29 July 2022

Botanix Quarterly Activity Report and 4C Quarterly Cash Flow Report

Key highlights

- **Completed acquisition of late-stage dermatology asset, Sofpironium Bromide gel, which has positive Phase 3 data and is being readied to file for FDA approval in Q3 CY2022**
- **Accelerated the transition of the Company from a development stage dermatology company to a near term commercial revenue producing pharmaceutical company**
- **Secured QIDP status for BTX 1801 which on approval provides an additional 5 years of valuable FDA exclusivity**
- **Available cash of $9.15m comprising $7.3m cash as at 30 June 2022 and a $1.85m drawdown facility secured post quarter end**

Philadelphia PA and Phoenix AZ, 29 July 2022: 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 report for the period ended 30 June 2022.

The quarter has been transformational for the Company, with the acquisition of the late-stage dermatology asset Sofpironium Bromide gel, for the treatment of "primary axillary hyperhidrosis" (a medical condition that results in excessive uncontrolled underarm sweating). Botanix has positive Sofpironium Bromide Phase 3 clinical study results in hand, where statistical significance was achieved in all primary and secondary endpoints. In addition, Sofpironium Bromide was found to have a favourable safety profile in the Phase 3 pivotal studies, as well as in a separate 48-week safety study.

The acquisition provides the trigger to significantly accelerate the transition of Botanix from a development, to a commercial stage dermatology company and neatly complements the Company's existing dermatology pipeline (ASX Announcement 4 May 2022).

INDICATION	PRODUCT	PHASE 1	PHASE 1B	PHASE 2	PHASE 3	APPROVED	STATUS (CY)
Axillary Hyperhidrosis (excessive underarm sweating)	Sofprionium Bromide						FDA approval filing planned for 3Q 2022
Moderate to severe acne	BTX 1503						Phase 3 study commencement pending
Rosacea	BTX 1702						Phase 2 study planned for completion 3Q 2022
Atopic Dermatitis	BTX 1204A						Canine study planned for completion 3Q 2022
Antimicrobial	BTX 1801						Phase 2 study preparing for launch in 2H 2022

Sofpironium Bromide - accelerating the path to revenue

Sofpironium Bromide is a new chemical entity developed to be a best-in-class, once daily, topically administered therapy for the treatment of primary axillary hyperhidrosis. Sofpironium Bromide blocks sweating, by binding to the receptor and thereby blocking the sweat signal, with recent Phase 3 studies demonstrating that approximately 85% of patients using Sofpironium Bromide experienced a clinically meaningful improvement in their condition over the course of the studies.

The successful acquisition of Sofpironium Bromide advances Botanix towards its goal of becoming a leading commercial dermatology company. Sofpironium Bromide is an exciting opportunity, with more than 15 million patients that suffer from hyperhidrosis in the US alone.[1] Existing therapies are not ideal, either because of the lack of efficacy, unfavourable side effect profile, risk of drug exposure to the skin, or pain from invasive procedures or surgery.

Botanix expects to file for FDA approval in Q3 CY2022 expecting a usual 12 month review period, with a US launch following, subject to receipt of FDA approval.

Sofpironium Bromide has already been licensed to Botanix's partner, Kaken Pharmaceuticals in Japan, who have already secured approval of sofpironium bromide 5% for the treatment of primary axillary hyperhidrosis from the Japanese equivalent of the FDA, the Pharmaceuticals and Medical Devices Agency ("PMDA"). Kaken Pharmaceuticals is expected to work closely with Botanix to support the approval of the product in the USA and will take the lead in filing for approvals in other Asian countries. Botanix is entitled to royalties and milestone payments from Kaken.

Clinical Studies and Drug Development

Subsequent to the end of quarter, the Company announced (ASX Announcement 7 July 2022) that both the rosacea (BTX 1702) Phase 1b / 2a clinical study and the canine dermatitis pilot study (BTX 1204A) are fully enrolled and on target for completion in Q3 2022.

BTX 1702: Phase 2 study for Papulopustular Rosacea

The Company's Phase 1b/2a randomised, double blinded, vehicle-controlled clinical study in patients with moderate to severe papulopustular rosacea was fully recruited at 30 June 2022. The study remains on track for completion in Q3 2022 (ASX Announcement 7 July 2022) and is designed to enable increased data capture and provide insights to support broader dermatology program.

The 8-week study conducted across 16 dermatology sites in Australia and New Zealand is investigating the safety and tolerability of two different concentrations of BTX 1702, alongside a vehicle (placebo) in 120 adults. The study also aims to examine the change in inflammatory lesion counts from baseline to day 57, the change in Clinician's Erythema Assessment (CEA) scale, and the proportion of patients with Investigator's Global Assessment (IGA) treatment success.

As part of the study design, Botanix has centralised the review of each clinical investigator's ratings for patient inclusion and is using advanced Canfield imaging technology across all sites to support clinical assessments. These initiatives should significantly enhance the quality and consistency of the data collected.

[1] Reports and Data, Hyperhidrosis Treatment Market by Treatment Type, By Disease Type, By End User, By Regional Outlook and Segment Forecasts 2022

BTX 1204A: Canine atopic dermatitis

Following encouraging data from a 28-day pilot study in canines completed in CY2021, Botanix launched its BTX 1204A proof of concept study in late 2021 with receipt of ethics approval and the initiation of sites across Australia and New Zealand. The study was fully enrolled during the quarter and the study is on track for completion in Q3 CY2022.

Atopic dermatitis in canines and humans is clinically and immunologically very similar. Further positive outcomes of this new study will support progress towards a late-stage Phase 2b clinical study in humans. Positive data from the BTX1204A study will also release opportunities for licensing or partnering the canine dermatitis application, with a company with an existing animal health presence for further development and commercialisation.

BTX 1801: Bacterial infections

The BTX 1801 program targets nasal decolonisation of bacteria in subjects who persistently carry these bacteria in their nasal cavities, with a view to preventing bloodstream bacterial infections in patients undergoing hemodialysis who have catheters which allow direct access (and infection) of their bloodstream.

During the quarter, the US FDA granted Botanix new Qualified Infectious Disease Product (QIDP) designation for BTX 1801. The new QIDP status applies to the use of BTX 1801 to "reduce the risk of *Staph. aureus* bloodstream infections in colonised patients dependent on central venous catheters-for-hemodialysis." QIDP status entitles BTX 1801 to receive an additional 5 years of valuable FDA exclusivity on successful approval which is in addition to exclusivity normally provided upon approval, as well as provides eligibility for 'fast track status' and 'priority FDA review'.

During the quarter, the Company also announced the presentation of two posters at the 32nd European Congress of Clinical Microbiology and Infectious Diseases (ECCMID). The two presentations of BTX 1801 data were entitled 'The Antimicrobial profile of BTX-1801: a new synthetic cannabidiol active against Gram-positive bacteria associated with serious infections' and 'The Bactericidal activity of BTX 1801: a synthetic cannabidiol with potent activity versus Staphylococcus aureus' which were well received.

Financial Overview

During the quarter, Botanix had net cash outflows of A$9.1m, with $5.9m expended on the acquisition of Sofpironium Bromide and activities associated with accelerating the filing for FDA approval of that asset, as well as A$2.1m invested in R&D activities for the balance of the Company's dermatology pipeline. Cash available comprises $7.3m cash at 30 June 2022 and a $1.85m drawdown facility provided by Radium Capital post quarter end, against an expected R&D refund of approximately $3.1m for the financial year ended 30 June 2022.

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 (USA) which is committed to the development of novel treatments for a range of common skin diseases. The Company has a mature dermatology pipeline with its first product, Sofpironium Bromide, for the treatment of primary axillary hyperhidrosis, planned to be filed for FDA in Q3 2022. The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea, 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.

Botanix leverages its proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases, which is utilised in its existing development programs and is being explored with a view to being utilized in a number of other product opportunities. To learn more please visit: http://www.botanixpharma.com/

For more information, please contact:

General enquiries	**Investor enquiries**	**Media enquiries**
Corporate Communications	Hannah Howlett	Haley Chartres
Botanix Pharmaceuticals	WE Communications	H^CK
P: +61 8 6555 2945	P: +61 450 648 064	P: +61 423 139 163
investors@botanixpharma.com	hhowlett@we-worldwide.com	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 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	June 2022

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	-	-
1.2	Payments for		
	(a) research and development (inc allocated staff costs)	(2,107)	(8,314)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) other staff costs	(262)	(900)
	(f) administration and corporate costs	(664)	(1,595)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	7	37
1.5	Interest and other costs of finance paid	(8)	(37)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	2,755
1.8	Other (Sofpironium Bromid FDA filing and associated costs including allocated staff costs)	(473)	(473)
1.9	**Net cash from / (used in) operating activities**	(3,507)	(8,527)

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	(7)
	(d) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(e) intellectual property	-	-
	(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)	(5,571)	(5,571)
2.6	**Net cash from / (used in) investing activities**	**(5,571)**	**(5,578)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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)	(41)	(152)
3.10	**Net cash from / (used in) financing activities**	**(41)**	**(152)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	16,416	21,555
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,507)	(8,527)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(5,571)	(5,578)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(41)	(152)
4.5	Effect of movement in exchange rates on cash held	(11)	(12)
4.6	**Cash and cash equivalents at end of period**	**7,286**	**7,286**

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	7,286	7,286
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)**	**7,286**	**7,286**

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	318
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	1,850[(1)]	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	1,850	-
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.		

[(1)]Botanix has set up a loan facility in July 2022 for $1,850,000 with Radium Capital secured against its R&D Tax Incentive claim with an interest rate of 15% per annum.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,507)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,286
8.3	Unused finance facilities available at quarter end (item 7.5)	1,850
8.4	Total available funding (item 8.2 + item 8.3)	9,136
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.6

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: 29 July 2022

Authorised by: Simon Robertson
Company Secretary
(Name of body or officer authorising release – see note 4)

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.