FirebrickPharma

27 July 2023

ASX Announcement

June 2023 Quarterly Activity Report

Q4 FY23 HIGHLIGHTS

- Phase 3 common cold trial exceeds 100% patient recruitment
- Phase 2 COVID-19 trial concludes with results expected end-July
- AAT conciliation meeting occurs and confidential discussions continue

Firebrick Pharma Limited (ASX:FRE) (**Company** or **Firebrick**) is pleased to provide its business activity update for the quarter ending 30 June 2023, along with its Appendix 4C quarterly cashflow report.

REVIEW OF QUARTERLY OPERATIONS

Phase 3 Common Cold Study

On 20 June 2023, we announced that the Phase 3 trial of Nasodine® Nasal Spray ("Nasodine") as a treatment for the common cold surpassed 100% of the recruitment target for the trial and that we intended to continue recruiting until approximately the end of July.

The Study aimed to recruit up to 500 subjects with early-stage colds (referred to as "ITT" population) to achieve a target of 196 subjects in the primary endpoint population, being those with a confirmed viral infection (referred to as the "ITTi" population). The primary endpoint is the impact of Nasodine on overall cold severity (Global Severity Score, GSS) in the ITTi, while the ITT is used for assessment of a range of secondary endpoints.

The trial started in 2022 and ran from May 2022 through October 2022, recruiting 224 subjects with colds, of whom 100 were virus-positive and qualified for the ITTi. The trial was then paused over the summer period and reopened on 21 March 2023. It re-opened for recruiting in March 2023 and achieved accelerated recruitment compared with 2022.

As a result, by 30 June 2023, we had recruited a total of around 440 ITT subjects, of whom around 210 qualified for the ITTi. Recruitment will close when the maximum of 500 ITT subjects is reached, which is expected to be around the end of July 2023.

The trial results will be used primarily to support international regulatory filings for Nasodine, including a European approval submission.

Phase 2 COVID-19 Study

Since early 2022, we have also been conducting a COVID-19 study to assess the potential for Nasodine to reduce viral shedding of SARS-CoV-2 in people with early COVID-19.

On 3 April 2023, we announced that the recruitment phase of this study had concluded, with 39 subjects completing the study. As noted in our announcement of 20 June 2023, the blinded results had been received and we were awaiting completion of the statistical analysis plan to finalise results, which are now expected by the end of July 2023.

AAT Appeal

During the quarter, the Company's appeal to the Administrative Appeals Tribunal (the **AAT**) continued. The appeal is seeking to overturn the TGA's decision not to approve Nasodine based on the existing Phase 3 data and gain immediate approval for Nasodine in Australia.

On 29 May 2023, we announced that the conciliation meeting between Firebrick and TGA, which had been scheduled for 30 May, has been deferred due to the unavailability of the nominated AAT Member on that date. Subsequently, the date of 19 July 2023 was agreed and the parties met for the conciliation meeting on that date.

In our announcement of 20 July 2023, we stated that the meeting was cordial with a frank exchange on the issues. Confidential discussions between the parties are ongoing and Firebrick is hopeful that an agreement on the approval of Nasodine can be reached.

Nasodine Patent Allowed in Canada

On 9 May 2023, we announced that our core patent covering Nasodine as a treatment and preventative for the common cold has now been allowed in Canada. Once this proceeds to grant, it will bring the number of countries where this patent has been granted to 28, now covering North America, Europe, Australia and other key markets (see announcement 25 October 2022 for list of countries). The patent expires in most countries in 2035 and in Australia, in 2034.

Financial Overview

At 30 June 2023, Firebrick held cash and cash equivalents of $2.355 million, compared with $3.44 million at the end of the March quarter. Net cash outflow from operations for the quarter was $2.08 million, 66.8% ($1.39m) of which was for R&D expenditure associated with the two clinical trials being undertaken by the Company. Almost all of the R&D expenditure will be eligible for the RDTI (R&D tax incentive), which is expected to be received in the September quarter. The June quarter operating expenses were approximately in line with operating expenditures in the previous two quarters.

The Company successfully raised $1.0 million during the quarter (before transaction costs) via a Placement led by Firebrick senior management team with support from sophisticated shareholders (ASX announcement 1 May 2023). This placement was designed to top up our cash reserves until we receive the RDTI income, expected in September, and to ensure we have adequate funding for the next 12 months. A total of 6.67 million new shares were issued at a price of $0.15 per share.

The Company provides the following disclosure required by ASX Listing Rule 4.7C.2 regarding a comparison of its actual expenditure (since admission date) compared with the "use of funds" statement in Section 8.3 of its Prospectus dated 26 November 2021 (lodged with ASX on 25 January 2022):

Use of Funds under Prospectus	**Budgeted Expenditure $'000 Over 2 years (Jan '22-Dec'23)**	**Actual Expenditure to 30 June 2023 $'000**
Research & Development	7,473	5,809
Sales & Marketing	2,039	447
Manufacturing & Distribution	48	-
General & Administration	3,274	3,529
Total operating expenses	**12,834**	**9,785**

Note: The above table is based on budgeted expenditure for the period 1 Jan 2022 – 31 Dec 2023. The actual expenditure is reported as per the ASX Listing Rules and is from admission of the Company on 28 January 2022. Depending on Firebrick's progress and success in its programs, the Company may or may not require new capital in the future to complete the development and commercialisation of its intellectual property portfolio.

As per item 6 of the attached Appendix 4C cashflow report for the quarter, payments to related parties and their associates of $184k comprised of Executive Chairman and Executive Director/COO remuneration and Non-Executive Director Fees, which was up on the March quarter value of $171k due to the timing of various payments.

This announcement has been authorised for release by the Board of Firebrick Pharma Limited.

- ENDS -

About Firebrick (ASX:FRE)

Firebrick is a pharmaceutical company founded with the mission to commercialise a nasal spray treatment for the common cold based on povidone-iodine as a broad-spectrum antimicrobial agent. The Company owns numerous granted and pending patents protecting the use of intranasal povidone-iodine for the treatment and prevention of the common cold and the prevention of pandemic viral diseases, including COVID-19. The Company also has a third patent family covering the Nasodine formulation. Firebrick is currently completing a second Phase 3 trial for Nasodine, to confirm its efficacy as a treatment for the common cold and support international approvals.

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Appendix 4C

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

Name of entity	
FIREBRICK PHARMA LIMITED	
ABN	**Quarter ended ("current quarter")**
64 157 765 896	30 June 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	1
1.2	Payments for		
	(a) research and development	(1,390)	(4,015)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(14)	(263)
	(d) leased assets (including premises)	(27)	(103)
	(e) staff costs	(186)	(732)
	(f) administration and corporate costs	(474)	(1,812)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	11	40
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,101
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,080)**	**(5,783)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(2)
	(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)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**(2)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,001	1,001
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	2
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(6)	(6)
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)	-	-
3.10	**Net cash from / (used in) financing activities**	**995**	**997**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,440	7,143
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,080)	(5,783)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(2)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	995	997
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**2,355**	**2,355**

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	2,355	3,440
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**2,355**	**3,440**

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	184
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.

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)	(2,080)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,355
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	2,355
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.1

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?

No, The R&D expenditures over the past year have been related to two clinical trials, one of which concluded in March 2023 and the other is expected to be completed in Q1 FY24, with a low level of R&D expenditure during the remainder of FY24.

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?

During the quarter ended 30 June 2023, the Group successfully raised $1M (before transaction costs) via a Placement led by several members of the Company's senior management and supported by existing sophisticated shareholders. The Group remains confident on raising further funds as and when the need arises. Further, the Company is anticipating an R & D Rebate of $1.8m which is expected to be received in October 2023.

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?
Yes, with the reduced R&D expenditure in FY24, the Company is confident about funding its operations from existing cash reserves. Further, the Company is anticipating an R & D Rebate of $1.8m which is expected to be received in October 2023.	

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: 27 July 2023

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.