

30 April 2021

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

Key highlights

- Botanix's data from its antimicrobial program published in Nature Research's *Communications Biology*, a leading peer-reviewed biological sciences journal
- Top-line data in the BTX 1801 Phase 2a study showed two different BTX 1801 formulations were safe, well tolerated and successful at eradicating *Staphylococcus Aureus*
- Ethics approval received for the commencement of the BTX 1702 Phase 1b clinical study for papulopustular rosacea, with expanded design expected to enrol first patients in Q2 CY2021
- Management team enhanced with three key hires in the US to drive clinical and commercial activities across the antimicrobial and dermatology programs
- Botanix in a strong financial position, holding cash balance of A\$23.3m as at 31 March 2021

Philadelphia PA and Perth Australia, 30 April 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 31 March 2021.

Clinical development

Antimicrobial platform: research data published and positive BTX 1801 Phase2a results announced

In January 2021, research data from Botanix's antimicrobial platform was published in Nature Research's peer-reviewed journal, *Communications Biology*. The article, "The antimicrobial potential of cannabidiol" represents the culmination of 2 years of research by Botanix and its collaborators including several leading international antimicrobial researchers, with all data generated fully-owned by Botanix and the subject of several patent applications. Notably, the article provided new insights into the mechanism of action by which cannabidiol works to kill bacteria as well as highlighting the discovery that cannabidiol can kill a subset of Gram-negative bacteria that includes the 'urgent threat' pathogen *Neisseria gonorrhoeae* which causes gonorrhea, as well as the bacteria that cause meningitis and legionnaires disease respectively.

In February 2021, Botanix announced positive top-line data from its BTX 1801 Phase 2a nasal decolonisation clinical study. Results of the BTX 1801 study showed the two formulations (ointment and gel) of BTX 1801 met the study endpoints which were focused on safety and eradication of Staph Aureus in the nasal cavity of study participants with confirmed carriage of bacteria. BTX 1801 was found to be safe and well tolerated, with all 66 enrolled participants completing the study. The incidence of adverse events was low, mild in severity and occurred at similar rates across the different treatment groups, with no severe events reported. Secondly, efficacy of both ointment and gel formulations at the primary endpoint of Day 12 was demonstrated. The positive top-line data from the

study supports continued development of BTX 1801 and informs Botanix's clinical development strategies for its broader antimicrobial platform.

In addition to the antimicrobial clinical development program, Botanix continues to actively explore other opportunities for its synthetic cannabidiol and cannabinoid analog assets (e.g. with different route of administration, improved bioavailability and potency) for the treatment of other human and animal bacterial infections.

Dermatology program: BTX 1702 study ethics approval received and enrolment on track to commence in Q2 CY2021

In March 2021, the Company announced the receipt of ethics approval for its expanded BTX 1702 Phase 1b clinical study for the treatment of papulopustular rosacea. The study was expanded to enable increased data capture and provide deeper insights for Botanix's broader dermatology pipeline. Changes include centralised review of each clinical investigator's rating and universal use of advanced Canfield imaging technology, which enhances the data quality and reduces the potential for site-to-site assessment variances. The study has been informed by mechanistic data previously generated by Botanix that showed synthetic cannabidiol exerts powerful anti-inflammatory and antimicrobial actions in skin – two key activities that are critical to successfully treating rosacea. Final preparations for the study are now underway and the Company expects to enrol first patients very shortly.

Given the overlap in disease characteristics between rosacea and acne, the BTX 1702 study will provide significant supporting information for the BTX 1503 acne program. Following the successful End of Phase 2 meeting with the FDA, Botanix has confirmed a drug development plan for BTX 1503 to support registration and plans to proceed with the clinical development of BTX 1503 pending the completion of the BTX 1702 rosacea clinical study.

Corporate

During the quarter, the Company announced the expansion of its management team with three key hires in the US with deep expertise in drug development and commercialisation. Dr Clarence Young was appointed Chief Medical Officer having recently held senior positions at Velicept Therapeutics and Iroko Pharmaceuticals, where he provided clinical and medical leaderships for 3 NDA filings and approvals. Anthony Robinson joined Botanix as Vice President of Development and brings a wealth of experience to the Company following his role as Vice President, Head of Clinical Operations, Program Management and Regulatory Affairs at Advicenne. Finally, Lynda Berne was appointed as Head of Commercial having held several senior and executive roles in the pharmaceutical industry, including 13 years at Bristol-Myers Squibb as Vice President, Infectious Disease Marketing and Vice President of Managed Health Care Sales. The expanded team underpins Botanix's plan to develop its pipeline, accelerate development and scale up commercial capabilities.

In March 2021, Vince Ippolito, President and Executive Chairman, presented at the ASX Small and Mid-Cap Conference. The conference was an opportunity to provide an update on key clinical programs including the positive BTX 1801 Phase 2a results and implication on the broader platform. Matt Callahan, Executive Director, also presented at Dermatology Drug Development Summit Europe,

focusing on the recent antimicrobial pre-clinical and clinical data in support of the combination of Permetrex™ and synthetic cannabidiol's broad applications in dermatology.

During the quarter, Botanix had net cash inflow of A\$4.3m, with A\$1.7m invested in R&D activities. At the end of the quarter, Botanix held A\$23.3m in cash, inclusive of the A\$6.9m R&D Tax Incentive Refund received in February 2021. 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 and which preferably leverage the performance of the Permetrex™ platform. 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. For the dermatology platform, the Company has received ethics approval to commence its Phase 1b rosacea study and following a successful meeting with the FDA, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration. 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")

March 2021

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	(1,716)	(6,375)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(421)	(841)
(f) administration and corporate costs	(373)	(1,005)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	20	98
1.5 Interest and other costs of finance paid	(13)	(44)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	6,877	6,877
1.8 Other (provide details if material)	-	10
1.9 Net cash from / (used in) operating activities	4,374	(1,280)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	(6)
(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	-	(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)	(31)	(93)
3.10	Net cash from / (used in) financing activities	(31)	(93)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	18,936	24,646
4.2	Net cash from / (used in) operating activities (item 1.9 above)	4,374	(1,280)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(6)

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)	(31)	(93)
4.5	Effect of movement in exchange rates on cash held	(1)	11
4.6	Cash and cash equivalents at end of period	23,278	23,278

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	2,178	2,621
5.2	Call deposits	21,100	16,600
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)	23,278	19,221

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	373
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)	4,374
8.2	Cash and cash equivalents at quarter end (item 4.6)	23,278
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	23,278
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
<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: 30 April 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.