

31 January 2025

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

Key highlights

- First *Sofdra*™ prescriptions were issued in December as part of the Patient Experience Program, with 100% refill follow up in January, proving up the telehealth and closed fulfilment systems
- Full commercial launch of *Sofdra* with the field sales force is now underway to be followed by the expanded digital program
- All sales professionals who will drive adoption of *Sofdra* in dermatology offices are now trained and certified and will be in the field next week
- The Patient Experience Program was successfully completed and was highly rated by participants, providing useful refinements of the telemedicine communication and fulfilment systems
- Botanix has now finalised contractual terms with all of the key US commercial payers (insurers) which reflect the target financial and patient access restrictions previously communicated
- Botanix has also completed all of the requirements for US government payer programs, with the consequence that from March 2025, *Sofdra* will be available for an additional ~80 million lives
- Q1 CY2025 will represent the first commercial quarter of revenue from *Sofdra* with full field and digital launch deployed and Q2 CY2025 is expected to reflect a significant ramp in revenue following that launch
- Cash position of A\$48.36 million at December 2024 quarter end, with no debt

Philadelphia PA and Phoenix AZ 31 January 2025: 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 31 December 2024.

Sofdra™ (sofpironium) topical gel, 12.45% full commercial launch underway

The December quarter represented an important milestone for Botanix with first prescriptions for *Sofdra* being issued as part of the Patient Experience Program and following the end of the quarter, first refills have now also been provided to patients. All of the patients in the patient experience program who received prescriptions successfully utilised the telehealth platform and received both their initial prescriptions and refills directly to their residences. Successful clearance of relevant payer requirements and frictionless buy down of the patients’ monthly co-pay (or gap payment), also meant that 100% of patients received their refills in January, proving up the telehealth and closed fulfilment system in advance of full commercial launch.

The quarter also provided confirmation that prescriptions representing all of the targeted payers were handled in accordance with the negotiated terms, meaning that no additional requirements were imposed for insurance approval, and where proof of diagnosis (or having tried Drysol or its equivalent) was required – this information was seamlessly provided to the payer and cleared relevant approvals.

Sales infrastructure and territory managers in the field

During the December quarter, Botanix's broader preparations for the full commercial launch of *Sofdra* were finalised, with the engagement of all regional managers, territory managers and marketing support positions as well as development of sales and marketing materials for field launch.

Botanix has now engaged 27 territory managers (sales professionals), including some of the most credentialed individuals in the dermatology industry, with 79 'President Club' wins (awarded to the top 10% of sales professionals annually) between them. Extensive online and in person training has now been completed, utilising the newly prepared and approved sales support materials, and this training has recently been certified at the Company's first national sales meeting just completed on 30 January at our offices in Phoenix, Arizona.

Botanix's highly motivated sales representatives will begin calling on dermatologists next week, to commence educating physicians and driving prescriptions, as part of the full commercial launch of *Sofdra*. They will be equipped with interactive tablet-based explainers and supported by the new full product website and telehealth and patient facing portal.

With less than 10 employees and contractors at the time of *Sofdra* approval in June 2024, the Botanix team has now grown to 25 (not including the territory managers who formally joined us in early January). Drawing talent from leading dermatology and specialty pharmaceutical companies in the USA with an average of over 20 years' experience, the Botanix team is now fully staffed and ready to accelerate prescriptions and revenue.

Patient Experience Program complete and improvements made

Knowledge gained from the *Sofdra* Patient Experience Program, created in collaboration with the International Hyperhidrosis Society, has provided valuable feedback from early patient access to *Sofdra*. The program has now ended and these (now) commercial users of the product, have provided actionable feedback regarding the telemedicine and fulfillment experience that Botanix has used to refine its processes ahead of the broader launch to significantly larger volumes of patients in Q1 CY2025.

Botanix conducted surveys with the initial users, which were completed before system optimization, and the results demonstrated significant overall satisfaction with the Botanix platform's overall ease of use, a preference for telemedicine over in-person physician visits and the "at home" delivery of *Sofdra* compared to the usual collection of prescriptions at a local pharmacy. Amongst other questions focused on procedural elements of the Program, patients reported that:

- 87% rated the telemedicine experience as "better or much better" than previous experience, compared to 13% who were neutral; and
- 93% rated the home delivery of *Sofdra* as preferable to picking it up themselves at the pharmacy.

Manufacturing, team, data systems and payers

During the quarter, the Botanix team also extended its manufacturing activities to ensure that sufficient inventories of Sofpironium Bromide drug, *Sofdra* bottles, applicators and other materials were made available to cover anticipated demand and able to be flexed to accommodate any accelerations in sales forecasts. The Company has now successfully completed multiple manufacturing campaigns, and has bottled and packaged finished product at our partner manufacturing facility at

CPL, as well as successfully utilised the logistics infrastructure responsible for transport, warehousing and supply to our pharmacy network SendRx. Data infrastructure, pharmacy and telemedicine systems have also been integrated and tested, and first refills have been provided to the Patient Experience Program participants in advance of full commercial launch this quarter.

Botanix has also finalised contractual terms with all of the key US commercial payers, which reflect the target financial and patient access restrictions previously discussed with them and as communicated to shareholders. The restrictions require a simple confirmation of diagnosis for primary axillary hyperhidrosis as per the label and that the patient has tried aluminum chloride as a prior therapy, with some only requiring simply the confirmation of diagnosis. These payers represent 167 million commercial lives who will be accessible for the full launch of *Sofdra* this quarter.

Botanix has also now completed all of the legal requirements for US government payer programs, with the consequence that from March 2025, *Sofdra* will be also government reimbursed for approximately 80 million additional government insured lives.

Q1 CY2025 activity, growth and revenue ramp

Following first prescriptions from the Patient Experience Program in December (which have provided first modest revenues from *Sofdra*), Botanix expects that Q1 CY2025 will represent the first commercial revenue quarter, as 100% of refills from those first prescriptions have been now filled in January and the sales team will be in the field next week generating new prescriptions from dermatologists. The full digital program will follow in March and so we expect that Q2 CY2025 will reflect a ramp on the Q1 revenue run rate, with the full deployment of both direct and digital sales channels. Botanix will be providing guidance to the market in relation to leading indicators that will be reported, in our half yearly update in February, which will enable shareholders and stakeholders to follow the development of the *Sofdra* opportunity from quarter to quarter, as sales increase.

Sofdra is the first and only new chemical entity approved by FDA to treat primary axillary hyperhidrosis, the third largest dermatology condition (after acne and atopic dermatitis), which impacts approximately 10 million patients in the US.¹ The disproportionate sweat production that characterises hyperhidrosis, results in a disabling medical condition with profound effects on the patient's quality of life.²

Financials

During the 31 December 2024 quarter, the Company issued the following securities:

Performance Rights

On 2 December 2024, the Company issued 36,000,000 performance rights to key management personnel pursuant to its Employee Rewards Plan. The issuances were subject to shareholder approval which was obtained at the Company's Annual General Meeting held on 4 November 2024. The performance rights vest based on the completion of various performance hurdles as outlined in the Company's 2024 Annual General Meeting Notice of Meeting announced on the ASX on 3 October 2024.

¹ Dolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, Archives of Dermatology Research. 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

Exercise of Options and Issuance of Ordinary Shares

On 7 October 2024, 3,422,643 ordinary shares were issued to employees upon exercise of options with an exercise price of \$0.089 expiring 7 October 2024. The exercise of options were performed under the Company's cashless exercise policies.

Remuneration of key management personnel

During the December 2024 quarter, the Company paid \$543,000 to Directors and Executive staff either on payroll or acting as consultants, all of whom represent key personnel. The payments were for the provision of services under staff, consulting, and Director contracts.

Cash position

At the end of the 31 December 2024, the Company has a cash balance of A\$48.36 million with zero debt (other than typical trade creditors).

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/>

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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 *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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity			
		Quarter ended (“current quarter”)	
ABN		31 December 2024	
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	423	798
1.2	Payments for		
	(a) Product manufacturing	(11,548)	(15,288)
	(b) Operating costs	(6,927)	(10,765)
	(c) Staff costs	(2,426)	(4,231)
	(d) General and administration	(2,169)	(4,445)
1.3	Dividends received	-	-
1.4	Interest received	563	1,182
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	R&D refund	1,500	1,500
1.8	Net GST (paid)/refunded	1	295
1.9	Net cash from / (used in) operating activities	(20,583)	(30,954)
2. Cash flows from investing activities			
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	(763)
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
	(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	-	(763)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	462
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	-	-
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)	(116)	(150)
3.10	Net cash from / (used in) financing activities	(116)	312
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	68,672	79,308
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(20,583)	(30,954)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(763)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(116)	312
4.5	Effect of movement in exchange rates on cash held	385	455
4.6	Cash and cash equivalents at end of period	48,358	48,358

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

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	48,358	68,672
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)	48,358	68,672

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	543
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)	(20,583)
8.2	Cash and cash equivalents at quarter end (item 4.6)	48,358
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	48,358

8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.35
<p><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></p>		
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
<p>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?</p>		
<p>Answer: N/A</p>		
<p>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?</p>		
<p>Answer: N/A</p>		
<p>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?</p>		
<p>Answer: N/A</p>		
<p><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></p>		

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 2025

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.