

28 April 2023

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

Key highlights

- **Successful mid-cycle review completed in 1Q 2023, with no significant issues have been identified by FDA along with no major clinical safety issues, no risk management issues, or advisory board requirements identified by FDA**
- **Updated independent market research from Triangle Insights confirms significant revenue opportunity for Sofpironium Bromide and positioning versus competitive products**
- **Following quarter completion, successfully raised \$10M via an institutional placement to new and existing shareholders with a number of life science firms joining the register**
- **Cash position of \$5.16 million at quarter end (not including \$10M capital raising)**
- **Activities in preparation for FDA approval and commercial launch accelerating, with Sofpironium Bromide labelling engagement with FDA expected this quarter and approval on track for September 2023**

Philadelphia PA and Phoenix AZ 28 April 2023: 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 March 2023.

Sofpironium Bromide mid-cycle review meeting

Botanix advised in March that the mid-cycle review meeting conducted by FDA with each of its internal review groups, had been successfully completed and reported to the Company. The mid-cycle review provides an opportunity for the FDA to identify if there are any significant remaining issues to be addressed in the review of the New Drug Application (NDA) for Sofpironium Bromide (SB).

The mid-cycle communication indicated no significant issues have been identified by FDA as a result of its review of product quality, non-clinical or clinical and that there were no major clinical safety issues, no risk management or advisory board requirements. Botanix had previously been advised that no advisory board meeting would likely be required, and FDA’s recent communication confirmed this, adding that the NDA presented no novel or complex regulatory issues in its view.

Finally, FDA indicated that continued discussions will focus on labeling, clinical outcome assessments, patient instructions and brand name. We expect that FDA will begin its engagement with Botanix in relation to the final label for SB this quarter and that progress will be made in relation to branding of the product with FDA.

Sofpironium Bromide commercial preparation for launch accelerating

During the quarter, Botanix also released a further update from the independent market research conducted by leading consultancy Triangle Insights. Triangle conducted a project where it surveyed physicians, payers (insurance companies) and patients on a blinded basis, concerning the positioning,

usage, pricing and access questions. A presentation was released on 8 March 2023 and is available here <https://botanixpharma.com/invest/#toggle-id-1>

Takeaways from the research conducted by Triangle include:

- a significant share of the prevalent population is undiagnosed and untreated, so an opportunity exists to activate large segments of the overall patient population (ie beyond the 3.7 million patients seeking treatment);
- dermatologists indicated that they would consider prescribing SB to 40-50% of all axillary hyperhidrosis patients – largely displacing other topicals and some oral drugs;
- to activate unmotivated patients that have failed existing therapies, a digital campaign would be useful and generally result in higher margins and profitability; and
- there is a potential to unlock a proportion of the ~6.7 million patients that have axillary hyperhidrosis, but are not currently or no longer seeking treatment with these highly profitable digital strategies.

With the successful mid-cycle review behind us, Botanix is now accelerating a range of other commercial preparation activities focused on engaging its digital strategy partners, defining the go to market distribution and sales approach, finalizing branding and packaging options and preparing for manufacturing and inventory management. More information on these activities will be forthcoming this quarter.

\$10M raised via institutional placement ('Placement')

Immediately following the completion of the quarter, Botanix welcomed the investment of \$10 million from new and existing institutional and sophisticated investors for a Placement of approximately 111.11 million new fully paid ordinary shares at A\$0.09 per New Share to raise A\$10.0 million in gross proceeds. The issue price of A\$0.09 represented a discount of 10% to the last close price on Friday, 31 March 2023. The proceeds from the Placement will be used to progress Botanix's lead development program, Sofpironium Bromide gel (15%), including costs associated with completing FDA review, manufacturing, satisfying milestone payments and preparing for commercial launch in the United States, as well as general working capital purposes and costs of the offer.

Other pipeline products

Botanix continues work to finalize the clinical study report for its rosacea study with BTX 1702 and close out activities at the various clinical sites in Australia and New Zealand, as well as complete the data package for ethics approval for the BTX 1801 development program, following the announcement of positive data from the Phase 2a study. The Company's focus remains, however, on preparing for and securing the approval of SB given the near term commercial and revenue generating potential for that product.

In parallel Botanix continues to explore opportunities to add soon to be approved and marketed products to its pipeline to bolster the revenue generation potential of the Company and to enhance its attractiveness, as both a stand-alone company or an M&A target.

Corporate

During the quarter, Botanix had net operating cash outflows of A\$1.68m, with A\$0.4m invested in research and development activities related to its CBD and Sofpironium Bromide assets. Cash outflows from investing activities was \$2m relating primarily to development costs of the Sofpironium Bromide asset. At the end of the quarter, Botanix held A\$5.16m in cash and subsequently raised \$10m from the Placement before costs.

Payments to related parties (\$0.22m) 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.

Release authorised by

Vince Ippolito

President and 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 Sofpironium Bromide for the treatment of primary axillary hyperhidrosis, through FDA approval. A mid-cycle review for the product has been successfully completed by FDA in 1Q 2023, which subject to other information that may be required by FDA, remains on track for approval for Q3 2023. Sofpironium Bromide is positioned to be a leading first line and second line therapy and 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), dermatitis 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/>

For more information, please contact:

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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. Likewise, comments from the FDA do not reflect a final decision on the information reviewed as part of any NDA submission and should not be construed to do so. These comments are preliminary and may be subject to change as FDA finalizes its review of any NDA and FDA may also identify other information that must be provided before any application can be approved. 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 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	107	385
1.2 Payments for		
(a) research and development (inc allocated staff costs)	(396)	(4,015)
(b) product manufacturing and operating costs	(462)	(676)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) other staff costs	(167)	(943)
(f) administration and corporate costs	(763)	(2,186)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	13	31
1.5 Interest and other costs of finance paid	(1)	(80)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,669
1.8 Other (Sofpironium Bromide – refer to Note 6)	(12)	(3,854)
1.9 Net cash from / (used in) operating activities	(1,681)	(7,669)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(2)	(7)
(d) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
(e) intellectual property (refer to Note 6)	(2,009)	(6,860)
(f) other non-current assets	-	-
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	(2,011)	(6,867)

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	13,460
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	-	(854)
3.5 Proceeds from borrowings	-	1,850
3.6 Repayment of borrowings	-	(1,850)
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (payment for right-of-use asset)	(33)	(122)
3.10 Net cash from / (used in) financing activities	(33)	12,484

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	8,716	7,286
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,681)	(7,669)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2,011)	(6,867)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(33)	12,484
4.5	Effect of movement in exchange rates on cash held	174	(69)
4.6	Cash and cash equivalents at end of period	5,165	5,165

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	5,165	8,716
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)	5,165	8,716

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	220
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 <i>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.</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)	(1,681)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,165
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	5,165
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.1
<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:	
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:	
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:	
<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: 28 April 2023

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.
6. The Directors elected to capitalise internally developed project development costs relating to its Sofpironium Bromide project as outlined in the Company's Half Year Report for the half year to 31 December 2022. Development costs associated with the Sofpironium Bromide project have been reclassified as Investing activities as opposed to Operating activities. The year to date totals have been adjusted by \$1,239,000 in items 1.8 and 2.1(e).