27 October 2023

ASX Announcement

September 2023 Quarterly Activity Report

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

REVIEW OF QUARTERLY OPERATIONS

Phase 3 Common Cold Study Results

On 9 August, we announced that the Phase 3 trial of Nasodine® Nasal Spray ("Nasodine") as a treatment for the common cold had completed recruitment. On 13 September 2023, we announced that the efficacy data had been reviewed by trial statisticians and the headline efficacy results had been provided to the Company.

The results were disclosed in a table attached to the announcement and showed that the trial did not meet its primary endpoint, which was the impact of Nasodine on overall cold severity (GSS) in subjects with a confirmed viral infection (ITTi). Moreover, the results indicated that the water placebo appeared to be more effective than Nasodine.

The results were at odds with all *in vitro* and *in vivo* data previously obtained on Nasodine and published data about povidone-iodine. Notably, they conflicted with our first Phase 3 trial results, which showed a significant GSS benefit of Nasodine in subjects with a confirmed viral infection. They also appeared to conflict the recently reported Phase 2 COVID-19 trial results, where Nasodine treatment led to 100% clearance of the SARS-CoV-2 virus from the nasal passages (see summary below).

The Company was concerned that the results were so unexpected and at odds with previous data that there may have been a systematic error or other issue, and an investigation was commenced to try to identify any causes of such an error. Subsequent to the end of the quarter and on 3 October, we announced that the preliminary investigation into the efficacy results had not revealed any such error and we closed that phase of the external investigation to avoid additional costs.

We remain sceptical about the reported efficacy data and will continue to review internally. Meanwhile, we have put on hold all other normal trial closure activities, including processing of all other patient data, database lock, and preparation of a clinical study report. As a result, from a reporting perspective, the trial is unclosed and incomplete.

Phase 2 COVID-19 Study

On 7 August 2023, we announced that the Phase 2 trial of Nasodine in COVID-19 had achieved its primary endpoint. The study, which was conducted in South Africa, recruited 39 subjects, 23 of whom were culture-positive and qualified for the primary endpoint population.

The primary endpoint was the reduction in viral load of SARS-CoV-2 over four days, based on quantification of culturable virus from throat and nasal swabs. Nasodine treatment resulted in 100% clearance of the virus by day 4, which was the day after completing the treatment regimen. This compared with 48% for placebo and the difference was statistically significant (p=0.028), so the trial achieved its primary endpoint.

The small number of subjects meant that it was not possible to detect statistically significant outcomes on the secondary endpoints, which included the impact on COVID-19 symptoms and the number of days to a RAT negative test, assessed over five days from start of treatment. However, there was a trend in favour of Nasodine on COVID-19 symptoms over the five days.

We are not planning further COVID-19 studies or intending to pursue regulatory approval for Nasodine use in COVID-19. However, the fact that Nasodine emphatically reduces viral shedding in the upper respiratory tract is considered an important finding that could support its use as a valuable nasal disinfection measure in a future pandemic.

Nasodine Forward Plans

In the announcement of 3 October, we stated that plans for submitting a marketing approval application to Europe were on hold and that we would continue discussions with TGA about pathways to approval in Australia, while the AAT appeal remains ongoing.

We also stated that we remain committed to the development of Nasodine for the common cold. This includes investigating alternative study designs and/or other aspects of the illness that may accelerate regulatory approvals.

Finally, we announced that we would actively pursue opportunities beyond the common cold. Some of these opportunities could be expedited and potentially lead to sales in several markets, starting in 2024.

Annual General Meeting

On 18 September 2023, the Company announced that it will be holding its Annual General Meeting at 3.00pm (AEDT) on Friday, 17 November 2023 as a virtual meeting.

The notice of meeting documents were despatched to shareholders 17 October and can be accessed on the Company's website at https://firebrickpharma.com/investors/ within the "ASX Announcements" tab.

Financial Overview

At 30 September 2023, Firebrick held cash and cash equivalents of $845,000, compared with $2.355 million at the end of the June quarter. Net cash outflow from operations for the quarter was $1.5million, of which 49.2% ($739k) was for R&D expenditure associated with the two clinical trials undertaken by the Company.

As announced on 3 October, the Company has taken action to reduce its cash expenditure to preserve funds to support its plans and expects to receive a substantial RDTI payment shortly.

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 Sep 2023 $'000**
Research & Development	7,473	6,548
Sales & Marketing	2,039	469
Manufacturing & Distribution	48	-
General & Administration	3,274	4,283
Total operating expenses	**12,834**	**11,300**

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 $205k comprised of Executive Chairman and Executive Director/COO remuneration and Non-Executive Director Fees, which was up on the June quarter value of $184k 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 in 2012 with the mission 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 owns numerous patents, know-how and other intellectual property around the use of intranasal povidone-iodine.

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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 September 2023

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	(739)	(739)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(22)	(22)
	(d) leased assets (including premises)	(27)	(27)
	(e) staff costs	(233)	(233)
	(f) administration and corporate costs	(493)	(493)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	6	6
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**	**(1,508)**	**(1,508)**

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)	-	-
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	(2)	(2)
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	2,355	2,355
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,508)	(1,508)
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)	(2)	(2)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**845**	**845**

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	845	2,355
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)**	**845**	**2,355**

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	205
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)	(1,508)
8.2	Cash and cash equivalents at quarter end (item 4.6)	845
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	845
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.6

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, R&D expenditure is expected to be significantly lower than the current level of net operating cash flows due to the conclusion of its two clinical trials during Q1 FY2024. In addition, the Group has taken steps to reduce the level of other operating costs.

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?

No, the Company has not taken any steps to raise further cash.

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 and other operating costs in the remainder of FY2024, and an expected RDTI receipt of $1.8m in Q2, the Group is confident about funding its operations from existing cash reserves.

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 October 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.