ASX/Media Release

30 April 2020

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

Key highlights

- **Review of clinical development programs has led to increased focus on the antimicrobial platform, with the dermatology platform continuing to progress in a cost-effective manner**
- **Recruitment of BTX 1801 Phase 2a clinical study to resume when COVID-19 restrictions ease**
- **US FDA granted QIDP designation for BTX 1801 subsequent to the quarter, entitling Botanix to an extra five years of market exclusivity, as well as eligibility for FDA fast-track status**
- **Additional data released from the BTX 1503 Phase 2 study and preparations underway for the end of Phase 2 meeting with the FDA – targeting the end of 2Q CY2020**
- **R&D tax refund of A$7.6m received and Botanix remains in a strong financial position, holding cash balance of A$30.43m as at 31 March 2020**

Philadelphia PA and Sydney Australia, 30 April 2020: Clinical stage cannabinoid 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 2020. Updates across Botanix's product portfolio incorporates the recently completed review of its clinical development activities (announced on 16 April 2020).

Clinical development

Antimicrobial platform: increasing interest in bacterial infections

In March 2020, Botanix announced significant progress with its antimicrobial platform and the commencement of a Phase 2a clinical study for BTX 1801, targeting the prevention of surgical site infections (SSIs). This program diversifies the Company's clinical pipeline and expands the product line beyond dermatological indications.

Botanix will be focusing its development resources primarily on its antimicrobial platform and the progression of its first clinical program for BTX 1801. Due to border closures, restricted flow of clinical material and the ability of Botanix staff to travel, the BTX 1801 Phase 2a clinical study will be conducted wholly within Western Australia (WA). As soon as travel requirements are eased, recruitment will resume, allowing the study to potentially be completed in 3Q CY2020.

Subsequent to the quarter, BTX 1801 received Qualified Infectious Disease Product (QIDP) designation from the United States (US) Food and Drug Administration (FDA) Office of Antimicrobial Products. The major incentive afforded to a product with QIDP status is an additional five years of regulatory exclusivity, on top of the standard regulatory protection that comes with approval of a New Drug

Application (NDA). The FDA program is open only to products that fulfill a strict set of qualifying criteria that demonstrate the product's novelty and its potential to treat a serious or life-threatening disease. Designation represents a compelling milestone and is a strong endorsement of Botanix's data. The Company will continue to work with the FDA to progress its 'fast-track' status application this quarter.

In addition, the Company continues to actively explore opportunities for its synthetic cannabidiol and its cannabinoid analogue assets in other secondary infections and across different routes of administration. This is inclusive of assessing opportunities to expand its pipeline of therapeutics that are responsive to both pandemic associated and resistant bacterial threats.

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

During the quarter, Botanix released additional data analysis of the Phase 2 BTX 1503 acne study, which supports the Company's selection of the 5% once daily dose of BTX 1503 for the planned Phase 3 program. The Company is preparing for an end of Phase 2 meeting with FDA which is designed to gain guidance and feedback from the regulator as to the path required to support a New Drug Application submission for BTX 1503. Subject to any disruptions caused by COVID-19, this meeting is targeted for the end of 2Q CY2020.

BTX 1204: development suspended

In March 2020, Botanix released clinical data from its Phase 2 study evaluating the safety and efficacy in patients with moderate atopic dermatitis (AD). While BTX 1204 was safe and well-tolerated, BTX 1204 did not achieve statistical significance in the primary and secondary endpoints.

Following the results, the Botanix team and extended key opinion leader group completed a review into the results. Further subgroup analysis of the primary and secondary endpoints did not identify any noteworthy trends or differences from the original outcomes. As such, Botanix has decided to suspend clinical development of BTX 1204.

BTX 1702: clinical study progressing once restrictions lifted

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 will evaluate the safety and tolerability of BTX 1702 in patients with moderate to severe papulopustular rosacea. In light of the current COVID-19 related restrictions, Botanix has decided to place the BTX 1702 (rosacea) program on hold until recruitment can resume with the expectation that enrolment can continue in a timely and consistent fashion.

Other clinical development programs

COVID-19 has created clinical development challenges globally including the widespread restrictions in place which has resulted in increased uncertainty until the situation resolves. The lockdown of borders and increased travel controls worldwide has resulted in the restricted flow of clinical trial material, inability for Botanix staff to travel to initiate studies at clinical sites and inability for subjects to enrol in clinical studies. As previously announced, Botanix has conducted a review across its

dermatology and antimicrobial platforms to prioritise resources and maximise return on development dollars invested in the next 24 months.

Corporate

During the quarter, Botanix had net cash inflows of A$3.13m. In January 2020, Botanix received a R&D Tax refund of A$7.6m for the 2018 / 2019 financial year. A$3.07m was expended on R&D activities, primarily to complete the BTX 1204 clinical study. At the end of the quarter, Botanix held A$30.43m in cash and remains in a strong financial position.

Subsequent to the quarter, significant operational cost reduction measures were announced and this is expected to be more than sufficient to progress the planned BTX 1801 (antimicrobial) and BTX 1702 (rosacea) programs. The cost reduction initiatives introduced include reducing staff and consultant headcount and reducing directors' fees, which will provide a cost saving of ~70% of headcount and Board costs on an annualised basis. All Board members have agreed to a reduction in base fees of 25% for a 12-month period, while the balance of directors' agreement terms remain the same. Additional workload will be assumed by executive directors to ensure continuity and the ability to scale back up as clinical development milestones are achieved.

The Company will continue to explore opportunities of non-dilutive funding opportunities for therapeutics that treat bacterial infections. The Company also continues to assess opportunities and partnerships for its Permetrex™ platform in the development of new products that can be rapidly brought to market for dermatological or antimicrobial applications.

In February 2020, Botanix announced changes to the composition of its Board. Matt Callahan re-joined the Board as an Executive Director and Rod Towner stepped down from his role as Non-Executive Director.

In March 2020, Vince Ippolito, President and Executive Chairman, presented the Company's progress at the Cowen Healthcare conference in Boston, US. Mr Ippolito's presentation provided an update on the progress of the key clinical programs to attendees from more than 325 public and private healthcare companies and investors. Earlier in the quarter, Botanix attended the JP Morgan Healthcare and Dermatology Summit conferences held annually in San Francisco, US.

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 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 has two separate cannabinoid development platforms, dermatology and antimicrobial products, both of which 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.

The Company is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabinoids with first enrolment for BTX 1801 Phase 2a study for the prevention of surgical site infections expected in CY2020. For the dermatology platform, preparations are also well advanced for an end of Phase 2 meeting with the FDA for its BTX 1503 acne program and the Company plans to progress its Phase 1b rosacea study in the near future.

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

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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 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	March 2020

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	(3,066)	(15,392)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(646)	(1,607)
	(f) administration and corporate costs	(746)	(2,117)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	38	132
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	7,561	7,561
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**3,141**	**(11,423)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(11)	(90)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	(61)

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**	**(11)**	**(151)**

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
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(3,159)
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**	*	**37,331**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	27,164	4,705
4.2	Net cash from / (used in) operating activities (item 1.9 above)	3,141	(11,423)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(11)	(151)

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)	-	37,331
4.5	Effect of movement in exchange rates on cash held	140	(28)
4.6	**Cash and cash equivalents at end of period**	**30,434**	**30,434**

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	10,434	7,062
5.2	Call deposits	20,000	20,102
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)**	**30,434**	**27,164**

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	542
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

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)	**(4,420)**[(1)]
8.2	Cash and cash equivalents at quarter end (Item 4.6)	**30,434**
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	**30,434**
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**6.88**

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

(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 2020

Authorised by: Somon Robertson
(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.