

22 January 2021

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

Key highlights

- Completed successful Pre-IND meeting with the FDA for BTX 1801, enabling clinical development in the US towards a New Drug Application
- Botanix's BTX 1801 antimicrobial Phase 2a clinical study completed and remains on track for data read out in 1Q CY2021
- BTX 1702 study poised to commence as restrictions are eased in Australia and New Zealand
- Botanix remains in a strong financial position, holding cash balance of A\$19.2m as at 31 December 2020
- Application for R&D Tax Incentive Refund totalling approximately A\$6.8m lodged

Philadelphia PA and Sydney Australia, 22 January 2021: 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 31 December 2020.

Clinical development

Antimicrobial platform: Phase 2a study completed and awaiting data

In November 2020, Botanix successfully completed a Pre-Investigational New Drug (Pre-IND) meeting with the US Food and Drug Administration's (FDA) Office of Infectious Diseases for the BTX 1801 synthetic cannabidiol antimicrobial product. The meeting provided Botanix with an opportunity to seek advice and clarification from the FDA on the development plan and data package required to initiate clinical studies for BTX 1801 in the US. In addition, Botanix gained feedback from the FDA on the drug development plan required for BTX 1801 to support a Fast-Track designation and New Drug Application (NDA) in light of its existing Qualified Infectious Disease Product (QIDP) designation. The FDA advised that the proposed drug development plan and data package presented were sufficient to initiate clinical development in the US and ultimately support an NDA submission. The FDA encouraged Botanix to request a Fast-Track designation for BTX 1801 following submission of an IND application.

In December 2020, all participants successfully completed the BTX 1801 antimicrobial Phase 2a clinical study and on track to announce data in 1Q CY2021. The double-blind, vehicle-controlled Phase 2a clinical study is 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. Volunteers underwent twice-daily treatments across a 5-day period. Following the clinical treatment period, Botanix commenced data collection to support database lock, data analysis and generation of top-line data.

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

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development assets. These include other bacterial infections, different routes of administration of the drug and new uses for cannabinoids with improved bioavailability and potency.

Dermatology program: BTX 1702 study poised to commence

The Company's BTX 1702 rosacea Phase 1b clinical study is poised to commence recruitment once travel and clinical trial conduct restrictions are eased across Australia and New Zealand. The 8-week randomised, double-blind, vehicle-controlled study will evaluate the safety and tolerability of BTX 1702 in patients with moderate to severe papulopustular rosacea. Botanix continues to monitor the situation closely and plans to begin recruitment for the BTX 1702 study in 1H CY2021.

Given the overlap in characteristics between rosacea and acne, the BTX 1702 study will provide supporting information for the BTX 1503 acne program. Following the successful End of Phase 2 meeting with the FDA, Botanix is reviewing the timetable for progression of the BTX 1503 Phase 3 study, pending the completion of the rosacea clinical study.

Corporate

During the quarter, Botanix had net cash outflows of A\$2.8m, with A\$2.2m invested in R&D activities. At the end of the quarter, Botanix held A\$19.2m in cash and remains in a strong financial position. During the quarter, the Company lodged an application for an R&D Tax Incentive refund of approximately A\$6.8m. If received, funds will be invested into product development. In addition, Botanix continues to assess opportunities and partnerships in the development of new products that can be rapidly brought to market for antimicrobial or dermatological 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.

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 the BTX 1801 Phase 2a study for the prevention of surgical site infections completed and awaiting data. For the dermatology platform, the Company has confirmed

a drug development plan for the BTX 1503 acne program to support registration and plans to initiate its Phase 1b rosacea study in 1H CY2021. 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 its 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

70 009 109 755

Quarter ended ("current quarter")

December 2020

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(2,245)	(4,267)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(159)	(420)
(f) administration and corporate costs	(414)	(739)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	22	78
1.5 Interest and other costs of finance paid	(15)	(31)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	3	10
1.9 Net cash from / (used in) operating activities	(2,808)	(5,369)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(1)	(6)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 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	(1)	(6)

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)	(32)	(62)
3.10	Net cash from / (used in) financing activities	(32)	(62)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	22,059	24,646
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,808)	(5,369)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1)	(6)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(32)	(62)
4.5	Effect of movement in exchange rates on cash held	3	12
4.6	Cash and cash equivalents at end of period	19,221	19,221

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	2,621	2,059
5.2	Call deposits	16,600	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)	19,221	22,059

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	260
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

7. Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	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)	(2,808)
8.2 Cash and cash equivalents at quarter end (item 4.6)	19,221
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	19,221
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	6.85
<i>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.</i>	
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	
<i>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.</i>	

(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: 22 January 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.