

31 July 2023

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

Key highlights

- Continued progress towards FDA approval of Sofpironium Bromide (SB) with approval on target for late September 2023
- Successfully acquired the royalty and milestone payment financial obligations due to Fresh Tracks Therapeutics Inc for US\$8.25M following quarter completion, significantly improving Botanix's future financial position regarding SB and positioning the Company for M&A opportunities
- Following quarter completion, 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 \$10.27 million at quarter end (not including \$12.5M capital raising or payment to Fresh Tracks of US\$8.25M)
- Activities in preparation for FDA approval and commercial launch accelerating, with further SB labelling engagement with FDA expected this quarter

Philadelphia PA and Phoenix AZ 31 July 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 30 June 2023.

Sofpironium Bromide (SB) progress towards approval

During the quarter, Botanix continued to make solid progress towards approval of SB for primary axillary hyperhidrosis by FDA, which remains on track for late September 2023. The Company continues to refine its commercial launch plans for SB, with agreements pending with key pharmacy and telemedicine platform partners, which are expected to be completed in the coming weeks. The Company has also engaged with a number of potential commercial personnel to join the team and expects to announce these additions and changes to functions before the end of August. Significant activity is now being focused on gaining approval for the proposed brand name and drafting agreements with key commercial partners relating to launch supplies, payers and distribution to be finalized following SB approval.

Activities for this quarter leading up to targeted approval will focus on labeling, patient instructions for use of SB and the proposed brand name.

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 SB gel. As outlined in Figure 1 below, Botanix was obliged to pay Fresh Tracks US\$4M on FDA approval of SB gel, US\$4M if approval is extended to another indication (such as for

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 in September following planned FDA approval of SB gel, 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 SB.

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

Botanix has maintained the Transition Services Agreement with Fresh Tracks that was also entered into in May 2022. Accordingly, the existing royalty of 5% of Net Sales will remain payable to the original inventor of SB gel (Bodor Laboratories).

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.

The buyout also comes at a strategically important time to Botanix. The FDA review of SB gel is targeted to be completed in late September 2023 and Botanix is currently preparing for commercial launch of the product following successful approval.

VALUE OF REGULATORY MILESTONES ~ \$12M	❖ Avoids targeted September \$4M “FDA approval and potential “EU/UK approval” and “other indication” (e.g hyperhidrosis on hands) milestones
VALUE OF SALES MILESTONES > \$160M	❖ Avoids all sales milestones which impact Botanix future profitability
ROYALTIES OF 12-20%	❖ Avoids all royalties due to Fresh Tracks which impacts Botanix future profitability
ENHANCE M&A AND EXIT OPPORTUNITIES	❖ With no royalties or milestones due to Fresh Tracks, the Sofpironium Bromide asset (and Botanix) are more attractive for M&A and exit opportunities

Figure 2 – Summary of benefits to Botanix from the Transaction

\$12.5 million raised via institutional placement

Immediately following the completion of 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\$3.52m, with A\$1.16m invested in research and development activities. Cash outflows from investing activities was \$978,000 relating primarily to development costs of the Sofpironium Bromide asset. At the end of the quarter, Botanix held A\$10.27m in cash and subsequently raised A\$12.5m from the Placement before costs and also paid Fresh Tracks US\$8.25m.

Payments to related parties as detailed in Section 6.1 of the Appendix 4C (\$207k) 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 targeted for the end of September 2023. 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 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")

30 June 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	133	518
1.2 Payments for		
(a) research and development (inc allocated staff costs)	(1,165)	(5,179)
(b) product manufacturing and operating costs	(582)	(1,258)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) other staff costs	(310)	(1,254)
(f) administration and corporate costs	(880)	(3,066)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	34	65
1.5 Interest and other costs of finance paid	-	(80)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,669
1.8 Other (Sofpironium Bromide)	(750)	(4,604)
1.9 Net cash from / (used in) operating activities	(3,520)	(11,189)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(1)	(8)
(d) investments	-	-
(e) intellectual property	(977)	(7,838)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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	(978)	(7,846)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	10,000	23,461
3.2	Proceeds from issue of convertible debt securities	128	128
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(614)	(1,469)
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)	-	(122)
3.10	Net cash from / (used in) financing activities	9,514	21,998

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	5,165	7,286
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,520)	(11,189)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(978)	(7,846)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	9,514	21,998
4.5	Effect of movement in exchange rates on cash held	86	18
4.6	Cash and cash equivalents at end of period	10,267	10,267

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	10,267	5,165
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)	10,267	5,165

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	207
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)	(3,520)
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,267
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,267
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1) <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>	2.92
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: 31 July 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.