

24 October 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 SEPTEMBER 2022

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

- Completed recruitment for the BIT225-010 Phase 2 clinical trial of BIT225 for treatment of HIV-1 infection that is underway at sites in Thailand.
- Completed recruitment for the BIT225-011 Phase 2 clinical trial of BIT225 for treatment of HIV-1 infection that is underway at sites in Australia.
- Commenced a human study of BIT225 for treatment of COVID-19 as a sub-study in the BIT225-010 HIV-1 Phase 2 trial underway at sites in 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.

HIV-1 Program

During the quarter ended 30 September 2022, Biotron completed recruitment of the BIT225-010 clinical trial underway in Thailand and, subsequent to the end of the quarter, completed recruitment of the BIT225-011 clinical trial underway in Australia. Both trials are Phase 2 clinical trials of BIT225 for treatment of HIV-1 infection.

The fully recruited BIT225-011 trial 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. The trial includes BIT225 treatment or placebo continuing for 12 weeks in combination with 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, Holdsworth House and East Sydney Doctors.

The second fully recruited trial, BIT225-010, is underway at sites in Thailand. This study includes people who are newly diagnosed as being HIV-1 positive but have not yet commenced ART. The trial includes BIT225 treatment or placebo continuing for 24 weeks in combination with ART.

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 30 September 2022, the Company received approval for, and commenced, a human study of BIT225 for treatment of COVID-19.

The trial is being run as a sub-study in the ongoing BIT225-010 HIV-1 Phase 2 trial underway in Thailand. As announced on 14 September 2022, 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.

Previous data showed that BIT225 demonstrated antiviral, immune modulatory and clinical benefit against SARS-CoV-2 in an accepted murine model of COVID-19 disease (announced 25 November 2021, 17 March 2022 and 2 May 2022).

The sub-study provides an efficient, cost-effective and timely opportunity to generate preliminary human data with BIT225 for this indication.

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 administered small molecule antiviral drug that has been evaluated in nine completed 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.

The Company is currently finalising a trial protocol and other necessary documentation for a Phase 2 trial of BIT225 as a potential treatment of COVID-19 based on guidance received in May 2022 from the USA Food and Drug Administration (FDA).

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

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.

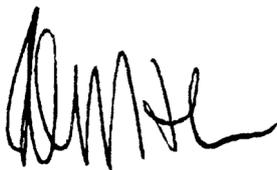
Biotron is working with other experienced groups to access key antiviral HBV assays and continues to make good progress. The aim is to identify a lead series to progress to preliminary safety studies and assessment in animal models of HBV infection.

The current pandemic highlights the importance of novel approaches such as Biotron's viroprolin 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 \$686,000 and \$210,000 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



Peter J. Nightingale
Company Secretary

pjn11408

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 September 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(686)	(686)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(210)	(210)
(f) administration and corporate costs	(162)	(162)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	5	5
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(1,053)	(1,053)
2. Cash flows from investing activities		
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 (3 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)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities		
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)	(9)
3.10	Net cash from / (used in) financing activities	(9)	(9)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,741	1,741
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,053)	(1,053)
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 (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(9)	(9)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	679	679

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	76	76
5.2	Call deposits	603	603
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	679	679

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

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

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,053)
8.2 Cash and cash equivalents at quarter end (item 4.6)	679
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	679
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	0.65

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: Yes.

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: Following the imminent lodgement of the Company's 2021/22 tax return, the Company will receive an R&D development grant rebate of approximately \$1.4 million, equivalent to 43.5% of the Company's eligible research and development expenditure on its antiviral drug development programs during that year. In addition, the Company is currently investigating other funding sources.

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: Yes, supported by funding from the R&D development grant rebate and potential other funding sources noted in item 8.6.2 above.

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: 24 October 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.