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31 January 2023

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 DECEMBER 2022**

Biotron Limited ('Biotron' or 'the Company') has achieved key outcomes including:

- Completed a rights issue plus a follow-on placement, raising \$6 million before costs. Proceeds will be used to:
  - Undertake a Phase 2 COVID-19 clinical trial.
  - Complete non-clinical assays for the Company's two Phase 2 HIV-1 clinical trials.
  - Develop next generation drugs for HIV-1 and COVID-19 programs.
  - Advance the Hepatitis B virus program.
  - Advance commercialisation activities.
  - support working capital and costs of the offer.
- Received an R&D Tax Incentive rebate of \$1,430,725 for the 2021/22 financial year.
- Continued dosing of enrolled patients in the two ongoing Phase 2 trials of BIT225 for treatment of HIV-1 infection that are underway at sites in Australia and Thailand.
- Continued the design, synthesis and testing of new compounds under the 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.

### **HIV-1 Program**

During the quarter ended 31 December 2022, Biotron continued dosing of patients enrolled into the two Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection that are underway at sites in Australia and Thailand. The trials had completed recruitment (as announced on 23 August 2022 and 4 October 2022) and completion of the clinical phase of the trial is expected shortly.

In 2021, 38.4 million people globally were living with HIV, with 1.5 million becoming newly infected with the virus and an estimated 650,000 people dying from AIDS-related illnesses. The global HIV drug market size in 2021 was estimated to be US\$30 billion. The increased prevalence of HIV-1 infections, percentage of patients on treatment due to improved disease awareness and the need for treatments to improve quality of life are expected to drive market growth to over US\$50 billion by 2030.

During the quarter under review, people enrolled in the trial continued to receive either BIT225 or placebo according to the clinical trial protocols. Once the clinical phases of the trials are complete, blood samples collected during the study will be analysed and once all analyses are complete, the trial database will be locked and the results subject to statistical evaluation. The study will then be unblinded and outcomes reported.

Other HIV-1 clinical-trial supporting activities undertaken during the quarter included preparation of laboratory protocols and finalising the selection of test sites for undertaking post-trial sample analyses. The assays to be run on blood samples collected during the trials are complex and have required careful consideration of detailed methodologies.

The clinical trial databases into which all trial data, including patient demographics, results of prescreening, screening and ongoing medical tests set out in the clinical trial protocols, as well as the results of all post-trial analyses, have been routinely monitored and checked for errors by external contractors.

Both trials are designed to generate data that extend the positive findings from previous clinical trials conducted by Biotron. The data will be central to demonstrating to potential pharmaceutical partners and regulatory authorities the safety and efficacy of BIT225 in patients with currently unmet medical needs.

Preliminary results from the trials are anticipated to be available in mid-2023.

## **SARS-CoV-2**

During the quarter ended 31 December 2022, the Company identified suitable trial sites and finalised a new clinical trial protocol and other necessary documentation for a standalone Phase 2 trial of BIT225 as a potential treatment of COVID-19 based on guidance received during 2022 from the USA Food and Drug Administration (FDA). Documentation is progressing through relevant ethics and regulatory submissions at identified trial sites and, subject to approvals, the trial is expected to commence shortly.

The trial design has taken into consideration the continually changing landscape of COVID-19. The Company has consulted with international clinicians, clinical research organisations and other relevant experts to design a study aimed to be recruited quickly and generate meaningful data in a very tight timeframe.

As previously advised (14 September 2022), Biotron added a COVID-19 sub-study to one of the Phase 2 HIV-1 clinical trials of BIT225, with any eligible person enrolled in the HIV-1 trial who becomes infected with SARS-CoV-2 will be intensively monitored for SARS-CoV-2 viral load and clinical symptoms over a 28-day period. While the study is small and end points are exploratory, the sub-study provided an efficient, cost effective and timely opportunity to study BIT225 for this indication in an at-risk population. As discussed above, the HIV-1 clinical trials are in progress, with data for both HIV-1 trials as well as the COVID-19 sub-study expected in mid-2023.

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.

### **Hepatitis B Program**

While the Company's main focus during the quarter has been its clinical programs for HIV-1 and COVID-19, the Hepatitis B virus (HBV) program continues to be an important preclinical program.

Biotron is working with other experienced groups to access key antiviral HBV 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.

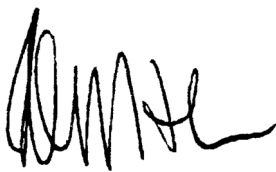
During the first quarter of 2023, focus will return to progressing the HBV preclinical program as well as advancing the identification of next-generation compounds for both HIV and SARS-CoV-2. During the quarter under review, detailed work plans were set up and studies initiated for each of these activities.

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 \$601,000 and \$211,000 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 \$148,000 for director fees, salaries and superannuation payments.

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

pjn11531

## 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")**

31 December 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(601)	(1,287)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(211)	(421)
(f) administration and corporate costs	(410)	(572)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	22	27
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,431	1,431
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>231</b>	<b>(822)</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 (6 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)	6,000	6,000
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	(428)	(428)
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)	(10)	(19)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>5,562</b>	<b>5,553</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	679	1,741
4.2	Net cash from / (used in) operating activities (item 1.9 above)	231	(822)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	5,562	5,553
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	<b>Cash and cash equivalents at end of period</b>	<b>6,472</b>	<b>6,472</b>

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	93	76
5.2	Call deposits	6,379	603
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>6,472</b>	<b>679</b>

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

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter  
\$A'000**

148

-

*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.

**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)	-	-
7.4 <b>Total financing facilities</b>	-	-

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

-

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)	-
8.2 Cash and cash equivalents at quarter end (item 4.6)	-
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	-
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	N/A

*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

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:

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:

*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: 31 January 2023.

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.