

31 January 2024

Botanix Pharmaceuticals Quarterly Activity Report and 4C Quarterly Cash Flow Report

Key highlights

- Successfully achieved an earlier than expected resubmission of the NDA for *Sofdra* in late December 2023
- Successfully raised \$13.5M via an institutional placement to new and existing shareholders with a number of new institutional investors
- Ramp up of commercial launch preparation activities for *Sofdra* continues with approval on target for late June 2024
- Cash position of \$18.31 million at December 2023 quarter end

Philadelphia PA and Phoenix AZ 31 January 2024: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “the Company”), is pleased to release its Quarterly Activity Report and Appendix 4C Quarterly Cash Flow report for the period ended 31 December 2023.

Sofpironium Bromide Gel 15% (“*Sofdra*”) NDA resubmission completed in 4Q CY 2023

In September 2023, 12 months after submission of the new drug application (NDA) for Sofpironium Bromide, Botanix received a “Complete Response” letter from FDA that solely focused on the Instructions for Use (“IFU”) document. The IFU is a paper insert in the product carton that instructs the patient how to use the product safely and effectively. Following rapid completion of revised Instructions for Use for *Sofdra*[™] and the required human factors validation study that assessed those instructions, the Company successfully achieved an earlier than expected resubmission of the NDA for *Sofdra* in late December 2023.

These resubmission materials were limited to the revised patient IFU, the new human factors validation study protocol and report; an updated use-related risk analysis and updated draft prescribing information, carton, and container labels; and the conditionally approved proprietary name (“*Sofdra*”) submission. Botanix also brought forward the annual safety update to FDA including the pharmacovigilance report from Japan and any new safety findings reported in the scientific literature (which would otherwise usually be filed in March each year).

Following the close of Q4 2023, Botanix’s resubmission was accepted by FDA as a complete response, and FDA confirmed that the resubmission of the *Sofdra* NDA is a ‘Class 2 response’ (i.e., a 6-month review period from resubmission), with the result that approval remains on target for late June 2024.

The Company continues to ramp up commercial launch preparation activities for *Sofdra* and has focused on engaging US payers (insurers) around contracting and pricing for the product, as well as preparing patient and physician-focused launch marketing and sales materials, testing telemedicine and supply chain elements, and finalising sales strategies.

A\$13.5 million raised via institutional placement

In December, Botanix finalised placement of A\$13.5 million in new shares, which was led by Botanix's existing institutional shareholders and included a significant number of new institutional investors under a placement to raise A\$13.5 million in gross proceeds ("**Placement**").

Proceeds from the placement will be applied towards preparation for commercial launch activities of *Sofdra* in the United States, as well as general working capital purposes and costs of the placement.

Corporate

During the quarter, Botanix had net operating cash outflows of A\$1.61m, with A\$0.25m invested in research and development activities. Cash outflows from investing activities was \$1.14m as a result of the continued advancement of its lead dermatology asset *Sofdra*. At the end of the quarter, Botanix held A\$18.31m in cash which is more than sufficient to fund the Company's operations through planned approval for *Sofdra* in late June 2024.

Payments to related parties as detailed in Section 6.1 of the Appendix 4C relate to salaries, fees, and superannuation (or equivalent) entitlements paid pursuant to agreements with Directors or associates were \$0.28m for the December 2023 quarter.

Release authorised by

Vince Ippolito

Executive Chairman

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix (US) which is progressing its lead product *Sofdra* for the treatment of primary axillary hyperhidrosis, through FDA approval. FDA is planning for a resubmission of the NDA for *Sofdra* in 1Q CY 2024 with approval targeted for mid-CY 2024. Sofpironium Bromide is positioned to be a leading first line and second line therapy and potentially represents a safe and effective new option for patients.

The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea (successful Phase 1b/2 study in 4Q 2022) and acne respectively. Botanix is also developing a topical antimicrobial product for the eradication of bacteria on the skin surface, initially in patients who are undergoing hemodialysis. To learn more please visit: <http://www.botanixpharma.com/>

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Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs, the Company's ability to obtain marketing approvals for its product candidates, the expected timing and/or results of regulatory approvals and the outcome and effects of Sofpironium Bromide and the market for Sofpironium Bromide. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Appendix 4C

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

Name of entity

Botanix Pharmaceuticals Limited

ABN

70 009 109 755

Quarter ended ("current quarter")

31 December 2023

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		497	799
1.2 Payments for			
(a) research and development (inc allocated staff costs)		(252)	(574)
(b) product manufacturing and operating costs		(154)	(154)
(c) advertising and marketing		-	-
(d) leased assets		-	-
(e) other staff costs		(700)	(1,134)
(f) administration and corporate costs		(1,015)	(1,983)
1.3 Dividends received (see note 3)		-	-
1.4 Interest received		21	41
1.5 Interest and other costs of finance paid		-	-
1.6 Income taxes paid		-	-
1.7 Government grants and tax incentives		-	-
1.8 Other (Sofpironium Bromide)		(10)	(802)
1.9 Net cash from / (used in) operating activities		(1,613)	(3,807)
2. Cash flows from investing activities			
2.1 Payments to acquire or for:			
(a) entities		-	-
(b) businesses		-	-
(c) property, plant and equipment		-	(36)
(d) investments		-	-
(e) intellectual property		(1,142)	(14,719)
(f) other non-current assets		-	-

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

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	-	-
2.6	Net cash from / (used in) investing activities	(1,142)	(14,755)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	13,500	26,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	1,925	2,336
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(951)	(1,576)
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 (payment for right-of-use asset)	-	-
3.10	Net cash from / (used in) financing activities	14,474	26,760

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,807	10,250
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,613)	(3,807)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,142)	(14,755)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	14,474	26,760
4.5	Effect of movement in exchange rates on cash held	(215)	(137)
4.6	Cash and cash equivalents at end of period	18,311	18,311

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

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	18,311	6,807
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	18,311	6,807

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	278
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⁽¹⁾ \$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.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,613)
8.2	Cash and cash equivalents at quarter end (item 4.6)	18,311
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	18,311

8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	11.4
<p><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></p>		
8.6	<p>If item 8.5 is less than 2 quarters, please provide answers to the following questions:</p>	
	<p>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?</p>	
	<p>Answer:</p>	
	<p>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?</p>	
	<p>Answer:</p>	
	<p>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?</p>	
	<p>Answer:</p>	
<p><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></p>		

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 January 2024

Authorised by: By the Board

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.