

## ASX/Media Release

6 March 2017

### **Botanix presents at the American Academy of Dermatology annual meeting**

- Botanix presented at the AAD annual meeting in Orlando, Florida
- Botanix showcased the BTX1503 acne program and progression to near term clinical trials to key industry opinion leaders
- Botanix also engaged with several large dermatology companies on potential collaborative commercial opportunities for the Permetrex™ technology

**Philadelphia PA, 6 March 2017:** Medical dermatology company Botanix Pharmaceuticals Limited (“Botanix” or the “Company”) is pleased to release a new investor presentation, which Botanix Executive Director, Matt Callahan, presented at the 75<sup>th</sup> American Association of Dermatologists (AAD) annual meeting in Orlando, Florida.

The presentation at the AAD annual meeting was used as a platform to provide key industry opinion leaders with an update on the Company’s lead clinical development program, involving the use of BTX1503 for the treatment of acne. Botanix was also able to showcase its rapid operational progress towards first clinical studies, which are expected to begin recruitment in 2Q 2017. Botanix is currently awaiting approval of its ethics submission for the commencement of the Australian Phase 1a study. Completion of this first study will be closely followed by an Australian pilot study in acne patients.

Botanix also engaged with several global pharmaceutical companies that have an interest in acne treatments and other dermatological conditions. The Company recently expanded its license to use the Permetrex™ drug delivery technology for all skin diseases, and has initiated discussions with selected dermatology partners on potential collaborations for the use of the Permetrex™ technology.

Botanix will continue to explore several commercial and product opportunities in parallel with its primary acne program.

#### **About Botanix Pharmaceuticals**

Botanix Pharmaceuticals 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 is preparing for the first human trials with synthetic cannabidiol utilising a proprietary drug delivery system (Permetrex™) for direct skin delivery of the therapy in 1H 2017 and plans to progress the development of 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.

**For more information, please contact:**

**General enquiries**

Matt Callahan  
Botanix Pharmaceuticals Ltd  
Executive Director  
P: +1 215 767 4184  
E: [mcallahan@botanixpharma.com](mailto:mcallahan@botanixpharma.com)

**Investor Relations**

Ben Walsh  
WE Buchan  
P: (02) 9237 2801  
E: [bwalsh@buchanwe.com.au](mailto:bwalsh@buchanwe.com.au)

**Media enquiries**

Arthur Chan  
WE Buchan  
P: (02) 9237 2805  
E: [achan@buchanwe.com.au](mailto:achan@buchanwe.com.au)



American Academy Dermatology  
March 2017

ASX:BOT  
[www.botanixpharma.com](http://www.botanixpharma.com)



# Overview

- ASX listed dermatology company focused on new treatments for serious skin diseases
- Lead product for acne utilizes a synthetic and pharmaceutical grade form of cannabidiol
- Permetrex™ is the drug delivery system that provides the technological advantage
- BTX1503 enters clinic in 2Q 2017 for safety and pilot efficacy studies in acne patients
- Multiple Permetrex™ enabled products in the development pipeline
- Experienced team with more than 10 FDA approvals between them

## Business focus:

- medical dermatology

## Lead program:

- BTX 1503 for acne

## Drug active:

- synthetic cannabidiol

## Drug delivery system:

- Permetrex™

# + Team with significant FDA success

3



**Matt Callahan**  
Director

- 3 FDA approved products
- IP and development specialist
- 15 years pharma experience
- Venture capital partner



**Dr Bill Bosch**  
Director

- 6 FDA approved products
- 26 years pharma experience
- Co-inventor of many drug delivery technologies including Nanocrystal®



**Dr Michael Thurn**  
COO

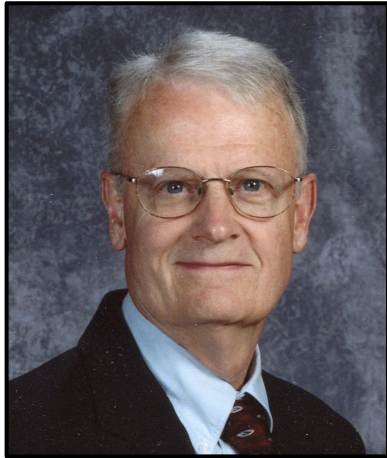
- Extensive acne development and clinical experience
- CEO Mimetica, Spinifex Pharma and Cytopia
- Toxicologist with TGA experience



**Mark Davis**  
VP Clinical/ Regulatory

- 30 years dermatology experience
- Former senior exec Medicis and Insys
- Development experience with synthetic cannabidiol

# + Experienced scientific team



**Dr Gene Cooper**  
Consultant

- 5 FDA approved products
- Expert in skin delivery
- Inventor of Permetrex™
- 40 years pharma experience



**Prof James Leyden**  
Scientific Advisor

- Emeritus Professor Dermatology at University of Pennsylvania
- World leading acne and skin specialist
- Co-inventor of numerous skin testing systems now used by industry



**Prof Diane Thiboutot**  
Scientific Adviser

- Professor of Dermatology at Penn State University
- Leading researcher in acne and rosacea as well as other serious skin diseases

# + Nothing new for the last 10 years and little expected

- No products have approved by FDA in the last 10 years containing a new drug
- All “new products” launched in this period contain combinations of old drugs in new formulations or packaging
- Multiple late stage new product failures in last 2 months (Novan Phase 3 – January 2017)





# Cannabidiol showing promising results

6

**ClinicalTrials.gov**  
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"  
Search for studies:  Search

Advanced Search | Help | Studies by Topic | Glossary

**Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting**

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results Text Size ▾

**101 studies found for: cannabidiol**  
[Modify this search](#) | [How to Use Search Results](#)

List | By Topic | On Map | Search Details

+ Show Display Options Download Subscribe to RSS

☐ Include only open studies ☐ Exclude studies with Unknown status

| Rank | Status                 | Study   |
|------|------------------------|---|
| 41   | Completed              | <a href="#">A Study to Investigate the Efficacy and Safety of Cannabidiol Seizures Associated With Lennox-Gastaut Syndrome in Children</a><br>Conditions: Epilepsy; Lennox-Gastaut Syndrome<br>Interventions: Drug: GWP42003-P; Drug: Placebo |
| 42   | Active, not recruiting | <a href="#">A Randomized Controlled Trial to Investigate Possible Drug-Drug Interactions Between Cannabidiol and Antiepileptic Drugs</a><br>Condition: Epilepsy<br>Interventions: Drug: Placebo; Drug: GWP42003-P                             |
| 43   | Recruiting             | <a href="#">A Randomized Controlled Trial of Cannabidiol (GWP42003-P) in Patients With Tuberous Sclerosis Complex (GWPCARE6)</a><br>Conditions: Tuberous Sclerosis Complex  |

**ClinicalTrials.gov**  
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"  
Search for studies:  Search

Advanced Search | Help | Studies by Topic | Glossary

**Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting**

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results Text Size ▾

**no studies found for: acne | cannabidiol**  
[Modify this search](#) | [How to Use Search Results](#)

List | By Topic | On Map | Search Details

Found no studies with search of: acne | cannabidiol

**Query Suggestions:**

No documents are found by all search clauses

Drop Conditions clause leaving [cannabidiol](#)

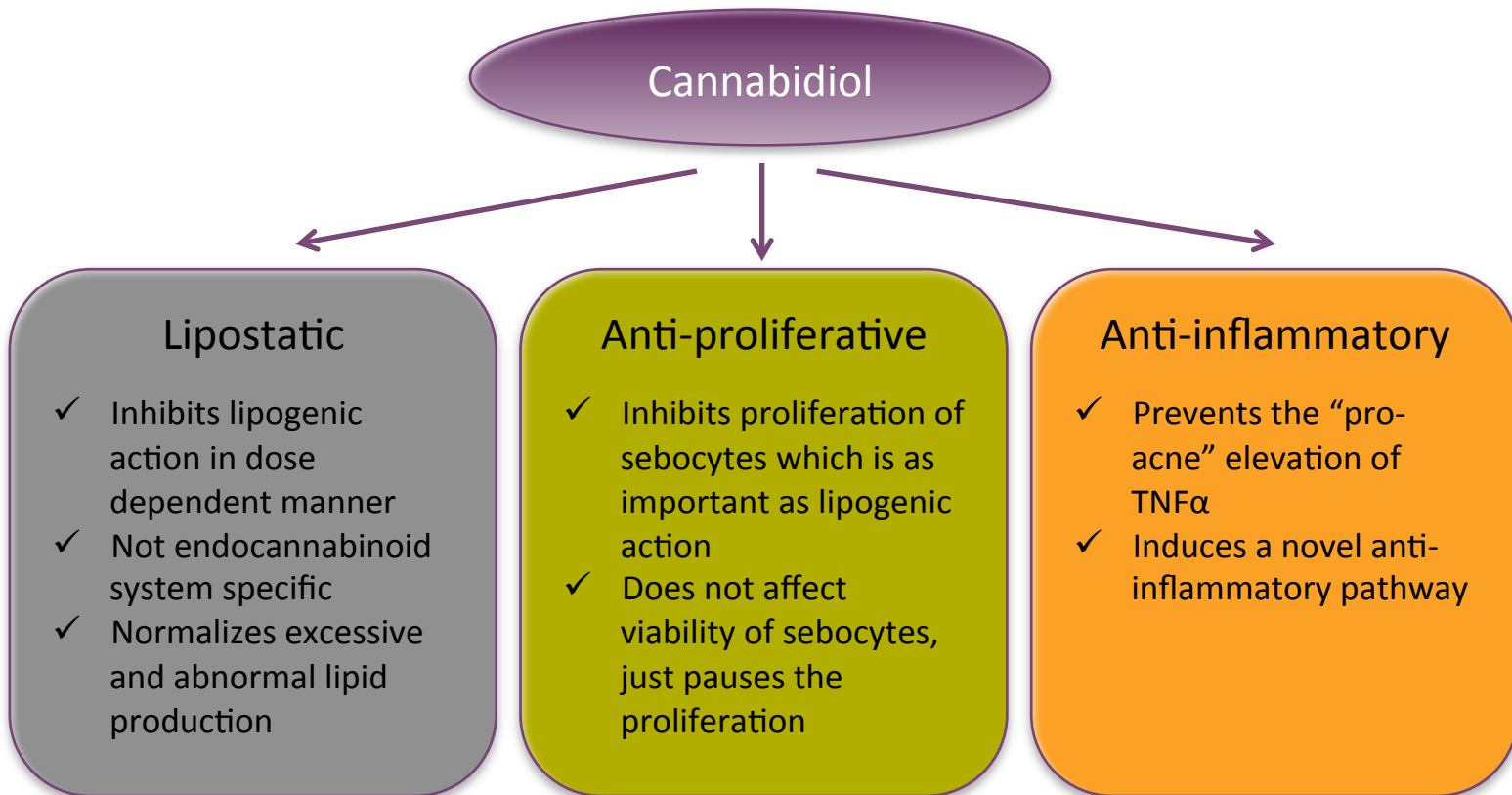
Drop Interventions clause leaving [acne](#)





# Cannabidiol mechanism of action

7



Source - Attila Oláh, Balázs I. Tóth, István Borbíró, Koji Sugawara, Attila G. Szöllösi, Gabriella Czifra, Balázs Pál, Lidia Ambrus, Jennifer Kloepper, Emanuela Camera, Matteo Ludovici, Mauro Picardo, Thomas Voets, Christos C. Zouboulis, Ralf Paus and Tamás Biró (2014). Cannabidiol exerts sebostatic and anti inflammatory effects on human sebocytes. *J Clin Invest* 124(9): 3713-3724

# + Source and purity of drug material is important

8



Extracted and purified

100+ chemicals

Multiple impurities

Scaled up to  $\approx$  1kg

Not registered with FDA

Must comply with FDA's "Guidance on Botanicals"

Synthetically manufactured

1 chemical

100% pure

Scaled up to 50kg

Registered with FDA

No additional compliance required

# + BTX1503 – leveraging a novel mechanism of action in acne



Switches off excessive oil or  
'sebum' production



Reduces  
inflammation



Blocks cell  
proliferation



Reduces infection



**BTX1503 targeting a benign side effect profile**

# + BTX1503 - planned positioning versus existing acne products

10

|                      | BTX1503 | Clindamycin | Topical retinoid | Adapalene | Minocycline | Erythromycin | Accutane |
|----------------------|---------|-------------|------------------|-----------|-------------|--------------|----------|
| <b>Reduces Sebum</b> | ✓       | ✗           | ✗                | ✗         | ✗           | ✗            | ✓        |
| Anti-inflammatory    | ✓       | ✗           | ✓                | ✓         | ✗           | ✗            | ✓        |
| Anti-microbial       | ✓       | ✓           | ✗                | ✗         | ✓           | ✓            | ✓        |
| <b>Topical</b>       | ✓       | ✗           | ✓                | ✓         | ✗           | ✗            | ✗        |
| Minimal side effects | ✓       | ✗           | ✓                | ✓         | ✗           | ✓            | ✗        |

*“...the ‘Holy Grail’ of acne treatments would be a topical that can influence sebum production or the physiochemical properties of sebum.”*

Prof Emeritus James Leyden

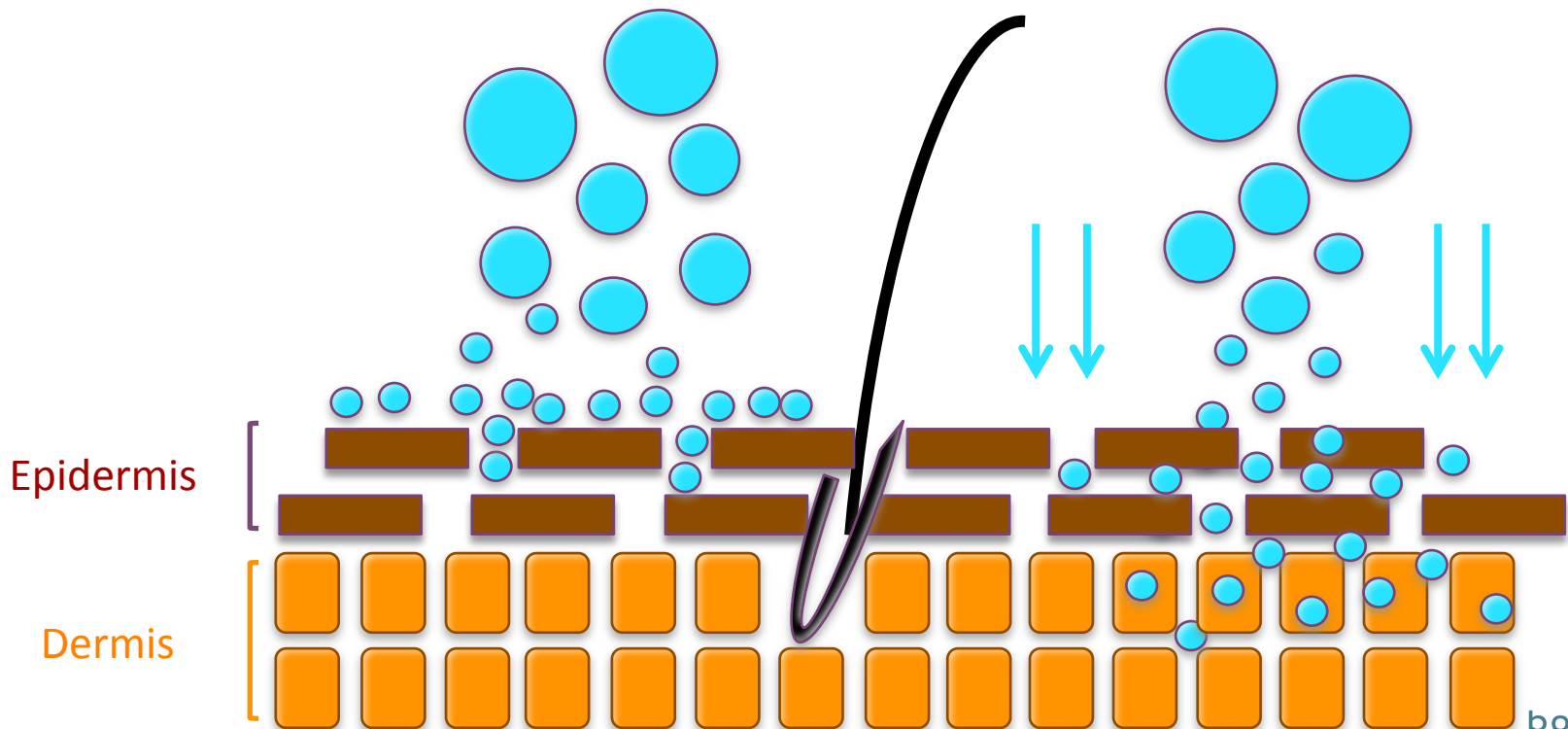
# + Permetrex™ - superior skin delivery

11

Oral delivery of cannabidiol is only 6% bioavailable

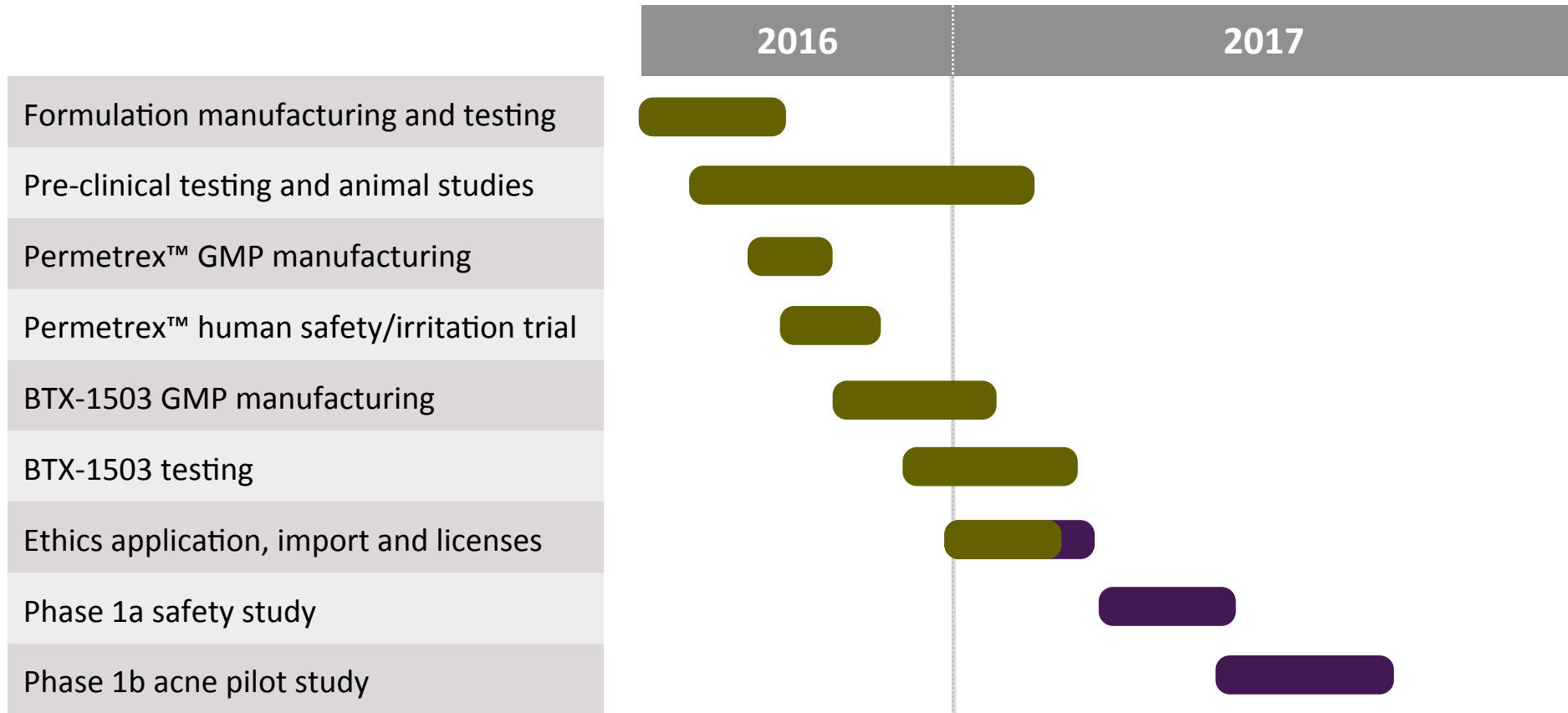
**Unmodified Drug**

**With Permetrex™**





# BTX 1503 – timeline

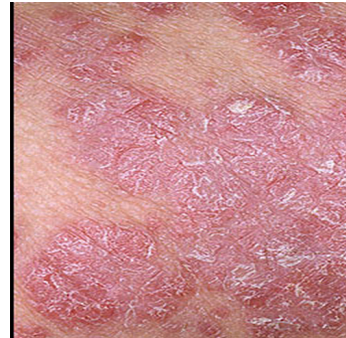


# + Pipeline – other products that utilize cannabidiol

13

## **BTX 1308 (psoriasis)**

- 7.5 million Americans have psoriasis
- Characterized by keratinocyte hyper-proliferation and increased expression of pro-inflammatory mediators into the skin.
- Cannabidiol has been shown to inhibit keratinocyte proliferation and have a novel anti-inflammatory effect



## **BTX 1204 (dermatitis)**

- US patient incidence estimated to be 31 million people – 10 -18% of children
- Cannabidiol has a potential role in reduction of itch and inflammation as well as potentially enhancing fat production in dry skin



## **Future**

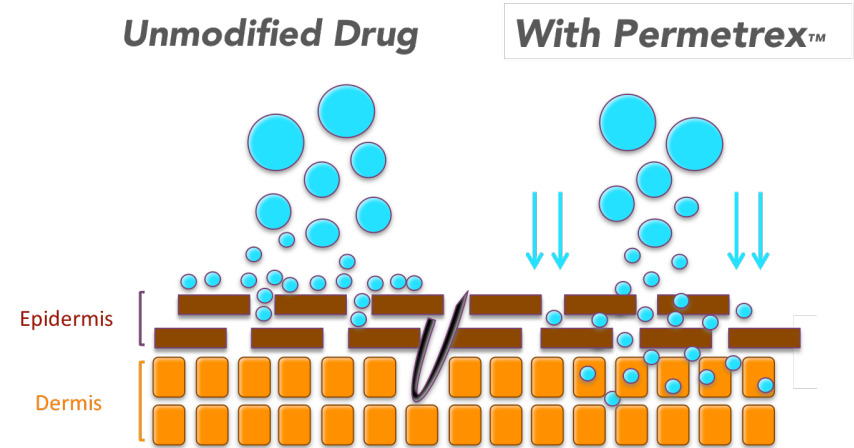
- Scientific support for other applications in melanoma and other skin diseases



# Permetrex™ enabled product opportunities

14

- Variety of prescription, cosmetic and OTC product opportunities are possible
- No need for alcohols that sting or dry out skin
- No need for preservatives that may irritate, as no water in formulations
- Active load may vary from 0.5% - 40%
- Actively seeking collaborations with partners on internal and external programs



Confidential Property of Botanix Pharma





# Upcoming news flow and milestones

---

15

- Ethics approval for first Phase 1 study
- Import licenses for BTX-1503 clinical trial material
- Collaborative research arrangements
- New product additions to pipeline (based on Permetrex™)
- Commencement of Phase 1a study
- Completion of Phase 1a study and results
- Commercial collaboration on pipeline product
- Commencement of Phase 1b study
- Completion of Phase 1b study and results
- New pipeline products data

- ✓ Significant unmet patient needs in serious skin diseases
- ✓ Novel synthetic cannabidiol treatment for acne with a growing evidence base
- ✓ Proprietary drug delivery system
- ✓ Fast and efficient development pathway, relative to usual pharmaceutical development
- ✓ Very large markets with few competing products in development
- ✓ Experienced team with track record of FDA approvals