

ASX/Media Release

24 April 2018

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

Key highlights

- Successfully completed the first BTX 1503 study in patients with moderate to severe acne, achieving significantly better results than current leading topical acne products
- Preparations well advanced to commence FDA regulated Phase 2 clinical trials of BTX 1503 in the US and Australia in 2Q CY2018
- Completed enrolment of the BTX 1204 Phase 1b atopic dermatitis patient study in advance of initial target, and remains on track to release data in 2Q CY2018
- Successfully completed a A\$15m significantly oversubscribed placement with strong institutional support

Philadelphia PA and Sydney Australia, 24 April 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 March 2018.

Clinical development

Lead product: BTX 1503 (Moderate to Severe Acne)

During the quarter, Botanix successfully completed a Phase 1b study in patients with moderate to severe acne for its lead product, BTX 1503. The study achieved all the BTX 1503 program goals, indicating that BTX 1503 has an excellent safety profile, is very effective at reducing the number of inflammatory and non-inflammatory acne lesions and provided an improvement in patient satisfaction. This significant reduction is greater than any other FDA approved topical acne product, for which data is available after 4 weeks of treatment.

During the quarter, Botanix continued to progress the preparation of an Investigational New Drug (IND) application for filing with the United States (US) Food and Drug Administration (FDA). FDA approval of the IND application will enable commencement of Phase 2 clinical trials in the US and Australia. The application is well advanced and study commencement remains on track for 2Q CY2018.

BTX 1503 is well positioned for further clinical development, following the successful completion of an oversubscribed placement in early February 2018. The BTX 1503 Phase 2 clinical trials are now fully funded and expected to commence in late 2Q CY2018 and take approximately 12 months to complete. The BTX 1503 Phase 2 clinical trials are designed to deliver data that allows Botanix to explore licensing and other corporate opportunities.

BTX 1204 (Atopic Dermatitis)

Botanix is currently in the final stages of the Phase 1b patient study for BTX 1204 for the treatment of atopic dermatitis (also known as ‘serious eczema’). Enrolment was successfully completed in early April 2018, in advance of Botanix management’s initial target, reflecting significant patient interest to participate in the study.

The Phase 1b study is designed to evaluate safety and assess for any treatment effects of BTX 1204 in patients with mild-to-moderate atopic dermatitis. The study involves thirty six patients receiving either BTX 1204 or vehicle (placebo) for a 4-week treatment period, and is being conducted with 4 leading Australian dermatology clinics, involving some of Australia’s leading dermatology key opinion leaders.

Botanix was able to accelerate the BTX 1204 study as it utilises the same active drug as BTX 1503, allowing Botanix to progress the BTX 1204 study, without needing to repeat the pre-clinical and clinical testing previously conducted for BTX 1503. This enables Botanix to rapidly develop the broader Botanix product pipeline, which also utilises synthetic cannabidiol and Permetrex™, and make the most of partnering opportunities.

Following completion of this study, Botanix plans to file an IND application with the FDA allowing Phase 2 clinical trials for BTX 1204, to test safety and efficacy.

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

During the quarter, Botanix continued to advance other pipeline products that utilise the Permetrex™ delivery technology. The Company commenced pre-clinical studies of BTX 1308, a novel treatment for psoriasis, with pre-clinical skin data expected in 2Q CY2018. Botanix plans to take BTX 1308 into a psoriasis patient study in 3Q CY2018.

In addition, during the quarter Botanix undertook pre-clinical testing of a new product designated BTX 1801. This new product is expected to be announced early in Q3 and will follow BTX 1308 into the clinic in 2H CY2018. BTX 1701 remains under review by the Company.

Business development and strategic partnerships (Permetrex™)

During the quarter, Botanix received cash payment for 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, 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 inflows of approximately A\$12.9m for the quarter, underpinned by the receipt of the A\$1.6m R&D tax incentive refund (January 2018) and the successful completion of the A\$15m

(before costs) significantly oversubscribed placement (February 2018). During the quarter, Botanix invested approximately A\$2.4m in R&D activities, primarily associated with BTX 1503 and BTX 1204 clinical programs. Botanix's continued focus on investing in the development of clinical programs, rather than administrative overheads, highlights a clear focus on prudent cash management. At the end of the quarter, Botanix held A\$15.1m in cash.

Forecast expenditure for the coming quarter is estimated to be A\$4.3m with approximately A\$4.0m planned to be spent on R&D, primarily associated with BTX 1503, BTX 1204, BTX 1308 and BTX 1801 clinical programs.

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 now successfully completed its first acne patient studies with BTX 1503 and is preparing for a Phase 2 clinical trials in 2Q CY2018, while concurrently completing a Phase 1b study for BTX 1204 in atopic dermatitis patients. 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 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 March 2018

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	145	145
1.2 Payments for		
(a) research and development	(2,422)	(5,295)
(b) staff costs	(95)	(273)
(c) administration and corporate costs	(261)	(767)
Dividends received (see note 3)	-	-
1.4 Interest received	18	65
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,633	1,633
1.8 Other (GST)	(89)	(34)
1.9 Net cash from / (used in) operating activities	(1,071)	(4,526)

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 (9 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	15,072	15,072
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	(1,104)	(1,124)
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	13,968	13,948

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	2,246	5,721
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,071)	(4,526)
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)	13,968	13,948
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of quarter	15,143	15,143

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	6,020	1,140
5.2 Call deposits	9,123	1,106
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)	15,143	2,246

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	95
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	3,980
9.2	Staff costs	100
9.3	Administration and corporate costs	250
9.4	Leased assets	-
9.5	Other (provide details if material)	-
9.6	Total estimated cash outflows	4,330

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: 24 April 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.