Biotron Limited
A.B.N. 60 086 399 144

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30 January 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 DECEMBER 2023

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

- Continued detailed post-clinical phase analyses of samples collected during the completed Phase trial of BIT225 for treatment of adults with COVID-19 (BIT225-012).
- Continued detailed post-clinical phase analyses of samples collected during the two completed Phase 2 trials of BIT225 for treatment of HIV-1 infection (BIT225-010 and BIT225-011).
- Continued post-clinical phase activities for all three Phase 2 trials including site monitoring and close-out, and finalising statistical analyses plans ahead of locking of trial databases and unblinding of data.
- 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.

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

During the second half quarter of 2023 the Company completed a Phase 2 clinical trial (BIT225-012) with its lead antiviral drug BIT225 for treatment of COVID-19 at sites in Thailand.

The trial commenced in May 2023, and was very quickly fully enrolled with dosing completed in August.

During the quarter ended 31 December 2023 the Company has been focused on post-trial activities that are essential parts of the clinical assessment of new drugs. 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 double blind, placebo-controlled 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.

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 the potential to be an important first in class drug for COVID-19 treatment.

During the quarter post-trial activities have also continued for the two HIV-1 Phase 2 clinical trials (BIT225-010 and -011). These important trials 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 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.

End of trial activities for all three clinical trials are primarily in the hands of external Contract Research Organisations (CROs) that are responsible for independent management and oversight of all data generated throughout clinical trials. Once all post-trial activities are completed, the trial database will be locked, the data unblinded and statistical analyses of the data can be completed.

As outlined in a market update on 14 December 2023 external factors beyond the Company's control that have impacted on timelines of data release. Firstly, the workload associated with completing three very complex, data-heavy Phase 2 trials. Secondly, the quantity of data that has been generated from trials involving up to 6 months of treatment plus several weeks follow-up post-dosing. And thirdly, in the aftermath of the COVID-19 pandemic, which caused significant delays across all aspects of clinical studies undertaken globally, many clinical studies in Australia are now in the same post-clinical stage and this is creating backlogs and delays with the CROs involved in the studies. The Company continues to work closely with the CROs involved with the trials to facilitate completion of all essential post-trial activities. Release of headline results is expected in coming weeks.

Hepatitis B Program

While the clinical programs for HIV-1 and COVID-19 continue to be the Company's main focus, its 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 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 $1,524,000 and $212,000 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.

In late 2023 an R&D Tax Incentive Registration was filed for eligible activities undertaken during the 2022/23 financial year. The Company expects to shortly receive a cash rebate of approximately $1.6 million from AusIndustry under the scheme.

By order of the Board

Peter J. Nightingale
Company Secretary

pjn12063

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	**31 December 2023**

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,524)	(2,540)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(212)	(423)
	(f) administration and corporate costs	(178)	(346)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	16	48
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**	**(1,898)**	**(3,261)**

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 (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)	-	-
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)	20	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)	(21)
3.10	**Net cash from / (used in) financing activities**	**9**	**(1)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	2,611	3,984
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,898)	(3,261)
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)	9	(1)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**722**	**722**

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	97	71
5.2	Call deposits	625	2,540
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)**	**722**	**2,611**

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	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.	**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'000**	**Amount drawn at quarter end $A'000**
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)	(1,898)
8.2	Cash and cash equivalents at quarter end (item 4.6)	722
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	722
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.38

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 research and development expenditures in the December quarter relate to three clinical trials which have completed expensive the clinical stage. Hence, future expenditures will be lower.

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 has lodged its annual income tax return and is expecting to receive the R&D rebate for the Company's eligible research and development expenditure on its antiviral drug development programs during the year 2022/2023. As in previous years the expected refund will 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: 30 January 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.