19 January 2023

ASX Announcement

December 2022 Quarterly Activity Report

Q2 FY23 HIGHLIGHTS

- $1.08 million R&D tax incentive received for R&D expenditure in FY22
- Phase 3 trial of Nasodine for the common cold paused over summer
- Phase 2 trial of Nasodine for Covid-19 continues recruitment
- Nasodine AAT appeal timetable announced
- Pharmaceutical composition patent for Nasodine accepted in Australia

Firebrick Pharma Limited (ASX:FRE) (**Company** or **Firebrick**) is pleased to provide its business update for the quarter ending 31 December 2022, along with its Appendix 4C quarterly cashflow report.

REVIEW OF QUARTERLY OPERATIONS

During the quarter, we received an R&D Tax Incentive payment of $1,081,266 for eligible R&D expenditure incurred in 2021/22. Most of this expenditure was associated with our two clinical trials of Nasodine® Nasal Spray ("Nasodine"), which commenced in the first half of calendar 2022.

Phase 3 Common Cold Study

As previously announced on 31 October 2022, the Company provided an update on the Phase 3 clinical trial in the treatment of the common cold (ACTRN12621000604808).

At the end of October, the trial had successfully recruited 224 subjects with early-stage colds into the ITT ('Intent-To-Treat' population), with approximately 100 subjects qualifying for the primary endpoint population of those with confirmed viral infection based on PCR of a throat/nasal swab (the ITTi).

Interim viral aetiology data were reported at the Annual General Meeting (**AGM**) on 23 November (ASX announcement: AGM Presentation). These indicated that the trial was achieving an on-target 45% viral positivity rate for the ITTi and the overall viral pattern was consistent with our previous Phase 3 trial and published literature on the common cold.

To avoid unnecessary trial running costs over the summer when cases are typically very low, Firebrick paused recruitment at all sites from 1 November 2022 with the plan to restart recruitment in March 2023. This timetable remains on schedule and depending on recruitment

at each site, the trial could be completed by mid-year with results announced in the July-September quarter.

The results of this trial will be important for international partnering and regulatory approvals in markets outside Australia. The results may also be important to support Australian approval if the AAT appeal process is unsuccessful.

AAT Appeal

Pursuant to the appeal we lodged with the Administrative Appeals Tribunal (**AAT** or the **Tribunal**) in August 2022, against the TGA's decision not to approve Nasodine based on the existing clinical efficacy data (the **Appeal**), on 1 December, a formal conference was held between the parties and the Tribunal. That conference yielded an agreement in principle to a timetable for the Appeal as follows (ASX announcement 1 December 2022):

(1) On or before 28 February 2023, Firebrick will provide the Tribunal and the TGA[1] with its Statement of Issues, Facts and Contentions (**SIFC**) and any expert evidence on which Firebrick relies.

(2) On or before 12 May 2023, the TGA will provide the Tribunal and Firebrick with its SIFC and any expert evidence on which it relies.

(3) On a date on or about 30 May 2023, a conciliation conference between the parties will take place, to be conducted by a Tribunal-appointed conciliator.

On 12 December, the Tribunal issued orders confirming the timing of (1) and (2), although confirmation of the conciliation meeting date is yet to be ordered.

If the conciliation occurs as currently scheduled and the parties reach an agreement on a pathway for the approval of Nasodine without further AAT proceedings, then Nasodine could be approved before the end of calendar 2023, allowing its market launch in early 2024. If the appeal process does not lead to an immediate approval of Nasodine, then we expect we will resubmit for approval after we obtain the results of the second Phase 3 trial, which should readout in the second half of calendar 2023.

Phase 2 COVID-19 Trial

As part of our plan to explore new indications for Nasodine beyond the common cold, we are conducting a Phase 2 trial in South Africa, assessing the potential role for Nasodine in the management of COVID-19. Recruitment continued during the quarter, although it was slow due to a lack of cases in the country. At the AGM (ASX announcement: AGM Presentation), we reported that 27 subjects had been recruited and recruitment would continue into 2023, with the trial to be closed by June 2023 regardless of total recruitment at that time. This would allow reporting of the trial results thereafter and a decision to be taken on whether we will undertake any further studies on this indication.

[1] Technically, the party to the proceeding is the Minister for Health and Aged Care

Composition Patent Accepted in Australia

During the quarter, we announced (ASX announcement dated 14 November) that a patent covering the unique formulation of Nasodine had been accepted in Australia.

The patent (number 2021203846) is titled: “Virucidal Formulations Containing Povidone-Iodine” and once granted, expires in June 2041. The patent will also be pursued in the US, Europe and other key markets. A range of formulations is covered in the patent, notably including PVP-I concentrations between 0.10% and 1.25%.

Annual General Meeting

The Company held its Annual General Meeting on 23 November 2022, with all resolutions being passed on a poll with circa 98.4% or greater of all votes cast being in favour of the resolutions. Shareholders approved amendments to the Company’s constitution by a sufficient majority as a special resolution.

Financial Overview

In the December quarter, net cash outflow from operating activities was $555k, being $1.124m less than the September quarter, due to receipt of the $1.08 million R&D tax incentive. All other expenditure was relatively stable when compared to the September quarter with R&D expenditure down 15.9% to $884k in the December quarter with the winding down of activity in the two clinical trials.

As at 31 December 2022, the Company had $4.9 million in cash reserves.

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 31 December 2022 $0'000
Research & Development	7,473	3,729
Sales & Marketing	2,039	372
Manufacturing & Distribution	48	-
General & Administration	3,274	2,114
Total operating expenses	**12,834**	**6,215**

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 $201k comprised of Executive Chairman and Executive Director/COO remuneration and Non-Executive Director Fees, which was up on the September quarter value of $147k 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 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:

Heidi Cuthbert
+61 411 272 366
heidi.cuthbert@multiplier.com.au

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	31 December 2022

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	1
1.2	Payments for		
	(a) research and development	(884)	(1,935)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(111)	(188)
	(d) leased assets (including premises)	(27)	(40)
	(e) staff costs	(208)	(368)
	(f) administration and corporate costs	(438)	(823)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	11	18
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	1,101	1,101
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(555)**	**(2,234)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(1)	(2)
	(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**	**(1)**	**(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	5,465	7,143
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(555)	(2,234)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1)	(2)

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)	-	2
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**4,909**	**4,909**

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	4,909	5,465
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)**	**4,909**	**5,465**

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	201
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)	(555)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,909
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,909
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	8.8

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: 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

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: 19 January 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.