

**ASX/Media Release**

**14 November 2017**

## **Botanix Pharmaceuticals 2017 Annual General Meeting Chairman's Address**

**Perth, 14 November 2017:** Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") is pleased to release the Chairman's Address to the Annual General Meeting to be held at 9am (WST).

### **About Botanix Pharmaceuticals**

Botanix Pharmaceuticals is a clinical stage medical dermatology company, which is dedicated to developing next generation therapeutics for the treatment of serious skin diseases. Our mission is to improve the lives of patients battling acne, psoriasis and atopic dermatitis, by providing new treatment options for conditions that currently are inadequately addressed, or are treated with therapeutics that are burdened with side effects profiles. Botanix is harnessing the untapped potential of a synthetic active pharmaceutical ingredient, known as cannabidiol, which has a well-established safety profile. Botanix has successfully completed its first-in-man studies with BTX 1503 and is currently conducting a follow-on clinical trial with acne patients in 2H 2017. The Company has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases and plans to progress the development of BTX 1503 for acne and its pipeline of other Permetrex™ enabled products alone, or in collaboration with partners.

For more information on Botanix, please visit [www.botanixpharma.com](http://www.botanixpharma.com) or follow us on Twitter @Botanixpharma.

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## **Botanix Pharmaceuticals 2017 Annual General Meeting Chairman Address (14 November 2017)**

Good morning. It is with great pleasure that I welcome you to Botanix's Annual General Meeting for the 2017 financial year. This is only our second AGM since changing the nature of our business and becoming a pharmaceutical company and I thank you for coming today.

It seems like a longer time, given the amount the company has achieved, but Botanix has only been in operation for less than 18 months following its listing in July last year. Standing here at the AGM last year we had just completed our first human study using the Permetrex<sup>TM</sup> skin delivery technology and we were rapidly advancing towards our first human study of BTX 1503 – our lead product for the treatment of moderate to severe acne. Much has happened since then and I'd like to take the opportunity today to provide an update on our progress to date and key milestones we expect to achieve in the coming 12 months.

However, before I provide an overview of our achievements so far, I want to reiterate our vision: Botanix is dedicated to the development of new dermatology products aimed at treating serious skin diseases, including acne, psoriasis, and atopic dermatitis. We all know someone who has been affected by these common diseases, and despite the commercial opportunity for new products in these areas remaining in the billions of dollars – unfortunately there remain 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.

In terms of our achievements in the last 12 months, I am very pleased to say that we have successfully met all our milestones within the timeframe we set down to achieve them. You don't often get to say that in the area of pharmaceutical development as you are required to work within a regulatory framework which is risk averse and often time consuming, but our success is a testament to the hard work and experience of our team and the fact that dermatology is in many ways, a less risky, less costly, and faster therapeutic area to develop new drugs than many others.

Our major achievement has been to successfully complete first in man studies for our acne program BTX 1503. In July, we announced the first study conducted anywhere in the world of topical synthetic cannabidiol together with the Permetrex<sup>TM</sup> drug delivery system for skin disease. This initial safety and pharmacokinetic study confirmed that the doses we have chosen are safe and non-irritating and most importantly, we were able to deliver high amounts of synthetic cannabidiol into the layers of the skins where the oil producing sebaceous glands are located.

Being able to transition from listing in July last year, to completing this first study within 12 months is extremely fast for a new drug. Our ability to move that quickly is partly due to the safety profile of cannabidiol, which has now been studied in more than 100 clinical trials for different diseases and will likely be approved for use in childhood epilepsy at approximately 20 times the dose we are using on the outside of the skin.

Upon receiving the positive data from this initial study for BTX 1503, we were able to again quickly secure ethics approval to go back into our first acne patient study which commenced in August 2017 and is planned to enrol all patients by the end of this year. We are working with 4 dermatology sites across Australia, including one in Fremantle, WA and will enrol up to 20 patients with moderate to severe acne who will take BTX 1503 for 4 weeks. We hope to see that the drug is safe in patients, but also that we see evidence of reduction of pimples and general improvement in skin condition. We plan for that data to be available in 1Q CY2018.

Given the interest in Botanix and general support for the sector, we were also able to bolster the balance sheet in May 2017 with a capital raising of A\$7.4m supported by a range of retail and small institutional investors. This has allowed us to more quickly advance products from our pipeline into development and we were pleased to announce a few weeks ago that first patient studies of our atopic dermatitis product BTX 1204 had commenced in Australia.

We haven't said too much about our atopic dermatitis program, but this is a very exciting follow-on from our acne program. Atopic dermatitis (or eczema) affects about 25 million people in the US and the disease has a significant effect on quality of life of patients and their families. The most common treatment is steroids which given the young age of these patients, is problematic, particularly for long term treatment. There have also been very few new drugs developed for dermatitis, but to give you some idea of the value of this market – last year Pfizer acquired Anacor for US\$5.2bn for its atopic dermatology product Crisaborole®, because they expect the product to generate more than US\$750m in sales per annum.

Our BTX 1204 program targets the same opportunity as Crisaborole®, but we hope to avoid the respiratory tract infection side effects and also have a better effect on reducing inflammation and infection on the skin. We will be enrolling 36 patients in the study and as Matthew Callahan will outline later, plan to have data available from this study in 2Q CY2018.

Finally, I want to provide a quick update as to what the Company is doing more broadly with the Permetrex™ platform as it is clear that the potential for this drug delivery technology will allow us to expand our own pipeline as well as potentially engage partners to rescue their products that are currently stranded in development. I am pleased to say that we are now working with several dermatology companies to significantly improve the delivery of drugs into the skin in disease areas ranging from hair loss to orphan and rare disease opportunities. These projects are funded by the partner and as they move back into the clinic with the improved Permetrex™ formulation for testing, we will have the opportunity to convert these arrangements into licenses which could deliver upfront and staged payments and royalties to augment the value of the Company in addition to our own development programs.

For a small company, we've achieved an enormous amount over the last year with two development programs in the clinic, paid engagements with partners on Permetrex™ and a wider pipeline of projects that we are eager to move forward. But as a small company, we are always conscious of the need to manage cash carefully and we continue to prioritise our investments in our acne and dermatitis programs. Significant milestones and value inflection points for the Company will come

from the announcement of the acne patient data in 1Q CY2018, as well as the dermatitis patient study outcome, as we continue to pursue partner and collaboration opportunities for the products and the Permetrex™ technology.

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, Matthew Callahan and Dr Bill Bosch, the management team, and employees for their diligence, dedication, and passion for our business, especially in light of what they've been able to achieve in the short time 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.