

ASX/Media Release

31 January 2018

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

### Highlights for the quarter ended 31 December 2017:

- Successful completion of Phase 1b BTX 1503 study in patients with moderate to severe acne, significantly better results than current leading topical acne products
- Recent results provide strong evidence of the impact synthetic cannabidiol can have on reducing inflammation, a key characteristic of dermatitis and other skin diseases
- Enrolment advancing rapidly on BTX 1204 atopic dermatitis patient study with results on schedule for 2Q CY2018
- Preparations well advanced to take BTX 1503 into Phase 2 acne patient study in North America and Australia in 2Q CY2018
- Continued generation of early stage revenue from paid collaboration with multiple partners to utilise Permetrex™, which may translate to future licensing opportunities

**Philadelphia PA and Sydney Australia, 31 January 2018:** Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “The Company”) is pleased to release its Appendix 4C Quarterly Cash Flow report for the period ended 31 December 2017.

### Clinical development

#### Lead product: BTX 1503 (Moderate to Severe Acne)

In late January 2018, Botanix announced the successful completion of its Phase 1b study in patients with moderate to severe acne for its lead product, BTX 1503. The study was designed to evaluate the safety, tolerability and pharmacology of BTX 1503.

The Phase 1b open label acne study was conducted at four of the leading acne investigative sites in Australia and enrolled 21 subjects with moderate to severe acne, with 18 subjects completing the study. Subjects were treated for 28 days and then assessed for safety, tolerability, and efficacy at Day 28 and at a follow-up visit on Day 35.

The study achieved all designated endpoints, with top line data indicating that BTX 1503 has an excellent safety profile, is very effective at reducing the number of inflammatory and non-inflammatory acne lesions and an improvement in patient satisfaction. On average, inflammatory lesions decreased by ~47% by Day 28 of the study. This significant reduction is greater than any other FDA approved topical acne product, for which data is available after 4 weeks of treatment.

The Phase 1b study followed on from the early completion of enrolment achieved in mid December 2017, ahead of Botanix’s end of December 2017 target. Further, testing was completed on the active

drug used in BTX 1503, which showed potent antibacterial activity against both antibiotic resistant and non-resistant strains of *Propionibacterium acnes* (*P.acnes*). In addition, Botanix completed a Pre-Investigational New Drug (IND) meeting with the US Food and Drug Administration (FDA) in October 2017.

Botanix plans to initiate a Phase 2 study for BTX 1503 in 2Q CY2018. The next key milestones include filing the IND application with the FDA and being permitted to proceed to conduct the planned Phase 2 Study. The randomised, double-blind, vehicle-controlled dose ranging Phase 2 study will enrol approximately 400 subjects with moderate and severe acne, across leading dermatology clinics in North America and Australia.

#### **BTX 1204 (Atopic Dermatitis)**

Botanix is currently conducting the Phase 1b study for BTX 1204 for the treatment of atopic dermatitis (also known as 'serious eczema'). In November 2017, first patients were enrolled into the study and the study is rapidly progressing. The Phase 1b study is a randomised, double blind, vehicle (placebo) controlled study, which is designed to evaluate the safety and tolerability of BTX 1204 in patients with mild to moderate atopic dermatitis.

The study will monitor for safety including local skin tolerability and assess for any treatment effects on atopic dermatitis lesions and associated symptoms, including itch, burning and stinging compared with the vehicle. Given the recruitment response, data from the study is expected to be available in 2Q CY2018.

#### **Pipeline products: BTX 1308 (Psoriasis), BTX 1801 (Undisclosed), BTX 1701 (Mild Acne)**

Botanix is also advancing other pipeline products that utilise the Company's proprietary Permetrex™ delivery technology in conjunction with synthetic cannabidiol. The Company plans to undertake further study of BTX 1308, a novel treatment for psoriasis in a range of pre-clinical skin and other models in 1Q CY2018. Botanix intends to leverage prior data from the BTX 1503 acne clinical program and the validated Permetrex™ delivery system studies, avoid the need to repeat pre-clinical and clinical testing to accelerate the clinical development of BTX 1308.

During the quarter, Botanix completed formulation work on BTX 1801, with pre-clinical testing expected to commence in 2Q CY2018. Botanix is currently reviewing plans to commence a small patient study for BTX 1701, a development product for the treatment of mild acne.

#### **Business development and strategic partnerships (Permetrex™)**

During the quarter, Botanix continued a number of paid collaborations with multiple partners to utilise the Permetrex™ delivery technology to formulate new drugs in development, with cash to be received in 1Q CY2018. These collaborations involve undertaking early stage paid formulation work for select collaborators, which will be followed by human skin testing and product characterisation work. This work helps to offset the Company's operational costs and may also translate into future licensing opportunities for the Permetrex™ platform which may provide immediate revenue and the potential for substantial revenues from milestone payments and royalties, at no additional cost to Botanix.

## Corporate

Botanix had net cash outflows of A\$2.0m during the quarter with A\$1.9m being spent on R&D activities, primarily associated with the Phase 1b patient studies for BTX 1503 and BTX 1204 and preparations for the Phase 2 study for BTX 1503. Botanix's continued investment into clinical development rather than administrative expenses highlights a clear focus on prudent cash management. At the end of the quarter, Botanix held A\$2.2m in cash. Subsequent to the quarter, Botanix received an R&D tax concession return of A\$1.6m and currently holds A\$3.2m in cash (as at 31 January 2018).

Forecast expenditure for the coming quarter is estimated to be A\$1.8m with majority of the spend (approximately A\$1.6m) planned to be spent on further clinical development primarily associated with BTX 1503, BTX 1204 and key pipeline products.

## About Botanix Pharmaceuticals

Botanix Pharmaceuticals is a clinical stage medical dermatology company, which is dedicated to developing next generation therapeutics for the treatment of serious skin diseases. Our mission is to improve the lives of patients battling acne, atopic dermatitis and other skin diseases, by providing new treatment options for conditions that currently are inadequately addressed, or are treated with therapeutics that are burdened with side effects profiles. Botanix is harnessing the potential of a synthetic form of a natural compound, which has a well-established safety profile and has been studied successfully in a range of other therapeutic areas. Botanix has successfully completed its first acne patient studies with BTX 1503 and is currently conducting another patient study in atopic dermatitis subjects for its second clinical program, BTX 1204. The Company has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases and plans to progress the development of BTX 1503, BTX 1204 and its pipeline of other Permetrex™ enabled products alone, or in collaboration with partners.

For more information on Botanix, please visit [www.botanixpharma.com](http://www.botanixpharma.com) or follow us on Twitter @Botanixpharma.

### 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 December 2017

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(1,854)	(2,873)
(b) staff costs	(86)	(178)
(c) administration and corporate costs	(186)	(506)
Dividends received (see note 3)	-	-
1.4 Interest received	9	47
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (GST)	126	55
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,991)</b>	<b>(3,455)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(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 (6 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	-	-

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	(20)
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)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	-	<b>(20)</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of quarter/year to date	4,237	5,721
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,991)	(3,455)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	(20)
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>2,246</b>	<b>2,246</b>

5.	<b>Reconciliation of cash and cash equivalents</b> 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	1,140	2,737
5.2	Call deposits	1,106	1,500
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>2,246</b>	<b>4,237</b>

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	81
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	

<b>8.</b>	<b>Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
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	1,580
9.2	Staff costs	105
9.3	Administration and corporate costs	165
9.4	Leased assets	-
9.5	Other (provide details if material)	-
9.6	<b>Total estimated cash outflows</b>	<b>1,850</b>

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:   
(Company secretary)

Date: 31 January 2018.

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.