

31 October 2022

ASX Announcement

September 2022 Quarterly Activity Report

Q1 FY23 HIGHLIGHTS

- R&D remains the focus for activities and expenditure in Q1 FY23
- Phase 3 trial of Nasodine® for the Common Cold progressed with new sites added
- Phase 2 COVID-19 trial of Nasodine® in South Africa slowed by low COVID cases
- AAT appeal proceeds

Firebrick Pharma Limited (ASX:FRE) (**Company** or **Firebrick**) is pleased to provide its business update for the quarter ending 30 September 2022, along with its Appendix 4C quarterly cashflow report.

REVIEW OF QUARTERLY OPERATIONS

During the quarter, the Firebrick team continued to drive recruitment into its two clinical trials: (1) the Phase 3 clinical trial to confirm the efficacy of Nasodine® Nasal Spray (“Nasodine”) in the common cold; and (2) the Phase 2 clinical trial of Nasodine targeting COVID-19.

In addition, we moved forward with the planned appeal to the Administrative Appeals Tribunal (**AAT**) against TGA’s decision not to approve Nasodine based on the existing efficacy data.

Phase 3 Common Cold Study

The Phase 3 trial for Nasodine in the treatment for the common cold is a confirmatory pivotal trial designed mainly to support EU and US registration of Nasodine.

As previously announced, it is a multi-centre, international study, aiming to recruit up to 450 adult subjects with early cold symptoms (referred to as the “ITT” or intent-to-treat population) to achieve a primary endpoint population of 196 subjects who are confirmed by PCR to have viral colds (referred to as the “ITT_i” or infected-ITT). The primary endpoint is the impact of Nasodine treatment (versus placebo) on overall cold severity in the 196 subjects. In an earlier Phase 3 trial, Nasodine delivered a statistically significant benefit (over saline nasal spray) in the 52 subjects in that study who were confirmed by PCR to have a viral infection.

The study recruitment was originally planned at 5 sites: 1 in South Australia (Adelaide), 2 in Victoria (Geelong and Ballarat) and 2 in South Africa. The trial started on 3 May 2022 with the first patient recruited at the Adelaide site. As noted in the July 2022 Quarterly Activity Report, the other 4 sites (in Victoria and in South Africa) were scheduled to come online by end July. They all subsequently achieved that target, but the late start significantly constrained recruitment at those sites. Subsequently, two additional sites were initiated in South Africa to bolster the numbers there.

At the end of the September quarter, the Adelaide site had achieved above-target recruitment for the ITTi, while the Victorian sites performed significantly below their target. Despite the late start, the South Africa sites performed well during August and September and have continued recruiting during October.

Phase 2 COVID-19 Study

As previously announced, the COVID-19 study is a trial at several sites in South Africa, designed primarily to show that in early COVID-19 cases, Nasodine leads to a significant reduction in nasal shedding of the SARS-CoV-2 virus.

The trial is scheduled to recruit up to 210 COVID-positive adults (ITT) to achieve a target treatment population of 144 subjects confirmed by viral culture to be shedding the virus (ITTi).

As noted in the Company's Annual Report, recruitment had effectively been paused after a lull in COVID cases in South Africa following a shallow fifth wave that ended in mid-June. The low number of cases continued through this quarter, with only 18 subjects enrolled by the end of the quarter. However, there has been a noticeable increase in PCR-positivity for SARS-CoV-2 during October, with recruitment resuming and the trial expected to continue.

AAT Appeal

As foreshadowed in our ASX announcement of 7 July 2022, the Company lodged its appeal (application for review of decision) with the AAT (Administrative Appeals Tribunal) on 2 August 2022. The AAT's role is to provide an independent merits review of decisions made by the Australian Government, including the TGA. The Company is seeking independent review of TGA's decision not to approve Nasodine based on the existing clinical efficacy data.

On 9 September 2022, by consent, the parties agreed to an adjournment of the proceeding for a period to allow further discussions between TGA and Company on the matter. The next step is a scheduled conference between the parties and the AAT on 1 December 2022, prior to which TGA is required to lodge all the documents in their possession or control that are relevant to the decision under review.

Financial Overview

In the September quarter, net cash outflow from operating activities was \$1.68m, of which \$1.05m (63%) was R&D. Almost all the R&D expenditure was associated with the two clinical trials.

As at 30 September 2022, the Company had \$5.47 million in cash reserves with an R&D tax incentive receipt of at least \$1m expected during the December quarter.

The Company provides the following disclosure required by ASX Listing Rule 4.7C.2 regarding a comparison of its actual expenditure since admission date against the "use of funds" statement in Section 8.3 of its Prospectus dated 26 November 2021 and 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 September 2022 \$0'000
Research & Development	7,473	2,845
Sales & Marketing	2,039	261
Manufacturing & Distribution	48	-
General & Administration	3,274	1,441
Total operating expenses	12,834	4,547

Note: The above table represents 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 \$147k comprised of Executive Chairman and Executive Director/COO remuneration and Non-Executive Director Fees.

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 in 2012 to develop and commercialise a nasal spray treatment for the common cold based around the potential of povidone-iodine as a broad-spectrum antimicrobial agent. The Company subsequently developed Nasodine® Nasal Spray ("Nasodine") and owns numerous granted and pending patents. Firebrick is currently undertaking two significant clinical trials: A Phase 2 trial of Nasodine in COVID-19 and a Phase 3 trial for Nasodine, to confirm its efficacy as a treatment for the common cold and support international approvals.

Media enquiries:

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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")

30 September 2022

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	(1,051)	(1,051)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(77)	(77)
(d) leased assets (including premises)	(13)	(13)
(e) staff costs	(160)	(160)
(f) administration and corporate costs	(385)	(385)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	7	7
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other	-	-
1.9 Net cash from / (used in) operating activities	(1,679)	(1,679)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(1)	(1)
(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	(1)	(1)

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	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	2

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7,143	7,143
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,679)	(1,679)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1)	(1)

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)	2	2
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	5,465	5,465

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	5,465	7,143
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other – IPO funds held on trust	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	5,465	7,143

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	147
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)	(1,679)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,465
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	5,465
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.3
<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: 31 October

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.