



RESTORING HEALTHY SKIN

# 2019 Outlook

*Transformative Year*

January 2019



# Botanix value proposition

Billion dollar markets, unmet patient needs and a novel mechanism of action for skin disease, supported by positive early data and a rapid and cost effective development timeline



## Large markets

Combined value of the markets for acne, atopic dermatitis and psoriasis prescription products exceeds US\$20bn p.a.



## Market need

No new products in 20 years in acne, only one new topical for atopic dermatitis and psoriasis in the last 15 years



## Novel products

Novel synthetic cannabidiol products have multiple mechanisms of action, with a very safe side effect profile

**Dermatology studies are faster and more cost effective, relative to other pharmaceutical areas**

# 2019 outlook

Transformative year ahead, with planned completion of two Phase 2 studies, a Phase 1b patient study, along with milestones for the broader pipeline and the Permetrex™ technology platform



**Multiple value inflection points**

Data read-outs in 2019 from **fully funded clinical studies** for psoriasis (2Q CY2019), acne (3Q CY2019) and atopic dermatitis (4Q CY2019) **will drive significant value increase**



**Growing data support**

Recent approval of first cannabidiol product (Epidiolex® for epilepsy) **validates the safety profile and potential of synthetic cannabidiol** as a new skin treatment



**Validation of pharma focus**

Initial wave of investment in the sector is now moving rapidly to pharmaceutical applications – **Botanix is one of the world's most advanced cannabinoid companies**



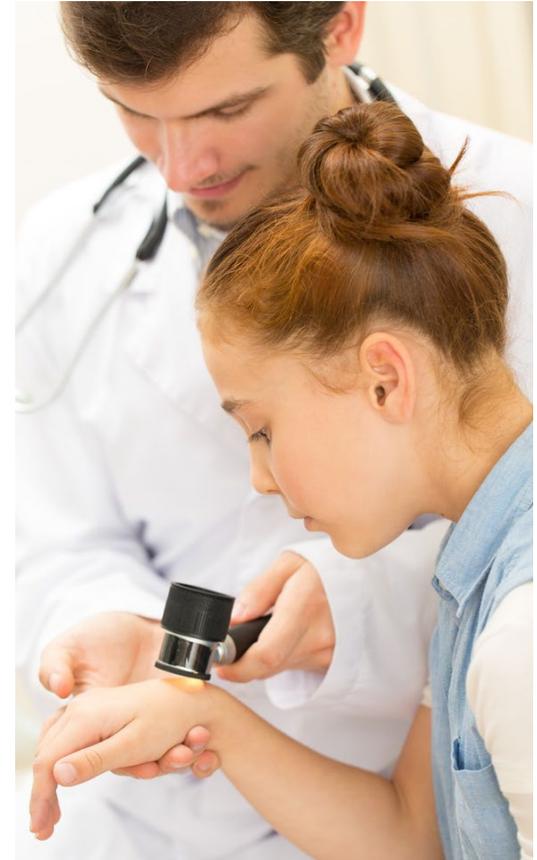
**Technology driven**

Novel skin delivery technology, Permetrex™ is **proven to enhance delivery of cannabidiol** compared to traditional approaches and provides a **novel IP position**



**Growing world class team**

Experienced team has **advanced product candidates to Phase 2 studies within 24 months** and is adding US capability to **accelerate commercialisation plans**



# Clinical programs with near term milestones

Leading Phase 2 acne and atopic dermatitis programs supported by exciting development pipeline, with Permetrex™ collaborations to augment revenue and news flow

| Product candidate     | Indication        | Pre-clin                   | Ph 1 | Ph 1b | Ph 2 | Status ( <i>upcoming milestones</i> )                                  |
|-----------------------|-------------------|----------------------------|------|-------|------|--|
| Synthetic cannabidiol | <b>BTX 1308</b>   | Psoriasis                  |      |       |      | Phase 1b patient study underway<br>(top line data early 2Q CY2019)     |
|                       | <b>BTX 1503</b>   | Moderate to severe acne    |      |       |      | Phase 2 clinical study underway<br>(recruitment complete in 2Q CY2019) |
|                       | <b>BTX 1204</b>   | Moderate atopic dermatitis |      |       |      | Phase 2 clinical study underway<br>(recruitment complete in 3Q CY2019) |
|                       | <b>BTX 1801</b>   | Antimicrobial              |      |       |      | Pre-clinical development<br>(patient study design 2Q CY2019)           |
| Permetrex™ programs   | Internal/external | Various                    |      |       |      | Ongoing studies with partners  |

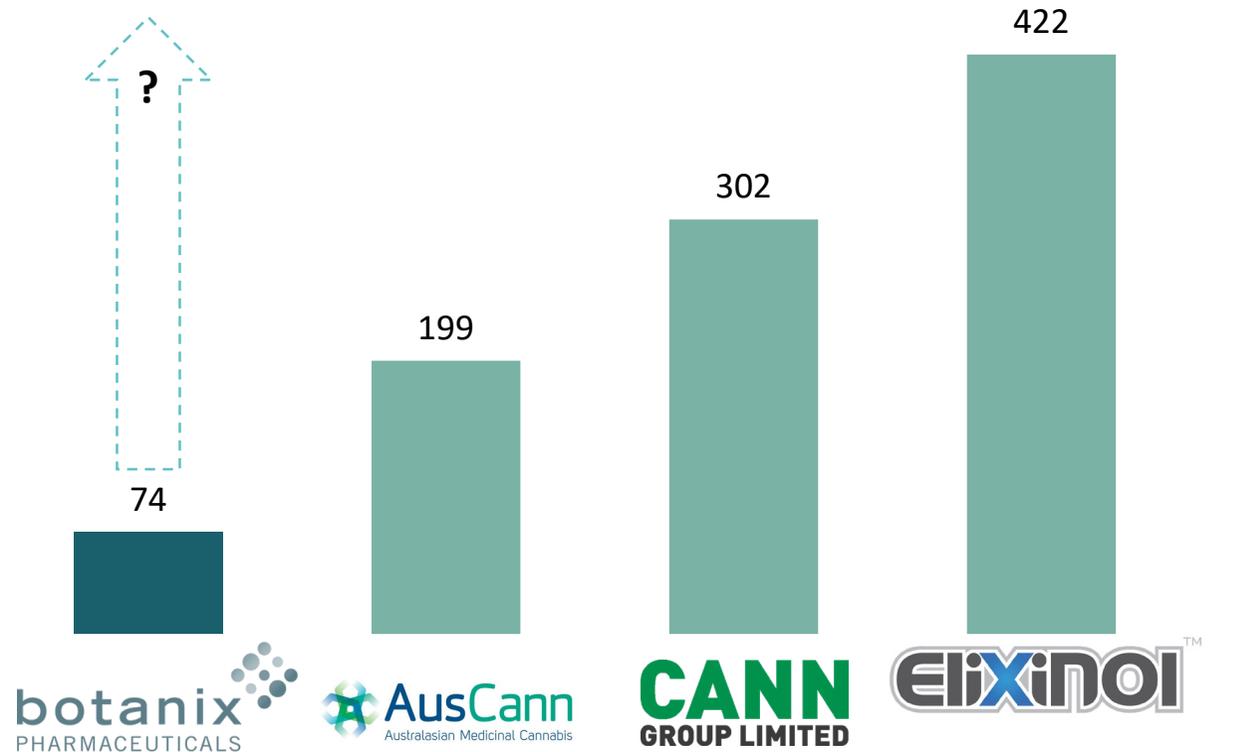
# Botanix has significant upside...

Botanix's focus on high value pharmaceuticals, with de-risked late stage studies underway, underpins its significant upside potential against cannabis-related ASX companies

## Botanix's key differentiating factors

- **Already generated positive clinical data** in dermatology indications, representing multi-billion dollar opportunities
- Targeting markets with **no new alternatives in 15 to 20 years**
- **Most advanced and broadest clinical program globally**, with two assets completing Phase 2 trials and another asset finishing Phase 1b
- **Unrivalled track record** of pharmaceutical development team
- Fully synthetic drug active approach, **avoids FDA issues and challenges** with botanical extracts

## Significant potential value upside (A\$m)<sup>1</sup>



1. Bloomberg

# ...compared to other dermatology companies in Phase 2 studies...

Botanix appears to be undervalued relative to comparable stage dermatology companies, with two Phase 2 trials underway targeting indications with significant addressable markets

## Value of Botanix relative to other dermatology companies whilst undergoing Phase 2 clinical trials (prior to data release)

| Company  | Market cap ranges while completing Phase 2 trials (A\$m) <sup>1</sup>                          | Key indications (Phase 2 or beyond)  | Duration                      |
|--|--|--|-------------------------------|
|    | 51  132      | Acne<br>Atopic dermatitis  | May-18 to Jan-19              |
|    | 265  726      | Psoriasis (and pruritus)   | Jul-17 to Dec-18 <sup>2</sup> |
|    | 360  737      | Hyperhidrosis (2b)<br>Acne (2a)  | Oct-14 to Feb-15 <sup>2</sup> |
|  | 862  1,198 | Chronic pruritus <sup>3</sup><br>Prurigo nodularis <sup>4</sup><br>Atopic dermatitis | Jan-18 to Apr-18 <sup>2</sup> |

1. Bloomberg (range based on minimum and maximum market cap during the duration of completing Phase 2 studies – based on closing prices) – note: US-listed companies market cap range converted to A\$ (USDAUD: 1.3786) for illustration purposes only
2. Company listed during the completion of respective Phase 2 trial, therefore market cap taken from IPO dates onward until release of respective Phase 2 results
3. Completed Phase 2 clinical trials prior to IPO
4. Undergoing Phase 3 clinical trials prior to IPO; targets rare disease with relatively small market size

# ...with significant re-rating potential if data continues to be positive

Botanix has one of the most advanced cannabidiol clinical programs globally, with potential for a significant value re-rating following multiple positive clinical study outcomes



## Lead products: BTX 1503 + BTX 1204

Both Phase II; targeting acne and atopic dermatitis

Target population: 100m patients p.a.<sup>2</sup>

Revenue potential: >US\$1.5bn p.a.<sup>3</sup>

## CBD source: Synthetic (100% pure)

Manufactured at industrial scale, facilitates relatively lower COGS

## Pipeline products:

Late stage development with published efficacy data and targeting multiple markets larger than lead products (psoriasis and antimicrobial markets worth >US\$20bn p.a.)

## Market cap (US\$m)<sup>1</sup>

US\$4.2bn

US\$54m



## Lead product: Epidiolex®

FDA Approved for Lennox-Gastaut / Dravet epilepsy

Target population: 43k patients p.a.<sup>4</sup>

Revenue potential: >US\$822m p.a.<sup>5</sup>

## CBD source: Naturally extracted

Manufacturing scale up and quality variation challenges leads to relatively higher COGS

## Pipeline products:

Focused on same epilepsy markets as Epidiolex® (product cannibalisation risk) or niche markets; in early clinical development with limited efficacy data published to date

Significant opportunity for value re-rating following successful results

1. Bloomberg (US\$)

2. GBI Research. Dermatology Therapeutics Market to 2018; American Academy of Dermatology; British Journal of Dermatology; Expert Review of Dermatology.

3. Symphony Health Solutions PHAST

4. Scrip (2018) Gottlieb: Epidiolex Approval Covers One Specific Cannabidiol Medication, Not Marijuana.

5. Datamonitor Healthcare's Forecast: Epilepsy, July 2017

# Small, but very experienced team

Global team with proven experience in dermatology and a track record of securing drug approvals



**Mr Matthew Callahan**

Founder + Board Executive Director



*Corporate + IP*

- Developed **4 products to date that have received FDA approval**
- Ex-investment director of 2 venture capital firms in life sciences
- Serial entrepreneur with extensive product development and launch experience



**Dr Michael Thurn**

Head Australian Operations



*Operations + Regulatory*

- Extensive start up life sciences experience across dermatology and US clinical trials
- **Previous MD of Spinifex Pharmaceuticals, which sold to Novartis for A\$700m**



**Dr Stephane Levy**

Chief Medical Officer



*Medical + Clinical*

- **Ex-CMO of global dermatology company Almirall and Vice President at Sanofi and Novartis**
- Broad commercial and clinical development experience



**Mr Jack Lawler**

VP Development



*Development + Clinical*

- **20 years clinical trial and development experience**
- Most recently VP at Egalet Corporation and Director at Viropharma (Shire)



**Dr Bill Bosch**

Board Executive Director



*Manufacturing + IP*

- **8 FDA approved products and inventor of the iCeutica SoluMatrix Technology**
- Founder of NanoSystems and co-inventor of drug delivery technology NanoCrystal



**Dr Judith Plon**

VP Regulatory Affairs



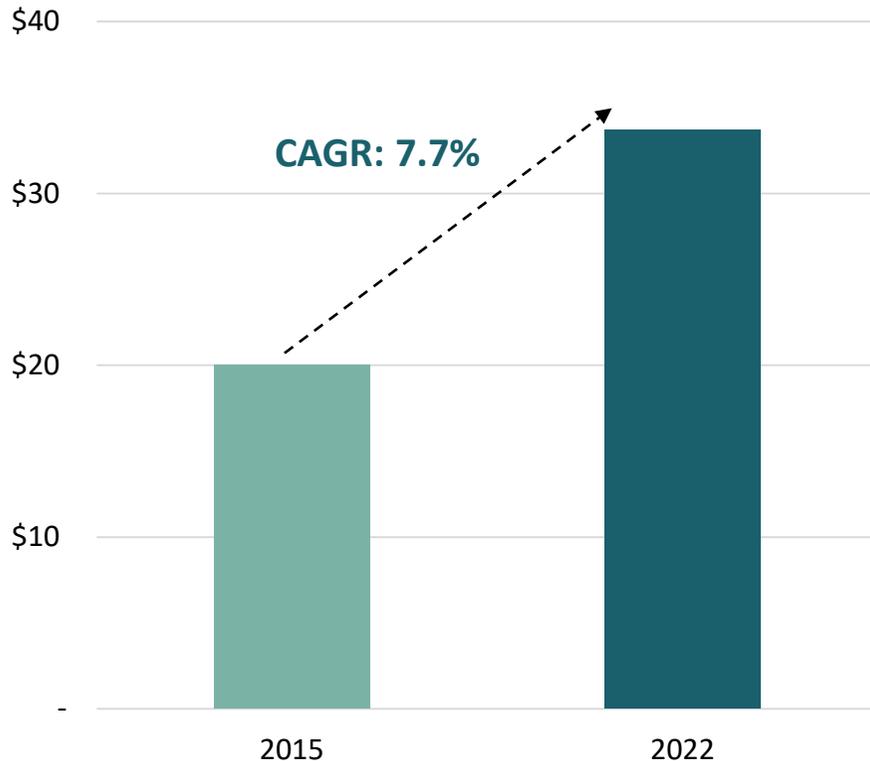
*Regulatory*

- **30 years regulatory experience with multiple FDA approved dermatology products**
- Ex-AVP Global Regulatory Affairs at Sanofi

# Broader dermatology market overview – many more opportunities

Global dermatology market expected to continue grow to US\$33.7bn by 2022<sup>1</sup> and pipeline of new products remains very thin

## Global dermatology market (US\$bn)



- **More than 3,000 types of dermatological conditions exist**, ranging in severity and clinical presentation
- Approximately **one third of the US population suffers** from an active skin condition
- The global dermatology market is estimated to be **worth US\$33.7bn by 2022**, representing an increase of >65% from 2015
- **Significant unmet medical need** for treatment options that:
  - Are effective via multiple pathways
  - Have improved safety/tolerability profiles
  - Allow for long-term use, especially in kids

1. *Koncept Market Research: Dermatology Market 2018*

# The next wave is pharmaceuticals...

Significant investment in the sector is now focused on products, particularly novel pharmaceutical products with attractive market opportunities



**thepharmaletter**  
\* Up to date news for the Pharmaceutical and Biotechnology industries

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## Pharma investing millions of dollars to develop medical marijuana products

### Big Pharma Getting in Bed with Cannabis: Tilray Deal with Sandoz (Novartis) Goes Global

#### Cannabis Sector Investment Thesis

Companies that pursue robust evidence for the *clinical* use of cannabis will distinguish themselves not only in *clinical* and *medical* applications of cannabis, but also in forthcoming *adult-use (recreational)* cannabis markets. With evidence from gold-standard clinical trials comes **physician adoption**, and with physician adoption comes **Pharma buy-in**: the gateway to a >US\$2T global Pharmaceutical market.

## Real Money

HOME DAILY DIARY ASSET CLASS SECTOR LATEST STREET NOTES AUTHORS

### The New Small Biotechs Heating Up the Medical Cannabis Space

These companies are working to plant their flag in a new landscape.

By **DEBRA BORCHARDT** + FOLLOW Jan 25, 2019 | 11:00 AM EST

### Generating Clinical Data Will Win in Medical Market

#### Cannabis Sector Investment Thesis

Companies that pursue robust evidence for the *clinical* use of cannabis will distinguish themselves not only in *clinical* and *medical* applications of cannabis, but also in forthcoming *adult-use (recreational)* cannabis markets. With evidence from gold-standard clinical trials comes **physician adoption**, and with physician adoption comes **Pharma buy-in**: the gateway to a >US\$2T global Pharmaceutical market.



## Marijuana Stocks Just Got a Boost from JPMorgan

By **Bill Alpert** Jan. 2, 2019 12:37 p.m. ET



# Forbes

## Want Safer Bets When Investing In Cannabis? Invest In Beer And Pharmaceutical Companies

**Mike Adams** Contributor  
Vices  
I cover various facets of the cannabis culture.



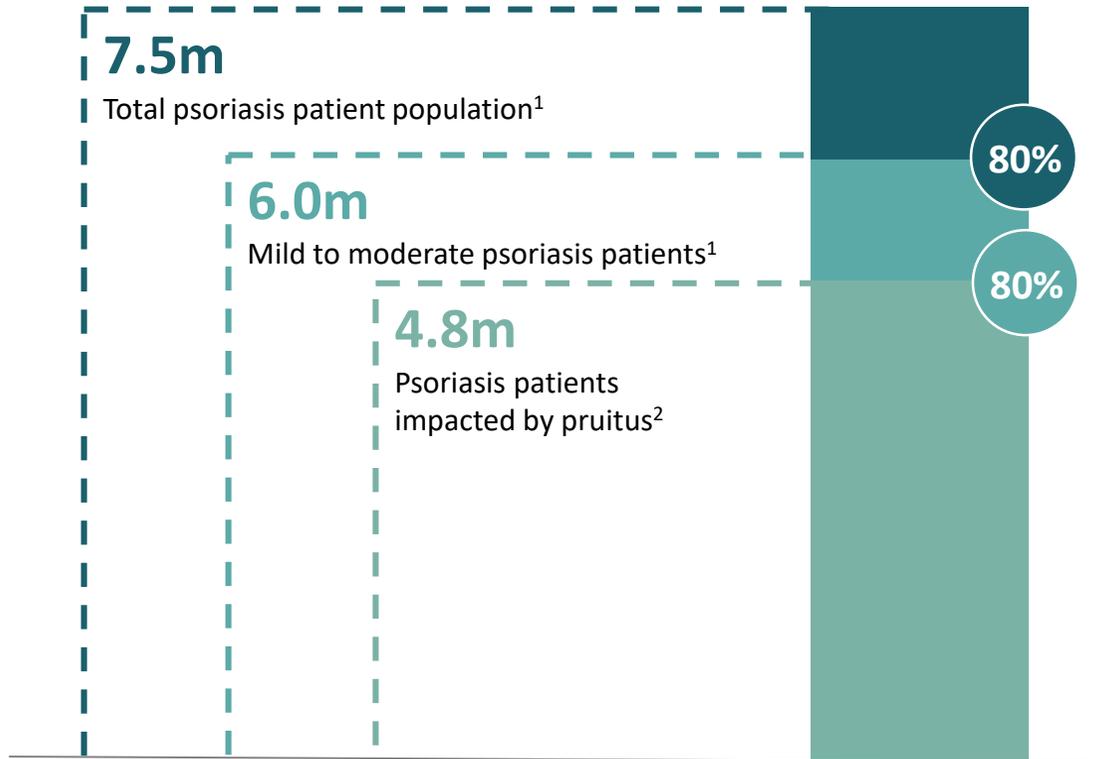
## Clinical pipeline

- BTX 1308: psoriasis
- BTX 1503: acne
- BTX 1204: atopic dermatitis



# Psoriasis – market opportunity

Despite the introduction of biologic injections for severe psoriasis, significant opportunity exists for mild to moderate patients and particularly those patients with pruritus (itch)



**US\$500-950/month**

Price range for 60-gram tube of current topical psoriasis therapies<sup>3</sup>

Additional opportunity for other indications and/or populations, including other inflammatory diseases

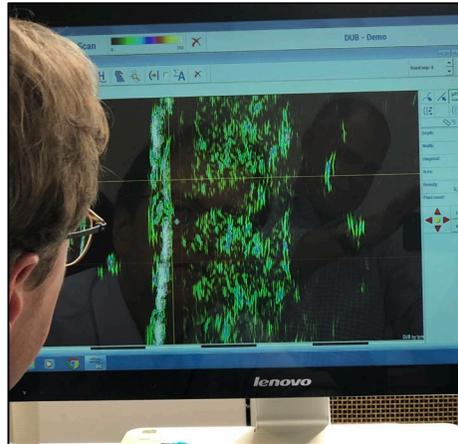
1. American Academy of Dermatology. *Skin conditions by the numbers*. Accessed November 2018.
2. Pruritus in Chronic Plaque Psoriasis. G Stinco. *Acta Dermatovenerol Croat*. 2014;22(2):122-8.
3. Includes Protopic, Elidel, Enstilar, Taclonex, Dovonex and Calcitriol

# Near term study completion – BTX 1308 for psoriasis

Phase 1b patient study is testing BTX 1308 against placebo (vehicle) and a widely used psoriasis drug in parallel

## Bioskin GmbH psoriasis plaque model<sup>1</sup>

*Novel multi-drug comparison study format in the same patient, provides high quality data on BTX 1308 efficacy*



- ✓ Multiple drugs can be studied on the same patient to check for comparative effect
- ✓ Includes measurement of change in height of the lesion confirmed by objective ultrasound
- ✓ Biopsies of each drug zone and also healthy skin data will elucidate the mechanism of action
- ✓ For the first time, biopsy data will define the anti-inflammatory, skin cell and immune modulation activity

Study de-risks psoriasis indication, as well as provides solid scientific support for broader mechanisms of action of cannabidiol in acne and atopic dermatitis

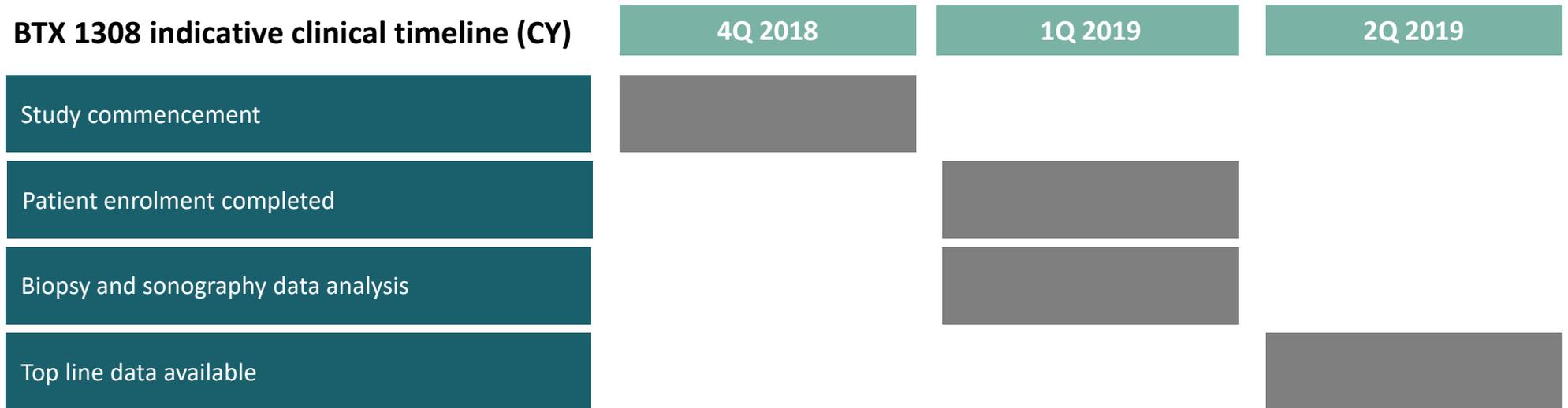
1. Bioskin GmbH psoriasis plaque model, multiple drugs can be studied on the same patient to check for comparative effect, including measurement of change in height of the lesion measured by ultrasound (sonography)

# Psoriasis study due for completion late 1Q CY2019

Study mostly enrolled with data planned to be available early in 2Q CY2019

- Fully funded study
- Successful data provides opportunity for corporate partnering
- Biological mechanism of action data from biopsies taken during study will support psoriasis and other programs

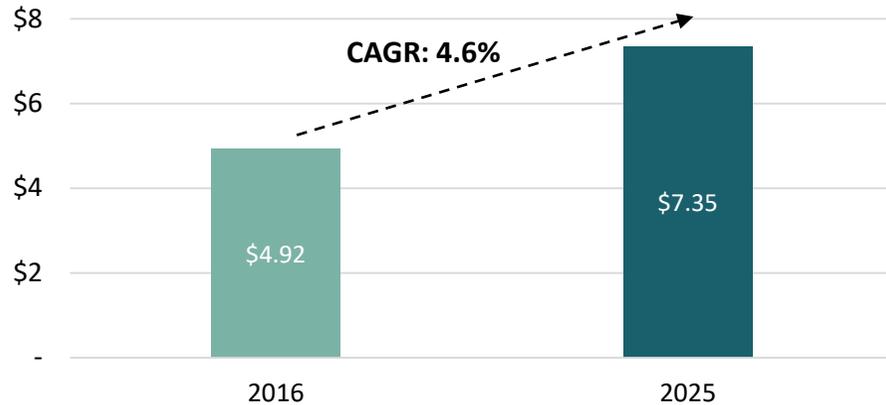
## BTX 1308 indicative clinical timeline (CY)



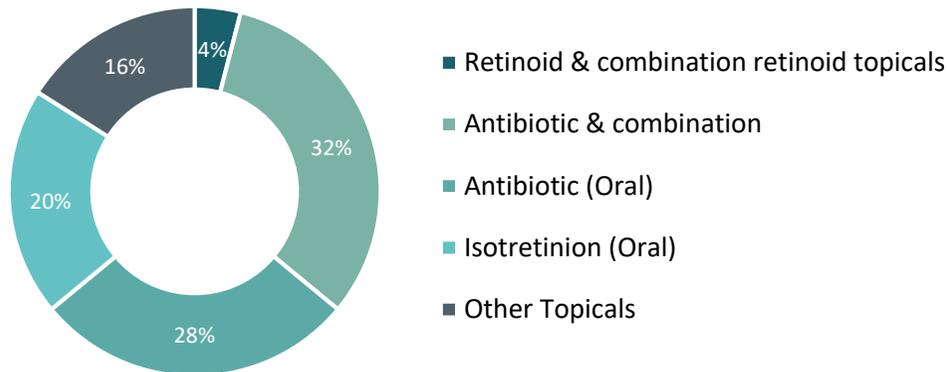
# Global acne market continues to grow

More than US\$5bn of acne products are sold each year with no new drugs approved to treat acne by FDA in more than 20 years

## Global acne market size (US\$bn)



## US acne market by therapeutic class (%)



Source: Persistence Market Research; TechNavio Global Acne Drug Markets 2016-2022; IMS Health

## Global acne market is projected to reach ~US\$7.3bn in 2025

- Key drivers: disease population growth and increasing prescription population
- Market size is largely attributable to the Americas (~90% market share in 2016)

## For moderate to severe acne, topical retinoids are the most commonly prescribed therapeutic class

- Accounts for ~32% of the US market
- Single active topical retinoid market ~US\$850m with 5m prescriptions p.a.

## Innovation in the acne market has been limited

- No new drugs approved in the US since Tazorac® (Allergan) in 1997

# Botanix's acne target market share exceeds US\$1.5bn p.a.

Competitive products with less ideal safety profiles and potentially poorer efficacy generate more than US\$1.5bn per annum between them in revenue

## Top oral brands

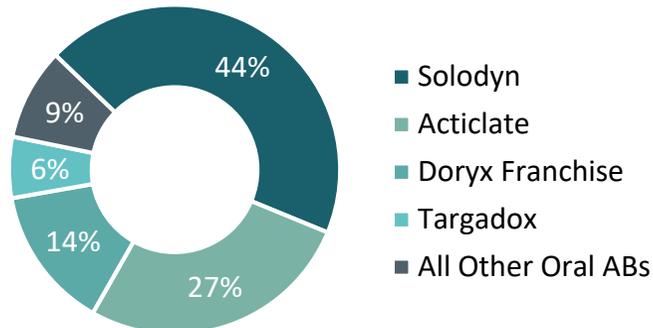
| Rank | Brands                                       | Revenue (US\$m) <sup>1</sup> | Scripts ('000) |
|------|--|------------------------------|----------------|
| 1    | <b>SOLODYN</b><br>Minocycline, Valeant       | \$492                        | 434            |
| 2    | <b>ACTICLATE</b><br>Doxycycline, Almirall    | \$234                        | 261            |
| 3    | <b>DORYX FRANCHISE</b><br>Doxycycline, Mayne | \$65                         | 132            |
| 4    | <b>TARGADOX</b><br>Doxycycline, Journey      | \$40                         | 63             |

## Top topical brands

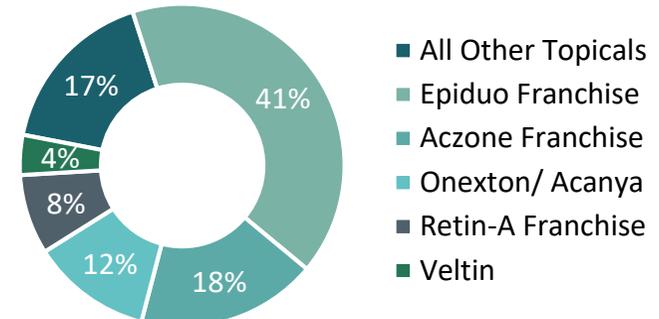
| Rank | Brands   | Revenue (US\$m) <sup>1</sup> | Scripts ('000) |
|------|--|------------------------------|----------------|
| 1    | <b>EPIDUO FRANCHISE</b><br>Adapalene+BPO, Galderma | \$659                        | 1,431          |
| 2    | <b>ACZONE FRANCHISE</b><br>Dapsone, Allergan       | \$298                        | 625            |
| 3    | <b>RETIN-A FRANCHISE</b><br>Tretinoin, Valeant     | \$219                        | 304            |
| 4    | <b>ONEXTON/ACANYA</b><br>Clindamycin+BPO, Valeant  | \$200                        | 410            |
| 5    | <b>VELTIN</b><br>Clindamycin+tretinoin, Almirall   | \$79                         | 151            |

Target  
market  
share  
>US\$1.5bn

## Prescription market share oral brands<sup>2</sup>



## Prescription market share topical brands<sup>2</sup>



Source: Symphony Health Solutions PHAST (accessed 1.2018)

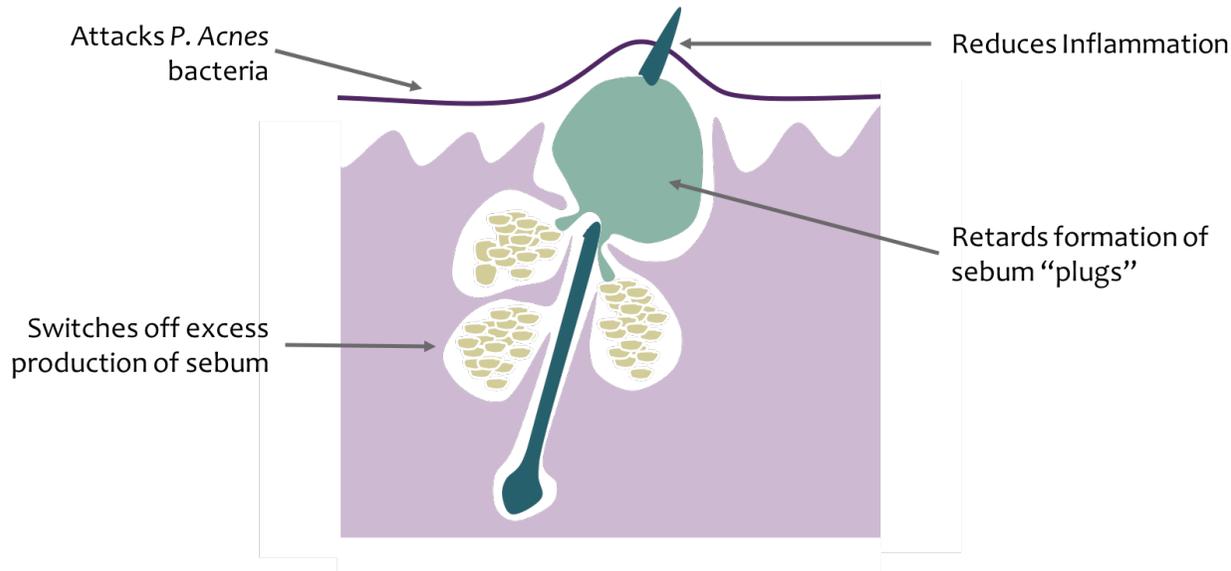
1. US \$ represent SHS metric (TRx MBS) or dollarized prescriptions

2. Market shares of the oral branded prescription acne drug market and the topical branded prescription acne drug market according to the total number of prescriptions

## Novel mechanism of action is proving out in studies

BTX 1503 is a safe and well tolerated topical treatment that addresses all of the 3 causes of acne (current topical treatments only treat inflammation or bacterial infection)

**BTX 1503 addresses acne pathologies in a CB1 and CB2 receptor independent manner<sup>1</sup>**



### Cannabidiol has been shown to...

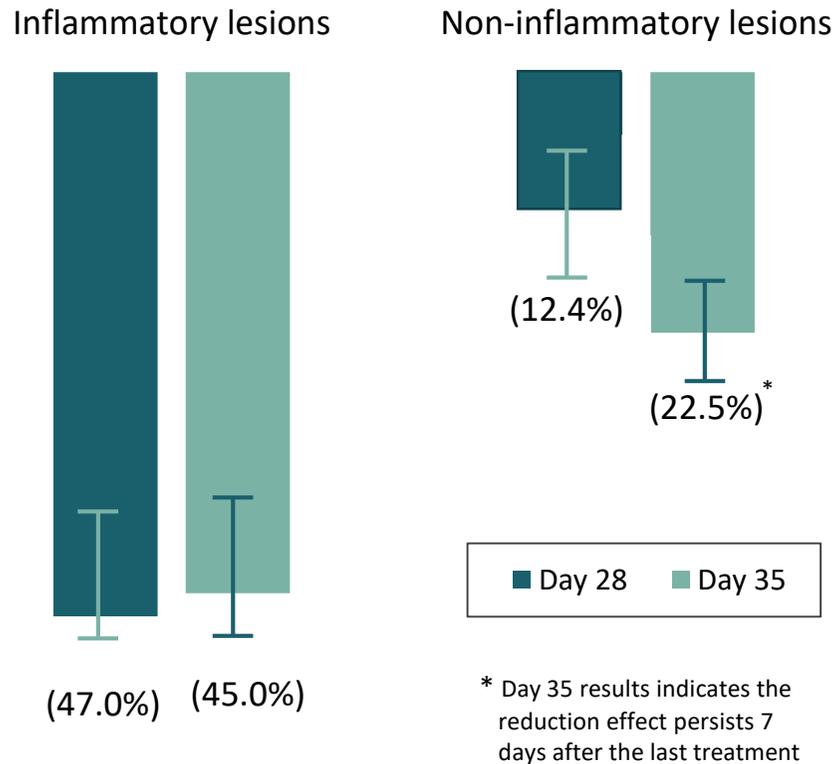
- ✓ Have anti-inflammatory effects on human sebocytes and to suppress sebocyte proliferation<sup>2</sup>
- ✓ Have potent anti-microbial activity against gram-positive bacteria<sup>3</sup>
- ✓ Inhibit human keratinocyte proliferation, through a non CB1/CB2 mechanism<sup>4</sup>

1. Rocha & Bagatin *Acne Vulgaris: an Inflammatory Disease Even Before the Onset of Clinical Lesions (2014). Inflammation and Allergy – Drug Targets June 13(3)*
2. Olah et al. *J Clin Invest. 2014;124(9):3713-3724*
3. Appendino et al. *J Natl Prod. 2008;71:1427-1430*
4. Wilkinson & Williamson. *J Derm Sci. 2007;45:87-92*

# Clinical data shows BTX 1503 outperforms leading acne products

4 week Phase 1b study data shows a marked reduction in inflammatory lesions, greater than any other FDA approved topical acne product<sup>1</sup>

## Lesion count reduction (%)



## Comparison with other FDA approved products

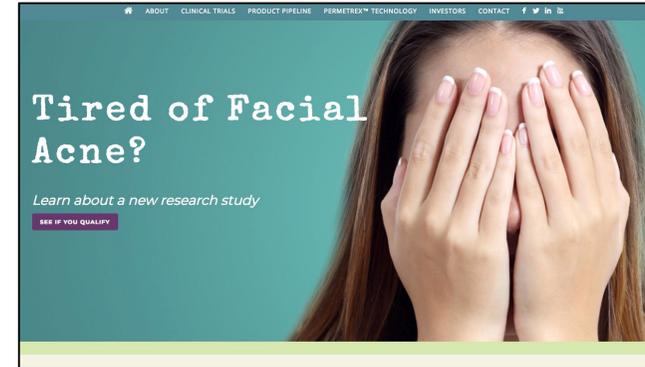
| Product  | Owner  | Lesion count reduction (%) <sup>2</sup> | 2017 annual revenue <sup>3</sup> |
|--|--|---|----------------------------------|
|  Epiduo <sup>®</sup>  | Galderma   | ~42%                                    | US\$659m                         |
|  | <ul style="list-style-type: none"> <li>✓ Combination of two drugs – benzoyl peroxide and adapalene</li> <li>✗ Common side effects include redness, skin peeling mild burning / stinging and dryness</li> </ul>                   |   |                                  |
|  Aczone <sup>®</sup> | Allergan   | ~38%                                    | US\$298m                         |
|  | <ul style="list-style-type: none"> <li>✓ Few side effects</li> <li>✗ Studies showed large placebo / vehicle effect – i.e. at 12 weeks Aczone reduced inflammatory lesions by 54% while vehicle achieved 48% reduction</li> </ul> |   |                                  |
| <b>BTX 1503</b>  | <b>Botanix</b>   | <b>~47%</b>                             | <b>-</b>                         |

1. Botanix data on file
2. Lesion count reduction based on average inflammatory lesion reduction at 4 weeks
3. Symphony Health solutions PHAST 2018

## Phase 2 patient study advancing on schedule

All sites are active and recruiting patients, with some Australian sites already reaching maximum recruitment numbers in early 1Q CY2019

- Fully funded study
- No safety issues arising from treated patients to date
- Positive feedback from dermatologists on study



### BTX 1503 indicative clinical timeline (CY)



# Atopic dermatitis – large unmet need for topical drugs

BTX 1204 addresses the need for a safe, non steroid topical option for chronic use with multiple mechanisms of action including anti-inflammatory, anti-microbial and immune modulating

## One of the most common skin diseases <sup>1</sup>

- 2% - 3% of adults
- 25% of children

## Large unmet needs across the atopic dermatitis population <sup>2</sup>

- Few safe and effective non-steroidal options suitable for chronic use
- New biologics address only the more severe populations – 75% of patients have mild to moderate disease <sup>3</sup>

## Paediatric population particularly has a need for a steroid alternative <sup>1</sup>

- Safety concerns with steroids are very high in the paediatric population (growth inhibition etc)

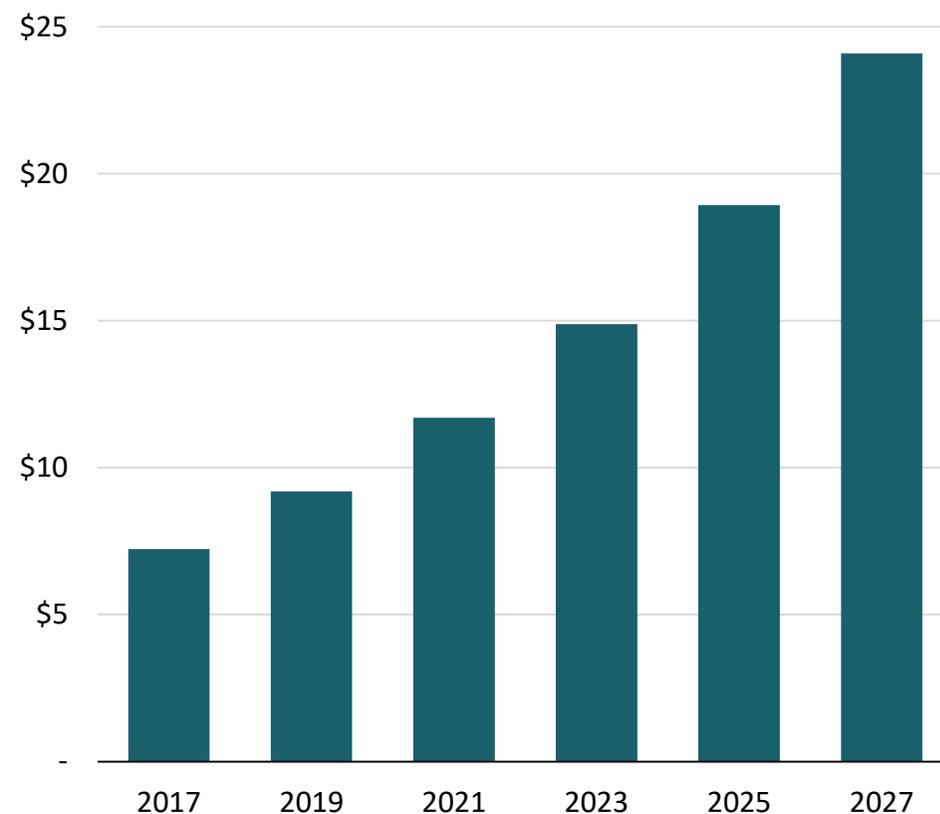
1. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al Guidelines of care for the management of atopic dermatitis, Section 1 diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol* 2014 Feb; 70(2):338-51.

2. Global Data. *Pharmapoint Atopic Dermatitis* Nov 2015.

3. Sanofi and Regneron Pharma. *Dupixent (dupilumab) injection 300mg. Full Prescribing Information.* Jan 2019.

4. *Symphony Health Services (PHAST) 2017*

## Projected AD market by revenue (US\$bn)<sup>4</sup>

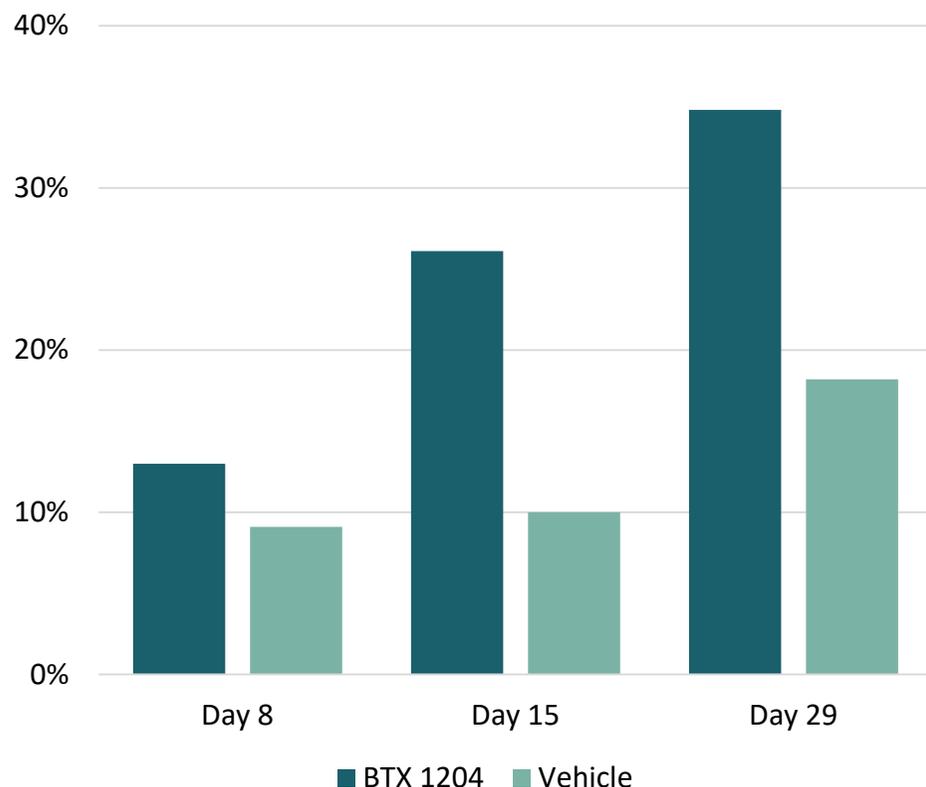




# Phase 1b study results support efficacy and safety potential

BTX 1204 was twice as effective as vehicle (with efficacy still increasing) and displayed a substantial improvement in the key signs of AD<sup>1</sup>

## Treatment success (%)<sup>2</sup>



### Efficacy still increasing at 4 week timepoint

- Achieved treatment success similar to many competitive topical products
- Data suggests longer treatment period for BTX 1204 possible for increased efficacy

### Clear separation from vehicle (placebo)

- Despite being a small study, BTX 1204 shows superiority over vehicle, starting at early time points

### Excellent safety profile

- Safety and tolerability established with no burning, stinging or application site adverse events
- BTX 1204 profile allows extended dosing which remains a key challenge with most available therapies

1. Botanix data on file. Results indicated substantial reduction in key signs of AD, providing confidence that unmet needs in AD can be addressed

2. Treatment success defined as a greater than, or equal to, a 4 point improvement in the signs and symptoms of AD

## BTX 1204: atopic dermatitis – Phase 2 study design

12 week randomised, double-blind, vehicle controlled study to evaluate the safety and efficacy of BTX 1204 in patients with moderate AD

### Design

- 2 dose groups: ~200 subjects
  - BTX 1204: ~100 subjects
  - Vehicle/Control: ~100 subjects
- ~25 US and Australian dermatology sites
- Children (> 12 years) and adults
- Moderate AD patients
- Treatment period of 12 weeks

### Endpoints

- **Primary endpoint**
  - Proportion of subjects with ISGA success defined as an ISGA score of “Clear” (0) or “Almost Clear” (1) with at least a 2 grade improvement from Baseline at Week 12
- **Secondary endpoints**
  - Change from Baseline in the Signs of AD
  - % body surface area (BSA) affected by AD
  - Time to achieve IGA success
- **Safety**
  - Adverse events and local tolerability



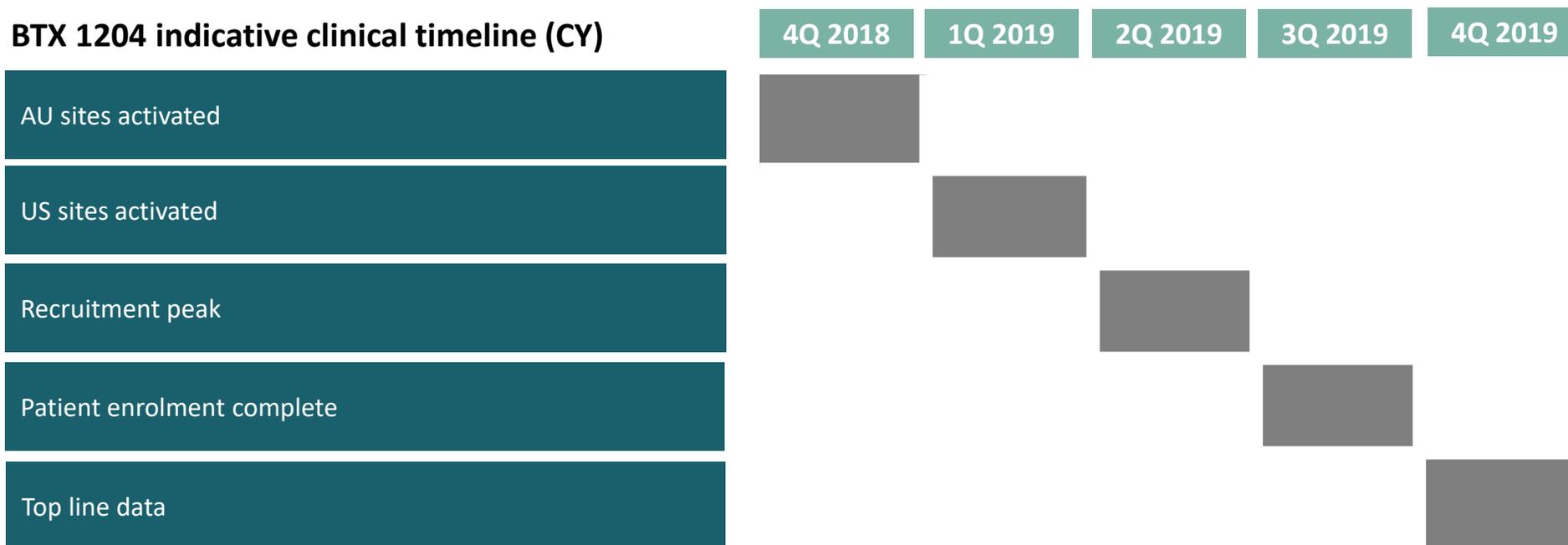
✓ First patients in 4Q CY2018 – fully funded

## BTX 1204: atopic dermatitis – Phase 2 study underway

Phase 2 study commenced in late 4Q CY2018 and targeting top line data in 4Q CY2019

- Program leverages existing data from BTX 1503 acne studies, lowering regulatory and safety hurdles
- Common DEA licensed dermatology clinics from BTX 1503 acne Phase 2 study, reduces cost and start-up timing

### BTX 1204 indicative clinical timeline (CY)



## Development pipeline

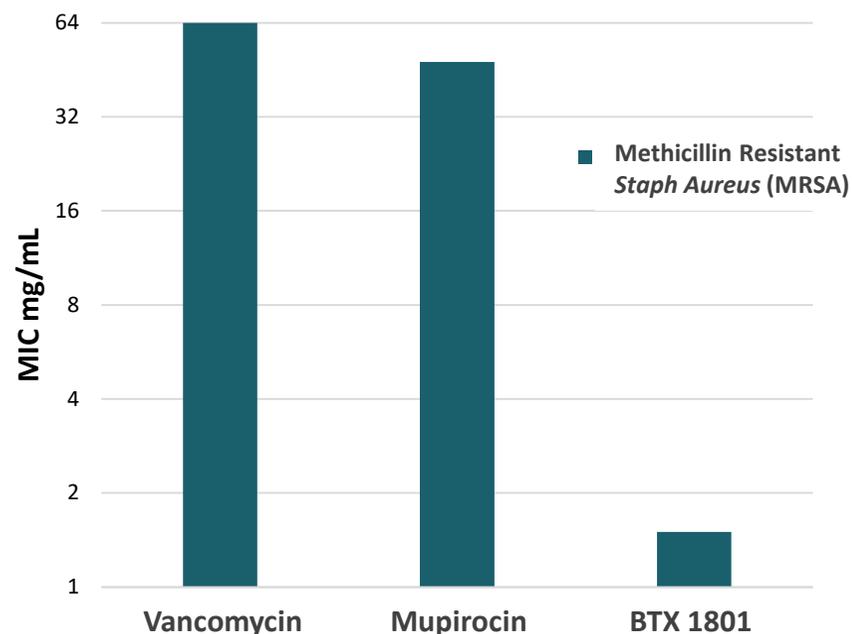
- BTX 1801: antimicrobial



# BTX 1801: novel antimicrobial for serious skin diseases

Natural potential of cannabinoids is enhanced by delivery with Permetrex™ technology

## Minimum Inhibitory Concentration (MIC) effect of BTX 1801 against industry standard antibiotics<sup>1</sup>



The lower the MIC – the more effective the drug is at killing the target bacteria and the less drug is required to have the desired effect

## BTX 1801 may have the following benefits

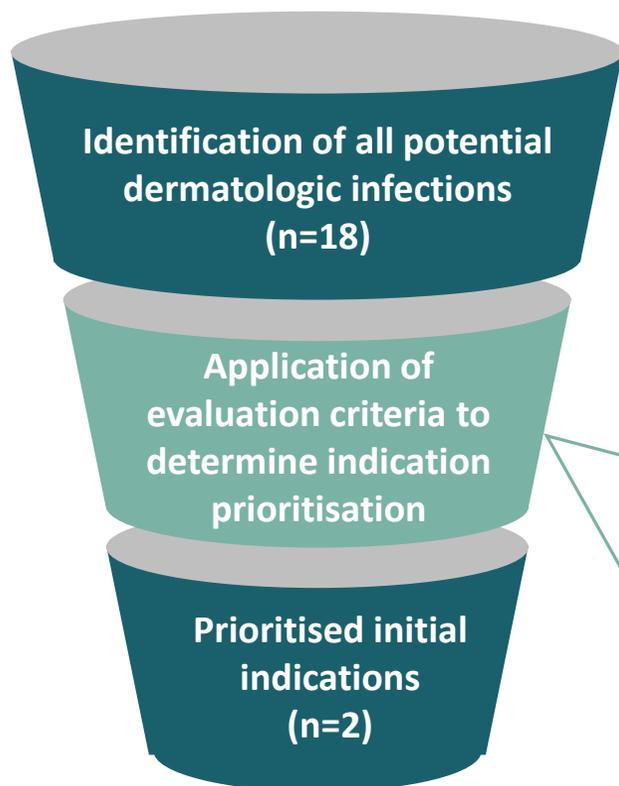
- ✓ Gram-positive bactericidal effect
- ✓ New mechanism of action
- ✓ Active against MRSA
- ✓ Topical application suited for skin infections
- ✓ Benign side effect profile based on previous clinical studies
- ✓ Ability to use long term
- ✓ Anti-inflammatory and skin barrier improvement properties
- ✓ Suitable for treatment of children (due to low toxicity)
- ✓ Prevent early use of IV antibiotics (significant side effects)

1. Vancomycin used to treat serious infections in many different parts of the body while Mupirocin used to treat certain skin infections

# BTX 1801 – market review complete for target indications

Review addressed the potential for BTX 1801 in a range of skin infections based on performance of the product, bacteria that can be effectively killed and competitive position of target indications

## Prioritisation of identified indications



### Guiding principles for prioritisation

Indications were assessed across a number of criteria to determine the applicability of BTX 1801 and their relative attractiveness as a pursuable indication.

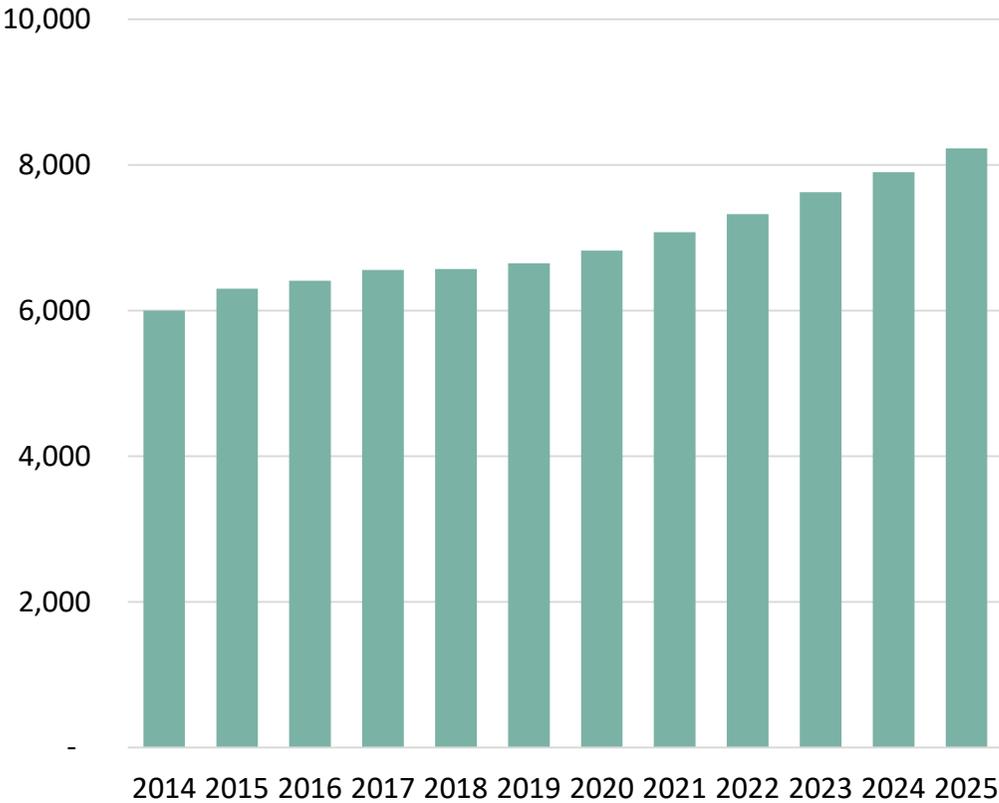
#### Criteria included:

| Criteria                         | Rationale  |
|----------------------------------|--|
| <b>Skin layer addressability</b> | <ul style="list-style-type: none"> <li>BTX 1801 can address infections impacting the epidermal and dermal skin layers</li> </ul>   |
| <b>Pathogen addressability</b>   | <ul style="list-style-type: none"> <li>Gram-positive infections were prioritised due to expectations for BTX 1801 efficacy within this group of pathogens</li> </ul>           |
| <b>Current standard of care</b>  | <ul style="list-style-type: none"> <li>Infections treated topically (as opposed to systemically) were prioritized</li> </ul>   |
| <b>Level of unmet need</b>       | <ul style="list-style-type: none"> <li>Physicians' perceived level of unmet need (e.g. rate of bacterial resistance) associated with each indication was considered</li> </ul> |
| <b>Disease epidemiology</b>      | <ul style="list-style-type: none"> <li>The overall incidence of each indication was considered to determine potential market size</li> </ul>                                   |

# Market for skin infections exceeds US\$6.5bn per annum

The market for skin infection drugs continues to increase with the challenges of resistance driving the price of more effective products higher

## Skin infection drugs market forecast 2014-2025 (US\$m)



- Skin infections are the most common healthcare-associated infection (HAIs) **accounting for 31% of all HAIs among hospitalised patients**
- **MRSA accounts for ~59% of skin and soft tissue infections (SSTIs)** presenting to the emergency department
- It is estimated that patients with a diagnosis of SSTIs face **prolonged hospital stays, treatment-associated risks, and potential long-term adverse outcomes, as well as a 2–11 fold increase in mortality risks**



Source: Visiongain 2015 Dermatological Drugs Market Forecast 2014-2025

## First two targets - for impetigo and bacterial folliculitis

Impetigo and bacterial folliculitis are two of the most common skin infections caused by *Staph Aureus* bacteria, where bacterial resistance to antibiotics is a growing problem

### Impetigo



- Common skin infection in children (school sores)
- Highly contagious, results in rupturable red sores
- Caused by *Staph Aureus* and *MRSA* bacteria
- Approximately 162m children each year suffer from Impetigo
  - 45% of Australian aboriginal children
- **Market size ~US\$446m<sup>1</sup>**

### Bacterial Folliculitis



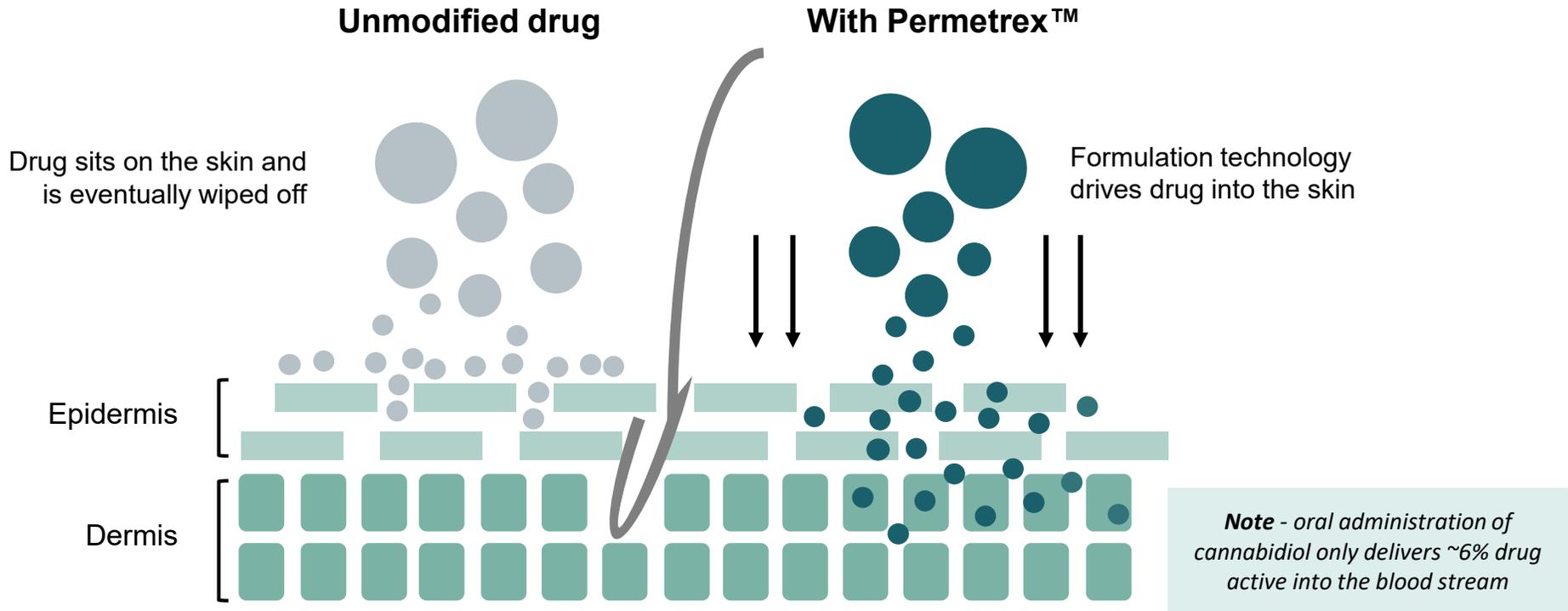
- Common skin infection involving inflammation of the hair follicle and pustules that may erupt
- Caused by *Staph Aureus* and *MRSA* bacteria
- Approximately 3m cases in the US alone
  - Incidence in people of African descent estimated to be up to 45%
- **Market size estimated to be ~US\$561m by 2023<sup>2</sup>**

1. Technavio Global Impetigo Treatment Market 2019-2023.

2. Folliculitis Market Rapidly Growing in Healthcare, Competitor Analysis, Complete Study of Current Trends and Forecast 2018-2023

# Permetrex™ skin delivery technology

Proprietary Permetrex™ technology delivers high doses of drug into the layers of the skin without use of permeation enhancers, preservatives, or irritating levels of alcohol / petrolatum additives

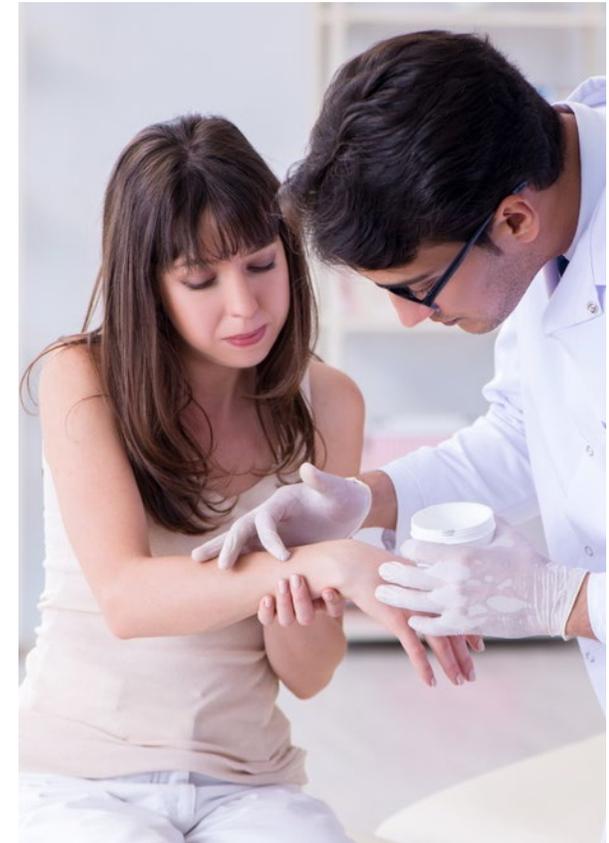
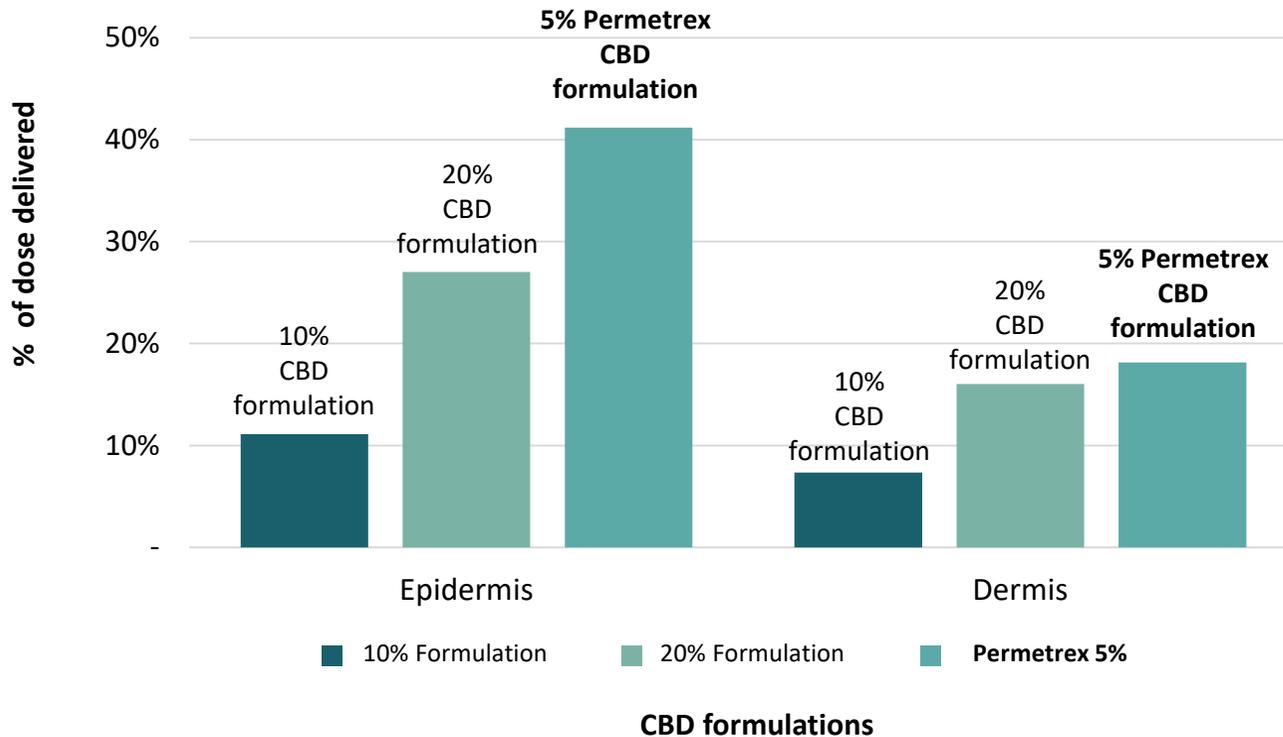


Botanix holds the exclusive rights to utilise Permetrex™ for all drugs that treat skin diseases

# Permetrex™ technology enables superior delivery of cannabidiol (CBD)

Permetrex™ delivers more CBD into the target layers of the skin, even though the CBD concentration of the BTX 1503 formulation is only 25% to 50% the concentration of alternative formulations

Cannabidiol (CBD) percentage delivery (%)<sup>1</sup>



1. Botanix data on file

## Outlook

- CY2019 - Transformative year



# Key catalysts

Significant clinical and operational milestones across multiple programs expected over the next 12 months

| Indicative activities and milestones |   | 1Q CY2019 | 2Q CY2019 | 3Q CY2019 | 4Q CY2019 | Upcoming milestones                      |
|--------------------------------------|---|-----------|-----------|-----------|-----------|--|
| <b>BTX 1308</b><br>Psoriasis         | Phase 1b study in psoriasis patients                  |           |           |           |           | <i>Top line data early 2Q CY2019</i>     |
| <b>BTX 1503</b><br>Acne              | Phase 2 multi-centre acne clinical study              |           |           |           |           | <i>Recruitment complete in 2Q CY2019</i> |
| <b>BTX 1204</b><br>Atopic dermatitis | Phase 2 multi-centre atopic dermatitis clinical study |           |           |           |           | <i>Recruitment complete in 3Q CY2019</i> |
| <b>BTX 1801</b><br>Antimicrobial     | Pre-clinical development                              |           |           |           |           | <i>Patient study design 2Q CY2019</i>    |
| <b>Permetrex™ collaborations</b>     | Research collaborations and partnership discussions   |           |           |           |           | <i>Ongoing studies with partners</i>     |



RESTORING HEALTHY SKIN

## Contact us

### Matt Callahan

Botanix Pharmaceuticals

Founder and Board Executive Director

P: +1 215 767 4184

E: [mcallahan@botanixpharma.com](mailto:mcallahan@botanixpharma.com)

### Visit us

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

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Botanix Pharmaceuticals Limited (ASX:BOT)

