

31 July 2024

The Manager CompaniesASX Limited  
20 Bridge Street  
Sydney NSW 2000

(3 pages by email)

Dear Madam

## **REPORT ON ACTIVITIES FOR THE QUARTER ENDED 30 JUNE 2024**

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

- Reported positive outcomes from the BIT225-011 Phase 2 HIV-1 clinical trial, with all primary objectives of the trial met.
- Continued detailed post-clinical phase activities and analyses of the BIT225-012 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.

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

During the June 2024 quarter, the Company reported positive outcomes from the completed Phase 2 HIV-1 clinical trial (BIT225-011) with its lead antiviral drug BIT225.

This longitudinal, open-label Phase 2 trial was designed to characterise the effect of BIT225 (200 mg, once daily) added to ongoing, suppressive standard of care antiretroviral therapy (cART) for twelve weeks in twenty HIV-1 infected, treatment-experienced participants who had achieved only partial immune reconstitution.

The primary objectives of the trial were to evaluate the safety and tolerability of BIT225 in this patient population, as well as determine the impact of the addition of BIT225 to cART on immune activation, inflammation and viral markers.

As reported, preliminary analysis of the safety data showed that BIT225 was safe and generally well tolerated at the 200 mg once daily dose, with no deaths or drug-related serious adverse events. The safety and tolerability profile of BIT225 in the current trial was congruent with that seen in previous trials. Observed Adverse Events (AEs) attributed to BIT225 were of similar incidence, and mild severity, to those previously reported for the drug. One person withdrew from the study following the first dose of study drug during the treatment period.

Baseline values for a range of immune activation, inflammation and viral assays were determined for each person during an initial 4-week Observation period. Subsequent values of the same markers were assessed during the 12-week Treatment period with BIT225, as well as during a 4-week Follow-up period after completion of BIT225 treatment. Analyses of Treatment and Follow-up values were compared to those obtained during the Observation period.

All participants maintained viral suppression throughout the study. Statistically significant differences ( $P < 0.05$ ) in the change from baseline were observed during the BIT225 treatment period for several pre-specified immune markers and cell populations. These included NK cells, a key cell type involved in combating viral infection, and T-regulatory cells. Changes in these cell populations have been noted in previous trials with BIT225 and suggest a possible immune modifying effect of BIT225 when used with cART.

Individuals who do not achieve full immune reconstitution following fully suppressive antiviral therapy represent an important portion of those with HIV infection. Studies suggest that immune non-responders (INR) represent 20% - 40% of those on current antiviral therapy. These individuals are at enhanced risk for serious comorbid conditions including neurocognitive, cardiovascular, renal and hepatic disorders that impair quality of life and drive healthcare expenditures.

Viroporin targeting drugs such as BIT225 uniquely combine immune modulation with antiviral activity and have the potential to address both the immune and viral pathogenesis of numerous viral infections in a clinically relevant fashion.

The results reported are preliminary and ongoing analysis of this BIT225-011 trial and the BIT225-010 HIV-1 trial in a treatment-naïve population will be reported when complete.

During the quarter, the Company has continued its focus on post-trial activities for the BIT225-012 trial. There is a major workload associated with monitoring 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. Once completed, the results of preliminary analyses will be reported.

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 Hepatitis B virus (HBV) program continues to be an important preclinical program.

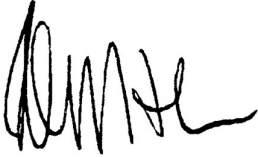
Biotron is working with other experienced groups to access key antiviral HBV assays and continues to make good progress. The aim is to identify a lead series to progress to preliminary safety studies and assessment in animal models of HBV infection.

Biotron's novel antiviral platform is focused on developing novel viroporin targeting drugs which have the potential to uniquely impact a broad range of existing and emerging viruses. The clinical data from the HIV trials have important implications for earlier stage programs as they demonstrate the feasibility of developing this novel class of antiviral drugs.

## Expenditures

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totaled \$582,000 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 \$148,000 for director fees, salaries and superannuation payments.

By order of the Board

A handwritten signature in black ink, appearing to read 'Peter J. Nightingale', written in a cursive style.

Peter J. Nightingale  
Company Secretary

pjn12261

## 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 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(582)	(3,636)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(211)	(845)
(f) administration and corporate costs	(96)	(807)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	8	71
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	1,645
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(881)</b>	<b>(3,572)</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 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)	(7)	(39)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>(7)</b>	<b>(19)</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	1,281	3,984
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(881)	(3,572)
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)	(7)	(19)
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>393</b>	<b>393</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	58	83
5.2	Call deposits	335	1,198
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>393</b>	<b>1,281</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

<b>Current quarter \$A'000</b>
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. <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)	-	-
<b>7.4 Total financing facilities</b>	<b>-</b>	<b>-</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)	(881)
8.2 Cash and cash equivalents at quarter end (item 4.6)	393
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	393
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>0.44</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 No. The Company's research and development expenditure varies from quarter to quarter based on the stage of its clinical trials. Three trials have completed the clinical phase and expenditures are expected to be lower as a result.

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: The Company will receive an R&D Tax rebate for the financial year ended 30 June 2024 which, based on R&D expenditures of \$3.6 million during the year and consistent with prior years, is anticipated to be in excess of \$1.0 million.

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, for the reasons given 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: 31 July 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.