ASX/Media Release

31 October 2019

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

Key highlights

- **Completed BTX 1503 Phase 2 acne clinical study with efficacy and safety results announced in October 2019 (subsequent to quarter end)**
- **Moving forward with preparations for BTX 1503 Phase 3 clinical program and an end-of-Phase 2 meeting with the US FDA**
- **BTX 1204 Phase 2 atopic dermatitis study entering the final stages, with recruitment on track to be completed in 4Q CY2019 and study data in 1Q CY 2020**
- **Completed formulation development and pre-clinical studies of BTX 1702 for the treatment of papulopustular rosacea**
- **Released new data for Botanix's cannabidiol antimicrobial development program**
- **New senior US-based executives appointed to drive Botanix's next phase of development**
- **Completed A$40m US-led institutional placement, providing funding for key clinical development programs and accelerate its broader commercialisation strategy**

Philadelphia PA and Sydney Australia, 31 October 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 September 2019.

Clinical development

BTX 1503: study completed with efficacy and safety results released in October 2019

During the quarter, Botanix completed the BTX 1503 Phase 2 clinical study ("Phase 2 Study"), which evaluated the safety and efficacy of BTX 1503 in patients with moderate to severe acne. Botanix released the results from the Phase 2 Study and the strength and statistical significance of Australian data, combined with the overall safety and efficacy, provides confidence for Botanix to proceed with preparation for Phase 3 clinical studies. The Company is planning an end-of-Phase 2 meeting with the US Food and Drug Administration (FDA).

Summary of Phase 2 top line data

- All doses of BTX 1503 were very safe, with no serious adverse events or treatment related discontinuations while achieving positive effects on acne lesion reductions
- BTX 1503 as a once daily application had the best performance, which from a compliance and commercial perspective, is the ideal dosing regime

- A strong and consistent impact on inflammatory lesions was seen across the entire study, with even greater non-inflammatory lesion reductions
- Australian sites showed clear separation of BTX 1503 5% once a day application (QD) from the vehicle for inflammatory and non-inflammatory lesions
- Patients in the US that received the vehicle had a high vehicle response which skewed the primary endpoint

Study review and next steps

As outlined in the recent announcement, the vehicle response seen with all US sites was unusually two to four times higher than that seen in Australia, for both inflammatory and non-inflammatory lesion reduction measures respectively. The Company is confident that the execution of the study protocol was consistent across geographies and within geographies, whereas the manufacturing and Phase 2 study supply was the key differences between the geographies. Botanix is actively investigating the reasons for this unusual US response and is working with external experts in both clinical management and manufacturing to review the study conduct, operations and materials.

Since commencing the Phase 2 Study, optimisation of the manufacturing scale and emergence of commercial suppliers of synthetic CBD have supported improvements in the process. These changes ensure the manufacturing process is scaled up with consistent equipment and simplified processes. Botanix has now secured a consistent supply of CBD (recently announced an agreement with Purisys the world's largest and most experienced synthetic CBD manufacturer) and Permetrex™ (from a global specialty chemicals company with a presence in 70 countries).

Following finalisation and review of the Phase 2 Study data, the Company is planning an end-of-Phase 2 meeting with the US FDA. Design of the Phase 3 program and timing will be reviewed by Botanix in consultation with the Company's key opinion leaders and clinical trial investigators based on the powering and other study conduct data drawn from the Phase 2 Study.

BTX 1204: Phase 2 clinical study entering the final stages

BTX 1204 Phase 2 atopic dermatitis clinical study is on track to complete patient recruitment in 4Q CY2019, with data expected to be released in 1Q CY2020. This study leverages existing data from the Phase 1b BTX 1204 patient study, which supports efficacy and safety potential.

The 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 – utilising many of the clinics part of the BTX 1503 study, which reduces study costs and time.

The formulations used in the BTX 1204 Phase 2 study, differ from those that were used in the BTX 1503 Phase 2 acne study, both in terms of vehicle composition and synthetic cannabidiol concentration. The study materials for the BTX 1204 study were also manufactured in only two batches for each country, using a more developed manufacturing process and set of controls than those used for BTX 1503.

Development pipeline: additional clinical development work continues

In September 2019, Botanix successfully completed formulation development and pre-clinical studies for a new product, BTX 1702, for the treatment of papulopustular rosacea. Papulopustular rosacea is a highly visible and distressing chronic inflammatory skin disease characterised by intensely inflamed skin and acne-like breakouts across the face, which affects more than 16m Americans.

The expedited BTX 1702 Phase 1b study is based on recent mechanistic data generated by Botanix demonstrating synthetic cannabidiols exerts powerful anti-inflammatory and antimicrobial actions in skin – two key activities critical to successfully treating rosacea.

Antimicrobial platform: new data strongly supports the potential of Botanix's expanding cannabidiol antimicrobial platform

In July 2019, Botanix released data from its new development program, AB 2367, conducted in collaboration with Prof. Dena Lyras at Monash University's Biomedicine Discovery Institute Department of Microbiology. The data from these new studies showed that AB 2367 is:

- A potent antibiotic effective against human and veterinary hypervirulent strains of the Gram-Positive bacteria *Clostridium difficile ("C. difficile")*
- Effective against the super hypervirulent epidemic strain of *C. difficile*, ribotype 027
- Effective against the hypervirulent epidemic strain of *C. difficile*, ribotype 078

Also, following the release of new BTX 1801 data in June 2019, additional work has been undertaken by Dr Mark Blaskovich at The University of Queensland's Institute for Molecular Bioscience's Centre for Superbug Solutions. The additional work by Dr Blaskovich is focused on understanding the mechanism of action by which cannabidiol kills bacteria. Preliminary data supports the rapid bactericidal activity of cannabidiol, indicating that it is likely acting on the different pathways targeted by traditional antibiotics.

Botanix has identified multiple human and animal health applications that leverage the unique properties of cannabinoids as A powerful Gram-Positive antibiotic. The Company continues to assess its options for the further development of its antimicrobial platform

Corporate

During the quarter, Botanix had net cash outflows of A$6.7m, with A$5.7m 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$37.3m in cash. Forecast cash outflows for R&D activities is estimated to be A$7.2m for the upcoming quarter as expenditure peaks for completion of the BTX 1503 Phase 2 acne study, the BTX 1204 Phase 2 atopic dermatitis study nears completion, and new investment is made in additional clinical development programmes. Forecast cash outflows also includes A$2.7m of one-off transaction costs in relation to the placement completed in August 2019. The Company is in a strong financial position following the recently completed US-led institutional placement.

In August 2019, Botanix completed a A$40m US-led institutional placement. The funds from the placement enables Botanix to execute its key clinical development programmes and accelerate its broader commercialisation strategy. The Company is also expecting to receive approximately A$7m in R&D tax incentive in 4Q CY2019. Botanix is now fully funded to progress the development of its rosacea and antimicrobial programs into the clinic and undertake supportive studies required prior to commencement of Phase 3 studies for BTX 1503.

During the quarter, Botanix appointed Mr Vince Ippolito as Executive Chairman of Botanix. This appointment followed the shareholder approval provided at the Botanix General Meeting in July 2019 of certain remuneration related matters. Mr Ippolito initially joined Botanix as President in May 2019.

In addition, Botanix bolstered its executive management team through the appointment of Mr Richard (Ric) Peterson as Chief Financial Officer (CFO) and Mr Howie McKibbon as Chief Commercial Officer (CCO). Mr Peterson has extensive dermatology industry experience, having served as CFO at multiple dermatology companies. Mr McKibbon has over 20 years of experience in the pharmaceutical industry, launching over 15 products and managing over 30 dermatology products. These appointments significantly strengthen the executive management team and provides valuable leadership, commercial knowledge and industry expertise to drive the Company's next phase of development.

In August 2019, it was announced that Executive Director Matthew Callahan was taking a temporary leave of absence from the Botanix Board, for personal reasons. Mr Callahan continues to consult to Botanix and intends to rejoin the Botanix Board shortly.

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 key global industry and scientific conferences. The Company presented at the following conferences:

- **ASM / ESCMID Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance (Boston, US; September 2019):** Dr Mark Blaskovich's updated poster presentation highlighted the unique properties of synthetic cannabidiol as a remarkably active Gram-Positive broad-spectrum antibiotic, that bacteria cannot form resistance to over time
- **International Cannabinoid Derived Pharmaceuticals Summit (Boston, US; September 2019):** The Company shared the podium with other leading clinical stage cannabinoid companies. The conference highlighted the growing interest in evidence-based cannabinoid therapeutics as the next wave of investment focus
- **Fall Clinical (Las Vegas, US; October 2019):** The Company met with potential partners and key opinion leaders and discussed its pipeline of clinical programs.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage synthetic cannabinoid company based in Perth (Australia) and Philadelphia (US) 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 serious skin diseases, leveraging the unique anti-inflammatory, immune modulating and antimicrobial properties of 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 has announced data from its Phase 2 clinical study and is moving forward with its clinical program with a Phase 2 FDA meeting. A Phase 2 patient study in atopic dermatitis is on target to complete enrolment in 4Q CY2019 with data in 1Q 2020. The Company has successfully completed a mechanism of action study for synthetic cannabidiol in skin disease, with positive data announced in June 2019 and is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabidiol, with first products planned to enter the clinic in 2H CY2019.

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

For more information, please contact:

General enquiries	**Investor enquiries**	**Media enquiries**
Corporate Communications	Joel Seah	Haley Chartres
Botanix Pharmaceuticals	Vesparum Capital	Hales[2] Communications
P: +61 8 6555 2945	P: +61 3 8582 4800	P: +61 423 139 163
investors@botanixpharma.com	botanixpharma@vesparum.com	haley@h-squared.com.au

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.

+Rule 4.7B

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	**Quarter ended ("current quarter")**
70 009 109 755	30 September 2019

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	(5,652)	(5,652)
	(b) staff costs	(597)	(597)
	(c) administration and corporate costs	(684)	(684)
	Dividends received (see note 3)	-	-
1.4	Interest received	8	8
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(6,925)**	**(6,925)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(6)	(6)
	(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 (3 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**	**(6)**	**(6)**

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	40,000	40,000
3.4	Transaction costs related to issues of shares, convertible notes or options	(498)	(498)
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**	**39,502**	**39,502**

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	4,705	4,705
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(6,925)	(6,925)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	(6)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	39,502	39,502
4.5	Effect of movement in exchange rates on cash held	34	34
4.6	**Cash and cash equivalents at end of quarter**	**37,310**	**37,310**

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	17,210	4,705
5.2	Call deposits	20,100	-
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)**	**37,310**	**4,705**

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	234
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** *Add notes as necessary for an understanding of the position*	**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	7,200
9.2	Staff costs	525
9.3	Administration and corporate costs	900
	Total Operating cash outflows	8,625
9.4	Other (capital raising costs – August Placement)	2,675
9.5	**Total estimated cash outflows**	**11,300**

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:  Date: 31 October 2019.

(Company secretary)

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.