

ASX/Media Release

31 July 2018

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

Key highlights

- Substantial progress across a diversified portfolio of drug development programs aimed at providing patients access to safer and more efficacious treatments for chronic skin diseases
- Lead product (BTX 1503), for the treatment of acne, has commenced Phase 2 clinical development in the US and Australia, with the first acne patients recruited
- Atopic dermatitis product (BTX 1204) successfully completed a Phase 1b study, with plans in place to commence a Phase 2 clinical study in patients with moderate atopic dermatitis
- Psoriasis product (BTX 1308) successfully completed formulation development and pre-clinical testing and will advance into a Phase 1b psoriasis proof of concept study
- Promising antimicrobial results were reported for BTX 1801, a novel antimicrobial product designed to treat serious skin infections
- Successfully completed an A\$8m placement. The Company is now fully funded to complete Phase 2 clinical trials for BTX 1503 and BTX 1204 and progress pipeline products (BTX 1308 and BTX 1801) into initial clinical development

Philadelphia PA and Sydney Australia, 31 July 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “The Company”) is pleased to release its Appendix 4C Quarterly Cash Flow report outlining substantial progress for the period ended 30 June 2018.

Clinical development

Lead product: BTX 1503 (Moderate to Severe Acne)

In May 2018, Botanix presented a poster at the International Investigational Dermatology (IID) Meeting in Orlando, Florida detailing the positive results from the BTX 1503 Phase 1b acne study. The poster highlighted the safety and large reduction in acne lesions seen after only 4-weeks of treatment with BTX 1503.

During the quarter, Botanix successfully advanced BTX 1503 into Phase 2 clinical development. The Company announced in June 2018 that the first patients were recruited following acceptance of the Investigational New Drug (IND) application for BTX 1503 by the US Food and Drug Administration (FDA) and receipt of the Human Research Ethics approval in Australia. The rapid progression of BTX 1503 as a new chemical entity from early formulation development to Phase 2 studies within 24 months, is without precedent.

The BTX 1503 Phase 2 clinical trial is being conducted in the US and Australia with over 30 leading dermatology sites and clinics participating in the trial. The targeted enrolment for the trial is 360 patients with moderate to severe acne, and the trial is expected to take approximately 12 months to complete. The BTX 1503 Phase 2 clinical trial has been designed to deliver data that allows Botanix to explore potential licensing and other corporate opportunities upon successful completion in mid-2019.

BTX 1204 (Atopic Dermatitis)

In early June 2018, Botanix announced the successful completion of a BTX 1204 Phase 1b atopic dermatitis (AD) patient study. Conducted in Australia, the data from this vehicle-controlled Phase 1b study showed that BTX 1204 has the potential to be a very effective and safe AD treatment. Data from the study showed that BTX 1204 was twice as effective as the vehicle in improving the key signs of AD during the 4-week treatment period and the twice daily application of BTX 1204 was well tolerated and no significant skin irritation was observed. In addition, the maximum treatment effect was not determined, indicating the potential to achieve further significant improvements in efficacy with a longer duration of treatment. The study demonstrated that BTX 1204 has an exceptional safety profile and the potential to achieve greater improvements in efficacy following extended dosing, which remains a major drawback and hurdle for other approved AD therapies.

Botanix is currently focused on progressing BTX 1204 into Phase 2 clinical development and is well advanced in preparing the US FDA regulatory package to support the planned Phase 2 clinical trial. The planned BTX 1204 Phase 2 clinical trial will be a 10 to 12 week randomised, double-blind, vehicle-controlled study involving patients with moderate AD. The study will involve both US and Australian clinical sites and is expected to complete by mid-2019.

BTX 1308 (Psoriasis)

During the quarter, Botanix successfully completed the required pre-clinical work to support initiation of clinical development of BTX 1308 for the treatment of psoriasis. The BTX 1308 formulation was successfully optimised and pre-clinical testing conducted further elucidated the mechanisms of action of BTX 1308 that resulted in modulating inflammation and the immune response, the hallmark features of psoriasis. Botanix is now preparing for a Phase 1b proof of concept study in psoriasis patients. The study will involve a collaboration with BioSkin, a German based clinical contract research organisation internationally recognised for their experience with the psoriasis plaque test. The study is planned to commence late 3Q CY2018 and is expected to take approximately 6 months to complete.

BTX 1801 (Antimicrobial)

During the quarter, Botanix also announced the successful completion of pre-clinical testing of BTX 1801, a novel antimicrobial with the potential to address the significant global public health issue of antimicrobial resistance. The pre-clinical testing showed that BTX 1801 was very effective at killing methicillin-resistant staphylococcus aureus (MRSA) strains of bacteria when compared to Permetrex™ or cannabidiol alone. The synergistic response observed demonstrates the potential for BTX 1801 to treat both acute and chronic skin infections. This coupled with the inherent anti-inflammatory properties of cannabidiol may elevate BTX 1801 to be the antimicrobial of choice for the treatment of

skin infections. Botanix is now focused on completing a market review and commercial assessment, in conjunction with key opinion leaders, to identify the preferred type of skin infection to target initially for BTX 1801, before embarking on clinical development.

More recently, Botanix announced a research collaboration with the University of Queensland's (UQ) Institute for Molecular Bioscience to further explore the scope and breadth of the antimicrobial activity of BTX 1801. This collaboration is supported through funding received from a successful Innovation Connections Grant awarded to Botanix and UQ by the Australian Government. The research collaboration will help facilitate the identification of the skin infection type to target for initial clinical studies with BTX 1801. Clinical development is planned for 4Q CY2018.

Business development and strategic partnerships (Permetrex™)

During the quarter, Botanix continued to work collaboratively 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\$2.1m for the quarter, underpinned by the successful completion of the A\$8.0m oversubscribed placement in June 2018. During the quarter, Botanix invested approximately A\$5.1m 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\$17.2m 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 the two Phase 2 clinical trials (BTX 1503, BTX 1204) and progressing other pipeline products (BTX 1308 and BTX 1801) into Phase 1b patient studies.

During the quarter, Botanix made significant progress to bolster its clinical development capability to execute on the two Phase 2 studies and two Phase 1b studies underway or planned for initiation in the coming months. In July 2018, the Company appointed Dr Stephane Levy as Chief Medical Officer and Ms Jillian Chapas-Reed as Senior Director of Clinical Operations. Dr Levy brings significant dermatology and clinical experience having held senior leadership positions with Almirall, Sanofi and Novartis previously. Ms Chapas-Reed brings recent relevant experience managing Phase 1, Phase 2 and Phase 3 clinical studies in the US and internationally. The Company continues to make exceptional clinical progress with a small, but experienced management and clinical development team, supported by several key consultants.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage medical dermatology company based in Perth, Australia and Philadelphia, PA. The Company's focus is the development of safe and effective topical treatments for acne, psoriasis, atopic dermatitis and other skin conditions. The active ingredient contained in Botanix products is a synthetic form of a widely studied natural compound. Treatment targets include inflammation, deterioration of the skin barrier, skin cell proliferation, pruritus (itch), excess sebum production and bacterial infection.

Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases. Botanix is working with multiple parties to test the application of Permetrex™ on both a fee-for-service and traditional license basis.

Botanix pursues a rapid clinical development strategy aimed at accelerating product commercialisation. The patient treatment duration of clinical studies is generally completed within a 4 to 12 week timeframe.

The Company completed its first acne patient studies with BTX 1503 in January 2018 and has commenced a Phase 2 clinical trial in June 2018 with completion expected in mid-2019. The Phase 1b BTX 1204 atopic dermatitis patient study concluded in June 2018 and preparation is underway for a Phase 2 clinical trial. A further Phase 1b BTX 1308 psoriasis patient study is also scheduled to commence in 3Q CY2018.

For more information on Botanix, please visit www.botanixpharma.com

For more information, please contact:

General enquiries

Matt Callahan
Botanix Pharmaceuticals
Founder & Executive Director
+1 215 767 4184
mcallahan@botanixpharma.com

Investor enquiries

Joel Seah
Vesparum Capital
P: +61 3 8582 4800
botanixpharma@vesparum.com

Media enquiries

Julia Maguire
The Capital Network
P: +61 419 815 386
julia@thecapitalnetwork.com.au

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 June 2018

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	-	145
1.2 Payments for		
(a) research and development	(5,087)	(10,382)
(b) staff costs	(175)	(448)
(c) administration and corporate costs	(314)	(1,081)
Dividends received (see note 3)	-	-
1.4 Interest received	43	108
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	1,633
1.8 Other (GST)	122	88
1.9 Net cash from / (used in) operating activities	(5,411)	(9,937)

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 (12 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	8,036	23,108
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	(532)	(1,656)
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	7,504	21,452

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	15,143	5,721
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,411)	(9,937)
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)	7,504	21,452
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of quarter	17,236	17,236

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	8,581	6,020
5.2	Call deposits	8,655	9,123
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)	17,236	15,143

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	172
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	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
	<i>Add notes as necessary for an understanding of the position</i>		
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: 30 July 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.