

ASX/Media Release

26 February 2019

## **Permetrex™ outperforms other CBD topical products**

### **Key highlights**

- **Tioga Research engaged to complete an independent comparative analysis of Botanix's lead product for acne, BTX 1503, against five other commercially available cannabidiol topical products**
- **Data demonstrates that BTX 1503 delivered >3x to >5x more drug to the target layers of the skin and each dose of BTX 1503 contained more CBD than any other product**
- **Study underpins Botanix's clinical development programs and reiterates the upside potential of Botanix's proprietary drug delivery system (Permetrex™)**

**Philadelphia PA and Sydney Australia, 26 February 2019:** Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") is pleased to release a presentation containing data from an independent analysis completed by Tioga Research, a contract research organisation (CRO), comparing Botanix's lead product for acne, BTX 1503, with other commercially available cannabidiol (CBD) creams or gels.

The comparative analysis demonstrated that, relative to the closest comparator CBD topical product, BTX 1503 delivered >5 times as much CBD to the epidermis and >3 times as much CBD to the dermis, and significantly more than other CBD topical creams and gels.

In addition, further analysis was completed by Tioga Research to determine the amount of CBD in other comparator products. Results indicated that BTX 1503 delivered more CBD in each dose used by patients in clinical studies, than in the entire package of each of the comparator products.

**Founder and Executive Director of Botanix, Matt Callahan, said:** "We are extremely pleased with the results of this comparable analysis, as delivering pharmaceuticals deep into the skin to treat disease remains a significant challenge in dermatology and medicine. Permetrex™ provides a significantly more effective way of delivering drugs via the skin without the use of traditionally used chemicals that irritate the skin."

Botanix is actively working with a number of pharmaceutical partners who are using the Permetrex™ delivery system to formulate their proprietary actives, into new and more effective formulations for clinical development and the Company welcomes new collaborations.

## 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 Phase 2 patient study is also underway with enrolment expected to be completed by in 3Q CY2019. 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 available in Q2 CY2019.

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

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# BTX 1503 outperforms other CBD topical products

*>3x to >5x more drug delivered  
to target layers of the skin*

February 2019

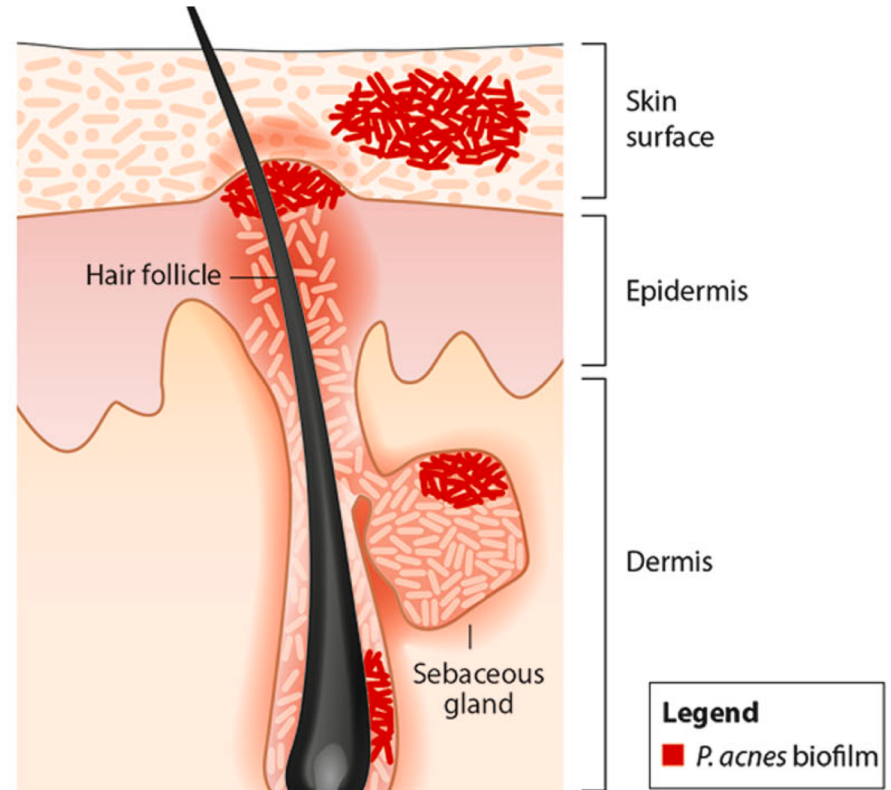


# Overview

Botanix commissioned a leading US skin testing laboratory, *Tioga Research* to make a head-to-head comparison of its lead product for acne (BTX 1503) with other commercially available OTC cannabidiol (CBD) containing creams and ointments

## Aims:

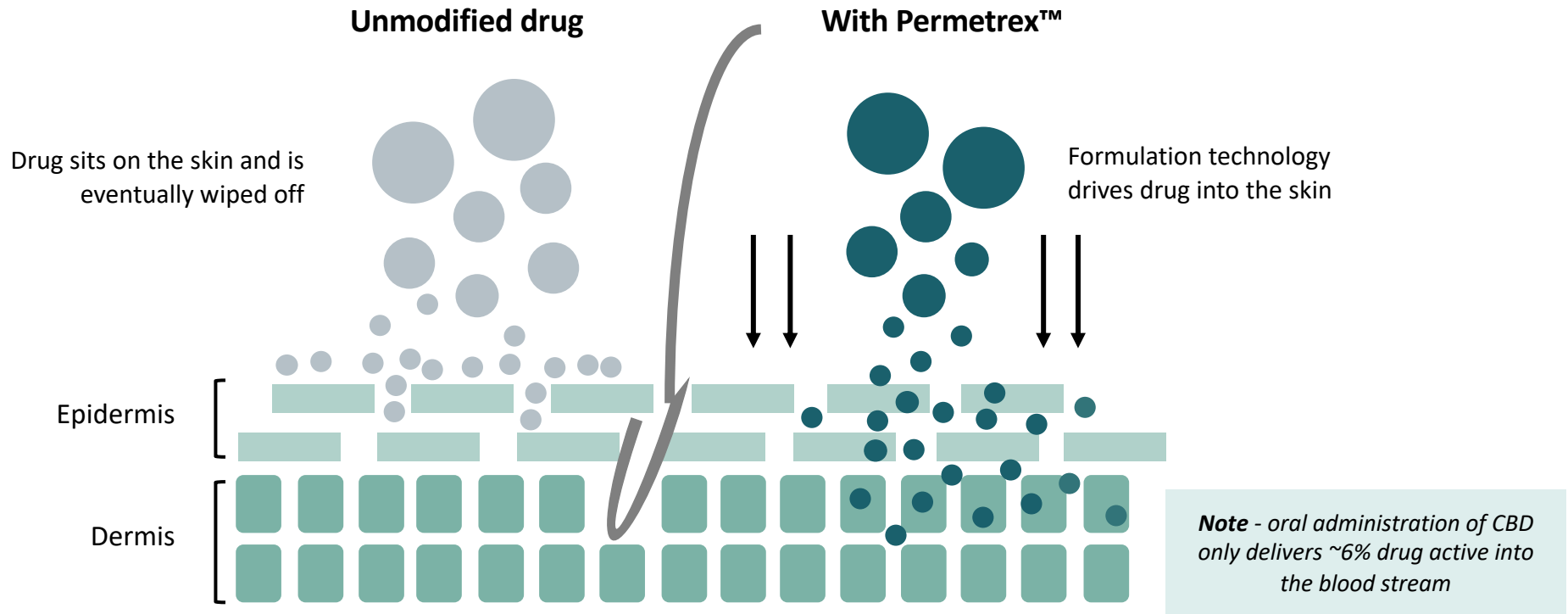
1. To show commercially available OTC topical products that contain CBD, fail to live up to the claimed content of CBD
2. To show commercially available OTC topical products that contain CBD, fail to deliver a therapeutically effective amount of CBD to the skin layers involved in the pathogenesis of common skin diseases





# BTX 1503 utilises Permetrex™ skin delivery technology

Permetrex™ delivers high doses of drug into the skin without using permeation enhancers, preservatives or irritating levels of alcohol (or petroleum) that other comparative products use

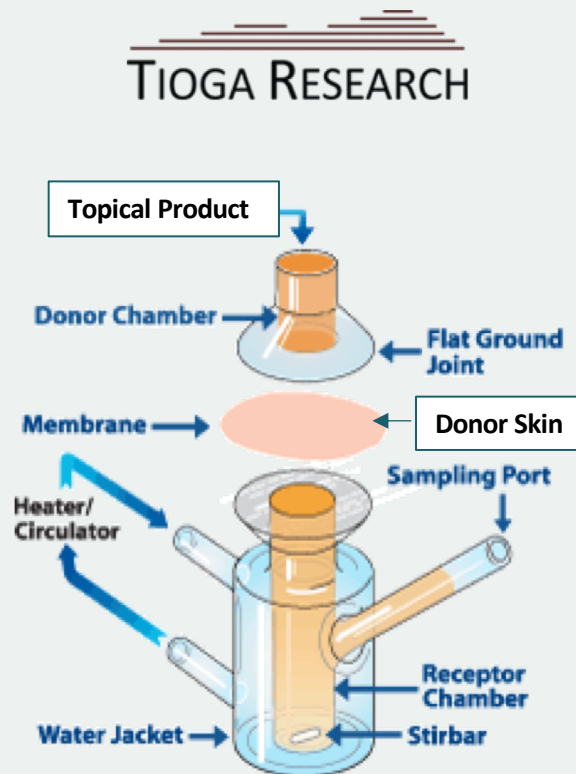


Botanix holds the exclusive rights to utilise Permetrex™ for all drugs that treat skin diseases

# Test system

The *Franz Cell* is an industry and regulatory accepted test method to assess the level of skin penetration of the active ingredient(s) in topical products

## Franz Cell



- ✓ Skin from a single human donor is the membrane
- ✓ Multiple topical products can be tested using the same donor skin, allowing a direct comparison between products
- ✓ Can accurately profile drug levels in the epidermis and dermis
- ✓ Good correlation between the Franz Cell results and skin penetration in healthy human skin
- ✓ Allows confirmation of drug levels in topical products to be compared against the claims made on the product label

# Test products

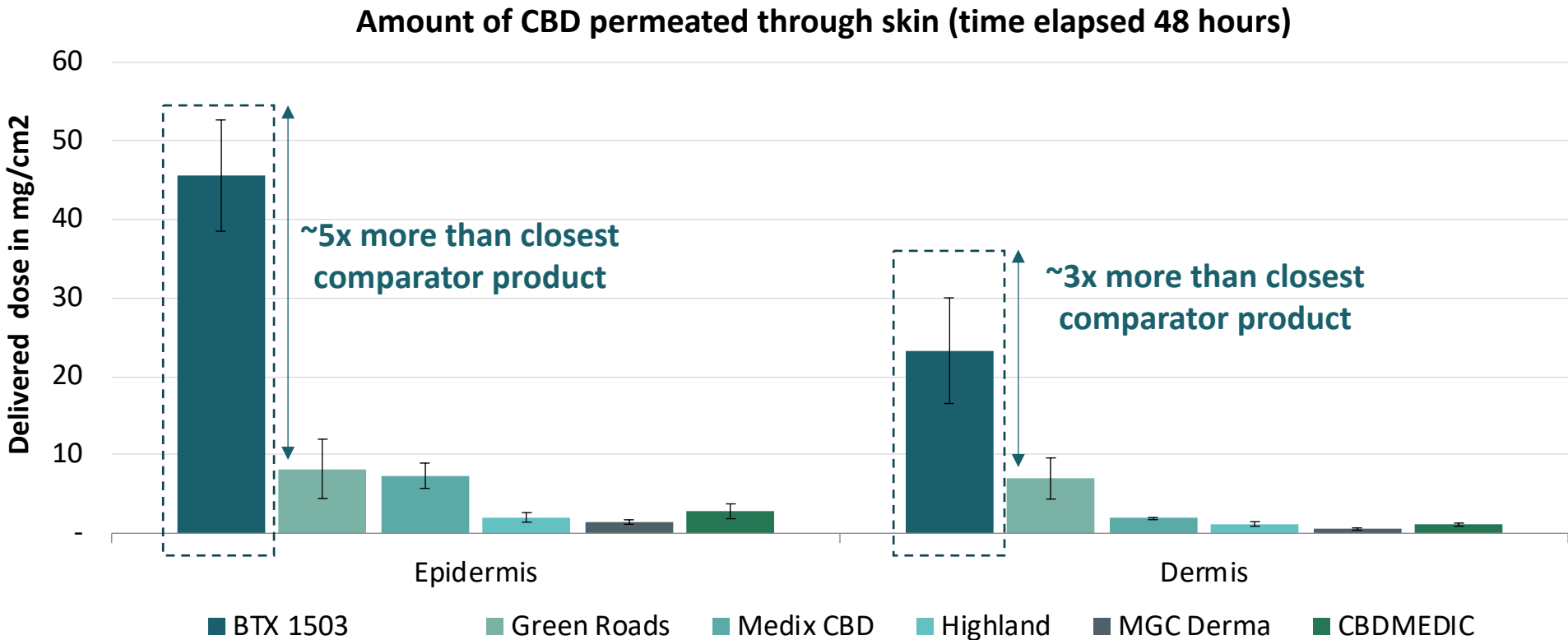
A range of CBD topical products currently marketed in Australia, Canada and the US

Product name	Manufacturer	Product type	Regulation	Label claim CBD content (mg/tube)
<b>TheraGreen™</b>	Green Roads	Cream	OTC	300
<b>Biotech Pain Relief</b>	Medix CBD	Cream	OTC	150
<b>Therapy+Hemp Cream</b>	Highland Pharms	Cream	OTC	200
<b>CBD Herbal Repair Cream</b>	MGC Derma	Cream	OTC	Undisclosed
<b>CBDMEDIC™ Back and Neck</b>	CBDMEDIC	Ointment	OTC	Undisclosed



# Independent comparative analysis of CBD delivered<sup>1</sup>

Data indicates that BTX 1503 significantly outperformed the other CBD topical products in delivering drug to targeted layers of the skin








Relative to the closest comparator, BTX 1503 delivers >5 times as much CBD to the epidermis and >3 times as much CBD to the dermis - significantly more than other creams and gels

1. Tioga Research (Botanix data on file)

# Independent comparative analysis of CBD content<sup>1</sup>

Botanix also engaged Tioga to analyse the amount of CBD that was actually in each of the test comparator products compared to the amount of CBD claimed in each product's label

Product name	Manufacturer	Label claim CBD content (mg/tube)		Tested CBD content (mg)
<b>TheraGreen™</b>	Green Roads	300		<b>24.5</b>
<b>Biotech Pain Relief</b>	Medix CBD	150		<b>11.2</b>
<b>Therapy+Hemp Cream</b>	Highland Pharms	200		<b>24.6</b>
<b>CBD Herbal Repair Cream</b>	MGC Derma	Not disclosed		<b>8.8</b>
<b>CBDMEDIC™ Back and Neck</b>	CBDMEDIC	Not disclosed		<b>14.9</b>

BTX 1503 delivers more CBD in each dose provided to a patient, than is in the entire tube or tub of each of these comparable products

1. Tioga Research - Botanix data on file



# Conclusions

Permetrex™ skin delivery technology delivers significantly more CBD to the layers of the skin than all the comparator products tested



## BTX 1503 delivers:

- more than 5x more drug to the outer layer (epidermis) of the skin
- more than 3x more drug to the deeper layers (dermis) layer of the skin



**One dose of BTX 1503 delivers more CBD than a whole tube or container of the comparator products**



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