13 October 2020

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

Key highlights

- **Recruitment is well advanced for the BTX 1801 Phase 2a clinical study to evaluate the safety, tolerability and efficacy of BTX 1801 as a nasal decolonisation agent for *Staph* and *MRSA***
- **Completion of a successful End of Phase 2 meeting for BTX 1503 for acne with the FDA**
- **BTX 1702 study is poised to commence recruitment once travel and clinical trial conduct restrictions are eased in Australia and New Zealand**
- **Botanix remains in a strong financial position, holding cash balance of A$22.1m as at 30 September 2020**

Philadelphia PA and Sydney Australia,13 October 2020: Clinical stage cannabinoid 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 September 2020.

Clinical development

Antimicrobial platform: Phase 2a clinical trial underway

In August 2020, Botanix commenced recruitment for its BTX 1801 Phase 2a clinical study to evaluate the safety, tolerability and efficacy of BTX 1801 for the prevention of surgical site infections. The double-blind, vehicle controlled Phase 2a clinical study has been designed to evaluate the safety and local tolerability of two formulations of BTX 1801 to decolonise *Staphylococcus aureus ('Staph')* and methicillin-resistant *Staphylococcus aureus ('MRSA' or 'Golden Staph')* from the nose of healthy adults. The Phase 2a clinical study will enroll approximately 60 healthy volunteers who will undergo twice-daily treatments across a 5-day period. The clinical trial design enables the study to be completed in a highly cost effective manner and efficiently, with Botanix targeting study completion in 4Q CY2020 with data to be available shortly thereafter.

In September 2020, Botanix released new data supporting its antimicrobial platform and BTX 1801 clinical development program. The first study, an *ex vivo* efficacy study ("the Human Skin Study"), demonstrated BTX 1801 eliminates *MRSA* from human skin explants infected with the bacteria after 24 hours of treatment in a dose dependent manner. The data from the Human Skin Study supports results previously reported by Botanix using explants from *porcine* skin and further validates the potential for BTX 1801 to decolonise *MRSA* from human skin in the current clinical study. There was no evidence of toxic effects on the skin, reflecting studies in minipigs that have confirmed the direct application of BTX 1801 to the nasal passage was safe and well tolerated.

A second study was also completed investigating the novel mechanism of action of synthetic cannabidiol. In the study, *Staph* was grown at room temperature on an agarose pad over 120 minutes.

Application of synthetic cannabidiol resulted in disruption of the bacterial membrane and cell death, preventing bacterial growth and multiplication. Together with the Human Skin Study, the data further supports the Phase 2a clinical study of BTX 1801.

In addition to the clinical development program for the prevention of post-surgical infections, Botanix is also actively exploring opportunities for its synthetic cannabidiol and cannabinoid analog development assets. These include other bacterial infections, different routes of administration of the drug and new uses for cannabinoids with improved bioavailability and potency.

BTX 1503 acne program:

In July 2020, Botanix achieved an important drug development milestone, with the completion of a successful End of Phase 2 meeting ('EOP2 Meeting') for BTX 1503 with the FDA. The EOP2 Meeting provided an opportunity for Botanix to seek confirmation from the FDA on the drug development plan for BTX 1503 to support registration, of which a critical component is the design of the Phase 3 clinical studies. The FDA highlighted the excellent safety profile of synthetic BTX 1503, by allowing several waivers for studies that are normally required for dermatology drug registration. The timetable of the progression of the BTX 1503 Phase 3 study is currently under review, pending the completion of the Company's BTX 1702 (rosacea) Phase 2 clinical study and lifting of COVID-19 restrictions.

BTX 1702 Rosacea program:

The Company's BTX 1702 rosacea program is poised to commence recruitment once travel and clinical trial conduct restrictions are eased across Australia and New Zealand. The 6-week randomised, double-blind, vehicle-controlled Phase 2b study will evaluate the safety and tolerability of BTX 1702 in patients with moderate to severe papulopustular rosacea. Given the overlap in characteristics between rosacea and acne, the study will also provide supporting information for the BTX 1503 acne program. Botanix continues to monitor the situation closely and will begin recruitment for the BTX 1702 Phase 2b study as soon as practicable.

Corporate

During the quarter, Botanix had net cash outflows of A$2.56m, with A$2.13 m invested in R&D activities. At the end of the quarter, Botanix held A$22.1m in cash and remains in a strong financial position. In September 2020, Botanix President and Executive Chairman Vince Ippolito participated in the 2020 ASX Small & Mid-Cap Virtual Conference. The presentation provided an overview of the current development programs as well as new data supporting Botanix's antimicrobial platform and attracted over 600 viewers. The Company will continue to explore opportunities of non-dilutive funding opportunities for therapeutics that treat bacterial infections. In addition, Botanix also continues to assess opportunities and partnerships in the development of new products that can be rapidly brought to market for dermatological or antimicrobial applications.

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.

Annual General Meeting Date

in accordance with ASX Listing Rule 3.13.1, the Company that it has scheduled the Annual General Meeting (AGM) of the Company to be held on 23 November 2020.

An item of business at the AGM will be the re-election of directors. The closing date for the receipt of director nominations is Tuesday , 20 October 2020. Nominations must be received at the Company's registered office no later than 5.00pm (Perth time) on Tuesday 20 October 2020

Release authorised by

Vince Ippolito
President and Executive Chairman

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage synthetic cannabinoid 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 cannabinoid development platforms, dermatology and antimicrobial products, both of which 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.

The Company is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabinoids with enrolment for BTX 1801 Phase 2a study for the prevention of surgical site infections well advanced. For the dermatology platform, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration and plans to progress its Phase 2b rosacea study in the near future.

To learn more please visit: https://www.botanixpharma.com/

For more information, please contact:

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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.

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 2020

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	(2,129)	(2,129)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(261)	(261)
	(f) administration and corporate costs	(219)	(219)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	57	57
1.5	Interest and other costs of finance paid	(16)	(16)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	8	8
1.9	**Net cash from / (used in) operating activities**	**(2,560)**	**(2,560)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(4)	(4)
	(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**	**(4)**	**(4)**

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 (provide details if material)	(30)	(30)
3.10	**Net cash from / (used in) financing activities**	**(30)**	**(30)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	24,646	24,646
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,560)	(2,560)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(4)

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)	(30)	(30)
4.5	Effect of movement in exchange rates on cash held	7	7
4.6	**Cash and cash equivalents at end of period**	**22,059**	**22,059**

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	2,059	4,646
5.2	Call deposits	20,000	20,000
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)**	**22,059**	**24,646**

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	370
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)	(2,560)
8.2	Cash and cash equivalents at quarter end (item 4.6)	22,059
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	22,059
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	8.6

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: 12 October 2020

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.