**ASX/Media Release**

**31 October 2018**

# Botanix Accelerates Product Development in September Quarter

## Key highlights

- **Accelerated development of the portfolio, with first product in Phase 2 clinical development (BTX 1503), second product about to commence Phase 2 (BTX 1204) and pipeline product BTX 1308 in Phase 1b clinical development**
- **Successful meeting with FDA regarding development of atopic dermatitis product BTX 1204**
- **Obtained approval for planned Phase 1b patient study of psoriasis product BTX 1308 to commence in 4Q CY2018**
- **Completed pre-clinical testing of BTX 1801, demonstrating potential for its treatment of acute and chronic skin infections**
- **Awarded grant from the Australian Government and formed research collaboration with the University of Queensland**
- **Presented at global conferences, providing an update on Botanix's diversified portfolio of drug development programs for treatments of chronic skin diseases**

**Philadelphia PA and Sydney Australia, 31 October 2018:** Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "The Company") is pleased to announce accelerated development across its portfolio of lead and pipeline products and provide its Appendix 4C Quarterly Cash Flow report for the period ended 30 September 2018.

## Clinical development

### Advancement of lead product, acne treatment BTX 1503

During the quarter, Botanix completed the Investigator's Meeting for the BTX 1503 Phase 2 clinical trial. The meeting brought together over 70 participants including investigators participating in the study and site coordinators from over 25 sites. Several acne clinicians and key opinion leaders also joined the meeting to discuss practicalities of drug applications, the study protocol, as well as specific instructions on lesion counting and patient assessment tools. The meeting received very positive feedback regarding data from the Phase 1b patient study, the planned patient recruitment rates, as well as the physician's assessment of the novel Permetrex™ BTX 1503 formulation which all participants had the opportunity to handle.

Botanix announced that the first patients were enrolled in the Phase 2 study in late June 2018 and enrolment rates have increased as additional dermatology clinics have joined the study following the Investigator's Meeting.

In September 2018, BTX 1503 was featured on 7News in which the feature highlights a positive patient testimony from one of the first patients enrolled in the BTX 1503 acne Phase 2 clinical trial. The 7News feature is available on the Company's website at www.botanixpharma.com/investors.

The 12-week clinical trial is a randomised, double-blind, vehicle-based study looking to evaluate the safety and efficacy of BTX 1503 on patients with moderate to severe acne. The trial has been designed to provide data to allow Botanix to explore potential licensing and other corporate opportunities upon completion in mid-2019.

**Further development of atopic dermatitis treatment BTX 1204**

During the quarter, Botanix successfully held a Pre-Investigational New Drug (Pre-IND) Meeting with the FDA's Division of Dermatology and Dental Products for BTX 1204. The meeting provided an opportunity to seek clarification and support from the FDA on the data package and development plan required to begin Phase 2 clinical studies in Australia and the US, as well as enabling the Company to gain consensus from the FDA on the required drug development plan for BTX 1204 to support a New Drug Application (NDA).

The Company is now well advanced in finalising the necessary logistical and regulatory arrangements required to support the planned commencement of a Phase 2 clinical trial. Due to the efficiencies Botanix can derive from running two Phase 2 studies in parallel, the study is expected to complete shortly after the completion of the current BTX 1503 acne Phase 2 trial.

**Obtained approval to commence study of psoriasis treatment BTX 1308**

In September 2018, Botanix announced the approval of its planned Phase 1b BTX 1308 psoriasis patient study by the Human Research Ethics Committee. The Phase 1b patient screening has commenced with first patients expected to be enrolled in 4Q CY2018. The study is expected to take approximately 3 to 4 months to complete.

Botanix is collaborating with German-based clinical contract research organisation BioSkin GmBH, for the study. BioSkin has received international recognition for their experience on the psoriasis plaque test, which has been clinically validated and utilised by several companies. The Phase 1b patient study is designed to assess the efficacy and safety of BTX 1308 on psoriasis plaques, and the product's ability to simultaneously compare multiple test products and formulations on the same patient.

**Completed pre-clinical testing of antimicrobial BTX 1801**

In July 2018, Botanix announced the successful completion of pre-clinical testing of BTX 1801, a novel antimicrobial. The pre-clinical testing showed that BTX 1801 was very effective at killing methicillin-resistant staphylococcus aureus 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.

BTX 1801 is a novel antimicrobial with the potential to address unmet needs in serious skin infections, with significant market opportunities. During the quarter, Botanix has 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.

**Enhanced research capabilities through new partnership and grant**

During the quarter, Botanix announced its partnership with The University of Queensland's Institute for Molecular Bioscience. The research collaboration will allow both organisations to further explore the antimicrobial activity of cannabidiol and Permetrex™, maintaining a focus on the continued development of BTX 1801.

The partnership follows the Company's reception of the Australian Government's *Innovation Connections Grant,* also obtained this quarter. The research collaboration will help facilitate the identification of the skin infection type to target for initial clinical studies with BTX 1801.

**Progressed business development and strategic partnerships for Permetrex™**

Botanix has continued to work with various partners on additional early stage formulation work and is looking to progress to human skin testing and product characterisation in the near term.

In October 2018, as part of the annual Fall Clinical Dermatology Conference, Botanix presented new data on the Permetrex™ skin delivery technology, where Botanix has compared the amount of cannabidiol that is delivered by its BTX 1503 acne formulation, against competing cannabidiol formulations at much higher doses.

The BTX 1503 Permetrex™ formulation at only 5% cannabidiol concentration was able to deliver much more active cannabidiol to the target layers of the skin, than comparative formulations that contained 10% (2x) and even 20% (4x) cannabidiol concentrations in alternative delivery systems. This new data provides additional validation of the superior drug delivery capabilities of the Permetrex™ technology and supports the potential of BTX 1503 to supply therapeutic levels of cannabidiol to relieve the burden of acne, for millions of patients worldwide.

These collaborations for Permetrex™ help offset operational costs incurred and provide viable prospects for future licensing opportunities of the Permetrex™ platform. This increases chances of immediate revenue, as well as revenue arising from milestone payments and royalties, at no additional costs to Botanix.

## Corporate

**Continued focus on investment in clinical development**

Cash outflows on R&D activities over the quarter were approximately A$2.6m, with a focus on developing key clinical programs. The Company'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$14.2m in cash, and is expecting to receive approximately A$4m from the R&D tax incentive refund from the ATO during the coming quarter.

Forecast cash outflows for the coming quarter are estimated to be approximately A$5.35m with approximately A$4.75m planned to be spent on R&D, primarily associated with the two Phase 2 clinical trials (BTX 1503 for acne and BTX 1204 for atopic dermatitis), the Phase 1b patient study for BTX 1308 (psoriasis) and progressing other pipeline products (including BTX 1801 for bacterial skin infections).

Botanix also presented at the 27th Congress of the European Academy of Dermatology and Venerology (EADV Congress), held in Paris, France and the annual Fall Clinical Dermatology Conference, held in Las Vegas, USA. The Congress and Conference provided opportunities to demonstrate the novel use of cannabidiol in dermatology, as well as a platform to announce updates on the progress of its key Phase 2 products BTX 1204 for atopic dermatitis and BTX 1503 for acne. The Company was able to engage with potential prospective partners, global market leading pharmaceutical companies, and market leading researchers that have an interest in the treatment of dermatological conditions.

**Botanix Executive Director Matt Callahan: "**The September quarter was another extremely productive one for Botanix and we are very pleased with our progress. The clinical development of our portfolio of lead and pipeline products is advancing rapidly, and we are receiving increasing recognition from partners, potential licensees and investors. We are well-placed to maintain our current momentum and look forward to updating the market on further developments."

**Ends**

## 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 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. The Phase 1b BTX 1308 psoriasis patient study is due to commence in 4Q 2018.

To learn more please visit: https://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

*+Rule 4.7B*

# 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** | **Quarter ended ("current quarter")** |
|---|---|
| 70 009 109 755 | 30 September 2018 |

| **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 | (2,566) | (2,566) |
| | (b) staff costs | (210) | (210) |
| | (c) administration and corporate costs | (263) | (263) |
| | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 30 | 30 |
| 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) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(3,009)** | **(3,009)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire: | | |
| | (a) property, plant and equipment | (5) | (5) |
| | (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** | **(5)** | **(5)** |

| **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 | - | - |
| 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** | **-** | **-** |

| **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 | 17,263 | 17.263 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (3,009) | (3,009) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (5) | (5) |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | - | - |
| 4.5 | Effect of movement in exchange rates on cash held | - | - |
| **4.6** | **Cash and cash equivalents at end of quarter** | **14,249** | **14,249** |

| 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 | 7,066 | 8,581 |
| 5.2 | Call deposits | 7,183 | 8,655 |
| 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)** | **14,249** | **17,236** |

| 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 | 74 |
| 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** *Add notes as necessary for an understanding of the position* | **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 | 4,750 |
| 9.2 | Staff costs | 310 |
| 9.3 | Administration and corporate costs | 250 |
| 9.4 | Leased assets | - |
| 9.5 | Other (provide details if material) | - |
| **9.6** | **Total estimated cash outflows** | **5,310** |

| 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: S H Robertson. Date: 31 October 2018.

(Company secretary)

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.