ASX/Media Release

31 January 2020

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

Key highlights

- **Efficacy and safety data from the BTX 1503 Phase 2 study provides confidence to proceed with the FDA end-of-Phase 2 meeting and preparations for a Phase 3 study**
- **Completed recruitment for the BTX 1204 Phase 2 atopic dermatitis study with data anticipated in the current quarter**
- **Received ethics approval for the BTX 1702 Phase 1b study for papulopustular rosacea with study start 1Q CY2020**
- **Progressed antimicrobial development program with new study to commence in late 1Q CY2020**

Philadelphia PA and Sydney Australia, 31 January 2020: 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 31 December 2019.

Clinical development

BTX 1503: proceeding to FDA end-of-Phase 2 meeting and preparation for the Phase 3 study

During the quarter, Botanix released results from 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. The strength and statistical significance of the Australian data combined with the overall safety and efficacy provides confidence to proceed with the FDA end-of-Phase 2 meeting and preparations for the BTX 1503 Phase 3 clinical study.

The efficacy and safety results demonstrated that BTX 1503 as a once daily application had the best performance, which from a compliance and commercial perspective, is the ideal dosing regime. The Company has commenced planning for an end-of-Phase 2 meeting with the FDA, which is expected to be held in 2Q CY2020. Outcomes from this meeting will inform the study design of the BTX 1503 Phase 3 clinical study.

As previously reported, the primary endpoint of reduction in inflammatory lesions did not achieve statistical significance and the results showed an unusually high vehicle response in the US arm of the study, which skewed the primary endpoint. Following the Phase 2 Study, the Company initiated a review of the Phase 2 Study conduct, including the high vehicle response in the US study arm in conjunction with experts in manufacturing, clinical development and statistical analysis.

The review concluded that the study was designed in compliance with The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidances, country-specific regulatory requirements (e.g. FDA, DEA, TGA) and appropriate ethics committees' approvals. The statistical review and additional analyses conducted did not uncover any trends or deficiencies in the data set that could explain the unusually higher vehicle response in the US.

Of promise was the large reductions in inflammatory and non-inflammatory lesions seen upon treatment with BTX 1503, with the BTX 1503 5% QD group consistently aligned with the greatest efficacy responses across the majority of the study's efficacy parameters.

The use of multiple clinical supplies batches and differences in processes and equipment between manufacturing sites was a confounding factor for the study. The review identified differences in the processes and equipment used to produce the Permetrex™ formulations (active and placebo) at the Australian manufacturing site, compared to the USA site. DEA import/export regulations at the time prevented a single formulated batch of CBD from being shared between the USA and Australia. The DEA challenges have now been removed with the de-scheduling of Purisys supplied CBD (from Schedule 1 to no scheduling at all) which will allow manufacturing to occur at a single site.

Outcomes from the review and investigation provide confidence for Botanix as it moves into planning for Phase 3 for BTX 1503 for acne, as well as other ongoing clinical programs. In addition to the de-scheduling of Purisys' CBD and the scale up of manufacturing that has occurred over the last few months, Botanix has secured commercial scale supply of the Permetrex™ components from a large international supplier, and also commissioned a new manufacturing vessel for Permetrex™ manufacturing. These supply chain changes and improvements will not only save Botanix considerable cost and time, but are also aimed at advancing the chemistry, manufacturing and controls (CMC) for future clinical studies and commercial manufacturing.

BTX 1204: recruitment completed and on track to report top line data in 1Q CY2020

During the quarter, Botanix completed patient recruitment for the BTX 1204 Phase 2 atopic dermatitis clinical study and top line data is expected to be released in 1Q CY2020. The 12-week randomised, double-blind and vehicle-controlled study evaluates the safety and efficacy of BTX 1204 in patients with moderate atopic dermatitis. 211 patients were enrolled across leading dermatology clinics across the US, Australia and New Zealand. This study leverages existing data from the BTX 1204 Phase 1b clinical study, which supports efficacy and safety potential.

BTX 1702: study initiated with recruitment commencing in 1Q CY2020

In December 2019, Botanix received ethics approval for its BTX 1701 Phase 1b clinical study for the treatment of papulopustular rosacea. The 6-week randomised, double-blind, vehicle-controlled study evaluates the safety and tolerability of BTX 1702 in patients with moderate to severe papulopustular rosacea. Patient recruitment is expected to commence in 1Q CY2020, with plans to enrol 120 patients across six dermatology clinic sites in Australia.

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

Antimicrobial platform: awarded a new grant and BTX 1801 Phase 2 set to commence shortly

In October 2019, Botanix was awarded a new *Innovation Connections Grant* of A$50,000 from the Australian Government to accelerate its medicinal chemistry program. The medicinal chemistry program is being conducted with assistance from scientists at The University of Queensland (UQ) and is targeting the creation of new synthetic and patentable analogs of CBD and to further investigate the antimicrobial activity of CBD.

During the quarter, Botanix continued to assess development options of its antimicrobial platform, and progressed development work to prepare BTX 1801 for a Phase 2 clinical study. The Company has completed optimised dosing and formulation work and has identified targeted indications and applications that leverage the unique properties of CBD as a powerful antibiotic with commencement of the study expected in late 1Q CY2020.

Corporate

In October 2019, Botanix entered into a supply agreement with Purisys, the industry's leading provider of pharmaceutical-grade CBD and other cannabinoids. The supply agreement covers Botanix's immediate and future supply of synthetic CBD (the active pharmaceutical ingredient in all Botanix's products) through to December 2027. In late November 2019, the US Drug Enforcement Administration (DEA) advised Purisys that the synthetic CBD produced by them, and used by Botanix, is no longer scheduled as a controlled substance. This de-scheduling significantly decreases the overall cost overheads (e.g. manufacturing, storing and shipping) and is expected to significantly improve the speed, risk and cost of developing Botanix's dermatology and antimicrobial products.

In November 2019, Dr Bill Bosch, Executive Director and Chief Scientific Officer, showcased the Company's expanding dermatology pipeline at the Dermatology Drug Development Summit in Boston, US. Dr Bosch's presentation titled *Topical Formulations of Cannabidiol for the Treatment of Skin Diseases* was presented at the 3rd annual summit, which attracted more than 150 dermatology leaders from around the world.

During the quarter, Botanix had net cash outflows of A$7.64m, with A$6.48m invested in R&D activities, primarily to complete and progress the BTX 1503 and BTX 1204 Phase 2 clinical studies and invest in additional clinical development programmes. At the end of the quarter, Botanix held A$27.2m in cash (excluding the A$7.6m R&D tax incentive refund received in January 2020).

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'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 acne patient study and is preparing for the end of Phase 2 meeting with the FDA. A Phase 2 patient study in atopic dermatitis is now fully recruited with data planned for 1Q CY2020 and its new Phase 1b rosacea study recently received ethics approval. The Company has also 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 1Q CY2020.

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	H^CK
P: +61 8 6555 2945	P: +61 3 8582 4800	P: +61 423 139 163
investors@botanixpharma.com	botanixpharma@vesparum.com	haley@hck.digital

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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Botanix Pharmaceuticals Limited	
ABN	**Quarter ended ("current quarter")**
70 009 109 755	31 December 2019

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	(6,482)	(12,134)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(508)	(1,105)
	(f) administration and corporate costs	(736)	(1,420)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	86	94
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(7,640)**	**(14,565)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(70)	(79)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	(61)	(61)

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**	**(131)**	**(140)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	40,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	490	490
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2,660)	(3,158)
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**	**(2,170)**	**37,332**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	37,310	4,705
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(7,640)	(14,565)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(131)	(140)

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)	(2,170)	37,332
4.5	Effect of movement in exchange rates on cash held	(205)	(168)
4.6	**Cash and cash equivalents at end of period**	**27,164**	**27,164**

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	7,062	17,210
5.2	Call deposits	20,102	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)**	**27,164**	**37,310**

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	176
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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

6.1 – Fees paid to Directors

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**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)	**(7,640)**
8.2	Cash and cash equivalents at quarter end (Item 4.6)	**27,164**
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	**27,164**
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**3.55**

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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

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

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

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: 31/01/2020

Authorised by: .....
(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.