

29 July 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 JUNE 2020**

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

- Completion of chronic toxicology studies of BIT225 by a leading international contract research organisation.
- Continuation of screening of Company compounds for activity against SARS-CoV-2, the causative agent of Covid-19.
- Continuation of designing, synthesising and testing new compounds under its Hepatitis B program.
- Presentation of new data on its lead anti-HIV-1 drug BIT225 at an international HIV-1 conference in July 2020.
- Appointment of a Chief Medical Officer to advise the Company on its HIV-1 development program.

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

During the quarter Biotron has continued 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 shown very 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, back in 2002–2004 when several of Biotron's compounds showed antiviral activity against SARS-1.

Screening for activity against SARS-CoV-2 is progressing well in a series of different assays to assess the impact of the compounds on markers of virus replication as well as immune markers. These assays will provide the best overall understanding of the potential of Biotron's compounds to treat COVID-19.

## **HIV-1 Program**

In July 2020, Biotron presented new data on its lead anti-HIV-1 drug BIT225 at the 23<sup>rd</sup> International AIDS Conference (AIDS 2020). The data demonstrates 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.

During HIV-1 infection, in order to attenuate host immune responses against the virus, specific cell surface markers that normally signal the immune system to attack the virus are downregulated. This downregulation enables the virus to evade the immune response and persist. These cells constitute a reservoir for the virus that enables it to persist despite ART.

The new data show that BIT225 restores these cell surface markers to normal. In addition, the new data also indicate that BIT225 increases a key marker linked to functionality, meaning that T cells are able to move around the body and restore immune function. The Vpu protein of HIV-1 is largely responsible for downregulation of cell surface markers that attenuate immune responses. This new study used wild-type virus as well as virus that had Vpu removed to show that BIT225's effects on the immune system are mediated directly through its inhibition of Vpu. These effects are additional to the known antiviral effect of BIT225.

The new data support and further extend Biotron's previous report that BIT225 "unmasks" HIV-infected cells and promotes immune recognition of the virus. Immune system recognition initiates the host defence processes including the clearance of virus. In combination with results from the Phase 2 clinical trial, these latest results support further clinical study of the potential anti-viral and immunological benefits of BIT225 therapy in combination with ART.

Chronic toxicology studies of BIT225 commenced in late 2019 and are now complete. These long-term toxicology studies are essential as they enable long-term dosing of BIT225 in the next stage of clinical trials 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 with its 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 is fortunate that this work is not materially impacted by Covid-related shutdowns and continues to make good progress.

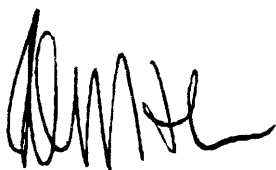
## Expenditures

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totalled \$600,000 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 \$7,661,000 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 'P. Nightingale', written over a horizontal line.

Peter J. Nightingale  
Company Secretary

pjn10424