

23 April 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 31 MARCH 2020**

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

- Expanding its antiviral screening program to include SARS-CoV-2, the causative agent of Covid-19.
- Presentation of new data from the BIT225-009 Phase 2 HIV-1 clinical trial at an international HIV-1 conference in March 2020.
- Receipt of \$753,026 under the R&D Tax Incentive scheme.

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

As announced on 6 February 2020, during the quarter, Biotron commenced testing compounds from its proprietary small molecule compound library for antiviral activity against SARS-CoV-2, the causative agent of the Covid-19 outbreak.

Biotron has had a long interest in coronaviruses and its scientists were the first to identify and publish data showing that the E protein of the coronavirus is a viroporin and a good target for antiviral drugs. Biotron has compounds within its library that have previously demonstrated good antiviral activity against a range of coronaviruses, including human coronaviruses that cause mild, cold-like symptoms as well as the coronavirus that was responsible for the outbreak of the SARS virus in 2003. Importantly, several compounds have broad-spectrum activity against multiple strains of coronaviruses.

Biotron continues to work with groups within Australia and overseas to assess whether its compounds can inhibit growth of the new SARS-CoV-2 coronavirus. This work is being done in a careful methodical, scientifically robust manner which is not a fast process.

## **HIV-1 Program**

On 12 March 2020, Biotron presented additional data from its successful BIT225-009 Phase 2 HIV-1 clinical trial at an international scientific conference. The Company has previously reported that its BIT225-009 Phase 2 HIV-1 clinical trial showed that BIT225 induced statistically significant changes to key immune cell populations. These changes were not seen in this or other trials with current approved anti-HIV-1 drugs.

The new data presented at the conference further characterises the previously reported immune modulating effects of BIT225 and shows that BIT225 “unmasks” HIV-infected cells that remain in the body despite treatment with approved anti-HIV-1 drugs.

These infected reservoir cells are usually hidden from the immune system and are the reason why life-long drugs are necessary to keep the HIV-1 infection under control. The data indicate that the addition of BIT225 to anti-HIV-1 drugs stimulates the innate immune system so that the body’s cells can “see” the HIV-infected reservoir cells and take the necessary steps to eliminate any residual virus.

The trial data, together with additional information from the ongoing, post-trial analyses, are showing us and, importantly, potential partners how BIT225 may play a role in the eradication of HIV-1. The results are encouraging and may have profound implications for the future treatment and cure of HIV-1 infection.

Chronic toxicology studies of BIT225 commenced in late 2019 and continue to be progressed with an international contract research organisation. These long-term toxicology studies are essential for extended 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.

## **Hepatitis B Program**

In addition to its HIV-1 clinical program, Biotron continues to progress its Hepatitis B virus (HBV) program. Like HIV-1, HBV can be treated with drugs that stop the virus replicating, but these do not eradicate the virus. Chronic infection with HBV can lead to complications such as cirrhosis and liver cancer, which cause close to one million deaths worldwide each year.

In pre-clinical studies in cell culture models, Biotron’s compounds have demonstrated significant anti-viral activity against HBV, reducing levels of cccDNA (covalently closed circular DNA), as well as other key viral markers. Biotron’s compounds have a unique mechanism of action and are expected to generate significant interest from potential partners in Biotron’s family of compounds.

Biotron is currently characterising the mechanism of action of the HBV compounds designed to result in the selection of a lead drug candidate to take forward to safety studies.

While Biotron’s work on its HBV compounds is preclinical, the data from these studies further validate Biotron’s approach to antiviral drug development and may provide the Company with an early stage development opportunity with an appropriate partner.

## **Expenditure**

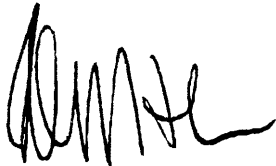
As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totalled \$464,000 and \$193,000 of related staff costs.

As disclosed in the Company's Quarterly Cash Flow Report, payments to related parties and their associates during the quarter totalled \$128,000 for director fees, salaries and superannuation payments.

## **Corporate**

During the quarter the Company received \$753,026 under the Australian Federal Government's R&D Tax Incentive Scheme. The Company is 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

pjn10306