29 April 2022

Botanix Quarterly Activity Report and 4C Quarterly Cash Flow Report

Key highlights

- **Botanix significantly strengthens its executive leadership team with the appointment Dr Patty Walker as Chief Medical Officer and Mr Howie McKibbon as Chief commercial Officer**
- **Danny Sharp also joins as Non-Executive Director bringing 30+ years capital markets experience and an expansive global private wealth network**
- **Pre-clinical work to support initiation of Phase 2 BTX 1801 antimicrobial study completed**
- **Completion of recruitment for both the Phase 2 BTX 1702 rosacea study and the BTX 1204 canine atopic dermatitis study remains on track for 2Q 2022 with data to follow**
- **Significant progress on broadening and maturing the Botanix pipeline with a number of new opportunities under late-stage assessment**
- **Strong cash position with approximately $16.4 million at the end of the quarter**

Philadelphia PA and Phoenix AZ, 29 April 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 31 March 2022.

The Company has made significant progress with its dermatology and antimicrobial clinical programs, and recent new hires now position Botanix to both accelerate the development of its existing pipeline, as well as crystallize a number of opportunities. Botanix remains in a very strong cash position with approximately $16.4 million in cash at the end of the quarter.

Clinical Studies and Drug Development

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 is progressing well and remains on track to complete patient enrolment in mid-2022.

The 8-week study at 16 dermatology sites across Australia and New Zealand is investigating the safety and tolerability of two different concentrations of BTX 1702, alongside a 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 and thereby improving the probability of success.

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 is on track to complete enrolment this quarter, with data expected shortly thereafter.

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

Following the announcement of positive data from the Phase 2a study in 2021, Botanix's antimicrobial clinical development program BTX 1801 is moving forward with a Phase 2 study planned to initiate in 2Q 2022 with ethics applications. 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.

Subsequent to the quarter end, the Company 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.

The Company was also recently granted Qualified Infectious Disease Product (QIDP) status for BTX 1801 by the FDA which covers usage of BTX 1801 for the "reduction of risk of S. aureus bloodstream infections in colonized patients on central venous catheter-dependent hemodialysis," which is the lead indication for the novel synthetic cannabidiol intranasal gel. This new designation represents the first such designation ever granted for a nasal decolonization agent for hemodialysis patients. The major incentive afforded to a product with QIDP status is an additional 5 years of regulatory exclusivity, on top of the standard regulatory exclusivity that comes with FDA approval of a New Drug Application (NDA). This incentive could potentially enhance the value of a successful product as it provides an extra 5 years of protection, during which period, generics cannot enter the market.

Botanix has recently completed a further round of animal studies and other preclinical work to enable a longer term, repeat dose study to be conducted in humans with confirmed bacterial colonisation. Ethics approval for the planned Phase 2 study is planned to be submitted in 2Q 2022.

Expanding the pipeline - Permetrex™ technology and new opportunities

During the quarter, the Company also remained active in efforts to expand the Botanix dermatology pipeline and has assessed several new drugs for acquisition, as well as collaborations to improve the delivery of different new drugs utilising the Permetrex™ drug delivery platform.

The Company has made significant progress in relation to its efforts to expand the pipeline and expects any new programs to be complementary to the Company's existing pipeline and provide support for Botanix's goal of becoming a leading dermatology drug development company.

Corporate Developments

As the Company progresses its clinical pipeline and begins preparation for the achievement of upcoming clinical milestones, it has significantly strengthened its executive leadership team with the appointment of Danny Sharp as Non-Executive Director, Howie McKibbon as Chief Commercial Officer and Dr Patricia Walker as Chief Medical Advisor.

Mr Sharp is highly experienced investment banker with a career that spans more than 30 years in the capital markets globally. Mr Sharp has advised the boards of technology and healthcare-based organisations and has an extensive network of institutional investors.

Howie McKibbon brings more than 20 years senior leadership experience in the pharmaceutical industry and was most recently the Senior Vice-President, Worldwide Commercial Operations at Dermavant Science, where he played a major role in building the company and acquiring the flagship psoriasis product tapinarof. Over the course of his career Mr McKibbon has launched 15 products including 11 in dermatology. He has managed over 30 dermatology products and played a significant role in two of the largest dermatology acquisitions with combined valuations of $7.8 billion.

Dr Patricia Walker is a board-certified dermatologist specialising in medical and aesthetic dermatology. Dr Walker brings over 20 years' experience developing and leading the approval process of key dermatology products including Tazorac® and Botox® Cosmetic, and has previously held the positions of President and head of R&D for Brickell Biotech, Chief Medical Officer for Kythera Biopharmaceuticals, Inc., Executive Vice President and Chief Scientific Officer for Allergan Medical Aesthetics and Vice President and Dermatology Therapeutic Area Head at Allergan.

These appointments significantly strengthen Botanix's leadership team and ensure it remains poised to capitalise on all upcoming clinical and commercial opportunities as it progresses through its clinical pipeline and explores the potential for adding additional assets to its catalogue.

Financial Overview

During the quarter, Botanix had net cash outflows of A$0.43m, with A$2.68m invested in R&D activities. During the quarter Botanix received a $2.75m Research and Development (R&D) Tax Incentive Refund for the 2020/2021 financial year. At the end of the quarter, Botanix held A$16.4m in cash and remains in a strong financial position.

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 focused company based in Perth (Australia) and Philadelphia (USA) committed to the development of pharmaceutical products that are underpinned by science and supported by well-controlled randomised clinical trials. The Company has two separate development platforms - dermatology and antimicrobial products - both of which currently leverage the unique anti-inflammatory, immune modulating and antimicrobial properties of cannabinoids, particularly synthetic cannabidiol or CBD. Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases, which it utilises 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	March 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(2,680)	(6,207)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(223)	(638)
	(f) administration and corporate costs	(240)	(931)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	6	30
1.5	Interest and other costs of finance paid	(9)	(29)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	2,755	2,755
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(391)**	**(5,020)**

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	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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 (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**(7)**

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)	(39)	(111)
3.10	**Net cash from / (used in) financing activities**	**(39)**	**(111)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	16,846	21,555
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(391)	(5,020)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(7)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(39)	(111)
4.5	Effect of movement in exchange rates on cash held	1	-
4.6	**Cash and cash equivalents at end of period**	**16,417**	**16,417**

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	7,317	3,846
5.2	Call deposits	9,100	13,000
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)**	**16,417**	**16,846**

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	276
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 $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)	(391)
8.2	Cash and cash equivalents at quarter end (item 4.6)	16,417
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	16,417
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	42

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.

(1) Net expenditure for the quarter excluding Research and Development tax incentive refund

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 April 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.