

ASX/Media Release

31 October 2017

Botanix Pharmaceuticals 4C Quarterly Cash Flow Report

Highlights for the quarter ending 30 September 2017:

- Completed Phase 1 safety, tolerability and pharmacokinetics clinical study of lead acne treatment product, BTX 1503
- Commenced Company's first patient study for BTX 1503, which is planned to be completed by the end of CY2017
- Successful meeting with FDA for BTX 1503, which clears the development path for Phase 2 studies in 1H CY2018
- First revenue from early stage formulation work utilising Permetrex™ undertaken with potential strategic partners, which may translate to future licensing opportunities

Philadelphia PA and Sydney Australia, 31 October 2017: 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 ending 30 September 2017.

Clinical development

Lead product: BTX 1503

In early July 2017, Botanix announced the successful completion of its open label Phase 1 study designed to evaluate the safety, tolerability, and pharmacokinetics for its lead acne program, BTX 1503. Top line data demonstrated that BTX 1503 has an excellent safety profile, with little to no skin irritation and no severe adverse events were recorded. This clinical study was the first to be conducted globally for the active synthetic cannabidiol for the treatment of skin disease, and was completed within 12 months of the Company's listing.

Following the Phase 1 study completion, during the quarter Botanix rapidly initiated its first patient study for its lead acne product, BTX 1503, at 4 dermatology clinics in Australia. The Phase 1b patient study is designed to evaluate the safety of BTX 1503 and will collect data concerning improvements in acne signs and symptoms in patients with moderate to severe disease. Study completion is planned by the end of December 2017, with data expected to be available in early Q1 CY2018.

The Phase 1b acne study will enrol up to 20 patients and each patient will receive BTX 1503 treatment over a 4-week period, under close supervision of a dermatologist. Safety assessments, including local skin tolerability to BTX 1503 will be performed and patients will also be monitored for treatment effects on lesion counts and for improvements in their acne, using an Investigator's Global Assessment (IGA) of acne severity.

This is the first study conducted anywhere in the world to investigate the potential clinical benefit of synthetic cannabidiol for the treatment of any skin disease (including acne). Acne is the most common skin disorder in the US affecting 40-50 million Americans, and more than 250 million patients worldwide each year. Acne has multiple pathogenic pathways including overproduction of oils, inflammation and bacterial infection, but currently the only product approved that has an effect on oil production (namely “Accutane” or “Roaccutane”), also carries significant side effects, including the risk of birth defects, lymphoma and suicide risks. Unlike Accutane or Roaccutane, which are taken as a tablet, BTX 1503 is a topically applied product that offers localised delivery to only those areas on the skin with the disease. This local delivery, combined with the numerous published safety studies on BTX 1503’s drug active (synthetic cannabidiol), suggests BTX 1503 will have a significantly better side effect profile than Accutane or Roaccutane.

BTX 1503 is targeting the prescription acne market that currently generates more than US\$4.5 billion in annual sales. Supporting scientific data suggests that BTX 1503 may inhibit the excessive production of oil in the skin, which is the primary cause of acne, as well as potentially reducing inflammation and bacterial infection.

Following completion of the Phase 1b acne patient study currently underway, Botanix plans to file an Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA). In support of those plans, in early October, Botanix successfully held a Pre-IND meeting with the FDA’s Division of Dermatology and Dental Products for BTX 1503. The Pre-IND meeting provided Botanix with an opportunity to seek clarification and support from the FDA on the development plan and data package required to begin Phase 2 clinical studies in the US. It also enabled Botanix to gain consensus from the FDA on the overall drug development plan required for BTX 1503 to support a New Drug Application (NDA) approval in the US.

Prior to the meeting, Botanix submitted a regulatory package detailing the proposed development plan and Phase 2 clinical study in patients with moderate to severe acne for BTX 1503, together with scientific rationale to support its therapeutic potential, GMP manufacturing standards and details of the human and animal safety data assembled to date. In response the FDA confirmed that the proposed development plan was adequate to support the commencement of the proposed Phase 2 clinical study.

Based on the FDA’s feedback, Botanix intends to file an IND application with FDA following completion and data analysis of the Phase 1b acne patient study which is currently underway in Australia. The successful filing of the IND, will allow the Company to proceed with its Phase 2 study program in the US in 1H CY2018, with a view to eventually securing FDA approval for BTX 1503 as the first new prescription product to treat acne, in more than 20 years.

BTX 1204 for Atopic Dermatitis

Subsequent to the quarter, Botanix today announced that it has received Human Research Ethics Committee (HREC) approval for its first patient study for BTX 1204, for the treatment of atopic dermatitis (also known as ‘serious eczema’). This Phase 1b patient 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 randomised study will collect data concerning the improvement of atopic dermatitis lesions and symptoms of atopic dermatitis including itch and burning/stinging compared with the vehicle, which contains no drug active. The study is planned to be completed in 1H CY2018.

Pipeline products: BTX 1308 and BTX 1701

Botanix is also advancing two pipeline products that utilise the Company's proprietary Permetrex™ delivery technology. Following completion of formulation development and testing work that is currently underway, the Company plans to undertake further study of BTX 1308, a novel treatment for psoriasis in a range of pre-clinical skin models in 1Q CY2018. Like its products for acne and atopic dermatitis (BTX 1503 and BTX 1204 respectively), BTX 1308 also utilises synthetic cannabidiol as the active pharmaceutical ingredient and Permetrex™ as the delivery system, but is a different dose and formulation to those products. Cannabidiol has been shown to directly inhibit keratinocyte (skin cell) proliferation and inhibit the immune response via multiple pathways, that are pivotal in the pathogenesis of psoriasis.

Botanix has recently been able to accelerate BTX 1204 into patient study based on its successful Phase 1 study for its acne product BTX 1503, which was completed in July 2017. Because BTX 1308 also utilises the same drug active as that used in BTX 1503 and BTX 1204 and is applied topically with the Permetrex™ delivery system, patient studies in psoriasis are expected to be accelerated without repeating all of the pre-clinical and clinical testing that BTX 1503 was required to complete. This opens up a number of partnering opportunities for BTX 1308 and other pipeline products that Botanix is developing.

The second pipeline product that the Company continued to progress during the quarter was BTX 1701, a development product for the treatment of mild acne. The Company has reviewed the commercialisation options for BTX 1701 and believes that the prescription market for a product with the profile of BTX 1701 is more commercially attractive than the over the counter (OTC) pathway, even though the latter is potentially faster and less costly. Prescription products attract 5 years of regulatory exclusivity from FDA (in addition to patent protection) and substantially higher pricing than OTC products and Botanix's modelling supports undertaking a rapid development program for BTX 1701 which will ultimately result in FDA approval as a new chemical entity for acne. In light of this conclusion and in order to manage its risk of undertaking multiple concurrent clinical programs (with BTX 1503 and BTX 1204), Botanix is reviewing its plans to commence a small patient study in 4Q CY2017 and is likely to postpone further development until 1Q CY2018 following the receipt of data from the BTX 1503 study.

Business development and strategic partnerships (Permetrex™)

During the quarter Botanix was able to initiate a number of paid collaborations with multiple partners to utilise the Permetrex™ delivery technology to formulate new drugs in development. 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. Multiple technology licenses can 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\$1.48 million the quarter with A\$1.02 million being spent on R&D activities, primarily associated with preparations for the BTX 1204 Phase 1b study, the BTX 1503 Phase 1b study and planning of the Phase 2 study for BTX 1503 in the US. At the end of the quarter, Botanix had A\$4.24 million in cash reserves. The Company is pursuing an application for a refund of eligible R&D expenditure for the year ended 30 June 2017, which is expected to be received in the current quarter, and will add to the cash reserves of the Company.

Forecast expenditure for the coming quarter is estimated to be A\$2.52 million with approximately A\$2.25 million planned to be spent on further clinical development primarily associated with BTX 1503 and BTX 1204, as well as testing of BTX 1308 and other pipeline products. Botanix's significant investment into clinical product development rather than administrative overheads highlights a clear focus on prudent cash management.

Successful completion of the BTX 1503 Phase 1b study will represent a significant milestone, acting to further de-risk the Company's overall clinical program. The recently announced patient study for BTX 1204 will likewise provide important validation of the potential for these new therapies and represents a significant value inflection point for the Company.

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, psoriasis and atopic dermatitis, 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 untapped potential of a synthetic active pharmaceutical ingredient, known as cannabidiol, which has a well-established safety profile. Botanix has successfully completed its first-in-man studies with BTX 1503 and is currently conducting a follow-on clinical trial with acne patients in 2H 2017. 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 for acne and its pipeline of other Permetrex™ enabled products alone, or in collaboration with partners.

For more information on Botanix, please visit 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")

30 September 2017

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	(1,019)	(1,019)
(b) staff costs	(92)	(92)
(c) administration and corporate costs	(320)	(320)
Dividends received (see note 3)	-	-
1.4 Interest received	38	38
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)	(71)	(71)
1.9 Net cash from / (used in) operating activities	(1,464)	(1,464)

2. Cash flows from investing activities		
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 (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	-	-

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	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	(20)	(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)	-	-
3.10	Net cash from / (used in) financing activities	(20)	(20)

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	5,721	5,721
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,464)	(1,464)
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)	(20)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of quarter	4,237	4,237

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	2,737	447
5.2	Call deposits	1,500	5,274
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)	4,237	5,721

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	89
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 <i>Add notes as necessary for an understanding of the position</i>	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	2,250
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	Total estimated cash outflows	2,520

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 October 2017.

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.