25 October 2021

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

Key highlights

- **Botanix's canine atopic dermatitis proof of concept study, BTX1204A, underway following positive data delivered during the initial pilot study in May 2021**
- **BTX 1702 Phase 1b/2a Rosacea Study is progressing well, and recruitment remains on track despite COVID restraints**
- **Highly experienced pharmaceutical executive Dr Jack Hoblitzell appointed as Senior Vice President of Pharmaceutical Development**
- **Preparation for the Phase 2 hemodialysis nasal decolonisation study, BTX 1801, is advancing with formulation and delivery studies underway**
- **Strong cash position of $19.57 million at quarter end with R&D tax return expected in the coming quarter**

Philadelphia PA and Perth Australia, 25 October 2021: 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 September 2021.

Clinical Studies and Drug Development

Dermatology: BTX1204A canine atopic dermatitis trial commences

Following the receipt of ethics approval, Botanix has now commenced its BTX 1204A proof of concept study in canines with atopic dermatitis across Australia and New Zealand. BTX 1204A is based on a new higher dose formulation of synthetic cannabidiol (CBD) in a novel Permetrex™ formulation which recently demonstrated strong efficacy in killing bacteria and providing separation between drug active and vehicle arms in the successful BTX 1801 Phase 2a study.

Up to 45 canines across three dermatology sites will be enrolled and two formulations of BTX 1204A (high dose and low dose) and a vehicle arm will be evaluated. Each canine will be treated twice daily with BTX 1204A applied topically, over a 28-day period. The study will evaluate the treatment's efficacy using the industry standard Enhanced Pruritus Score (EPS) and Canine Atopic Dermatitis Extent and Severity Index (CADESI-04).

This study follows encouraging data from a canine pilot study that completed in May 2021. Further positive outcomes of this new study will support progress towards a late-stage Phase 2b clinical study in humans with atopic dermatitis, as well as provide a number of potential commercial opportunities for the Company to partner with and drive licensing programs across the animal health sector.

The potential benefit of BTX 1204A in canine and human atopic dermatitis is supported by studies that indicate synthetic CBD addresses multiple factors of disease pathology, inhibits itch[i] and repairs skin

barrier dysfunction[ii,iii], is a potent antimicrobial against *Staph Aureus* bacteria[iv], and has broad anti-inflammatory properties. There is significant unmet need for an effective, safe and topically applied therapeutic to treat atopic dermatitis. In the US alone, approximately 31 million people have a form of the disease, with 1 in 10 people in the general population developing symptoms during their lifetime[v,vi].

Rosacea: BTX 1702 Phase 1b/2 study progressing well

BTX 1702 is the Company's Phase 1b/2a randomised, double blind, vehicle-controlled clinical study in patients with moderate to severe papulopustular rosacea which commenced in June 2021. The study will investigate the safety and tolerability of two different concentrations of BTX 1702 alongside a vehicle (placebo) in 120 adults over an eight-week treatment period.

The study has been designed to enable increased data capture and to provide additional insights to support Botanix's broader dermatology platform. This includes use of advanced Canfield imaging technology in all sites to support clinical assessment and improve patient tracking, as well as centralised review of each clinical investigator's ratings for patient inclusion and some endpoint assessments. The Company believes these process and technology improvements will greatly enhance quality of the study data and help reduce the potential for site-to-site variability.

Recruitment of patients into the study across sites in Australia and New Zealand remains on track, despite COVID-19 related delays and is expected to complete in mid 2022.

Antimicrobial: BTX 1801 Phase 2 study preparations well advanced

Preparations for the next clinical study in the BTX 1801 development program are well advanced following the announcement of positive data from the Phase 2a study in 1Q 2021. The program is designed to kill Staph aureus and MRSA in the noses of haemodialysis patients, in order to help prevent life-threatening bloodstream infections that occur when those bacteria exit the nose and enter the catheter that these patients have implanted in their chests.

Haemodialysis patients undergoing dialysis regularly - three to five times per week - yet despite the significant health risks of having a long term central venous catheter, treatments to prevent bloodstream infections are limited to the application of antiseptics at the catheter entry site[vii,viii].

Other issues with the use of antiseptics include the potential degradation of the catheter's plastic construction and potential to cause patient toxicities.[ii] Limited current preventative measures mean there is an urgent need and significant market opportunity for novel approaches to prevent bloodstream infections in haemodialysis patients.

Plans to progress BTX 1801 into a further Phase 2 study are well progressed and the Company is currently completing formulation work, finalising packaging options to enable efficient application to each nostril and undertaking animal studies to complete the data package for ethics approval. Commencement of the study will follow the completion of this work early in 1Q CY2022.

Corporate

Appointment of Senior Vice President of Pharmaceutical Development

In September 2021 Dr Jack Hoblitzell was appointed as Senior Vice President of Pharmaceutical Development bringing over 30 years' experience in leading world-class technical operations to manufacture and deliver branded, specialty and generic pharmaceuticals.

Dr Hoblitzell has previously held senior leadership positions at leading therapeutic and pharmaceutical companies including Assertio Therapeutics Inc., Pfizer, King Pharmaceuticals, Ivax Pharmaceuticals and Teva Pharmaceuticals. Dr Hoblitzell is an expert in M&A due diligence, manufacturing technology transfer and integration in addition to manufacturing for pivotal studies and regulatory submission documentation which will be invaluable as it progresses through its clinical study program.

Permetrex™ Opportunities and Business Development

During the quarter, the Company also continued to advance its exploration of new opportunities to expand its dermatology platform. As part of this, the Company has focused on sourcing additional pharmaceutical targets that can be better delivered by using Permetrex™ as the formulation approach, as well as identifying development stage dermatology products with best-in-class activity, where Botanix can leverage its clinical, manufacturing and regulatory infrastructure to accelerate these products into later stage studies and partnering opportunities.

Cash position

During the quarter, Botanix had net cash outflows of A$1.98m, with A$1.35m m invested in R&D activities. At the end of the quarter, Botanix held A$19.57m in cash and remains in a strong financial position. The Company is expecting to receive its claim under the R&D tax incentive program in 4Q CY2021, which will further strengthen the Company's cash 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 clinical stage dermatology 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 complimentary 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.

The Company is developing a pipeline of product candidates with recent positive data from its BTX 1801 Phase 2a antimicrobial study and its Phase 1b/2a rosacea clinical study is currently enrolling patients. Following a successful meeting with the FDA, the Company has also confirmed a drug development plan for the BTX 1503 acne Phase 3 program to support registration. In addition, Botanix plans to advance its BTX 1204A atop dermatitis program to a proof of concept canine study in Q3 CY2021 following encouraging early data from a recent pilot study. 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 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.

[i] Eagelston et al. Dermatol Online J. 2018 Jun 15; 24 (6);
[ii] BTX 1308 Phase 1b clinical study – BOT data on file

[iii] Tan et al. Mal Med Rep 2017: 16(6) 8883-8867
[iv] BTX 1801 Phase 2a clinical study – BOT data on file
[v] Hanifin JM, Reed ML, Eczema Prevalence and Impact Working Group. A population-based survey of eczema prevalence in the United States. Dermatitis. 2007;18(2):82-91
[vi] Silverberg JI, Hanifin JM. Adult eczema prevalence and associations with asthma and other health and demographic factors: a US population-based study. J Allergy Clin Immunol. 2013;132(5):1132-1138
[vii] CDC recommends the use of antiseptics greater than 0.5% chlorhexidine with alcohol, 70% alcohol, or 10% povidone-iodine.
[viii] 'Hemodialysis Central Venous Catheter Scrub-the-Hub Protocol', CDC, 2016, https://www.cdc.gov/dialysis/prevention-tools/scrub-protocols.html

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	September 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,348)	(1,348)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(215)	(215)
	(f) administration and corporate costs	(388)	(388)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	18	18
1.5	Interest and other costs of finance paid	(11)	(11)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,944)**	**(1,944)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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)**	**(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)	(35)	(35)
3.10	**Net cash from / (used in) financing activities**	**(35)**	**(35)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	21,555	21,555
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,944)	(1,944)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(7)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(35)	(35)
4.5	Effect of movement in exchange rates on cash held	(2)	(2)
4.6	**Cash and cash equivalents at end of period**	**19,567**	**19,567**

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	19,567	19,567
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)**	**19,567**	**19,567**

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	237
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)	(1,944)
8.2	Cash and cash equivalents at quarter end (item 4.6)	19,567
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	19,567
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	10

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: 25 October 2021

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.