

# ASX/Media Release

#### **19 November 2018**

# **Botanix Pharmaceuticals 2018 Annual General Meeting Chairman's Address**

**Perth 19 November 2018:** Medical dermatology company Botanix Pharmaceuticals Limited ("Botanix" or the "Company") is pleased to release the Chairman's Address at the Annual General Meeting to be held at 9:30am (AWST).

# For more information, please contact:

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### **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<sup>TM</sup>) for direct skin delivery of active pharmaceuticals in all skin diseases. Botanix is working with multiple parties to test the application of Permetrex<sup>TM</sup> 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 has commenced in September 2018.

To learn more please visit: <a href="https://www.botanixpharma.com/">https://www.botanixpharma.com/</a>



# Botanix Chairman's 2018 Annual General Meeting Address (19 November 2018)

Good morning. It is with great pleasure that I welcome you to Botanix's Annual General Meeting for the 2018 financial year. Thanks for being here. So much has happened in the last year that the last AGM seems like more than a year ago.

Standing here at the AGM last year we were advancing towards our first patient study of BTX 1503 – our lead product for the treatment of moderate to severe acne. In the 12 months since that meeting, we've successfully completed that first acne patient study, kicked off a Phase 2 study for the same indication, successfully completed our first patient study for atopic dermatitis, are within weeks of starting the Phase 2 program for that indication, and also commenced our first patient study in psoriasis in recent weeks. With so much happening, I'd like to take the opportunity today to provide an update on our progress and milestones we expect to achieve in the coming 12 months.

Before I jump into that update, however, I think it's important to reiterate our vision for Botanix to "be the leading dermatology company developing novel cannabinoid treatments for serious skin diseases". We all know someone who has been affected by acne, atopic dermatitis and psoriasis, but despite the commercial opportunity for new products in these areas remaining in the billions of dollars – there continues to be many unmet needs. The statistic that the Company continues to focus on is that there have been no new products approved to treat acne in more than 20 years – that (amongst others) is a statistic we plan to disrupt with our BTX 1503 program.

Last year I was very pleased to say that we had successfully met all of our milestones within the timeframe we set out to achieve. This year I am pleased to advise that we have again repeated that success in bringing our Phase 1b acne and atopic dermatitis patient studies in on schedule, as well as maintaining the planned timing for commencement of our Phase 2 acne and Phase 1b psoriasis studies.

This is an amazing achievement by the team, particularly as we are now running studies in the USA, which means we have had to coordinate with not just the FDA, but also the DEA who maintain a strict licensing and approvals process, which requires all of our dermatology clinics to install safes to hold our test articles, as well as be licensed and inspected by State based DEA inspectors. Complying with some of the DEA requirements has been onerous - and in some cases - required innovative last-minute thinking to figure out where to put a 750-pound safe in a clinic, on the 8th floor of a commercial building.

Two of our major achievements for the year have been the successful completion of our first patient studies for our acne program BTX1503 and our atopic dermatitis program BTX 1204.

Our acne patient study data was announced at the end of January this year and showed that BTX 1503 was very safe and also reduced inflammatory lesions by 47% on average after only 4 weeks of treatment. This rapid reduction in the number of pimples was better than comparable topical acne products, which generate revenue of close to \$1billion per annum. Subsequent analysis of the data also suggested a positive effect on inflammation in the skin, which bodes very well for our other



development projects such as atopic dermatitis and psoriasis, where controlling inflammation is a key outcome.

With the success of our first acne patient study, the team moved rapidly to design and initiate a Phase 2 study in 360 patients, which we kicked off in early July and is enrolling patients as I speak. This much larger study will be operated across about 25 sites in the US and 10 sites in Australia and we plan to have data from this study around the middle of 2019.

Our second successful patient study was for atopic dermatitis, which reported results in late June this year. This vehicle-controlled study demonstrated significant improvements in mild to moderate patients with atopic dermatitis over the course of 4 weeks, and the excellent safety profile and rising efficacy gave us confidence to also take BTX 1204 into a Phase 2 study program this year. The Phase 2 for BTX 1204 will kick off in the coming weeks and we hope to have the majority of patients enrolled in this 200 patient study by mid-2019.

Botanix has only been listed for about 27 months, but in that time, we have transitioned from an idea, through successful early clinical studies and now into Phase 2 studies. This is not only a testament to the safety and efficacy potential of synthetic cannabidiol and our novel PermetrexTM delivery system, but also a testament to the hard work by the small and experienced team that Matt has led at Botanix over the last 2 years.

We have progressed the Company rapidly in a very capital efficient manner, with fully funded studies for our two Phase 2 programs and our Phase 1b psoriasis program. With a bit more than A\$14 million in the bank at the end of September and expecting another A\$4 million in R&D tax returns in the coming month, we are well funded to execute on our plans in the coming 12 months.

Before I provide a quick update on our development pipeline and corporate activities, I wanted to make a couple of comments concerning the development and growing maturity of the cannabinoid space internationally. When Matt and Michael Thurn first started attending dermatology conferences 24 months ago – companies looked at them strangely when they mentioned Botanix was studying synthetic cannabidiol for the treatment of serious skin diseases. In the last 24 months, that attitude has changed as the interest in cannabinoid therapies across a range of diseases has exploded, and significant capital has poured into the sector in pursuit of new opportunities in medicine, general health and recreational usage of cannabinoids.

We've recently seen the first approval of cannabidiol for Epilepsy with GW Pharma's FDA approval for Epidiolex®, as well as more than 140 different studies getting underway with cannabidiol for diseases ranging from epilepsy, to pain and PTSD. Despite this — Botanix remains the ONLY company undertaking well-controlled FDA regulated studies in skin disease and now leads this research area globally. Matt and our Executive Board Director, Bill Bosch, have been in dialogue with an increasing number of strategic players given the growing interest and feedback on Botanix programs have been very positive to date.

Finally, I wanted to draw your attention to a couple of upcoming milestones for the Company that I believe will further gain the attention of the investing public and provide deserved share price



appreciation. First, we expect to generate data from our Phase 1b psoriasis patient study in Q1 CY2019. This study will include biopsies of patient's skin, which will be analysed by one of the world's leading researchers to highlight for the first time, the mechanism of action for cannabidiol's anti-inflammatory and immune modulation benefits. This data will inform not only the scientific basis for the drug's effect in psoriasis, but also the mechanism for dermatitis and a range of other diseases that can be targeted by cannabidiol.

Secondly, we continue to make good progress with our partnering efforts with the PermetrexTM skin delivery technology. We have completed a number of projects with dermatology company partners where we've generated revenue to help offset our costs and hope to convert some of those projects into license arrangements in the course of 2019.

Finally, I'd like to highlight the contribution of our Australian head of operations Dr Michael Thurn who along with Matt Callahan has driven the success of the Botanix programs over the last 24 months. With the move of more of our programs to the USA, we are beginning to add resources in the Philadelphia office with the recent recruitment of our Chief Medical Officer Dr Stephane Levy, our Director of Clinical Operations, Jillian Chapas-Reed and head of regulatory, Dr Judith Plon. We will continue to assess the structure of the organization as we move into later stage clinical studies and begin to position the Company for commercialization activities in the USA

In closing, I would like to thank each of our existing shareholders for your support over the past year and trust that you are as excited as we are about where the Company is going. I would also like to thank our Executive Directors, the management team, consultants and employees for their diligence, dedication and passion for our business, especially in light of what they've been able to achieve in the months since listing.

Finally, I would also like to thank my fellow Board members for their hard work and dedication throughout the past financial year.

Thank you.			

Graham Griffiths, Chairman.