

26 April 2024

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 2024**

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

- Reported positive outcomes from the BIT225-010 Phase 2 HIV-1 clinical trial, with all primary objectives of the trial met.
- Continued detailed post-clinical phase activities and analyses of the BIT225-011 Phase 2 clinical trial of BIT225.
- Continued detailed post-clinical phase activities and analyses of the BIT225-012 Phase 2 clinical trial of BIT225 for treatment of adults with COVID-19.
- Continued the design, synthesis and testing of new compounds with the aim of identifying next-generation lead anti-HIV-1 and anti-SARS-CoV-2 drugs and a lead candidate for HBV.
- Received an R&D Tax Incentive cash rebate of \$1,645,114 for the 2022/23 financial year.

### **HIV-1 and SARS-CoV-2/COVID-19 Clinical Programs**

During the first quarter of 2024, the Company reported positive outcomes from the completed Phase 2 HIV-1 clinical trial (BIT225-010) with its lead antiviral drug BIT225.

The double-blind placebo-controlled Phase 2 trial was designed to characterise the effect of BIT225 (200 mg, once daily for 24 weeks) added to a standard of care antiretroviral therapy (cART: 50 mg Dolutegravir (DTG), 300 mg Tenofovir disoproxil fumarate (TDF) and 200 mg Emtricitabine (FTC)) in 27 (18 BIT225: 9 Placebo) treatment naïve people infected with HIV-1. Study participants were followed for a one month period following 24 weeks of BIT225 or placebo dosing. All individuals continued on cART as per standard treatment guidelines post-study.

The primary objectives of the trial were to evaluate the safety, efficacy and impact of BIT225 administered with cART on selected inflammatory and immune markers in this patient population.

The Company reported that preliminary analyses of data from the BIT225-010 trial provided confirmation of the results of previous trials in people infected with HIV-1. BIT225 was safe and generally well tolerated at the 200mg once daily dose, with no deaths or drug-related serious adverse events. All participants achieved viral suppression and none were considered virologic failures.

The data indicated that the addition of BIT225 to cART resulted in a more rapid reduction in HIV-1 levels in the blood during the second phase of viral decay, compared to cART alone. Analyses of several immune activation and inflammatory markers in the blood showed changes that are consistent with those seen in earlier trials and suggest a possible immune modifying effect of BIT225 when used with cART.

These preliminary, positive trial data are very encouraging. The blood viral load reduction data are consistent with BIT225 having an impact on viral reservoirs. Current cART is efficient at rapidly and durably reducing virus levels in the blood, but this does not translate into clearance of long-lived reservoirs of HIV-1. The observed changes to immune markers and cells further the results from the previous BIT225-009 trial and suggest the utility of targeting viroproins as a new class of antiviral drugs.

Additional analyses are ongoing.

During the quarter, the Company has continued its focus on post-trial activities for the remaining two Phase 2 clinical trials – BIT225-011 and BIT225-012. There is a major workload associated with monitoring of all aspects of the completed trial to ensure that all information within patient master files, and subsequently in trial databases, is correct and compliant with international regulatory guidelines.

The BIT225-011 HIV-1 Phase 2 trial, together with the BIT225-010 HIV-1 Phase 2 trial (discussed above), have been designed to generate data that extend the positive findings from previous clinical trials conducted by Biotron in which BIT225 was shown to have positive effects on key immunologic markers of improved health outcomes.

The BIT225-012 SARS-CoV-2 Phase 2 trial aims to determine if 7 days of treatment with BIT225 commenced within 3 days of onset of COVID-19 symptoms results in reduction in SARS-CoV-2 blood viral load, clinically favourable changes in viral, inflammatory and immune activation markers, as well as improvement in clinical symptoms of COVID-19.

The Company understands the high level of interest of shareholders in the outcomes of the completed clinical trials. Trials such as BIT225-011 that include longitudinal analyses of a multitude of immunological markers involve complex, time-consuming modeling and consultation with relevant experts. Good progress is being made and the Company looks forward to reporting results during the second quarter of 2024.

The data from all three Phase 2 trials 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.

## **Hepatitis B Program**

While the clinical programs for HIV-1 and COVID-19 continue to be the Company's main focus, the Company's 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.

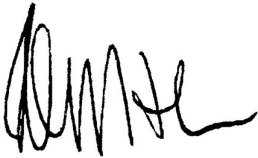
The COVID-19 pandemic highlights the importance of novel approaches, such as Biotron's viroporin compounds, which have the potential to target a broad range of existing and emerging viruses.

## **Expenditures**

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totaled \$514,000 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 totaled \$149,000 for director fees, salaries and superannuation payments.

During the quarter under review, the Company received an R&D Tax Incentive cash rebate of \$1,645,113.64 for the 2022/23 financial year.

By order of the Board

A handwritten signature in black ink, appearing to read 'Peter J. Nightingale', written over a white background.

Peter J. Nightingale  
Company Secretary

pjn12156

## 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 March 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(514)	(3,054)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(211)	(634)
(f) administration and corporate costs	(365)	(711)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	15	63
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,645	1,645
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>570</b>	<b>(2,691)</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 (9 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 Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	20
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)	(11)	(32)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>(11)</b>	<b>(12)</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	722	3,984
4.2 Net cash from / (used in) operating activities (item 1.9 above)	570	(2,691)
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 (9 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(11)	(12)
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>1,281</b>	<b>1,281</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	83	97
5.2	Call deposits	1,198	625
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>1,281</b>	<b>722</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	149
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.

7. <b>Financing facilities</b> <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>	<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
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8. <b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	570
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,281
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	1,281
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: 26 April 2024.

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.