

ASX/Media Release

30 April 2019

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

Key highlights

- **Substantial clinical progress, with psoriasis (BTX 1308) study completed and awaiting data, acne (BTX 1503) study nearing completion of recruitment, and atopic dermatitis (BTX 1204) study progressing as planned**
- **Independent comparative analysis indicates Permetrex™ outperforms other CBD topical products, by delivering significantly more drug to the target layers of the skin**
- **Released new data on BTX 1801 for anti-infective applications supports unprecedented bacterial killing and significant market opportunity**
- **Recent additions to Board and management enhances capability and positions Botanix for next phase of growth**
- **Botanix's data and clinical studies presented independently by dermatology key opinion leaders at the American Academy of Dermatology annual meeting**

Philadelphia PA and Sydney Australia, 30 April 2019: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce further progress across its product portfolio and release its Appendix 4C Quarterly Cash Flow report for the period ended 31 March 2019.

Clinical development

BTX 1308 Phase 1b psoriasis patient study completed and awaiting data

During the quarter, Botanix completed the patient treatment portion of its BTX 1308 Phase 1b psoriasis study in collaboration with German-based clinical contract research organisation BioSkin GmbH ("BioSkin") and an Australian dermatology clinic. All patients have now been treated for the pilot period and skin punch biopsies have been taken from treated and untreated skin, which are now being processed and analysed by one of the world's leading researchers in inflammatory diseases and immune responses. Top line data from the study is on schedule to be available in 2Q CY2019.

BTX 1503 Phase 2 acne clinical study nearing completion of full recruitment

During the quarter, Botanix continued to advance the Phase 2 clinical study for its lead product, BTX 1503 for the treatment of moderate to severe acne. Strong patient recruitment continues with all US and Australian clinical sites fully activated and rapidly recruiting study participants. Botanix remains on track to complete recruitment in 2Q CY2019 with data expected to be available in 3Q CY2019.

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.

Accelerating recruitment of patients in the BTX 1204 Phase 2 atopic dermatitis study

During the quarter, Botanix also successfully completed an Investigator’s Meeting for the Phase 2 atopic dermatitis clinical study, following ethics approval received in December 2018. The meeting was well received by the investigators and site coordinators from more than 13 dermatology clinics across Australia and New Zealand. Atopic dermatitis key opinion leaders and clinicians joined the meeting to discuss the study protocol, the practicalities of drug application, as well as specific instructions on patient assessment tools that will be used for the study outcomes.

Since the Investigator’s Meeting, the Company has continued to attract growing interest in the clinical study and a number of new sites have continued to join the study resulting in an acceleration of patient recruitment. The BTX 1204 Phase 2 study is fully funded and the Company remains on track to deliver data in late 4Q CY2019.

The Phase 2 atopic dermatitis clinical study is a 12-week randomised, double-blind and vehicle-controlled study to evaluate 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.

Clinical application for novel antimicrobial (BTX 1801) identified and advancing

During the quarter, Botanix also made substantial progress in the planning for a clinical program to leverage the unique bacterial killing properties of synthetic cannabidiol in the Company’s proprietary skin delivery technology, Permetrex™.

Antimicrobial resistance is an increasingly serious threat to global public health, where attributed deaths are anticipated to reach more than 10m p.a. by 2050 and are expected to cost the global economy more than US\$100tn¹. *Staphylococcus Aureus* and Methicillin Resistant *staphylococcus aureus* (MRSA or “golden staph”) infections cost the US economy more than US\$10bn each year with 40m patients estimated to be at risk of surgery related infections². Widespread and prolonged usage of the dominant antibiotic *mupirocin* has led to a rapid emergence of *mupirocin* resistant staph infections with resistance rates of up to 81% being reported³.

¹ Tackling Drug Resistant Infections Globally Final Report and Recommendations (2016), The Review on Antimicrobial Resistance

² Strategies to Prevent Surgical Site Infections in Acute Care Hospitals: 2014 Update Infection Control and Hospital Epidemiology

³ Mupirocin Resistance: clinical implications and potential alternatives for the eradication of MRSA Journal of Antimicrobial Chemotherapy Volume 70 Issue 10 Oct 2015

Botanix plans to finalise plans for the design of a Phase 1b/2a clinical study for BTX 1801 during 2Q CY2019 with a view to commencing the study following successful completion of its lead programs in acne and/or atopic dermatitis.

Progressed business development and positive independent analysis results for Permetrex™

During the quarter, Tioga Research, a contract research organisation, was engaged to complete an independent comparative analysis between Botanix's lead product for acne (BTX 1503) against other commercially available CBD products.

The analysis demonstrated that relative to the closest comparator CBD topical product, BTX 1503 delivered significantly more active ingredients than other CBD topical creams and gels. Further analysis was also completed to determine the amount of CBD in other comparator products. The results of this analysis indicated that BTX 1503 delivered more CBD in each dose used by patients in clinical studies, than the amount of CBD available in the entire package of each of the comparator products.

These data demonstrate the superior delivery of CBD into the target layers of the skin by the Company's proprietary drug delivery technology, Permetrex™. Botanix continues to actively work with a number of pharmaceutical partners who are using the Permetrex™ delivery system to formulate their proprietary actives, into new and more effective formulations for clinical development.

Corporate

Botanix had net cash outflows of A\$4.3m during the quarter with A\$4.2m invested in R&D activities, primarily associated with its clinical programs. At the end of the quarter, Botanix held A\$9.3m in cash. Botanix continues to demonstrate prudent cash management with forecast cash outflows for R&D activities for the upcoming quarter estimated to be A\$4.0m, primarily to complete two Phase 2 clinical studies (BTX 1503 and BTX 1204), rather than administrative overheads.

With great sadness, the Company announced the passing of Mr Graham Griffiths, Non-Executive Chairman of Botanix. The Company appointed Dr Stewart Washer as interim Non-Executive Chairman. Dr Washer is an experienced executive with more than 20 years of Board and senior executive experience in medical technology and biotechnology companies.

During the quarter, the Company appointed Dr Michael Thurn, Head of Australian Operations, as Executive Director. Dr Thurn brings extensive knowledge in drug regulation, drug discovery, pre-clinical and clinical development across dermatology in Australia and the United States, having held various senior leadership roles in both listed and private companies.

In March 2019, Botanix's CBD clinical data and product programs were presented independently by dermatology key opinion leaders in Washington at the annual American Academy of Dermatology (AAD) meeting. In addition, the Company also met with multiple industry partners to present an update on Botanix's clinical programs (BTX 1503 and BTX 1204) and ongoing psoriasis study (BTX 1308).

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage medical dermatology company based in Perth, Australia and Philadelphia, PA. The Company's focus is the development of safe and effective topical treatments for acne, psoriasis, atopic dermatitis and other skin conditions. The active ingredient contained in Botanix products is a synthetic form of a widely studied natural compound. Treatment targets include inflammation, deterioration of the 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 patient treatment duration of clinical studies is generally completed within a 4 to 12-week timeframe.

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 completion of enrolment expected in mid-2019. The BTX 1204 atopic dermatitis Phase 2 patient study is also underway with enrolment expected to be completed by in 3Q CY2019. Finally, Phase 1b BTX 1308 psoriasis patient study is nearing completion with data anticipated to be available in 2Q 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")

31 March 2019

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	(4,235)	(11,561)
(b) staff costs	(160)	(575)
(c) administration and corporate costs	(304)	(960)
Dividends received (see note 3)	-	-
1.4 Interest received	33	104
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	69
1.9 Net cash from / (used in) operating activities	(4,597)	(8,306)

2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	(11)
(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 (9 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	-	(11)

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	328	328
3.4 Transaction costs related to issues of shares, convertible notes or options	(24)	(24)
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	304	304

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	13,531	17,263
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(4,597)	(8,306)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	(11)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	304	304
4.5 Effect of movement in exchange rates on cash held	37	(25)
4.6 Cash and cash equivalents at end of quarter	9,275	9,275

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	2,858	4,449
5.2 Call deposits	6,417	9,082
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)	9,275	13,531

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	108
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 <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
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	4,050
9.2 Staff costs	180
9.3 Administration and corporate costs	300
9.4 Leased assets	-
9.5 Other (provide details if material)	-
9.6 Total estimated cash outflows	4,530

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

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- This statement gives a true and fair view of the matters disclosed.

Sign here: 
(Company secretary)

Date: 30 April 2019.

Print name: Simon Robertson

Notes

- 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.
- 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.
- 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.