ASX/Media Release

30 July 2020

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

Key highlights

- **US FDA granted Botanix QIDP designation for its antimicrobial BTX 1801, entitling Botanix to an extra five years of market exclusivity, as well as eligibility for FDA fast-track status**
- **Recruitment of the BTX 1801 Phase 2a antimicrobial clinical study to commence in the coming weeks and will be conducted wholly within Western Australia**
- **Botanix successfully completed its BTX 1503 end of Phase 2 meeting with the FDA**
- **BTX 1702 for rosacea study remains on hold until COVID-19 travel restrictions ease, however preparations remain ongoing to ensure enrolment can proceed safely and efficiently**
- **Botanix is in a strong financial position, holding cash balance of A$24.6m as at 30 June 2020 and expects a tax refund of ~A$5-$7m is expected for R&D activities for financial year 2019/20**

Philadelphia PA and Sydney Australia, 30 July 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 30 June 2020.

Clinical development

Antimicrobial platform: Phase 2a clinical trial initiation

In April 2020, Botanix was granted Qualified Infectious Disease Product (QIDP) designation from the United States (US) Food and Drug Administration (FDA) Office of Antimicrobial Products for its antimicrobial drug candidate BTX 1801. The major incentive afforded to a product with QIDP status is an additional five years of regulatory exclusivity, which is applied in addition to the standard regulatory protection that comes with approval of a New Drug Application (NDA). Botanix fulfilled a strict set of qualifying criteria that demonstrated BTX 1801's novelty and its potential to treat a serious or life-threatening disease.

During the quarter, Botanix continued to progress its FDA 'fast-track' status application. In addition to the clinical development program for the prevention of post-surgical infections, Botanix also continues to actively explore other opportunities for its synthetic cannabidiol and novel cannabinoid analog development assets. These include addressing other bacterial infections, enabling different routes of drug administration, and synthesizing new cannabinoids with improved bioavailability and potency.

The BTX 1801 Phase 2a clinical study is poised to commence enrolment in Western Australia in the coming weeks and has experienced delays due to COVID-19 related restrictions, preventing the movement of clinical material and human resources. Botanix will enrol approximately 60 healthy

volunteers in the study who will undergo twice-daily treatments across a 5-day period. The double-blind, vehicle controlled BTX 1801 Phase 2a clinical study has been designed to evaluate the safety and local tolerability of two formulations of BTX 1801 to decolonise *Staphylococcus aureus ('Staph')* and methicillin-resistant *Staphylococcus aureus ('MRSA' or 'Golden Staph')* from the nose of healthy adults. The Company will initiate the study when it can be executed safely and cost effectively, with the study expected to be completed by early 4Q CY2020 with data available soon thereafter.

Dermatology program: continuing to progress key assets

Botanix successfully completed its BTX 1503 end of Phase 2 (EOP2) meeting with the FDA in early July to gain guidance and feedback from the FDA as to the pathway required to support a NDA submission for BTX 1503. The EOP2 meeting was held by teleconference, given current COVID-19 travel and social distancing restrictions, and provided an opportunity for Botanix to seek confirmation from the FDA on the drug development plan for BTX 1503 to support registration.

A critical component of the development plan was the design of the Phase 3 studies. The FDA highlighted the excellent safety profile of synthetic BTX 1503, by allowing several waivers for studies that are normally required for dermatology drug registration. The FDA also provided feedback on the development program and agreement was reached on the required co-primary efficacy endpoints for the Phase 3 studies. The BTX 1503 Phase 3 study timetable is currently under review, pending the completion of the BTX 1702 rosacea Phase 2 clinical study and lifting of COVID-19 restrictions.

The BTX 1702 rosacea program is poised to commence recruitment once travel and clinical study conduct restrictions are eased across Australia and New Zealand. Botanix continues to monitor the situation closely and will initiate the BTX 1702 study as soon as practicable.

Corporate

During the quarter, Botanix had net cash outflows of A$5.9m, with A$4.7m invested in R&D activities. At the end of the quarter, Botanix held A$24.6m in cash and remains in a strong financial position. An R&D tax incentive claim for a refund of ~A$5m to ~A$7m is expected to be lodged in respect of R&D activities for the year ended 30 June 2020.

In April 2020, significant cost reduction measures were enacted with the objective to optimise Botanix's cash runway to enable funding of planned clinical development programs which underpins value creation. The cost reduction initiatives included reduction of staff and consultant headcount and directors' fees, which will provide a cost saving of ~70% of headcount and Board costs on an annualised basis. All Board members 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 was assumed by executive directors to ensure continuity and the ability to scale back up as clinical development milestones are achieved.

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, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration and plans to progress its Phase 1b rosacea study in the near future.

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	June 2020

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	(4,663)	(20,055)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(946)	(2,553)
	(f) administration and corporate costs	(381)	(2,498)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	48	181
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	7,561
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(5,942)**	**(17,364)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**-**	**(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	30,434	4,705
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,942)	(17,364)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(151)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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	154	125
4.6	**Cash and cash equivalents at end of period**	**24,646**	**24,646**

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	4,646	10,434
5.2	Call deposits	20,000	20,000
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)**	**24,646**	**30,434**

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	355
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)	(5,942)
8.2	Cash and cash equivalents at quarter end (item 4.6)	24,646
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	24,646
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	4.15

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

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

8.6.1 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

8.6.2 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

8.6.3 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

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

(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 July 2020

Authorised by: .Simon Robertson
Company Secretary
(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.