

ASX/Media Release

31 July 2019

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

Key highlights

- Interim data from the BTX 1308 Phase 1b study established the mechanism of action of cannabidiol in skin disease and confirms BTX 1308 has significant anti-inflammatory activity
- Ground-breaking data released from BTX 1801 study which highlights the antimicrobial nature of cannabidiol
- Appointment of proven industry leader, Mr Vince Ippolito, as Executive Chairman and President of Botanix
- BTX 1503 Phase 2 acne and BTX 1204 Phase 2 atopic dermatitis studies remain on track for completion
- Botanix continues to build awareness of at key global industry and scientific conferences

Philadelphia PA and Sydney Australia, 31 July 2019: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “the Company”) is pleased to announce further progress and development across its product portfolio and release its Quarterly Activities Report and Appendix 4C Quarterly Cash Flow report for the period ended 30 June 2019.

Clinical development

BTX 1503: recruitment complete with final patients completing Phase 2 acne clinical study

Botanix is currently in the final stages of the BTX 1503 Phase 2 clinical study, for the treatment of patients with moderate to severe acne. During the quarter, Botanix completed patient recruitment for the study, with final patients due to complete the in-life phase of study in 3Q CY2019 with data to be released shortly thereafter.

This 12-week, randomised, double-blind, vehicle-controlled clinical study, evaluates the safety and efficacy of BTX 1503 on patients with moderate to severe acne. The study has been designed to provide data to allow Botanix to explore potential licensing and other corporate opportunities upon completion. There remains a substantial demand for new drugs to treat acne given that no drugs with a new mechanism of action, have been approved by the FDA in more than 20 years.

The results of the BTX 1503 Phase 2 clinical study, combined with the recent mechanism of action data released in June 2019 (discussed below in BTX 1308), will form the basis of a comprehensive clinical and scientific package for planned partnerships and other commercial activities.

BTX 1204: Phase 2 atopic dermatitis clinical study is advancing

Botanix's BTX 1204 Phase 2 atopic dermatitis clinical study is underway and recruitment for the study is expected to be completed in 4Q CY2019 with data to be released shortly thereafter. This program leverages existing data from the Phase 1b BTX 1204 patient study and utilises many of the dermatology clinics that are part of the BTX 1503 study, which reduces the study cost and time.

This 12-week randomised, double-blind and vehicle-controlled study evaluates the safety and efficacy of BTX 1204 in patients with moderate atopic dermatitis. Approximately 200 patients will be enrolled across leading dermatology clinics across the US, Australia and New Zealand.

BTX 1308: study established the mechanism of action of cannabidiol in skin disease

In June 2019, Botanix released interim results from the BTX 1308 Phase 1b psoriasis mechanism of action study. The study was conducted in collaboration with German-based clinical contract research organisation BioSkin GmbH ("BioSkin") and Professor Jim Kreuger at Rockefeller University in New York.

The interim results confirmed that BTX 1308 has significant anti-inflammatory and immune modulating activity in skin disease. The data confirmed that Permetrex™ effectively delivers cannabidiol (CBD) to target skin layers of a single treated lesion and triggers significant alterations in inflammatory and immune response pathways. Further details on the study and results is available in Botanix's ASX release on 19 June 2019 titled "Study Confirms Anti-Inflammatory and Other Properties of CBD"

BTX 1801: Botanix released ground-breaking data demonstrating the antimicrobial nature of CBD

In June 2019, Botanix released successful new data from the BTX 1801 studies. The studies were conducted in collaboration with Dr Mark Blaskovich at The University of Queensland's Institute for Molecular Bioscience's Centre for Superbug Solutions and supported by Innovation Connections, an Australian Government grant.

The studies demonstrated that CBD has the potential to be a powerful new broad-spectrum Gram-Positive antibiotic. The studies confirmed that BTX 1801 rapidly kills Gram-Positive Staphylococcus Aureus ("staph") and methicillin resistant Staphylococcus Aureus ("MSRA"). The data also showed that despite extensive exposure to CBD, antibiotic resistant bacteria do not develop resistance to CBD.

Further, the proof of concept for BTX 1801 efficacy was demonstrated in an animal wound infection and biofilm models. The data validates the significant antimicrobial properties of CBD, which addresses the predominant challenge with a majority of skin diseases, along with the complications that arise from acute and chronic skin infections.

The next phase of development is to optimise the dosing strategy for clinical development and proceed with a clinical study in a target infection indication. Botanix is continuing to assess its options for the development of its antimicrobial platform.

Corporate

During the quarter, Botanix had net cash outflows of A\$4.6m with A\$4.3m invested in R&D activities, primarily to progress the two Phase 2 clinical studies (BTX 1503 and BTX 1204). At the end of the quarter, Botanix held A\$4.7m in cash.

Forecast cash outflows for R&D activities is estimated to be A\$5.7m for the upcoming quarter, as BTX1503 nears completion and BTX1204 meets enrolment milestones. The Company is currently in a trading halt pending an announcement in relation to a capital raising to fund completion of its existing studies and for its future activities.

In May 2019, the Company appointed Mr Vince Ippolito as President of Botanix. Mr Ippolito brings a proven track record with over 30 years of experience in the pharmaceutical industry, including more than 20 years of experience in dermatology, where he has been involved in the launch of over 20 branded dermatology products. Mr Ippolito also played a leading role in two large dermatology transactions with a combined valuation of ~US\$7.8bn, including the recent US\$5.2bn sale of Anacor to Pfizer. Mr Ippolito will lead Botanix's commercial operations globally, which includes engagement with potential partners and commercial planning for Botanix's development pipeline. Following the quarter, Mr Ippolito was appointed as President and Executive Chairman of the Botanix Board. Dr Stewart Washer will step down from interim Non-Executive Chairman and maintain his position on the Botanix Board as a Non-Executive Director.

During the quarter, Botanix continued to drive awareness of the potential benefits of its treatments with potential investors and strategic partners with an active presence at global industry conferences. The Company attended and / or presented at the following conferences:

- **May 2019:** Canaccord Genuity Cannabis Conference (New York)
- **June 2019:** Jefferies Healthcare Conference (New York)
- **June 2019:** 24th World Congress of Dermatology (Milan)

In addition, Dr Mark Blaskovich from The University of Queensland's Institute for Molecular Bioscience's Centre presented the new BTX 1801 data at the American Society for Microbiology meeting in San Francisco in June 2019. Dr Mark Blaskovich's presentation received significant interest and his presentation was well received.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage 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's focus is the development of safe and effective topical treatments for acne, psoriasis, atopic dermatitis and other skin conditions, together with a development platform of antimicrobial drug candidates.

The active ingredient contained in Botanix products is a synthetic form of cannabidiol. Treatment targets for skin diseases include inflammation, deterioration of the skin barrier, skin cell proliferation, pruritus (itch), excess sebum production and bacterial infection.

Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases. Botanix is working with multiple parties to test the application of Permetrex™ on both a fee-for-service and traditional license basis. Botanix pursues a rapid clinical development strategy aimed at accelerating product commercialisation.

The Company completed its first acne patient studies with BTX 1503 in January 2018 and has commenced a Phase 2 clinical study in June 2018 with patient treatment expected to complete in 3Q CY2019. The BTX 1204 atopic dermatitis Phase 2 patient study is also underway with enrolment expected to complete in 4Q CY2019. A mechanism of action study for Phase 1b BTX 1308 (psoriasis) has recently completed, with positive interim data announced in June 2019. Development of a pipeline of product candidates that leverages the antimicrobial properties of cannabidiol are also moving forward and first products are planned to enter the clinic in 2H CY2019.

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

For more information, please contact:

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Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 - Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

Botanix Pharmaceuticals Limited

ABN

70 009 109 755

Quarter ended ("current quarter")

30 June 2019

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	(4,325)	(15,886)
(b) staff costs	(278)	(853)
(c) administration and corporate costs	(247)	(1,207)
Dividends received (see note 3)	-	-
1.4 Interest received	18	122
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	4,617
1.8 Other	-	69
1.9 Net cash from / (used in) operating activities	(4,832)	(13,138)

2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	(2)	(13)
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) property, plant and equipment	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) 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)	(13)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	268	596
3.4	Transaction costs related to issues of shares, convertible notes or options	(3)	(27)
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)	-	-
3.10	Net cash from / (used in) financing activities	265	569

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	9,274	17,263
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,832)	(13,138)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2)	(13)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	265	569
4.5	Effect of movement in exchange rates on cash held	(1)	(24)
4.6	Cash and cash equivalents at end of quarter	4,705	4,705

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	4,705	2,858
5.2	Call deposits	-	6,417
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)	4,705	9,275

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	161
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
6.3	Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	
6.1 – Directors fees		

7.	Payments to related entities of the entity and their associates	Current quarter \$A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
7.3	Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	


8.	Financing facilities available	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
	Add notes as necessary for an understanding of the position		
8.1	Loan facilities	-	-
8.2	Credit standby arrangements	-	-
8.3	Other (please specify)	-	-
8.4	Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

9.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	5,760
9.2	Staff costs	490
9.3	Administration and corporate costs	510
9.4	Leased assets	-
9.5	Other (provide details if material)	-
9.6	Total estimated cash outflows	6,760

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-

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.

Sign here: 
(Company secretary)

Date: 31 July 2019.

Print name: Simon Robertson

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.