Biotron Limited
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30 October 2024

The Manager Companies
ASX Limited
20 Bridge Street
Sydney NSW 2000 (8 pages by email)

Dear Madam

REPORT ON ACTIVITIES FOR THE QUARTER ENDED 30 SEPTEMBER 2024

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

- Reported outcomes from the BIT225-012 Phase 2 COVID-19 clinical trial. The trial met the primary safety and tolerability end point but did not meet the primary efficacy end point.
- Continued the 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.
- Extended its early stage Dengue virus program to assess activity of a subset of Biotron's compounds against all four Dengue virus subtypes in cell cultures.
- Subsequent to the end of the reporting period, received an R&D Tax Incentive rebate of $1,814,495 for the 2023/24 financial year.

During the September quarter, the Company reported outcomes from the completed Phase 2 COVID-19 clinical trial (BIT225-012) with its lead antiviral drug BIT225.

As reported (6 September 2024), the trial met the primary safety and tolerability end point with observed adverse events congruent in severity and frequency with those seen in previous trials of BIT225.

The trial did not meet the primary efficacy end point in this population as assessed by the change in SARS-CoV-2 nasal viral load. There were no statistically significant differences between drug and placebo groups based on change in SARS-CoV-2 nasal viral load, kinetics of change or time to negative SARS-CoV-2 PCR when compared to baseline values on Day 1 to dosing completion on Day 7.

The groups were similar in terms of time to sustained clinical recovery and time to clinical improvement.

Day 1 to Day 7 was selected as the timeframe for the primary efficacy analyses and was pre-specified in the Statistical Analysis Plan (SAP). Analyses were performed as set out in the SAP, in accordance with Good Clinical Practice (GCP) and international regulatory requirements.

Once the dataset was complete and unblinded, it was noted that four trial participants did not demonstrate quantifiable levels of nasal SARS-CoV-2 virus on Day 1. All participants had positive PCR at entry (Day 1), however, in these four individuals, levels of viral RNA were below the limits of quantification. A *post hoc*, exploratory evaluation from Day 3, when all participants had quantifiable viral load measurements, to Day 9 was performed.

In this analysis nasal viral load declines slowed in the Placebo group after Day 6, while continuing at a relatively consistent rate in the two BIT225 dosage groups, resulting in lower viral loads in the BIT225 dosage groups compared to placebo. The difference between the active (BIT225) and placebo arms was significant (P = 0.02), especially in those starting with higher initial viral loads.

While of interest, and potentially informing further study of BIT225 in SARS-CoV-2 infection, these *post hoc* exploratory analyses do not change the formal outcomes of the trial.

This double-blind, placebo-controlled Phase 2 trial was designed to characterise the effect of BIT225 (200mg or 400mg daily) administered for 7 consecutive days in sixty individuals newly diagnosed with SARS-CoV-2 infection at several sites in Thailand.

As reported (6 September 2024), the Company considers that the outcomes may have been adversely impacted by the widespread levels of immunity to SARS-CoV-2 infection in the community afforded by vaccination and prior infection as well as the exclusion from the trial of people at high risk of progression to severe COVID-19 (due to the availability of other treatment options for that population). The preclinical data of BIT225 in a mouse COVID-19 model that supported the BIT225-012 clinical study remain some of the best in the field.

The recently reported positive outcomes from the two Phase 2 HIV-1 trials, BIT225-010 and BIT225-011, added to the previous positive data of BIT225. The drug has demonstrated broad spectrum antiviral activity in preclinical and clinical studies.

Biotron remains focused on its platform of viroporin antagonists which uniquely combine direct-acting antiviral and immunomodulatory activities across numerous viruses responsible for important human disease. Its portfolio extends beyond BIT225 and includes next-generation compounds for its HIV-1 and SARS-CoV-2 programs, as well as compounds with activity across a broad range of viruses including Hepatitis B virus (HBV), influenza, Dengue virus and others.

Viroporin inhibitors such as BIT225 uniquely combine direct-acting antiviral (DAA) and immunomodulatory activities, in contrast to existing antiviral drug classes that focus on DAA only.

During the quarter under review, the Company has continued to characterise the antiviral activity of its anti-HBV compounds in cell-based assays. In addition, several compounds were assessed for their ability to inhibit all four Dengue virus subtypes in cell-based assays. These investigations are ongoing, with the aim of identifying a lead series for progression into formal preclinical studies.

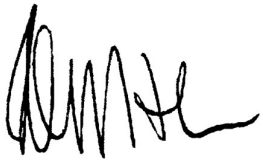
In parallel with continuing development of its early stage programs, the Company is currently undertaking a detailed review of all programs as it continues to investigate pathways to a commercial outcome to benefit shareholders.

Expenditures

As disclosed in the Company's Quarterly Cash Flow Report, expenditure on these research and development activities during the quarter totaled $289,000 and $166,000 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 $103,000 for director fees, salaries and superannuation payments.

Subsequent to the end of quarter the Company received an R&D Tax Incentive rebate of $1,814,495 for the 2023/24 financial year.

By order of the Board



Peter J. Nightingale
Company Secretary

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Appendix 4C

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

Name of entity	
BIOTRON LIMITED	
ABN	**Quarter ended ("current quarter")**
60 086 399 144	**30 September 2024**

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	(289)	(289)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(166)	(166)
	(f) administration and corporate costs	(153)	(153)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	3	3
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**	**(605)**	**(605)**

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)	2	2
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	500	500
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)	(7)
3.10	**Net cash from / (used in) financing activities**	**495**	**495**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	393	393
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(605)	(605)
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)	495	495
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**283**	**283**

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	46	58
5.2	Call deposits	237	335
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)**	**283**	**393**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	103
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.	**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.*	**Total facility amount at quarter end $A'500**	**Amount drawn at quarter end $A'500**
7.1	Loan facilities	500	500
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**500**	**500**

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.

During the quarter. the Company entered into a loan facility of $500K with Integral Admin Services Pty Ltd at 1.33% per month, the lender has a first ranking charge over the Company's R&D rebate. The maturity 5 business days of the earlier of Biotron receiving an R&D rebate from the ATO or the borrower having sufficient funds to repay the Amount Owing. Subsequent to the end of the quarter Biotron received the R&D rebate and repaid the loan facility in full.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(605)
8.2	Cash and cash equivalents at quarter end (item 4.6)	283
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	283
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.47

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. Net operating cashflows are expected to decline as the payments for research and development in the September quarter relates to expenses incurred for three clinical trials which have completed.

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 Subsequent to the end of the September quarter, the Company received $1.8m of R&D rebate for the Company's 2023/2024 research and development expenditure on its antiviral drug development program.

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: 30 October 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.