

ASX/Media Release

31 January 2019

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

Key highlights

- **Rapid development across three clinical programs for the treatment of acne (BTX 1503), atopic dermatitis (BTX 1204) and psoriasis (BTX 1308)**
- **BTX 1204 Phase 2 atopic dermatitis clinical study underway with good early recruitment**
- **BTX 1308 Phase 1b psoriasis study underway and expected to be completed in 1Q CY2019**
- **Bolstered cash balance following receipt of A\$4.6m R&D Tax Incentive refund**
- **Presented at global conferences and engaged with prospective partners, leading pharmaceutical companies and researchers**

Philadelphia PA and Sydney Australia, 31 January 2019: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “The Company”) is pleased to announce further progress across its product portfolio and release of its Appendix 4C Quarterly Cash Flow report for the period ended 31 December 2018.

Clinical development

Rapid advancement of lead product, acne treatment BTX 1503

During the quarter, Botanix advanced the Phase 2 clinical study for its lead product, BTX 1503 for the treatment of moderate to severe acne. All US and Australian clinical sites have now been activated, resulting in the acceleration of recruitment during the quarter. The Company remains on track to complete recruitment for the study by mid-CY2019 with data available in 3Q CY2019.

The 12-week, randomised, double-blind, vehicle-controlled clinical study evaluates the safety and efficacy of BTX 1503 on patients with moderate to severe acne. The study has been designed to provide data to allow Botanix to explore potential licensing and other corporate opportunities upon completion.

Patient recruitment for BTX 1204 Phase 2 atopic dermatitis study underway and new sites joining

During the quarter, Botanix commenced patient recruitment for the BTX 1204 Phase 2 atopic dermatitis clinical study following the receipt of ethics approval in December 2018. Approximately 200 patients will be enrolled for a 12-week randomised, double-blind, vehicle-controlled study. The study is being conducted across leading dermatology clinics in Australia, New Zealand and the US with enrolment for the study expected to be completed in 3Q CY2019. The study will assess treatment effects on the key signs of atopic dermatitis in conjunction with monitoring safety, tolerability and patient satisfaction.

The achievement of the ethics approval follows a 4-week Phase 1b patient study that showed significant improvement in signs of atopic dermatitis (versus placebo). In addition to these positive results, the study demonstrated BTX 1204's efficacy was still increasing at the 4-week timepoint which combined with the excellent safety profile of the product, suggests a longer treatment period may enable BTX 1204 to potentially exceed industry performance. BTX 1204 has the potential to be an effective, topically applied product which is superior to other products currently available on the market, which is larger and growing faster than the acne market.

BTX 1308 psoriasis patient study enrolment almost complete

In early November 2018, Botanix treated the first patient in its BTX 1308 psoriasis Phase 1b patient study. The study is testing a new formulation of synthetic cannabidiol combined with the Company's novel Permetrex™ skin delivery technology.

Botanix is collaborating with German-based clinical contract research organisation BioSkin GmbH ("BioSkin") and an Australian dermatology clinic. BioSkin has received international recognition for its experience with the 'psoriasis plaque test', which is clinically validated and is utilised by many leading dermatology companies. The study allows for multiple comparisons of formulations, at the same time, on the same patient which enhances data quality and shortens treatment duration.

The Phase 1b patient study is designed to assess the safety and efficacy of BTX 1308 on psoriasis plaques or lesions and will also capture detailed data from biopsies that will be completed for a subset of patients. Unique to this clinical study, the biopsy data will provide for the first time mechanism of action information for cannabidiol in skin diseases. The Phase 1b patient study will be completed in 1Q CY2019 with data available in early 2Q CY2019.

Continued development and target market review of novel antimicrobial (BTX 1801)

During the quarter, Botanix also continued to investigate the antimicrobial properties of its pipeline product BTX 1801, in collaboration with The University of Queensland's (UQ) institute for Molecular Biosciences. The partnership has focused on exploring the scope and breadth of the antimicrobial activity of BTX 1801 as part of the *Innovation Connections Grant* awarded to Botanix and UQ by the Federal Government.

Antimicrobial resistance is a significant and growing global concern, there have been no new classes of antibiotics discovered since 1984¹ and deaths attributed to antimicrobial resistance are expected to reach 10m p.a. by 2050².

Botanix's proprietary drug delivery system, Permetrex™ combined with the antimicrobial impact of cannabidiol provides an exciting opportunity to potentially treat a range of different skin infections. During the quarter, Botanix worked with external consultants to identify target markets for skin infections that can be addressed with BTX 1801. The engagement allowed Botanix to examine which

¹ Pew Charitable Trusts; Deak et al. Progress in the Fight Against Multidrug Resistant Bacteria?; A Review of FDA Approved Antibiotics 2010-2015. 31 May 2016. DOI: 10.7326/M16-0291

² Tackling Drug Resistant Infections Globally Final Report and Recommendations (2016), The Review on Antimicrobial Resistance

bacteria can be killed effectively with the new product, what layers of the skin can be targeted and what current treatments exist or may be competitive to BTX 1801 in those target skin infections.

Output from the review process is described in more detail in the presentation titled “2019 Outlook” to be released today. The findings concluded that while there are many potential indications that could be successfully addressed by the potential benefits of BTX 1801, the two most attractive indications to address initially are bacterial folliculitis and impetigo.

Folliculitis is a common skin condition in which hair follicles become inflamed, usually due to bacterial or fungal infection. The infection can spread and turn into nonhealing crusty sores. Methicillin-resistant *S. aureus* (“MRSA” or “golden staph”) can cause folliculitis, and folliculitis is among the infections contributing to the increasing prevalence of community-acquired MRSA infections. The incidence of folliculitis is very common with about 3m cases found per year in the US alone. Emerging economies account for a major share of the global folliculitis market which is expected to grow at the CAGR of ~4.7% during the forecast period and is estimated to reach US\$561.3m by 2023.

Impetigo (or school sores) is a common, highly contagious skin infection which primarily affects infants and children. It predominantly tends to occur in environments with hot and humid weather conditions and global studies conclude that more than an estimated 162m children between the ages of two and five years old have suffered from the disease. A recent Telethon Kids Institute study found that about 45% of Aboriginal children living in remote communities across northern Australia are affected by impetigo at any one time – the highest prevalence in the world. Antibiotic creams are used to treat impetigo, but antibiotic resistance is a growing problem.

Progressed business development and strategic discussions for Permetrex™

In October 2018, as part of the annual Fall Clinical Dermatology Conference, Botanix presented new data demonstrating its Permetrex™ technology enables superior delivery of cannabidiol into the target layers of the skin, against competing cannabidiol formulations at much higher doses. This data provides additional clinical validation of the superior drug delivery capabilities of Permetrex™.

Botanix continues to work with various partners on additional early stage formulation work and is in active discussions to progress to human skin testing and product characterisation in the near term. These collaborations for Permetrex™ help offset operational costs incurred and provide viable prospects for future licensing opportunities of the Permetrex™ platform.

Corporate

Focused on clinical development and engaging with prospective partners

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\$13.5m in cash.

After receipt of the R&D Tax Incentive refund Botanix had net cash outflows of A\$0.72m during the quarter with A\$4.6m invested in R&D activities. The increased R&D spend related to the two Phase 2

clinical studies (BTX 1503 for acne and BTX 1204 for atopic dermatitis), the Phase 1b patient study for BTX 1308 (psoriasis) and progressing pipeline products. The R&D tax incentive refund received of A\$4.6m will be invested into the development of Botanix's product portfolio.

Forecast cash outflows on research and development activities for the coming quarter are estimated to be approximately A\$4.45m, with the majority of research and development expenditure committed to the acne and atopic dermatitis Phase 2 studies.

Increased conference exposure

In December 2018, Botanix presented at the International Cannabinoid Derived Pharmaceuticals Summit in Boston. This Summit provided an opportunity to showcase the breadth and depth of Botanix's clinical programs focused on skin disease. The Company engaged with potential prospective partners, global market leading pharmaceutical companies, and market leading researchers in the treatment of dermatological conditions.

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 study in June 2018 with completion of enrolment expected in mid-2019. The BTX 1204 atopic dermatitis patient Phase 2 study is also underway with enrolment expected to be completed by in Q3 2019. Finally, Phase 1b BTX 1308 psoriasis patient study is in late stage enrolment and will be complete by the end of 1Q CY2019 with data shortly thereafter.

To learn more please visit: <https://www.botanixpharma.com/>

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 December 2018

| 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 | (4,760) | (7,326) |
| (b) staff costs | (205) | (415) |
| (c) administration and corporate costs | (393) | (656) |
| Dividends received (see note 3) | - | - |
| 1.4 Interest received | 41 | 71 |
| 1.5 Interest and other costs of finance paid | - | - |
| 1.6 Income taxes paid | - | - |
| 1.7 Government grants and tax incentives | 4,617 | 4,617 |
| 1.8 Other | - | - |
| 1.9 Net cash from / (used in) operating activities | (700) | (3,709) |

| | | |
|--|-----|------|
| 2. Cash flows from investing activities | | |
| 2.1 Payments to acquire: | | |
| (a) property, plant and equipment | (6) | (11) |
| (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 (6 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 | (6) | (11) |

| | | | |
|-------------|---|----------|----------|
| 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 | 14,249 | 17,263 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (700) | (3,709) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | (6) | (11) |
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | - | - |
| 4.5 | Effect of movement in exchange rates on cash held | (12) | (12) |
| 4.6 | Cash and cash equivalents at end of quarter | 13,531 | 13,531 |

| 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 | 4,449 | 7,066 |
| 5.2 | Call deposits | 9,082 | 7,183 |
| 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) | 13,531 | 14,249 |

| 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 | 180 |
| 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 |
|-----|--|--|---|
| | Add notes as necessary for an understanding of the position | | |
| 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 | 4,450 |
| 9.2 | Staff costs | 180 |
| 9.3 | Administration and corporate costs | 300 |
| 9.4 | Leased assets | - |
| 9.5 | Other (provide details if material) | - |
| 9.6 | Total estimated cash outflows | 4,930 |

| 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 January 2019.

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.