31 January 2023

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

Key highlights

- **FDA accepted NDA filing for Sofpironium Bromide as sufficiently complete for a substantive review**
- **FDA confirmed that a mid-cycle review of the NDA is planned for 1Q 2023**
- **Independent market research project completed by Triangle Insights confirms significant revenue opportunity for Sofpironium Bromide and positive feedback from key physician, payer (insurance) and patient stakeholders, who were surveyed on a blinded basis**
- **Successfully raised $5.96M via a placement to institutional shareholder Antares Capital and Shareholder Purchase Plan to existing holders**
- **Successful Phase 1b/2 clinical study for BTX 1702 in rosacea completed**
- **Cash position of $8.72 million at quarter end, with pivotal Sofpironium Bromide mid-cycle review meeting due this quarter**

Philadelphia PA and Phoenix AZ 31 January 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 December 2022.

Sofpironium Bromide FDA approval progress and 1Q 2023 mid-cycle review meeting

Botanix advised in December that it had received confirmation from FDA that the Sofpironium Bromide New Drug Application (NDA) was accepted for substantive review and that no outstanding filing issues were identified. FDA also confirmed that they are not planning to hold an advisory committee meeting to discuss the application.

FDA also confirmed that a mid-cycle review of the NDA is planned for this quarter (1Q 2023). The mid-cycle review provides internal FDA review teams with an opportunity to discuss the status of the Sofpironium Bromide application, confirm timelines and identify whether there remain any other significant issues relating to the NDA review, which will be communicated to Botanix. The absence of any outstanding significant review issues, would substantially de-risk the probability of NDA approval.

Sofpironium Bromide commercial preparation for launch accelerating

During the quarter, Botanix also released an 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 successful Phase 3 clinical data generated for Sofpironium Bromide and a range of positioning, usage, pricing and access questions. A presentation was released on 18 November 2022 and is available here https://botanixpharma.com/invest/#toggle-id-1

Takeaways from the research conducted by Triangle include:

- Patients generally self-manage their symptoms for months or years before approximately 80% of patients present to a dermatologist for assistance;
- typical patients start with prescription antiperspirants as first line therapy, with about 60% of more severe patients progressing to a stronger second line therapy such as Qbrexa wipes or other oral tablets. More serious patients may progress to Botox injections or surgery;
- all of the survey respondents identified efficacy and access as two key unmet needs in the hyperhidrosis treatment market, with side effects of the stronger second and third line therapies presenting a concern also;
- physicians rated Sofpironium Bromide very highly over competitive products such as Qbrexa and Botox noting the excellent efficacy, no need for the patient to touch the drug when applying it and the side effect profile;
- patients also rated Sofpironium Bromide highly noting the efficacy, side effect profile, ease of use and once daily convenience;
- finally payers were assured by the clinical efficacy and safety profile of Sofpironium Bromide and the need for additional options for hyperhidrosis patients in the market.

Botanix is currently undertaking a range of other commercial preparation activities ranging from submitting potential brand names for FDA clearance, to mapping novel distribution and prescription channels and sales infrastructure options.

$5.96M raised via institutional placement and SPP

During the quarter, Botanix welcomed the investment of $5 million by Antares Capital. Antares is a dedicated asset management business, that manages more than $33.4bn on behalf of Australian investors with significant experience in the healthcare sector. Antares engaged extensively with Botanix while researching a possible investment in the company. Botanix also completed a Shareholder Purchase Plan (SPP) to existing holders bringing the raising to a total of $5.96M in 4Q 2022.

Increase in business development activity

Inbound interest from potential partners, co-promotion companies and licensees who have expressed interest in Sofpironium Bromide continues to increase as it has progressed successfully through submission, formal acceptance and towards mid-cycle review in the NDA approval process. Given the substantial track record of our Chairman Vince Ippolito, our COO Howie McKibbon and the balance of the team in successfully launching dermatology products, the Company's preferred strategy remains to commercialize Sofpironium Bromide itself, utilizing a small focused sales force and innovative patient engagement and distribution model.

In parallel Botanix continues to explore opportunities to add 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, as it navigates the mid-cycle review milestone in the coming

months. Botanix has been pleased with the interest in its activities generated through attendance at a number of dermatology and pharmaceutical conferences recently including JP Morgan, Winter Clinical and Maui Derm.

Other pipeline products

In October 2022, Botanix announced the successful completion of the BTX 1702 clinical study for papulopustular rosacea. There were no serious adverse events observed during the Study and all arms were safe and well tolerated. For the exploratory efficacy endpoints, both doses of BTX 1702 showed clinically positive results, with the 10% dose showing superior results. Botanix is working to finalize the clinical study report and close out activities at the various clinical sites in Australia and New Zealand before beginning the preparation of regulatory documents for a pre-IND meeting with FDA.

The Company is currently conducting formulation work and animal studies to 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 drug product is designed to kill Staph aureus and MRSA in the noses of haemodialysis patients, in order to help prevent life-threatening bloodstream infections that occur when those bacteria exit the nose and enter the catheter that these patients have implanted in their chests.

Corporate

Botanix was pleased to announce during the quarter that Chief Commercial Officer, Dr Howie McKibbon has been appointed Chief Operating Officer, reflecting a broadening role as Botanix moves rapidly towards becoming a revenue generating Company following the anticipated approval of Sofpironium Bromide in 3Q 2023. Dr McKibbon has more than 20 years of leadership experience in the pharmaceutical industry, including working as Senior-Vice President, Sales and Marketing at Anacor Pharmaceuticals; Senior Vice-President, Worldwide Commercial Operations at Dermavant Science; and Vice-President, Dermatology and Immunology at Medicis Pharmaceuticals. Howie has launched 15 products including 11 in dermatology, and managed over 30 dermatology products and also played a significant role in two of the world's largest dermatology acquisitions with combined valuations of $7.8 billion.

During the quarter, Botanix had net cash outflows of A$1.36m, with A$3.89m invested in research and development activities related to its CBD and Sofpironium Bromide assets. US$2M (A$2.98m) was paid to Brickell Biotech Inc. subsequent to the receipt of the positive "Day-74 letter" from FDA after NDA filing (refer to ASX announcement dated 4 May 2022). At the end of the quarter, Botanix held A$8.72m in cash.

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.

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 is expected in 1Q 2023 with approval on track 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 and the Company's ability to obtain marketing approvals for is product candidates. 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	**Quarter ended ("current quarter")**
70 009 109 755	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	-	278
1.2	Payments for		
	(a) research and development (inc allocated staff costs)	(300)	(3,619)
	(b) product manufacturing and operating costs	(214)	(214)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) other staff costs	(376)	(776)
	(f) administration and corporate costs	(951)	(1,423)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	13	18
1.5	Interest and other costs of finance paid	(72)	(79)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	3,669	3,669
1.8	Other (Sofpironium Bromide FDA filing and associated costs including allocated staff costs)	(3,589)	(5,081)
1.9	**Net cash from / (used in) operating activities**	**(1,820)**	**(7,227)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(5)	(5)
	(d) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(e) intellectual property	(3,429)	(3,612)
	(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 (Acquisition of Sofpironium Bromide assets)		
2.6	**Net cash from / (used in) investing activities**	**(3,434)**	**(3,617)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	6,460	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	(434)	(854)
3.5	Proceeds from borrowings	-	1,850
3.6	Repayment of borrowings	(1,850)	(1,850)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payment for right-of-use asset)	(45)	(89)
3.10	**Net cash from / (used in) financing activities**	**4,131**	**12,517**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	10,081	7,286
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,820)	(7,227)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3,434)	(3,617)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	4,131	12,517
4.5	Effect of movement in exchange rates on cash held	(242)	(243)
4.6	**Cash and cash equivalents at end of period**	**8,716**	**8,716**

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	8,716	10,081
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)**	**8,716**	**10,081**

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	282
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[(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)	(1,820)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,716
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,716
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	4.8

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:

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:

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: 31 January 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.