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Advancing new treatments for skin disease and infection



# Investor Presentation

October 2021

# Botanix Pharmaceuticals: a leader in topical drug development

Clinical stage dermatology company developing new treatments for common skin diseases and infection, leveraging its novel delivery technology Permetrex™



## Pharmaceutical focus

Leveraging novel skin delivery technology (Permetrex™) and novel drug mechanisms of action, including synthetic cannabidiol (CBD)



## Topically driven

Targeting key dermatology and antimicrobial indications with topical treatments that are safe, well tolerated and validated by clinical efficacy



## Significant markets

Pipeline targeting multi-billion dollar markets with no new products approved by FDA in decades for these indications, with physician and patient demand for new treatments



## World-class team

World-class and experienced team with significant dermatology and antimicrobial drug track record and development expertise



## Near-term catalysts

Multiple upcoming catalysts including completion of Phase 1b/2 rosacea study, commencement Phase 2 antimicrobial study, canine AD data readout and new Permetrex™ opportunities

# Botanix: World Class Board and Management team

## Board of Directors



**Vince Ippolito**

President and Executive Chairman

- ❖ COO of Anacor and Medicis with 17 years at Novartis
- ❖ More than 30 years experience in pharma with 20+ years within dermatology



**Matt Callahan**

Executive Director

- ❖ Serial founder and ex-investment director of two venture capital firms in life sciences
- ❖ Developed four products through FDA approval and launch



**Dr Bill Bosch**

Executive Director

- ❖ 20+ years experience in pharma industry
- ❖ Co-inventor of SoluMatrix™ drug delivery technology and NanoCrystal® Technology



**Dr Stewart Washer**

Director

- ❖ Currently a board member of Orthocell, Cynata Therapeutics and Emyria
- ❖ 20+ years of experience in medical tech, biotech and agrifood

## Executive Management & Advisers

**Dr Clarence Young**

Chief Medical Officer

- ❖ Recently Chief Medical Officer at Veliccept Therapeutics
- ❖ Senior leadership roles at Iroko Pharmaceuticals, Novartis and GlaxoSmithKline

**Anthony Robinson**

VP of Development

- ❖ Recently Vice President at Advicenne
- ❖ Senior leadership roles at Aquestive Therapeutics, Intromune and Shire Pharmaceuticals

**Lynda Berne**

Head of Commercial

- ❖ Founder of BAL Pharma Consulting
- ❖ 13 years senior leadership roles in pharmaceuticals industry

**Dr Jack Hoblitzell**

SVP Pharmaceutical Development

- ❖ 30+ years leading world-class technical operations to manufacture and deliver pharmaceuticals
- ❖ Senior leadership roles at Assertio Therapeutics, Pfizer, King, Ivax and Teva

**Dr Ira Lawrence**

Advisor

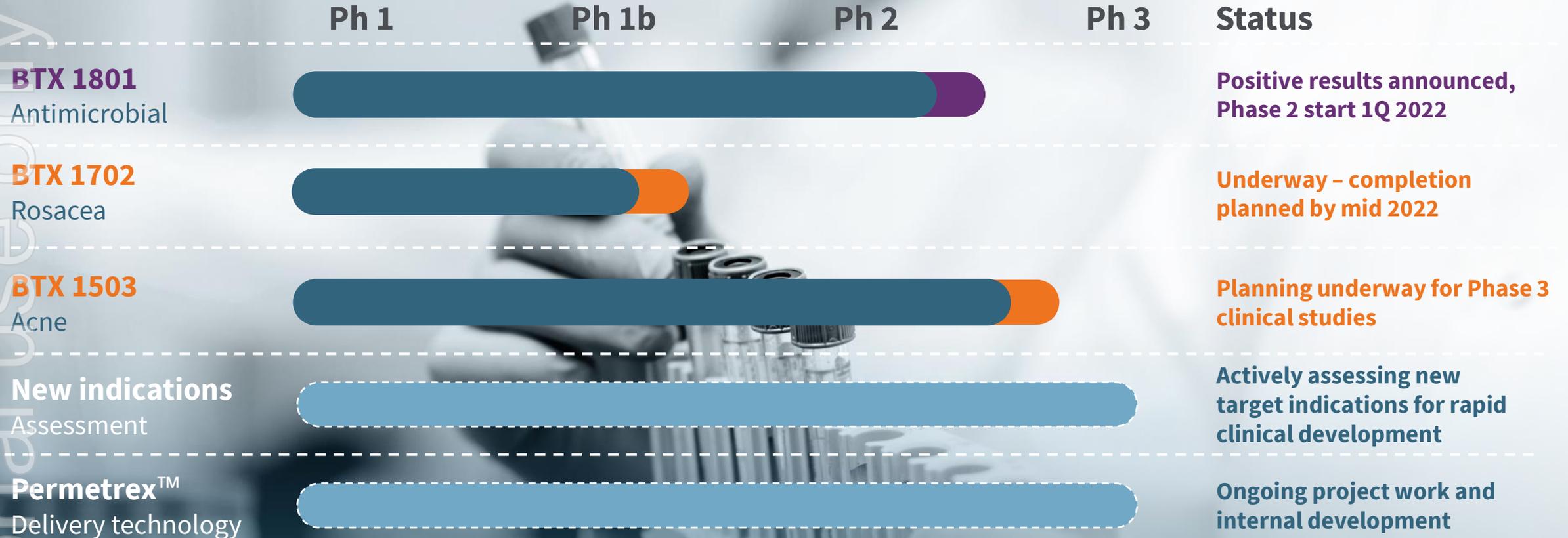
- ❖ 30+ years of senior level leadership experience within the global pharmaceutical and medical device industries

# Synthetic cannabinoids are well suited to treat skin diseases and infections

Botanix's studies show synthetic CBD to:<sup>1</sup>

- ✓ Be safe and well tolerated
- ✓ Have broad anti-inflammatory properties
- ✓ Have a strong and consistent impact on skin lesions
- ✓ Have anti-microbial properties – kills *Staph aureus*<sup>2</sup>
- ✓ Have potential for widespread use across human and animal health
- ✓ Have anti-inflammatory and anti-microbial properties important for dermatology conditions including acne, rosacea and dermatitis

# Advanced late-stage pipeline

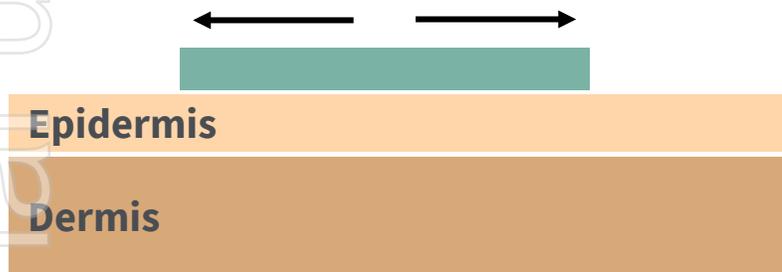


# Permetrex™: skin delivery technology fuels pipeline potential

Unique in delivering high doses of drug into the layers of the skin without using permeation enhancers, preservatives, or irritating levels of alcohol / petroleum derivatives

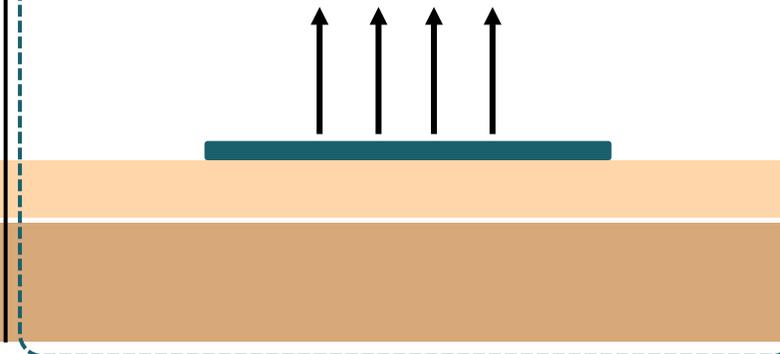
## 1. Initial application

Target drug is incorporated in Permetrex™ formulation which spreads easily over skin surface



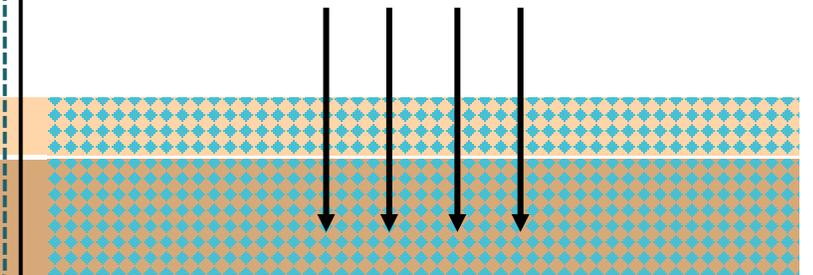
## 2. Evaporation of solvent

Volatile majority of formulation evaporates – leaving a minority of highly concentrated drug solution on the skin surface



## 3. Delivery into the skin

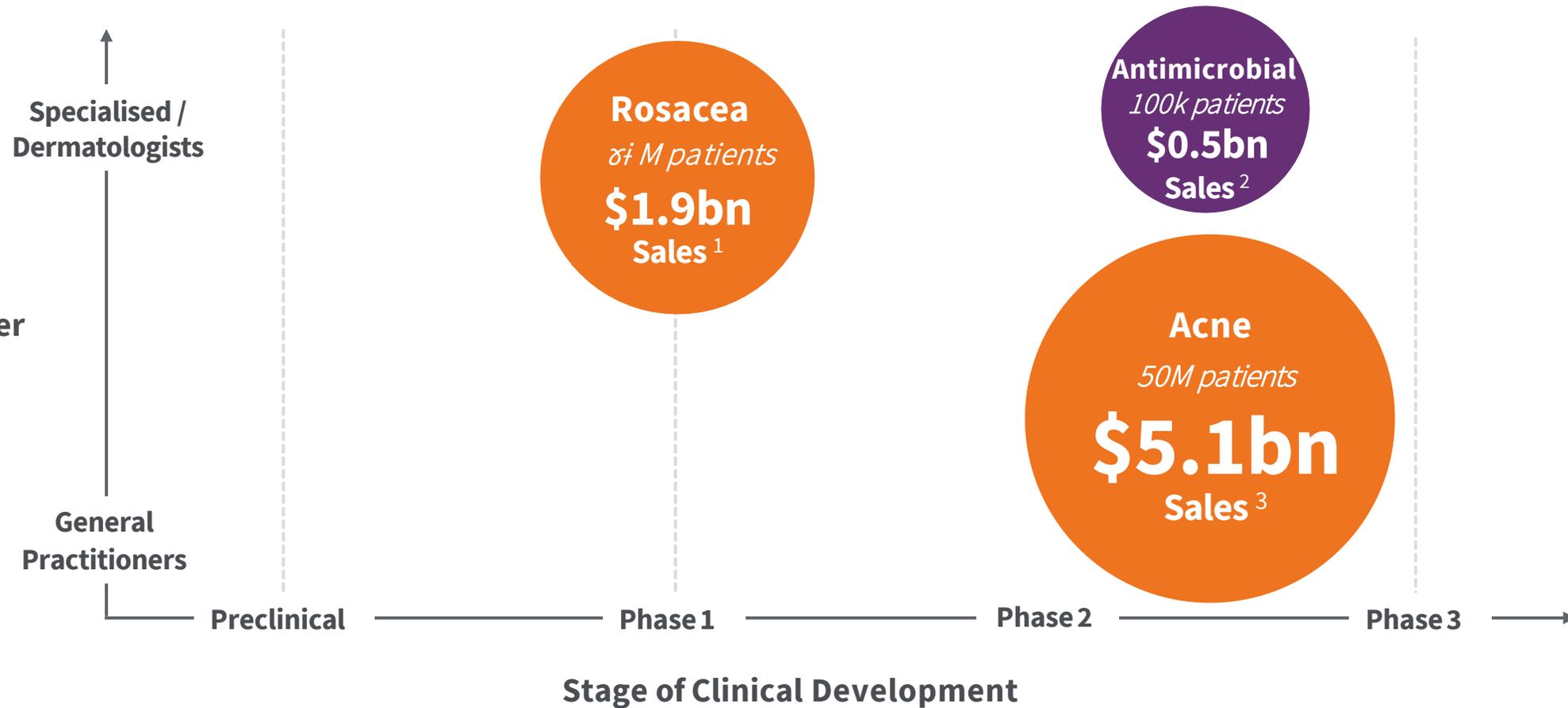
Rapid change in concentration of drug as result of evaporation, drives drug into the skin and is designed not to leave excess excipients on the surface



**Permetrex™ is used in Botanix's pipeline products and improves delivery for other drugs in development<sup>1</sup>**

# Target markets with significant annual revenues & unmet needs

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1. Grandview Research. [www.Grandview\\_research.com](http://www.Grandview_research.com)  
 2. Using GSK Bactroban Nasal Pricing/BTX 1801 pricing to be developed following analyses of potential impact on healthcare system; assumes 5% YOY pricing following product approval/launch  
 3. Symphony Health Solutions, METYS, data ending December 2019 – weighted

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# Dermatology programs



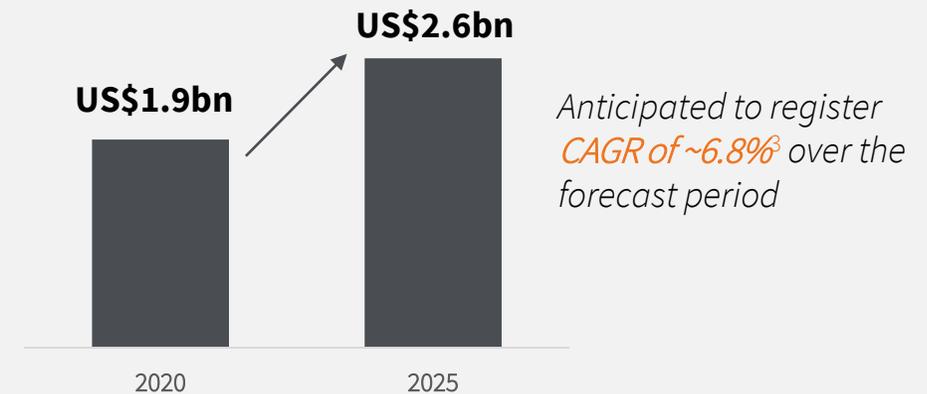
# BTX 1702: high impact of rosacea on patients and significant market opportunity

❖ Papulopustular rosacea is a highly visible **chronic skin disease** characterised by **redness (inflammation) and acne-like-break-outs**<sup>1</sup>

❖ Patients diagnosed with Rosacea tend to have higher incidences<sup>2</sup> of:

- Depression
- Social anxiety
- Embarrassment
- Decreased quality of life

A rapidly growing market: Rosacea market projected to grow to US\$2.6bn by 2025<sup>3</sup>



- ❖ Affects ~5.5% of the global population<sup>4</sup>, ~430m individuals, women are more likely to be affected than men
- ❖ 85% of patients are > 30 years old<sup>5</sup>
- ❖ Currently over 16m Americans affected<sup>6</sup> by rosacea, with ~5m medical treatment prescriptions<sup>7</sup> in the US alone
- ❖ Active treatment seekers looking for new solution to rosacea

# BTX 1702: Rosacea Phase 1b/2 study is underway

Improved data capture design with dose ranging over 8 week treatment period



- ❖ Study designed to enable increased data capture & provide insights to support broader dermatology program
- ❖ All sites using **Canfield imaging technology** supporting clinical assessment, tracking & analysis
- ❖ Recruitment going to plan, despite COVID restrictions

## ❖ **Four dose groups, ~120 patients:**

- BTX 1702 high dose - twice daily: 40 patients
- BTX 1702 low dose - twice daily: 40 patients
- Vehicle - twice daily: 40 patients

## ❖ **Sites:** ~15 dermatology sites across Australia and NZ

## ❖ **Patients:** adults (18+ years) with moderate to severe papulopustular rosacea

## ❖ **Treatment period:** 8 weeks

## ❖ **Endpoints:**

- Safety and tolerability
- Change in inflammatory lesion counts from baseline at days 15, 29 and 57
- Proportion of patients with Investigator's Global Assessment (IGA) treatment success
- Change in Clinician's Erythema Assessment (CEA) scale
- Imaging and patient reported outcomes

# BTX 1503: Acne in preparation for Phase 3 and future filing

Successful End-of-Phase 2 FDA meeting and completion of Rosacea BTX 1702 study (with higher dosing and enhanced data capture) will inform final design for P3 Acne study

## Study update

- ✓ End of Phase 2 meeting with FDA successfully completed, supported by overall efficacy and safety, and significance of Australian data on further analysis<sup>1</sup> in 2020 of late 2019 P2 study data<sup>2</sup>.
- ✓ FDA highlighted excellent safety profile of BTX 1503, allowing several waivers for studies typically required for dermatology drug registration
- ✓ Co-primary efficacy endpoints<sup>3</sup> agreed for Phase 3
- ✓ Important milestone providing clarification on activity to move forward
- ✓ Confirmed drug development plan to support filing and registration for treatment of moderate and severe acne
- ❖ Planning underway for Phase 3 clinical studies to be informed by completion of BTX 1702 Phase 1b/2 study

## Sizable acne prescription market



**22m** total prescriptions in 2019 growing ~5% year-on-year<sup>4</sup>



**US\$5.1bn** in sales in 2019<sup>4</sup>



**>2m** p.a. active, diagnosed acne patients under HCP care<sup>5</sup>



**~40m to ~50m** acne sufferers<sup>6</sup> (~10m mod-to-severe)



**60%** of acne patients are managed by 5,000 HCPs<sup>7</sup>

1. ASX 4 Mar 2020, Additional BTX 1503 data analysis 2. ASX 22 Oct 2019 BTX 1503 data and progression to Phase 3 3. Co-primary efficacy endpoints: (1) Absolute change from baseline in inflammatory and absolute change from baseline in non-inflammatory lesion at Week 12; (2) Proportion of patients with an Investigators Global Assessment (IGA) of "clear" or "almost clear" and at least a 2-grade improvement in IGA from baseline at Week 12

4. Symphony Health Solutions, METYS, data ending December 2019 – weighted; 5. Symphony Health Solutions, MAT, ending April 2019; 6. AAD. Acne Stats and Facts. <https://www.aad.org/media/stats-numbers>; 7. Symphony Health Solutions, IDV Vantage, February 2019

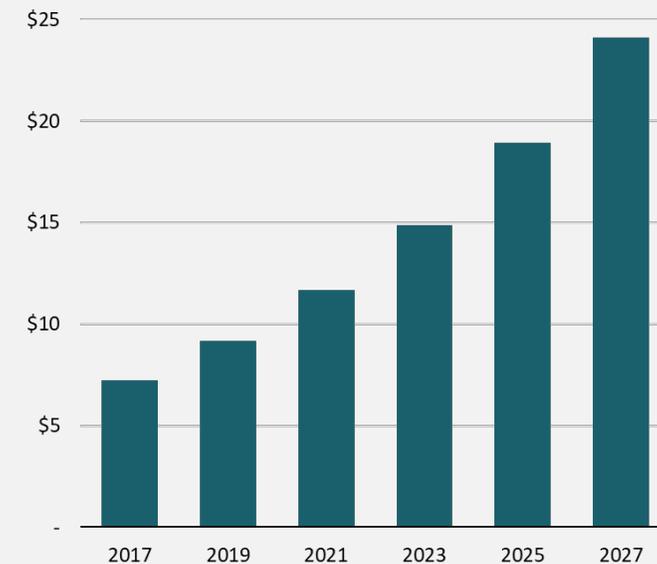
HCPs:: Healthcare Professionals

# BTX 1204A: Meeting need for safe, non-steroid for chronic use in Atopic Dermatitis



- ❖ Atopic dermatitis is one of the most common skin diseases<sup>1</sup>:
  - 2% - 3% of adults, 25% of children
  - 90% of patients are mild to moderate<sup>3</sup>
- ❖ Patients see flare-ups of itch, red inflamed rash and excessive dryness or scaling
- ❖ Significant unmet need with limited options for safe and effective treatment chronic disease, biologics are reserved for severe population
- ❖ Pediatric population needs tolerable steroid free alternative<sup>1</sup>

### Atopic Dermatitis Market (\$B)



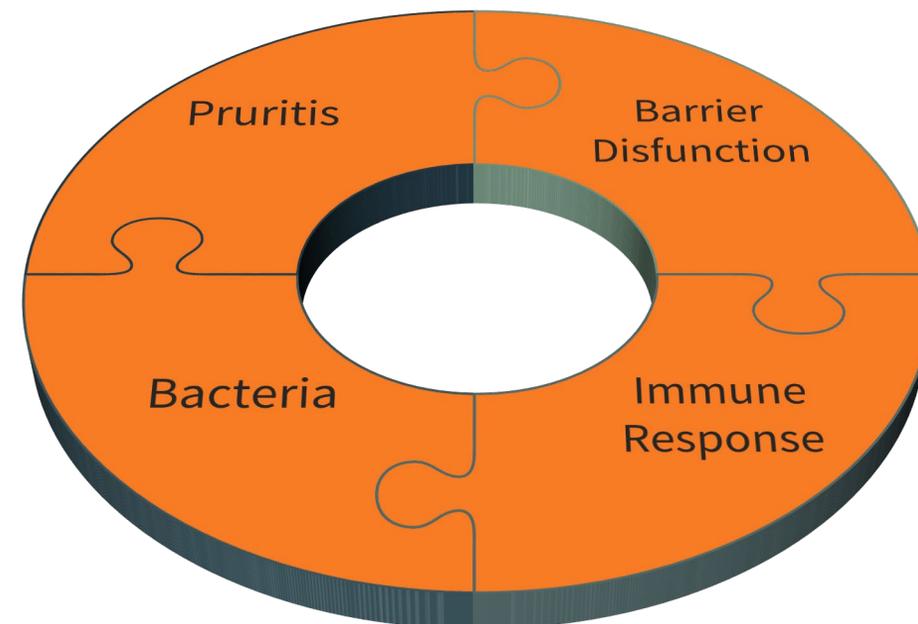
*Symphony Health Services (PHAST) 2017*

- ❖ Affects 20-25M Americans<sup>2,3</sup>
- ❖ Almost 85% cases present by the age of 5 years<sup>6</sup>
- ❖ Severe population is ~10% of patients

# Atopic dermatitis – chronic inflammatory disease for both canines and humans



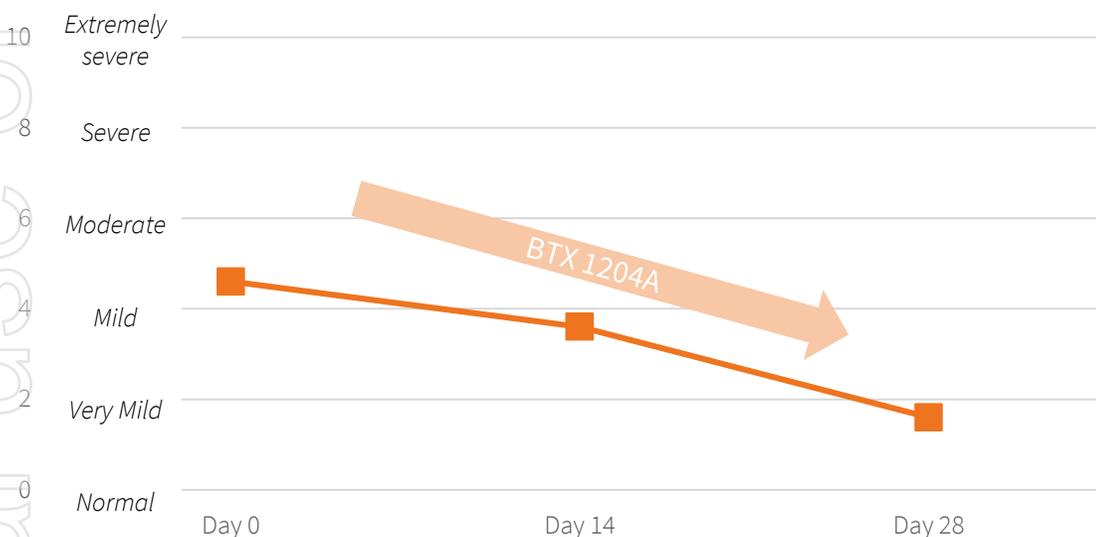
- ❖ Canines naturally and commonly develop a pruritic dermatitis that is clinically and immunologically extremely similar to human AD<sup>1</sup>
- ❖ Dogs and humans with AD also have similar problems with skin barrier function – these problems cause the skin to be very dry and prone to Staph Aureus infections<sup>2</sup>
- ❖ Canine models are increasingly used as screening tools for new therapeutic development, including dose ranging and safety assessments
- ❖ Canine studies are faster and more cost effective than human studies and help de-risk later stage studies



# BTX 1204A: Dermatitis data supports further development

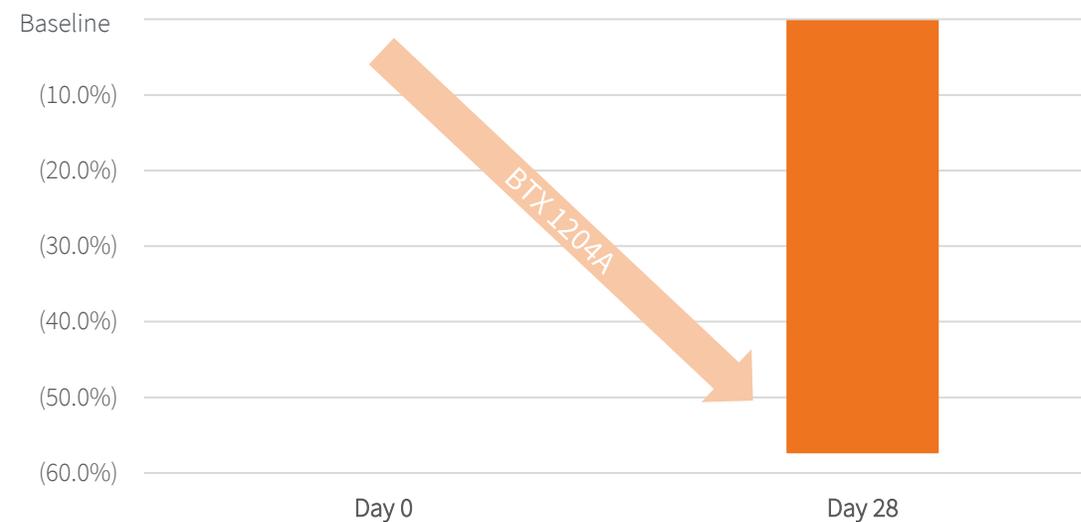
Pilot canine study with higher dose and novel Permatrex™ formulation showed reduction itch and lesions - dermatitis in canines and humans is clinically and immunologically very similar

BTX 1204A: Pruritus (itch) mean ESP scores <sup>1,2</sup>



BTX 1204A showed decrease in pruritus over a 28 day period, resulting in average pruritus rating of Very Mild (post-treatment)

BTX 1204A: % reduction from baseline (CADESI-04) <sup>1,3</sup>



BTX 1204A had positive effect, showing decrease in pruritus over a 28 day period, resulting in a ~57.3% reduction from baseline

# BTX 1204A: Atopic dermatitis development strategy

Larger POC canine study underway<sup>1</sup>, will inform licensing in animal health & potential re-launch of late-stage P2b clinical program in 2022

## Proof of Concept Canine Study Parameters

### ❖ Four dose groups, up to 45 dogs:

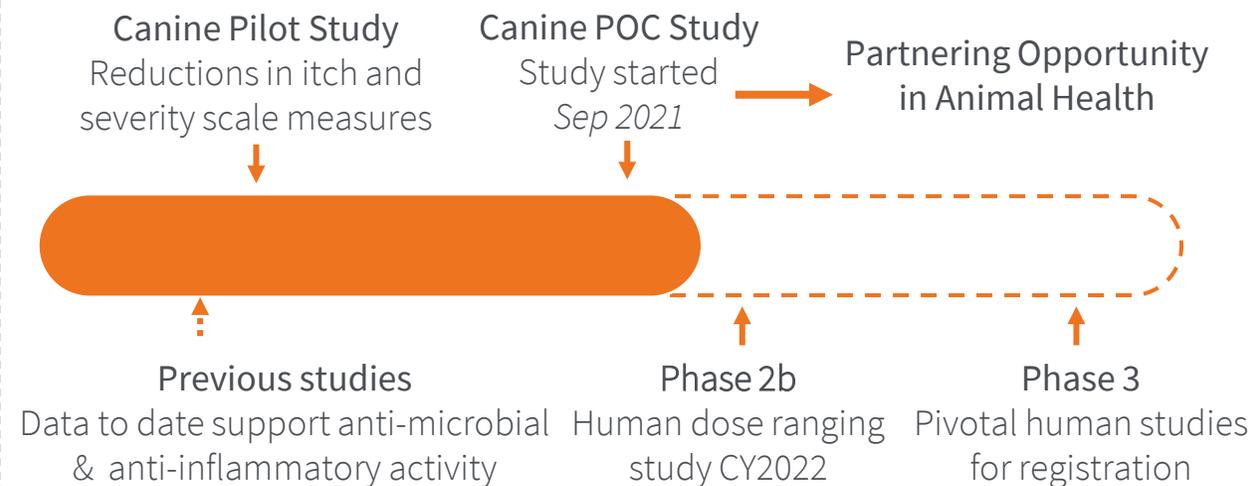
- BTX 1204A high dose: 15 dogs
- BTX 1204A low dose: 15 dogs
- Vehicle: 15 dogs

### ❖ Sites: 3 Australian sites

### ❖ Treatment period: Twice daily treatment for 28 days

### ❖ Endpoints: Treatment effectiveness using Enhanced Pruritus Score<sup>2</sup>; Canine Atopic Dermatitis Extent and Severity Scale Index<sup>3</sup>

## Planned pathway to approval



Successful outcome opens up partnering opportunity & supports progression to Phase 2b human study in atopic dermatitis.

# Anti-microbial development update

## BTX 1801

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# BTX 1801: Demonstrated clinical efficacy vs *S. aureus* in Phase 2a study



Staphylococcus aureus (*S. aureus* or 'staph') is a common bacterium that lives on skin and in nasal passages. It can cause skin infection and serious or life-threatening **blood stream infections**, pneumonia or bone and joint infections.



## Safety & tolerability

- ✓ Safe and generally well tolerated at doses of active drug up to 20%
- ✓ All 66 participants successfully completed the BTX 1801 study
- ✓ No severe adverse events reported<sup>1</sup>



## Efficacy

- ✓ Efficacy of ointment and gel formulations demonstrated for primary endpoint at Day 12
- ✓ Eradication rates as high as 76.2% at Day 7, with eradication effects extending through to Day 28, despite no treatment after Day 5

# BTX 1801: Haemodialysis patients with central venous catheters at risk of bloodstream infections



## Haemodialysis

- ❖ Replicates the functions of the kidneys in patients with kidney failure, by using a machine to filter and clean the blood



## Rationale for selection

- ❖ Infection is a leading cause of death with 20% to 40% of haemodialysis patients eventually dying from an infection<sup>1</sup>



## Significant health risks

- ❖ Risks for central venous catheter-related complications were as high as 30% and 38%, at 1 and 2 years respectively<sup>2</sup>
- ❖ Central venous catheter patients (approx. 160,000) make up more than 70% of blood infections in the dialysis population<sup>2</sup>

**11.8%**

of patients were readmitted within 12 weeks of hospitalisation related to Staph aureus infections<sup>1</sup>

**US\$734m**

Market for nasal decolonisation of haemodialysis patients at risk of blood stream infection by 2030<sup>3</sup>

**~US\$32k**

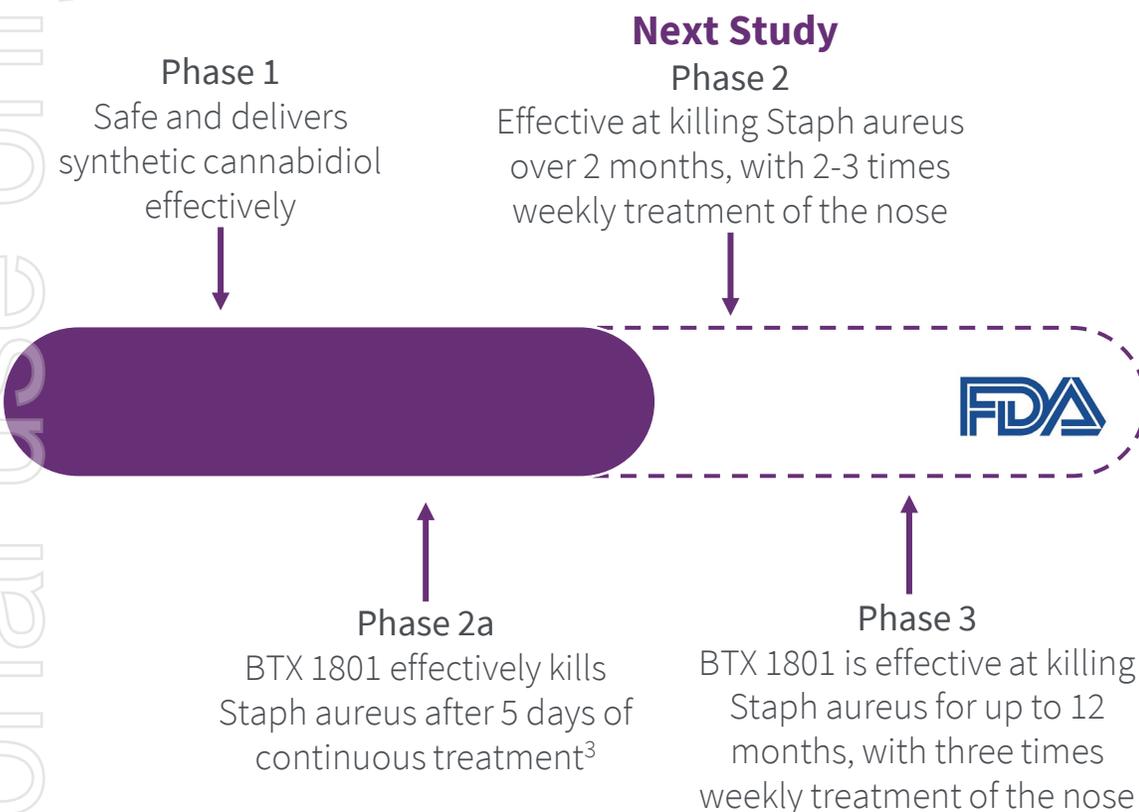
Mean cost (per episode) of treating Staph aureus blood stream infections, including re-admissions and outpatient costs<sup>1</sup>

**US\$1bn**

Estimated annual cost of treating bacteraemia in haemodialysis patients with central venous catheters<sup>2</sup>

# BTX 1801: Clinical development moving quickly to meet need

Targeting nasal decolonisation of Staph in patients undergoing haemodialysis to reduce incidence of life threatening blood stream infections



## FDA incentives provide accelerated development and increased market exclusivity

- QIDP<sup>1</sup> status**
  - ❖ Extra 5 years (total of 8 years) exclusivity from generic competition
  - ❖ Attractive economic benefits from FDA approval
- Fast track status**
  - ❖ Following IND submission, allows increased consultation with FDA
  - ❖ De-risks clinical trials and accelerates development pathway
- LPAD<sup>2</sup> status**
  - ❖ Allows smaller, fewer and / or shorter clinical trials for FDA approval



Botanix plans to apply for all three programs to accelerate development, reduce clinical costs and increase exclusivity

# Executing on key clinical milestones

- ❖ **Antimicrobial: BTX 1801 positive Phase 2a study results**  
*Positive results announced, further Phase 2 study start Q1 2022*
- ❖ **Rosacea: BTX 1702 Phase 1b study start**  
*Recruitment currently underway, target completion mid 2022*
- ❖ **Acne: BTX 1503 planning for Phase 3 clinical studies**  
*Pending completion BTX 1702 Phase 1b/2 study*
- ❖ **Dermatitis: BTX 1204A canine proof of concept study underway**  
*To inform potential animal health licensing and re-launch Phase 2b human study - data anticipated 1H 2022*
- ❖ **New indications and Permetrex™ opportunities**  
*Actively assessing new indications and opportunities for rapid clinical development*



# Botanix Pharmaceuticals: a leader in topical drug development

Clinical stage dermatology company developing new treatments for common skin diseases and infection leveraging its novel delivery technology Permetrex™



Developing novel skin delivery technology (Permetrex™) and novel mechanisms of action, including synthetic cannabidiol (CBD)



Late stage pipeline targeting dermatology and antimicrobial indications with topical treatments that are safe, well tolerated & clinically validated



Multi-billion dollar growth markets, with demand for new treatments and unmet needs.



Established IP position and protection



World-class , experienced team with significant track record and development expertise



Executing on pipeline across anti-microbial, rosacea, dermatitis and acne indications. Near term catalysts: Ph1b/2 Rosacea and Ph2 antimicrobial studies, new indications for rapid development

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