

31 July 2024

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

Key highlights

- FDA approved Botanix's New Drug Application for *Sofdra*[™] (sofpironium) topical gel, 12.45%
- *Sofdra* is the first and only new chemical entity approved for the treatment of primary axillary hyperhidrosis (excessive underarm sweating), in adults and children 9 years of age and older
- Botanix is on track to launch its patient experience program in Q3 CY2024, resulting in first prescriptions for *Sofdra* in early Q4 CY2024
- Completed successful institutional placement raising \$70.00 million
- Cash position of \$79.31 million at June 2024 quarter end with no debt

Philadelphia PA and Phoenix AZ 31 July 2024: Clinical dermatology company, Botanix Pharmaceuticals Ltd (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 2024.

Sofdra[™] (sofpironium) topical gel, 12.45% approved

Botanix announced during the quarter that the US Food and Drug Administration (FDA) has approved *Sofdra*[™] (sofpironium) topical gel, 12.45% which is a prescription medicine used to treat primary axillary hyperhidrosis (excessive underarm sweating) in adults and children 9 years and older. *Sofdra* is the first and only new chemical entity approved by FDA to treat primary axillary hyperhidrosis and presents a novel safe and effective solution for patients who have lacked treatment options for this socially challenging medical condition.

Hyperhidrosis is a condition characterised by abnormally increased sweating, beyond that required to regulate body temperature.¹ The disproportionate sweat production that characterises hyperhidrosis, results in a disabling medical condition with profound effects on the patient's quality of life. Hyperhidrosis affects work productivity, daily routine activities, emotional well-being and personal relationships.² Hyperhidrosis is the third largest dermatology condition (after acne and atopic dermatitis), which impacts approximately 10 million patients in the US with primary axillary hyperhidrosis.³

Botanix is preparing to launch *Sofdra* starting with its Patient Experience Program in late Q3 CY2024, to enable highly qualified patients to gain early access to *Sofdra*. These patients will be guided through the telemedicine and payer reimbursement processes, to be the first commercial users of the product.

A broader digital launch of *Sofdra* will follow in Q4 CY 2024 and Botanix expects to receive first prescriptions from these sales in Q4 CY2024. Botanix expects to field a sales force in Q1 2025, targeting high decile prescribers of therapeutics for hyperhidrosis across the USA.

¹ Oshima Y, Tamada Y. Classification of systemic and localized sweating disorders. In: Yokozei H, Murota H, Katayama I, editors. Perspiration research. Current problems in dermatology, vol 51. Basel: Karger; 2016. p. 7–10

² Hamm H, Naumann MK, Kowalski JW, Kutt S, Kozma C, Teale C. Primary focal hyperhidrosis: disease characteristics and functional impairment. *Dermatology*. 2006;212(4):343–353. doi: 10.1159/000092285

³ Doherty, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, *Archives of Dermatology Research*

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Corporate

On 21 June, Botanix announced that it had closed a placement to institutional and sophisticated investors for the placement of 233,333,334 new fully paid ordinary shares at \$0.30 per new share, to raise \$70.00 million in gross proceeds ("**Placement**"). The Placement proceeds are intended to fund the launch of Sofdra™ in the United States, including sales force and marketing infrastructure, digital marketing costs and the telemedicine platform, manufacturing costs, as well as support services, working capital and costs of the Placement.⁴

The Placement was strongly supported and resulted in a number of new Australian and international institutions becoming shareholders in Botanix.

Financial

During the quarter, Botanix had net operating cash outflows of \$2.63 million. The cash outflows from investing activities were \$0.55 million as a result of the continued advancement of its lead dermatology asset *Sofdra*™ through to the FDA approval achieved during the quarter. As noted above, Botanix completed a \$70.00 million placement, deriving net cash flows (after capital raising costs) from financing activities of \$65.78 million. At the end of the quarter, Botanix held \$79.31 million in cash with no debt (other than typical trade creditors), which will fund the Company's operations as it ramps up manufacturing and sales activity of its *Sofdra* product.

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 \$0.32 million for the June 2024 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 has received FDA approval for its lead product *Sofdra*™ for the treatment of primary axillary hyperhidrosis. *Sofdra* is the first and only new chemical entity approved by FDA to treat primary axillary hyperhidrosis and presents a novel safe and effective solution for patients who have lacked treatment options for this socially challenging medical condition

To learn more please visit: <http://www.botanixpharma.com/>

⁴ The use of funds is Botanix' current intention at the date of this announcement. As with any budget, intervening events and new circumstances have the potential to affect the manner in which funds are ultimately applied. The Botanix Board reserves the right to alter the way in which the funds are applied.

For more information, please contact:

General enquiries

Corporate Communications

Botanix Pharmaceuticals

P: +61 8 6555 2945

investors@botanixpharma.com

Investor enquiries

Hannah Howlett

WE Communications

P: +61 450 648 064

hhowlett@we-worldwide.com

Media enquiries

Haley Chartres

HACK

P: +61 423 139 163

haley@hck.digital

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 *Sofdra*[™] and the market for *Sofdra*. 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.

Sofdra Important Safety Information & Indication

Indication

Sofdra (sofipironium) topical gel, 12.45% is a prescription anticholinergic medicine used on the skin (topical) to treat excessive underarm sweating (primary axillary hyperhidrosis) in adults and children 9 years of age and older.

IMPORTANT SAFETY INFORMATION

***Sofdra* is for use on the skin in the underarm area only. Wash your hands right away after you apply *Sofdra*. Do not touch your underarms after applying *Sofdra*. *Sofdra* is flammable. Avoid heat and flame while applying *Sofdra*.**

Who should not use *Sofdra*?

Do not use *Sofdra* if you have certain medical conditions that can be made worse by taking an anticholinergic medicine such as glaucoma, severe ulcerative colitis (UC) or certain other serious bowel problems associated with severe UC, myasthenia gravis, and Sjogren's syndrome.

What should I tell my healthcare provider before using *Sofdra*?

- **Tell your healthcare provider about all of your medical conditions**, including bladder or kidney problems, problems passing urine, if you are pregnant or breastfeeding, or plan to become pregnant or breastfeed. It is not known if *Sofdra* will harm your unborn baby or pass into your breast milk.
- **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, especially any anticholinergic medicines.

What are possible side effects of *Sofdra*?

Serious side effects may include:

- **Blurred vision.** Stop using *Sofdra*, call your healthcare provider right away, and do not drive or operate machinery or do hazardous work until your vision is clear.
- **New or worsened urinary retention.** Stop using *Sofdra* and call your healthcare provider right away if you experience difficulty urinating, urinating frequently, urination in a weak stream or drips, full bladder or difficulty emptying your bladder.

The most common side effects of *Sofdra* include dry mouth; blurred vision; pain, redness, swelling, itching, and irritation in the underarm area; dilation of the pupils of your eyes (mydriasis); and problems with urination. These are not all of the possible side effects of *Sofdra*. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Botanix at 1-866-763-6337.

Keep *Sofdra* and all medicines out of the reach of children.

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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 2024

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		132	1,064
1.2 Payments for			
(a) research and development (inc allocated staff costs)		(175)	(875)
(b) product manufacturing and operating costs		(358)	(585)
(c) advertising and marketing		-	-
(d) leased assets		-	-
(e) other staff costs		(409)	(1,907)
(f) administration and corporate costs		(1,483)	(4,683)
1.3 Dividends received (see note 3)		-	-
1.4 Interest received		19	76
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)		(355)	(2,240)
1.9 Net cash from / (used in) operating activities		(2,629)	(9,150)
2. Cash flows from investing activities			
2.1 Payments to acquire or for:			
(a) entities		-	-
(b) businesses		-	-
(c) property, plant and equipment		(4)	(40)
(d) investments		-	-
(e) intellectual property		(549)	(16,403)
(f) other non-current assets		-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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	(553)	(16,443)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	70,000	96,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	4,855
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4,224)	(5,800)
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	65,776	95,055

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	17,325	10,250
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,629)	(9,150)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(553)	(16,443)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	65,776	95,055
4.5	Effect of movement in exchange rates on cash held	(610)	(403)
4.6	Cash and cash equivalents at end of period	79,308	79,308

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	79,308	17,325
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)	79,308	17,325

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	320
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. 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)	(2,629)
8.2	Cash and cash equivalents at quarter end (item 4.6)	79,308
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	79,308

8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)

30.2

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 July 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.