **Hepatitis B Program**

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 \$1,112,000 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 \$143,000 for director fees, salaries and superannuation payments. Biotron's cash position of \$6,226,000 places the Company in a sound financial position as it focuses on achieving commercial outcomes for its programs.

By order of the Board

A handwritten signature in black ink, appearing to read 'Peter J. Nightingale', written in a cursive style.

Peter J. Nightingale  
Company Secretary

pjn10547