

28 July 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 30 JUNE 2022**

During the quarter ended 30 June 2022 Biotron Limited ('Biotron' or 'the Company') achieved key outcomes including:

- Extended the previous findings on the effectiveness of Biotron's lead antiviral drug BIT225 by demonstrating the ability of the drug to protect against severe disease in established SARS-CoV-2 infection in an animal model of human COVID-19.
- Received guidance from the USA Food and Drug Administration (FDA) relating to the proposed clinical development of BIT225 for the treatment of COVID-19.
- 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 and Hepatitis B virus (HBV) programs, with the aim of identifying a next-generation lead anti-HIV-1 drug and a lead candidate for HBV.

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

During the quarter ended 30 June 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.

Previous data 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. The latest data, announced on 2 May 2022, demonstrated that BIT225 was equally effective whether given before infection or 48 hours after an infection had been established.

The latest results indicate that BIT225 can both prevent and treat SARS-CoV-2 disease in this internationally recognised model of COVID-19.

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 antiviral 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.

As announced on 30 May 2022, Biotron has received guidance from the USA Food and Drug Administration (FDA) for development of BIT225 as a potential treatment of COVID-19. The guidance provides clarity on the design of a Phase 2 trial including end points for such a study in the evolving COVID treatment landscape.

The Company is now consulting with clinical research organisations to identify potential trial sites and work through the logistics and costs of undertaking a COVID-19 treatment trial.

## **HIV-1 Program**

During the quarter ended 30 June 2022, Biotron continued recruitment of the two previously announced Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection. As stated in the Report on Activities released on 26 April 2022 patient recruitment had been adversely impacted by the wave of the Omicron variant of SARS-CoV-2 during the first quarter of 2022, resulting in lower than anticipated recruitment rates. However, in recent weeks recruitment rates have increased, and the trials are expected to be fully recruited early in the 3Q2022.

Preliminary results for the BIT225-011 trial are still anticipated to be available in late 2022, with preliminary results for the BIT225-010 trial expected in early 2023.

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 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) is underway at sites in Thailand. This study includes people newly diagnosed as being HIV-1 positive but not yet commenced ART with BIT225 treatment or placebo continuing for 6 months in combination with ART.

The 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**

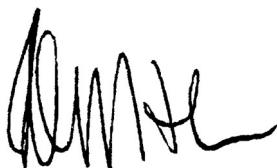
Biotron continues to design, synthesise and test new compounds with the aim of identifying a lead candidate for Hepatitis B virus (HBV). Biotron is working with other experienced groups to access key assays and continues to make good progress. The aim is to identify a lead series to progress to preliminary 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 \$670,000 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.

By order of the Board



Peter J. Nightingale  
Company Secretary

pjn11312

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

BIOTRON LIMITED

**ABN**

60 086 399 144

**Quarter ended ("current quarter")**

30 June 2022

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(670)	(2,620)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(206)	(819)
(f) administration and corporate costs	(144)	(554)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	3
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,559	1,559
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>540</b>	<b>(2,431)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(9)	(38)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(9)</b>	<b>(38)</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	1,211	4,211
4.2	Net cash from / (used in) operating activities (item 1.9 above)	540	(2,431)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(9)	(38)
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>1,742</b>	<b>1,742</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	59	109
5.2	Call deposits	1,683	1,102
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>1,742</b>	<b>1,211</b>

**6. Payments to related parties of the entity and their associates**

- |     |                                                                                         | <b>Current quarter<br/>\$A'000</b> |
|-----|-----------------------------------------------------------------------------------------|------------------------------------|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 144                                |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | -                                  |

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*

Director fees, salaries and superannuation payments.
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## Quarterly cash flow report for entities subject to Listing Rule 4.7B

**7. Financing facilities**

*Note: the term "facility" includes all forms of financing arrangements available to the entity.*

*Add notes as necessary for an understanding of the sources of finance available to the entity.*

	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	<b>-</b>	<b>-</b>

**7.5 Unused financing facilities available at quarter end**

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7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

N/A

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	540
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,742
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	1,742
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>N/A</b>

*Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.*

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

*Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.*

## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 28 July 2022

Authorised by: By the Board.  
(Name of body or officer authorising release – see note 4)

## Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.