23 July 2021

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

Key highlights

- **Successful launch of BTX 1702 rosacea clinical study, currently under COVID related restrictions, with sites initiated in Australia, and New Zealand start up pending**
- **Encouraging results achieved from the BTX 1204A pilot study of canines with atopic dermatitis, with preparation underway to commence a proof of concept canine study**
- **Preparation for the BTX 1801 Phase 2b clinical study targeting the nasal decolonisation of Staph aureus in haemodialysis patients to prevent bloodstream infections is well progressed and expected to initiate in 4Q CY2021**
- **Support for Botanix's research on the antimicrobial potential of cannabidiol published by a leading South American academic group in BioRxiv**
- **Actively reviewing a number of opportunities to leverage the unique properties of the Permetrex™ technology platform to deliver new dermatology drugs**
- **Botanix in a strong financial position, holding cash balance of A$21.6m at 30 June 2021**

Philadelphia PA and Perth Australia, 23 July 2021: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to release its Quarterly Activities Report and Appendix 4C Quarterly Cash Flow report for the period ended 30 June 2021.

Clinical studies and drug development

Rosacea: BTX 1702 Phase 1b clinical study underway

Following ethics approval, Botanix launched its BTX 1702 Phase 1b rosacea clinical study in June. The study is a randomised, double blind, vehicle-controlled study in patients with moderate to severe papulopustular rosacea and will investigate the safety and tolerability of two different concentrations of BTX 1702 along with a vehicle (control) arm in adults over an 8-week treatment period. The study plans to enrol approximately 120 patients in 12 dermatology clinical sites across Australia and New Zealand. Botanix launched the BTX 1702 rosacea clinically study, currently under COVID related restrictions, during the quarter – with sites already initiated in Australia and currently recruiting patients and the first site in New Zealand expected to be initiated in the near term. Additional sites are being reviewed to potentially speed up recruitment, if lockdowns continue intermittently throughout the planned study duration.

The BTX 1702 clinical study has been designed to enable increased data capture, as well as to provide additional insights to support Botanix's broader dermatology platform. This includes universal use of advanced Canfield imaging technology to support clinical assessments and improve patient tracking, as well as centralised review of each investigator's ratings for patient inclusion and some endpoint assessments. The Company believes that these process and technology improvements to the study

design will greatly enhance quality of the study data and help reduce the potential for site-to-site variability.

Papulopustular rosacea is a highly visible and distressing chronic inflammatory skin disease, characterised by intensely inflamed skin and acne-like breakouts across the face. The disease affects more than 16m Americans and up to 415m people worldwide[i]. Women are more likely to have rosacea than men and more than 85% of patients are over the age of 30 years old[ii].

Dermatology program: Encouraging results from BTX 1204A Pilot Study in canines

In May 2021, the Company announced encouraging results of BTX 1204A pilot study in canines with atopic dermatitis. BTX 1204A demonstrated that the new higher dose topical formulation showed significant reduction on average in both the Enhanced Pruritus Score and the Canine Atopic Dermatitis Extent and Severity Index scale. Canine atopic dermatitis is clinically and immunologically similar to human atopic dermatitis, and so this study serves as an excellent surrogate for human disease.

BTX 1204A is based on a new higher dose formulation of synthetic cannabidiol (CBD) in a novel Permetrex™ formulation – which was used in the successful BTX 1801 Phase 2a study and showed excellent efficacy in killing bacteria and excellent separation between drug active and vehicle arms. Botanix plans to advance BTX 1204A to a proof of concept canine study this quarter which, if successful, provides potential opportunities for partnering the product for animal health applications and may support progression to a Phase 2b study in humans in 2022.

Antimicrobial platform: Preparation of BTX 1801 Phase 2b clinical study underway

In May 2021, Botanix launched the next phase of the BTX 1801 development program, targeting the nasal decolonisation of *Staphylococcus aureus* (Staph aureus) in haemodialysis patients to prevent life-threatening bloodstream infections. This followed an extensive assessment by key opinion leaders of the positive data from BTX 1801 Phase 2a study, clinical data generated to date and a thorough review of potential market opportunities.

Haemodialysis patients undergoing dialysis regularly (3 to 5 times per week), are at a high risk of bloodstream infections, due to their treatment requiring frequent use of catheters – which in the first year are central lines with direct access to the patient's heart. Despite the significant health risks, the treatment to prevent bloodstream infections is essentially limited to the application of antiseptics at the catheter site[iii,iv]. 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.

Botanix intends to leverage a range of existing US Food and Drug Administration (FDA) programs to accelerate BTX 1801 clinical development, reduce clinical costs and increase the potential exclusivity period. Plans to progress BTX 1801 into a Phase 2b study are well progressed and Botanix plans to initiate the study in 4Q CY2021 following completion of preparatory studies in the coming months.

Antimicrobial platform: Publication of further support for CBD as a promising antimicrobial

In April 2021, Botanix's research on the antimicrobial potential of CBD was supported by the publication of research data from leading South American academic group in online journal BioRxiv (BioRxiv paper). The BioRxiv paper follows the earlier publication of Botanix's research in Nature

Research's peer-reviewed journal, *Communication Biology*, in January 2021. The BioRXiv paper supports Botanix's discovery that synthetic CBD can also kill a select group of Gram-negative bacteria, including the bacteria responsible for the sexually transmitted disease gonorrhoea and increasingly challenging *Clostridioides difficile* infections.

Permetrex™ technology: leveraging the platform to deliver new drugs

During the quarter the Company continued its activities focused on assessing a number of new drugs that can be more effectively delivered utilising the Permetrex™ drug delivery platform. Leveraging historical work Botanix has completed for partners in a range of dermatology diseases, the Company is reviewing a number of opportunities to either rescue stranded assets that currently are unable to deliver enough active drug to the target site in the skin, or which may benefit from the improved safety, efficiency and / or cosmetic elegance of the Permetrex™ technology. These opportunities are expected 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

In May 2021, Botanix held an investor conference call hosted by Vince Ippolito, Present and Executive Chairman, and Matt Callahan, Executive Director. Botanix management provided an update on the key clinical development programs, including the progression of BTX 1801 antimicrobial platform and BTX 1702 rosacea study, and responded to questions from analysts, investors and shareholders.

At the end of the quarter, Botanix held A$21.6m in cash. During the quarter, Botanix had net cash outflows of A$1.7m, with A$1.2m invested in R&D activities. 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. 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 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 Phase 1b rosacea clinical study 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.

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[i] [i] Gether L, Overgaard LK, Egeberg A, Thyssen JP. Incidence and prevalence of rosacea: a systematic review and meta-analysis. *Br J Dermatol* 2018 Feb 25. Boi: 10.1111/bjd.16481

[ii] www.rosacea.org/patients/all-about-rosacea

[iii] CDC recommends the use of antiseptics greater than 0.5% chlorhexidine with alcohol, 70% alcohol, or 10% povidone-iodine.

[iv] '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	June 2021

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	(1,159)	(7,534)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(275)	(1,116)
	(f) administration and corporate costs	(248)	(1,253)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	5	104
1.5	Interest and other costs of finance paid	(12)	(56)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	6,877
1.8	Other (provide details if material)	-	10
1.9	**Net cash from / (used in) operating activities**	**(1,689)**	**(2,968)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(2)	(8)
	(d) investments	-	-
	(e) intellectual property	-	-
	(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 (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(2)**	**(8)**

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)	(32)	(125)
3.10	**Net cash from / (used in) financing activities**	**(32)**	**(125)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	23,278	24,646
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,689)	(2,968)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(8)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(32)	(125)
4.5	Effect of movement in exchange rates on cash held	-	10
4.6	**Cash and cash equivalents at end of period**	**21,555**	**21,555**

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	2,055	2,178
5.2	Call deposits	19,500	21,100
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)**	**21,555**	**23,278**

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	225
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)	(1,689)
8.2	Cash and cash equivalents at quarter end (item 4.6)	21,555
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	21,555
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	12.8

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: 23 July 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.