31 October 2023

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

Key highlights

- **Submission of final component required for FDA approval of *Sofdra*™ (the 'Instructions for Use') is on target for Q1 CY 2024, targeting approval mid-CY 2024**
- **Successfully acquired the royalty and milestone payment financial obligations due to Fresh Tracks Therapeutics Inc, significantly improving Botanix's future financial position regarding SB and positioning the Company for M&A opportunities**
- **Successfully raised $12.5M via an institutional placement to new and existing shareholders with a number of new life science investors joining the register**
- **Cash position of $6.8 million at quarter end with approximately $2 million expected from R&D tax return in November**
- **Activities in preparation for FDA approval and commercial launch accelerating, with telemedicine partner appointed and pharmacy partner appointment pending**

Philadelphia PA and Phoenix AZ 31 October 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 October 2023.

Sofpironium Bromide (SB) progress towards resubmission in 1Q CY 2024

During the quarter, the Company announced that it had received a communication from the U.S. Food and Drug Administration (FDA) in respect of its New Drug Application (NDA) for Sofpironium Bromide gel ("*Sofdra*™") for the treatment of primary axillary hyperhidrosis (excessive sweating). The only deficiency identified in the communication, was focused on the "Instructions for Use" for *Sofdra*. The Instructions for Use is a paper insert in the product carton, that instructs the patient how to use the product safely and effectively. An Instructions for Use document is required for this product (unlike, for example, a tablet or capsule), as *Sofdra* is contained in a pump and once dispensed, is applied to each underarm with an applicator.

FDA indicated that it required additional edits to the Instructions for Use document and minor wording additions to the product carton and bottle label, followed by another short human factors validation study, before the NDA can be resubmitted. No efficacy, safety, pharmacology, non-clinical or chemistry, manufacturing, and controls (CMC) issues were identified as deficiencies, and no additional clinical studies are required to support resubmission and approval of *Sofdra*. As a result, when Botanix resubmits the NDA application in early 1Q CY 2024, it will be focused solely on the instructions provided to patients, and no additional review issues are anticipated on resubmission.

Since receiving the communication from the FDA at the end of September, the Botanix team have:

- redrafted the Instructions for Use document, with input from two separate expert consultancy groups to address FDA's comments in relation to notifications to "wash hands with soap and water" and other formatting suggestions;
- completed a *pilot* human factors study utilizing the updated Instructions for Use to test the effectiveness of the updated document and optimize the protocol for the human factors *validation* study;
- manufactured *Sofdra* placebo gel, bottles, and cartons to supply the planned human factors validation study;
- prepared and submitted an end of review Type A meeting request to FDA for a face-to-face meeting to discuss the planned resubmission of the NDA and gain alignment on Botanix's plans for resubmission. This meeting is likely to occur in late November or early December;
- secured a slot in December to complete the human factors validation study with the updated Instructions for Use;
- commenced preparation of the NDA resubmission shell for filing with FDA once the data from the human factors validation study is available in early 1Q CY 2024.

As outlined in the Company's announcement dated 26 September 2023, given that the commercial launch of *Sofdra* was previously planned for 1Q 2024, the resubmission and target approval timing is likely to only delay Botanix's commercialization plans by only 3-6 months. The Company believes that this delay in launch will not materially impact the market opportunity for the product, given that 3.7 million patients are currently being treated for primary axillary hyperhidrosis in the U.S. and approximately 10 million patients suffer from the condition.[1]

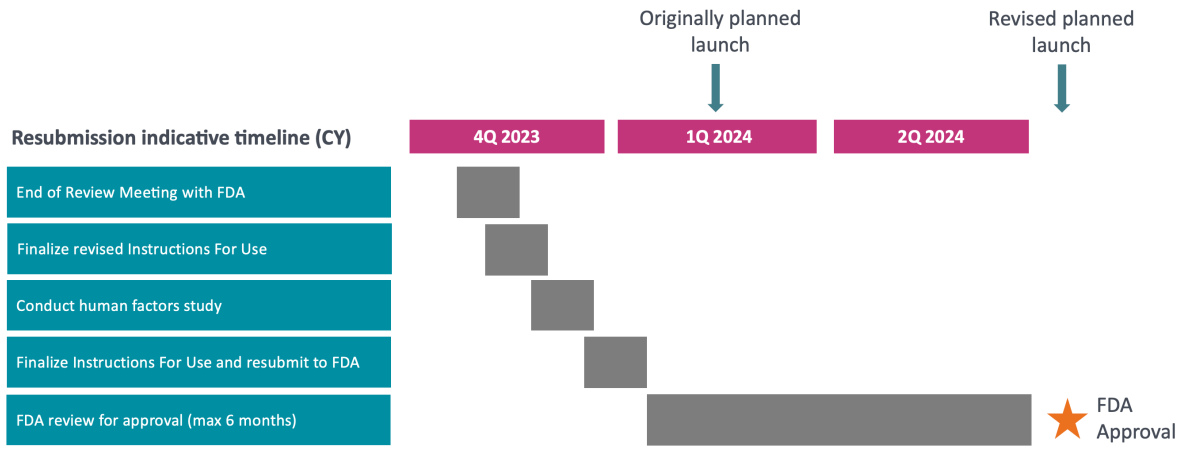

Figure 1 – Anticipated timeline for resubmission and FDA Approval

Buyout and extinguishment of royalties and milestones owed to Fresh Tracks

On 26 July 2023, Botanix completed an agreement with Fresh Tracks Therapeutics Inc (**Fresh Tracks**) to extinguish all of the potential future financial obligations owed to Fresh Tracks under the Asset Purchase Agreement for *Sofdra*. As outlined in Figure 1 below, Botanix was obliged to pay Fresh Tracks US$4M on FDA approval of *Sofdra*, US$4M if approval is extended to another indication (such as for

[1] International Hyperhidrosis Society; Dolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, Archives of Dermatology Research

palmar or plantar hyperhidrosis) and US$4M for approval in the UK or Europe. The Company was also obliged to pay sales milestones of up to US$160M which commence upon reaching the first US$75M of Net Sales, as well as to pay royalties ranging from 12% to 20% on Net Sales from initiation of commercial sales.

In exchange for the payment of US$8.25M to Fresh Tracks all of these future financial obligations due have been extinguished. Given that Botanix was otherwise on target to pay Fresh Tracks US$4M on FDA approval of *Sofdra*, the additional US$4.25m payment amount is relatively modest, compared to the significant future potential payments that would otherwise be payable to Fresh Tracks as regulatory and sales milestones and royalties on Net Sales of *Sofdra*.

Financial Obligations to Fresh Tracks	Current Commitment to Fresh Tracks (USD)	After Royalty Buyout Transaction (USD)
Upfront payment to buyout future milestone and royalty payments	→	$8.25m
FDA Approval for SB (target September)	$4m →	Nil
Marketing approval for SB in EU or UK	$4m →	Nil
Approval of SB in another indication	$4m →	Nil
Sales Milestones (once Net Sales exceed $75m - up to $1.8 billion p.a)	~$160m →	Nil
Royalties on Net Sales	12-20% →	Nil*

*Note – Botanix will retain an obligation to the head licensor, Bodor Laboratories, to pay a 5% royalty on Net Sales made by Botanix

Figure 2 – Comparison of financial obligations to Fresh Tracks before and after Transaction

The buyout was particularly attractive to Botanix, not only because of the relatively modest payment made to Fresh Tracks in respect of extinguishing the potential future financial obligations to Fresh Tracks, but because the buyout will consolidate the control and financial benefits of SB gel to Botanix, which is expected to make it much more attractive to potential M&A or other commercial partners in the future.

$12.5 million raised via institutional placement

During the quarter, Botanix welcomed the investment of $12.5 million from new and existing institutional and sophisticated investors pursuant to a placement of 104,166,667 new fully paid ordinary shares at A$0.12 per New Share (**Placement**). These new shares issued under the Placement rank pari-passu with existing Botanix fully paid ordinary shares from their date of issue.

Proceeds from the Placement have been primarily used to extinguish the future milestone and royalty payments due to Fresh Tracks and the remaining proceeds will be used to cover costs associated with finalising FDA review and preparing for commercial launch in the United States, as well as general working capital purposes and costs of the offer.

Corporate

During the quarter, Botanix had net operating cash outflows of A$2.19m, with A$0.32m invested in research and development activities. Cash outflows from investing activities was $13.61 relating primarily to development costs of *Sofdra*. At the end of the quarter, Botanix held A$6.8m in cash which is more than sufficient to fund the Company's operations through planned approval for *Sofdra* in mid-CY 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 $0.27m for the September 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), 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 is 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	**Quarter ended ("current quarter")**
70 009 109 755	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	302	302
1.2	Payments for		
	(a) research and development (inc allocated staff costs)	(322)	(322)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) other staff costs	(433)	(433)
	(f) administration and corporate costs	(968)	(968)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	20	20
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)	(792)	(792)
1.9	**Net cash from / (used in) operating activities**	**(2,193)**	**(2,193)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(36)	(36)
	(d) investments	-	-
	(e) intellectual property	(13,577)	(13,577)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(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**	**(13,613)**	**(13,613)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	12,500	12,500
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	411	411
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(625)	(625)
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**	**12,286**	**12,286**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	10,250	10,250
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,193)	(2,193)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(13,613)	(13,613)

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)	12,286	12,286
4.5	Effect of movement in exchange rates on cash held	76	76
4.6	**Cash and cash equivalents at end of period**	**6,806**	**6,806**

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	6,806	10,250
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)**	**6,806**	**10,250**

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	277
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)	(2,193)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,806
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,806
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.1

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: 31 October 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.