

20 April 2023

ASX Announcement

March 2023 Quarterly Activity Report

Q3 FY23 HIGHLIGHTS

- Pivotal Phase 3 common cold trial re-opens on schedule for patient recruitment
- AAT appeal progresses on schedule with filing of FRE's evidence
- Nasodine paediatric development plan filed towards a European marketing application later in calendar 2023

Firebrick Pharma Limited (ASX:FRE) (**Company** or **Firebrick**) is pleased to provide its business activity update for the quarter ending 31 March 2023, along with its Appendix 4C quarterly cashflow report.

REVIEW OF QUARTERLY OPERATIONS

Phase 3 Common Cold Study

In an important development, the Phase 3 trial of Nasodine® Nasal Spray ("Nasodine") as a treatment for the common cold resumed recruitment on schedule in March 2023.

On 21 March 2023, we announced that the trial had received the necessary approvals to re-open and that recruitment had started at two sites in Australia – Geelong and Adelaide – with three sites in South Africa planning to start recruiting the following week. Two of the three South Africa sites have since started recruiting. Overall, recruitment is progressing well, even though it is still early in the common cold season.

Overall, we need to recruit 196 adult subjects with confirmed viral colds, who are also PCR-positive for a respiratory virus (other than SARS-CoV-2). In 2022, the trial successfully recruited 224 subjects, of whom 100 had a confirmed viral infection. To complete the trial in 2023, we need to recruit a further 96 subjects with confirmed viral infection, and to achieve that we may need to recruit another 200-250 subjects, depending on the rate of virus positivity in subjects. Starting recruitment in March this year puts us in a good position to complete all recruitment by around July.

Phase 2 COVID-19 Study

In 2022, we also started a COVID-19 study to assess the potential for Nasodine to eliminate or significantly reduce viral shedding of SARS-CoV-2 in people with early COVID-19. Shortly after the end of the Quarter, we announced (ASX announcement 3 April 2023) that this study had been closed for recruitment and the results were expected to be announced in June 2023. If the results are positive, then they could pave the way for Nasodine to play an important role in future pandemics.

AAT Appeal

During 2022, the Company filed an appeal with the Administrative Appeals Tribunal (the **AAT** or **Tribunal**), seeking to overturn the TGA's decision not to approve Nasodine based on the existing Phase 3 data. In the December Quarter, the Company held an initial conference with the TGA and the Tribunal, after which a timetable for the process was announced (ASX announcement 1 December 2022).

On 2 March 2023, Firebrick completed the first step in that timetable, by filing its Statement of Issues, Facts and Contentions (**SIFC**) and associated expert evidence. The Company now looks forward to receiving the TGA's SIFC (and expert evidence) by 12 May 2023, as per the timetable, in anticipation of the conciliation meeting scheduled for 30 May 2023. If the conciliation is successful, the potential exists for approval of Nasodine later in 2023.

Paediatric Investigation Plan Filed

On 21 February 2023, we announced that the Paediatric Investigation Plan (**PIP**) Nasodine had been filed with the European Medicines Agency Paediatric Committee (**PDCO**), in preparation for filing for marketing approval of Nasodine in Europe later this year.

The PIP addresses the development program for Nasodine in children, which will take place after Nasodine is approved in Europe for adult use. The PIP anticipates two pivotal clinical trials – the first in adolescents (children aged 12-17) and the second in children aged 6-11.

If the proposed paediatric studies are accepted and then successfully completed, Firebrick would seek approval for use of Nasodine in both paediatric subsets in Europe as well as in Australia.

Financial Overview

At 31 March 2023, Firebrick held cash and cash equivalents of \$3.44 million, compared with \$4.91 million at the end of the December quarter. Net cash outflow from operations was \$1.47 million, 47% of which (\$0.69m) was for R&D expenditure associated with the two clinical trials being undertaken by the Company. Almost all of this R&D expenditure will be eligible for the RDTI (R&D tax incentive), which is expected to be received in the September quarter.

The March quarter operating expenses were approximately in line with operating expenditures in the previous two quarters.

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 31 March 2023 \$'000
Research & Development	7,473	4,419
Sales & Marketing	2,039	433
Manufacturing & Distribution	48	-
General & Administration	3,274	2,842
Total operating expenses	12,834	7,694

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 \$171k comprised of Executive Chairman and Executive Director/COO remuneration and Non-Executive Director Fees, which was down on the December quarter value of \$201k 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. Positive Phase 3 trial results will also be important for securing regulatory approvals and partnerships in major markets outside Australia.

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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

64 157 765 896

Quarter ended ("current quarter")

31 March 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	1
1.2 Payments for		
(a) research and development	(690)	(2,625)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(61)	(249)
(d) leased assets (including premises)	(36)	(76)
(e) staff costs	(178)	(546)
(f) administration and corporate costs	(515)	(1,338)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	11	29
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	(1,469)	(3,703)
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 (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)	-	-
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)	-	-
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	-	-
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	-	2

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,909	7,143
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,469)	(3,703)
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 (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	2
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	3,440	3,440

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	3,440	4,909
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)	3,440	4,909

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	171
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	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)	(1,469)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,440
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,440
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.3
	<i>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.</i>	
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: N/A	
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: N/A	
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: N/A	
	<i>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.</i>	

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: 20 April 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.