**28 January 2022**

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

## Key highlights

- **Botanix's canine atopic dermatitis program, BTX 1204A, is progressing well and on track to finish enrolment this quarter**
- **BTX 1702 Phase 1b/2a Rosacea Study continues to progress well with enrolment on target to be completed mid-year**
- **Pre-clinical work to support the initiation of a Phase 2 human study for its BTX 1801 antimicrobial program is complete with the clinical study planned to initiate at the end of this quarter**
- **Strong balance sheet with $16.8 million in cash at closing of 4Q 2021 with R&D tax return expected 1Q 2022**

**Philadelphia PA and Perth Australia, 28 January 2022**: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to release its Quarterly Activity Report and Appendix 4C Quarterly Cash Flow report for the period ended 31 December 2021.

### Clinical Studies and Drug Development

**Rosacea: BTX 1702 Phase 1b/2a study is advancing**

As previously announced, the Company is currently undertaking a Phase 1b/2a randomised, double blind, vehicle-controlled clinical study in patients with moderate to severe papulopustular rosacea.

The study commenced in late June 2021 and the study is on track to complete enrolment in mid-2022. As part of the 8-week study, which is taking place at 15 dermatology sites across Australia and New Zealand, 40 patients will receive a high dose, 40 patients will receive a low dose and the remaining 40 patients will receive the vehicle (placebo). All patients will be dosed twice daily.

The study will investigate the safety and tolerability of BTX 1702, and examine the change in inflammatory lesion counts from baseline at days 15, 29 and 57, the proportion of patients with Investigator's Global Assessment (IGA) treatment success, the change in Clinician's Erythema Assessment (CEA) scale as well as a number of other imaging and patient reported outcomes

Botanix's rosacea study represents research of strategic importance for the Company's wider clinical development as the results will provide key safety and efficacy data, as well as validate the implementation of centralized review of each clinical investigator's ratings and some endpoint assessments for consistency and quality control.

**Dermatology: BTX 1204A canine atopic dermatitis program on track**

In September 2021, the Company announced the launch of the canine atopic dermatitis program (BTX 1204A proof of concept study with receipt of ethics approval and the initiation of sites across Australia and New Zealand. Recruitment remained strong despite Christmas closures and the study is on track to complete enrolment this quarter, with data expected in early 2Q 2022.

BTX 1204A is based on a higher dose formulation of synthetic cannabidiol (CBD) in a novel Permetrex™ formulation, which has been demonstrating strong efficacy in killing bacteria over the last months. Given the similarity in disease between humans and canines, successful outcomes from the POC study will drive licensing programs for animal health and also support progression to a late-stage Phase 2b clinical study in humans with atopic dermatitis.

**Antimicrobial: BTX 1801 clinical development moving forward**

Following the success of its Phase 2a study reported in 2021, Botanix's antimicrobial clinical development program, BTX 1801, is moving forward with a Phase 2 study planned to initiate in late 1Q 2022. Botanix has recently completed a further round of animal studies and other preclinical work to enable a longer term, repeat dose study to be conducted in humans with confirmed bacterial colonisation.

The BTX 1801 program is designed to target nasal decolonisation of *Staph aureus* and *MRSA* in patients undergoing haemodialysis with a view to reducing the incidence of life-threatening blood stream infections. Infections frequently occur due to the placement of the central venous catheter in the chest directly below the nose, with direct access into the bloodstream adjacent to the heart. There are no approved products to decolonise the nasal passages of patients undergoing haemodialysis and commercial work undertaken by Botanix, demonstrates a significant market opportunity for such a therapy.

The Company also intends to leverage a range of existing US FDA programs, including, Qualified Infection Disease Product (QIDP), Fast Track and the grant of Limited Population Pathway for Antimicrobial and Antifungal Drugs (LPAD) status to accelerate the development of BTX 1801, reduce clinical costs and increase the FDA exclusivity period for the product.

## Financial overview

During the quarter, Botanix had net cash outflows of A$2.7m, with A$1.9m invested in R&D activities. At the end of the quarter, Botanix held A$16.8m in cash and remains in a strong financial position. Botanix expects receipt of its R&D tax return in 1Q 2022 which will further strengthen its cash reserves.

Payments to related parties as detailed in Section 6.1 of the Appendix 4C relate to salaries, fees and superannuation (or equivalent) entitlements paid pursuant to agreements with Directors or associates.

## Upcoming milestones and outlook

Botanix continues to progress its pipeline of dermatology and infection focused products and is excited to be working towards a number of important clinical and other milestones in 2022 including:

- Antimicrobial BTX 1801: filing of ethics approval in Q1 2022 and commencement of Phase 2 study in Australia treating subjects over a 9 week period intermittently to show xtended effect of BTX 1801;
- Rosacea BTX 1702: Phase 1b/2a study recruitment targeted for completion by mid-2022;
- Acne BTX 1503: planning for Phase 3 clinical studies, informed by the successful completion of the BTX 1702 Phase 1b/2 study;
- Dermatitis BTX 1204A: canine proof of concept study targeting completion of enrolment 1Q 2022 with data early in 2Q 2022. Success to drive licensing programs for animal health and support progression to a late-stage Phase 2b clinical study in humans with atopic dermatitis; and
- New indications and Permetrex™ opportunities and business development: Activity to acquire new opportunities that either leverage the Permetrex™ technology platform and/or can be progressed rapidly through clinical development towards approval.

Release authorised by

**Vince Ippolito**
President and Executive Chairman

## About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage dermatology Company based in Perth (Australia) and Philadelphia (USA) committed to the development of pharmaceutical products that are underpinned by science and supported by well-controlled randomised clinical trials. The Company has two complimentary development platforms - dermatology and antimicrobial products - both of which currently leverage the unique anti-inflammatory, immune modulating and antimicrobial properties of cannabinoids, particularly synthetic cannabidiol or CBD. Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases, which it utilises in its existing development programs and is being explored with a view to being utilized in a number of other product opportunities.

The Company is developing a pipeline of product candidates with recent positive data from its BTX 1801 Phase 2a antimicrobial study and its Phase 1b/2a rosacea clinical study is currently enrolling patients. Following a successful meeting with the FDA, the Company has also confirmed a drug development plan for the BTX 1503 acne Phase 3 program to support registration. In addition, Botanix plans to advance its BTX 1204A atop dermatitis program to a proof of concept canine study in Q3 CY2021 following encouraging early data from a recent pilot study. To learn more please visit: http://www.botanixpharma.com/

## For more information, please contact:


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## Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

# Appendix 4C

## Quarterly cash flow report for entities subject to Listing Rule 4.7B



**Name of entity**

Botanix Pharmaceuticals Limited

| **ABN** | **Quarter ended ("current quarter")** |
|---|---|
| 70 009 109 755 | December 2021 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (6 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | - | - |
| 1.2 | Payments for | | |
| | (a) research and development | (1,911) | (3,259) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | - | - |
| | (d) leased assets | - | - |
| | (e) staff costs | (200) | (415) |
| | (f) administration and corporate costs | (573) | (960) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 6 | 24 |
| 1.5 | Interest and other costs of finance paid | (9) | (20) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | - | - |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(2,687)** | **(4,630)** |

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 2.1 | Payments to acquire or for: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | - | (7) |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) other non-current assets | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 months) $A'000 |
|---|---|---|---|
| 2.2 | Proceeds from disposal of: | | |
| | (a) entities | - | - |
| | (b) businesses | - | - |
| | (c) property, plant and equipment | - | - |
| | (d) investments | - | - |
| | (e) intellectual property | - | - |
| | (f) 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** | **-** | **(7)** |

| **3.** | **Cash flows from financing activities** | | |
|---|---|---|---|
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | - | - |
| 3.2 | Proceeds from issue of convertible debt securities | - | - |
| 3.3 | Proceeds from exercise of options | - | - |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | - | - |
| 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 (payment for right-of-use asset) | (35) | (71) |
| **3.10** | **Net cash from / (used in) financing activities** | **(35)** | **(71)** |

| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash and cash equivalents at beginning of period | 19,567 | 21,555 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (2,687) | (4,630) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | - | (7) |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 months) $A'000 |
|---|---|---|---|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | (35) | (71) |
| 4.5 | Effect of movement in exchange rates on cash held | 1 | (1) |
| **4.6** | **Cash and cash equivalents at end of period** | **16,846** | **16,846** |

| 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 | 3,846 | 19,567 |
| 5.2 | Call deposits | 13,000 | - |
| 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)** | **16,846** | **19,567** |

| 6. | Payments to related parties of the entity and their associates | Current quarter $A'000 |
|---|---|---|
| 6.1 | Aggregate amount of payments to related parties and their associates included in item 1 | 369 |
| 6.2 | Aggregate amount of payments to related parties and their associates included in item 2 | - |

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*Add notes as necessary for an understanding of the sources of finance available to the entity.* | **Total facility amount at quarter end $A'000** | **Amount drawn at quarter end $A'000** |
|---|---|---|---|
| 7.1 | Loan facilities | - | - |
| 7.2 | Credit standby arrangements | - | - |
| 7.3 | Other (please specify) | - | - |
| 7.4 | **Total financing facilities** | - | - |

| | | |
|---|---|---|
| 7.5 | **Unused financing facilities available at quarter end** | - |

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

| |
|---|
| |

| 8. | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (item 1.9) | (2,687) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 16,846 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 16,846 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | 6 |

*Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.*

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

| |
|---|
| Answer: N/A |

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

| |
|---|
| Answer: N/A |

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

| |
|---|
| Answer: N/A |

*Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.*

(1) Net expenditure for the quarter excluding Research and Development tax incentive refund

## 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.

Date: 28 January 2022

Authorised by: Simon Robertson
Company Secretary
(Name of body or officer authorising release – see note 4)

**Notes**

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow 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 cash flow 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.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.