

26 April 2022

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 2022**

During the quarter ended 31 March 2022 Biotron Limited ('Biotron' or 'the Company') achieved key outcomes including:

- Confirmed and extended previous findings on the effectiveness of Biotron's lead antiviral drug BIT225 against SARS-CoV-2 in an animal model of human COVID-19 through demonstration of 100% survival despite administration of a lethal dose of the virus.
- Submitted a proposal to the USA Food and Drug Administration to conduct a human clinical trial to assess the efficacy of BIT225 for the treatment of COVID-19 under the Coronavirus Treatment Acceleration Program, a special emergency program for potential coronavirus therapies.
- Continued the recruitment for two Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection at sites in Australia and Thailand.
- 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 31 March 2022, the Company announced new data that confirms and extends previous findings that BIT225 had demonstrated substantial and clinically meaningful efficacy against SARS-CoV-2 in a series of animal and cell-based studies performed at The SCRIPPS Research Institute, La Jolla, CA, USA.

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The latest data, reported on 17 March 2022, demonstrated that BIT225 protected against COVID related death in K18 transgenic mice (a strain generated to be infectable with SARS-CoV-2, resulting in severe COVID) that were infected with a lethal dose of the virus. Control mice that were not dosed with BIT225 all died by Day 8 post-infection with SARS-CoV-2 from severe COVID. In contrast, 100% of mice treated with BIT225 continued to gain weight as per age expectations and remained healthy through to Day 12 when the study was terminated.

As in the previous study announced in November 2021, the BIT225 treated mice once again had significantly lower viral loads of SARS-CoV-2 in their lungs compared to drug free control animals.

BIT225 belongs to a new class of antiviral drugs known as viroporin inhibitors. Viroporins are virus-encoded proteins that are central to establishing and maintaining infections through modulation of the body's immune system. BIT225 is Biotron's lead antiviral, clinical stage, investigational, orally-dosed small molecule drug that has been evaluated in nine clinical trials involving healthy volunteers, patients with HIV-1 infection, patients co-infected with Hepatitis C virus ('HCV') and HIV-1 and patients with HCV (as monotherapy and in combination with pegylated interferon-alfa and ribavirin).

Despite the availability of SARS-CoV-2 vaccines, there remains a need for oral drugs to treat the infection and prevent severe disease, especially in at-risk individuals. BIT225 has an established human safety profile and has the potential to be an important first-in-class drug for COVID-19 treatment.

In consultation with its USA based advisors and consultants, Biotron has submitted a proposal to the USA Food and Drug Administration ('FDA') to conduct a human clinical trial to assess the efficacy of BIT225 for the treatment of COVID-19 under the Coronavirus Treatment Acceleration Program, a special emergency program for potential coronavirus therapies.

Guidance from the FDA will inform the final design of a suitable international trial and will be a key component of the Company's outreach to potential partners.

### **HIV-1 Program**

During the quarter ended 31 March 2022, Biotron has continued recruitment of the two previously announced Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection.

One of the trials (BIT225-011) will investigate the impact of BIT225 in HIV infected people who have been taking approved anti-HIV-1 treatment ('ART') for an extended period with well controlled HIV-1 infection but who have not achieved full immune reconstitution despite long term durably suppressive ART.

This group, estimated to encompass more than one third of the HIV treated population, is at an increased risk of clinical progression to AIDS and other morbidities and has higher rates of mortality than HIV infected patients who have attained full immune reconstitution. The trial is in progress at sites in Sydney, Australia including St Vincent's Hospital and Holdsworth House.

The second trial (BIT225-010), which is underway at sites in Thailand, includes people newly diagnosed as being HIV-1 positive but who have not yet commenced ART. The trial will continue with BIT225 treatment or placebo continuing for 6 months in combination with ART.

The outbreak of the Omicron variant of SARS-CoV-2 in late 2021/early 2022 has resulted in unavoidable delays at the trial sites in recruitment for the two trials. The two HIV-1 trials are now expected to conclude in the second half of 2022. Preliminary results for the BIT225-011 trial are still anticipated to be available in late 2022 and preliminary results for the BIT225-010 trial are expected in early 2023.

Both trials 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.

### **Hepatitis B Program**

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

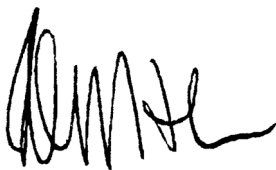
The current pandemic highlights the importance of novel approaches such as Biotron's viroporin compounds which have the potential to target a broad range of existing and emerging viruses.

### **Expenditures**

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totalled \$809,000 and \$206,000 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.

Subsequent to the end of the quarter, the Company received an R&D Tax Incentive rebate of \$1,558,525 for the 2020/21 financial year, further strengthening the Company's cash position.

By order of the Board



Peter J. Nightingale  
Company Secretary

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