

8 December 2021

## Botanix Roadshow Presentation

### Key highlights

- **Botanix has released a corporate presentation being utilized for a non-deal roadshow with institutional investors this week, as well as a presentation at the Switzer Small and Micro Cap Virtual Investor Day taking place today**
- **Presentation updates on the progress of the BTX 1702 rosacea clinical study, with recruitment progressing well towards completion in mid 2022, as well as progress towards commencing the BTX 1801 Phase 2b antimicrobial study in early 2022 and completion of the BTX 1204A pilot study in canines with atopic dermatitis in 1H 2022**
- **Botanix remains in a strong financial position, holding cash balance of A\$19.57m at 30 September 2021**

**Philadelphia PA and Perth Australia, 8 December 2021:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or “the Company”), is pleased to release an updated corporate presentation as attached.

The presentation is being utilised as part of meetings with investors being conducted this week as well as a presentation at the Switzer Small and Micro Cap Virtual Investor Day. Botanix is in a strong financial position and so no capital raising is planned arising from these meetings.

Release authorised by

**Vince Ippolito**

President and Executive Chairman

### About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage dermatology company based in Perth (Australia) and Philadelphia (USA) committed to the development of pharmaceutical products that are underpinned by science and supported by well-controlled randomised clinical trials. The Company has two complimentary development platforms - dermatology and antimicrobial products - both of which currently leverage the unique anti-inflammatory, immune modulating and antimicrobial properties of cannabinoids, particularly synthetic cannabidiol or CBD. Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases, which it utilises in its existing development programs and is being explored with a view to being utilized in a number of other product opportunities.

The Company is developing a pipeline of product candidates with recent positive data from its BTX 1801 Phase 2a antimicrobial study and its Phase 1b/2a rosacea clinical study is currently enrolling patients. Following a successful meeting with the FDA, the Company has also confirmed a drug

development plan for the BTX 1503 acne Phase 3 program to support registration. In addition, Botanix is advancing its BTX 1204A atop dermatitis program to a proof of concept canine study, following encouraging early data from a recent pilot study. To learn more please visit: <http://www.botanixpharma.com/>

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**Cautionary Note on Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

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Advancing new treatments for skin disease and infection



# Investor Presentation

December 2021

# 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

# 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

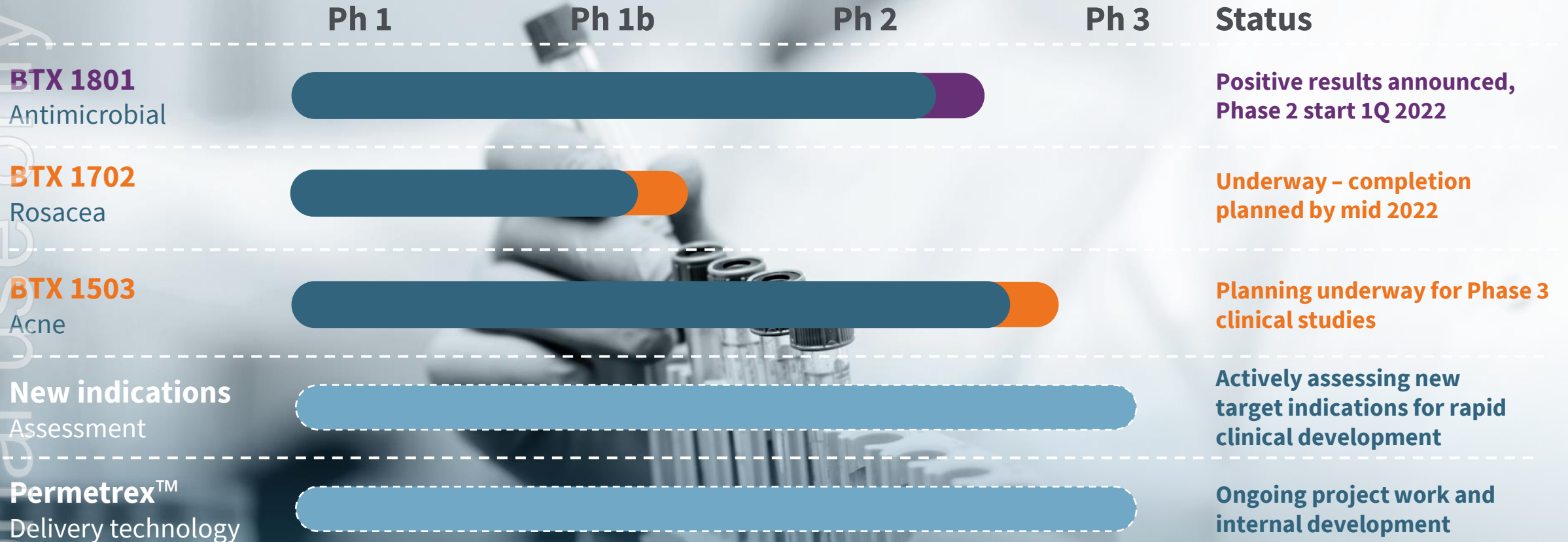
Multiple upcoming catalysts including completion of Phase 1b/2 rosacea study, commencement Phase 2 antimicrobial study, canine AD data readout and new Permetrex™ opportunities

# 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

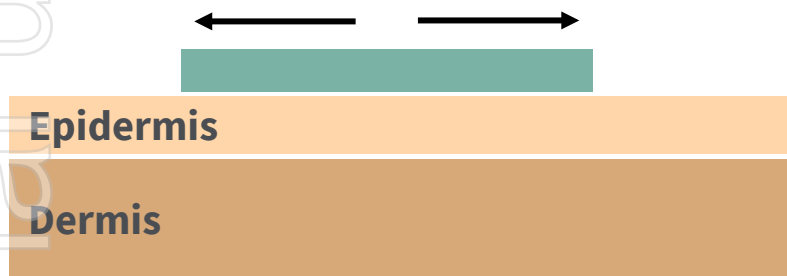


# Permetrex™: skin delivery technology fuels pipeline potential

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

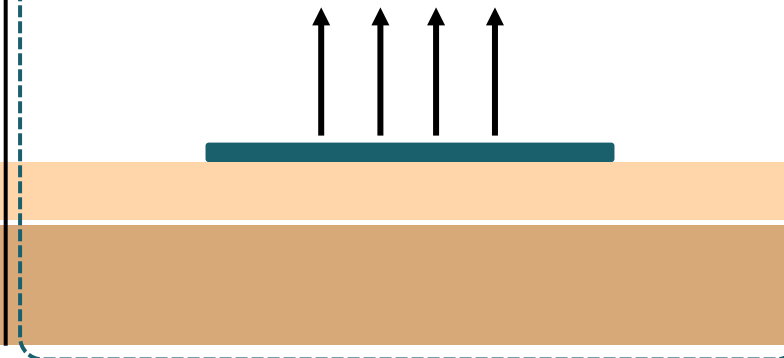
## 1. Initial application

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



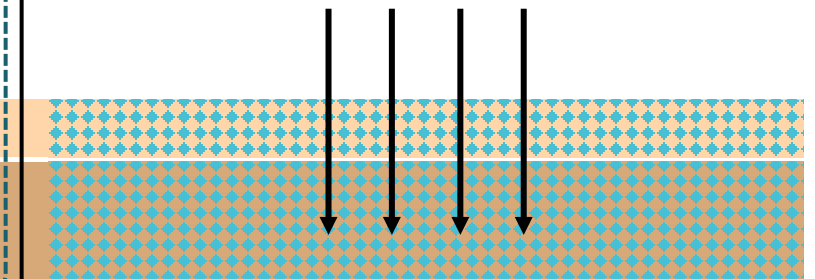
## 2. Evaporation of solvent

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



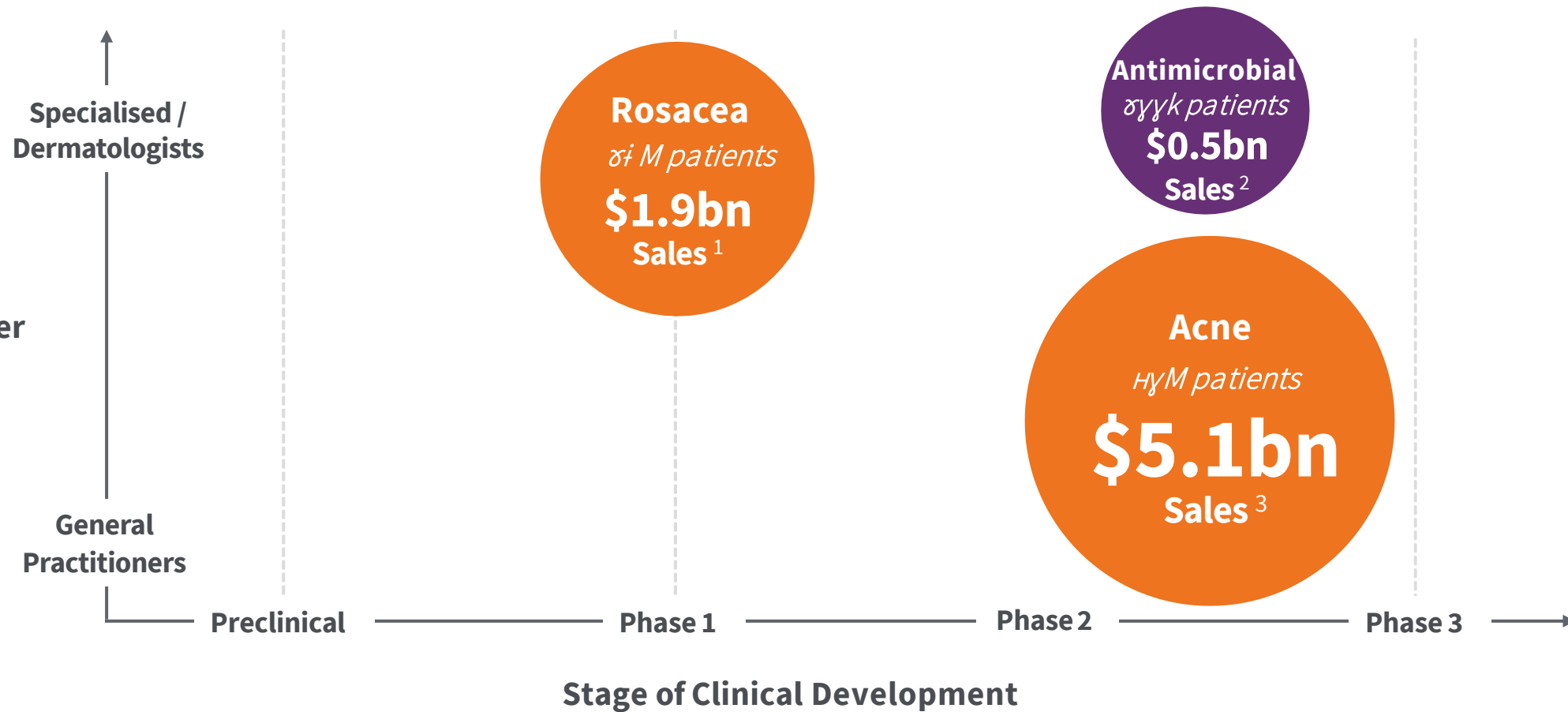
**Permetrex™ is used in Botanix's pipeline products and improves delivery for other drugs in development<sup>1</sup>**

1. Topical dosage forms include: solutions, creams, gels, ointments, foams or pastes



# Target markets with significant annual revenues & unmet needs

Personal use only



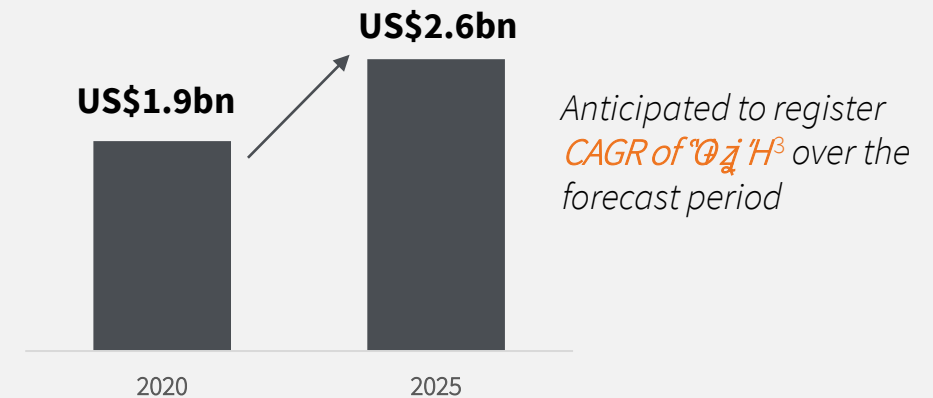
# Dermatology programs



# 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

## ❖ **Three 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

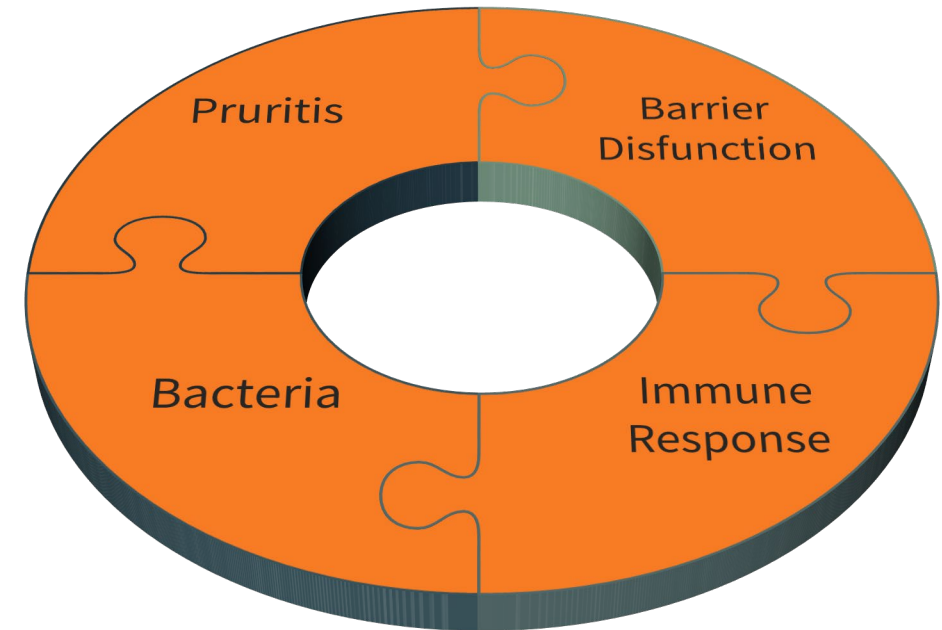
## ❖ **Endpoints:**

- 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

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



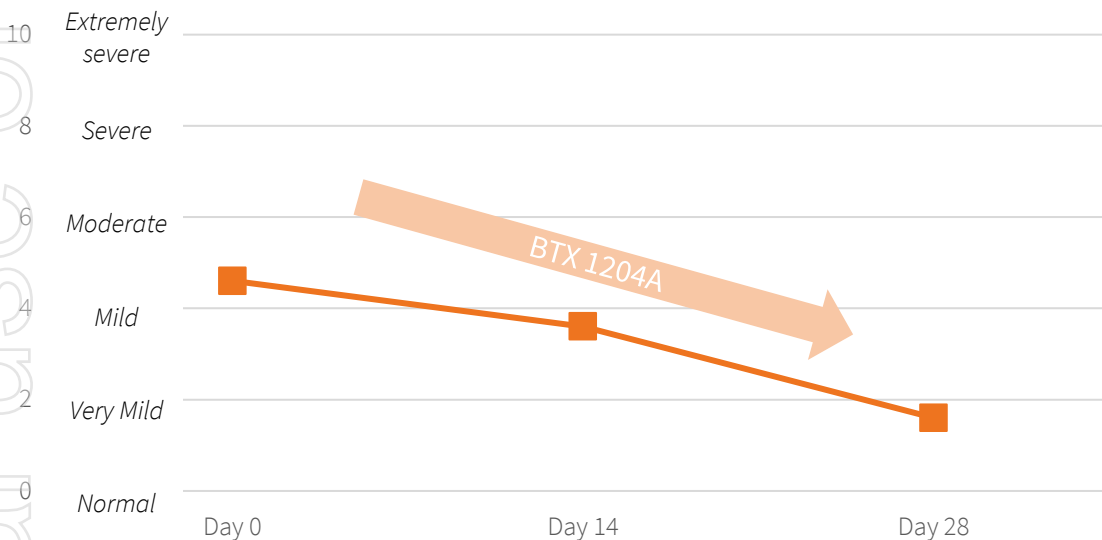
- ❖ Canines naturally and commonly develop a pruritic dermatitis that is clinically and immunologically extremely similar to human AD<sup>1</sup>
- ❖ Dogs and humans with AD also have similar problems with skin barrier function – these problems cause the skin to be very dry and prone to Staph Aureus 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

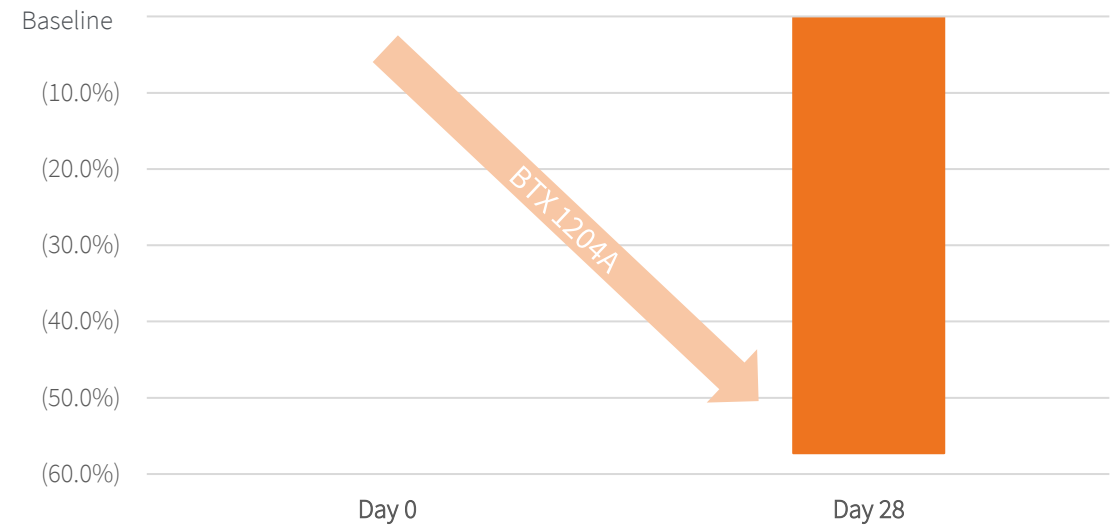
Pilot canine study with higher dose and novel Permetrex™ formulation showed reduction itch and lesions - dermatitis in canines and humans is clinically and immunologically very similar

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 severity 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:

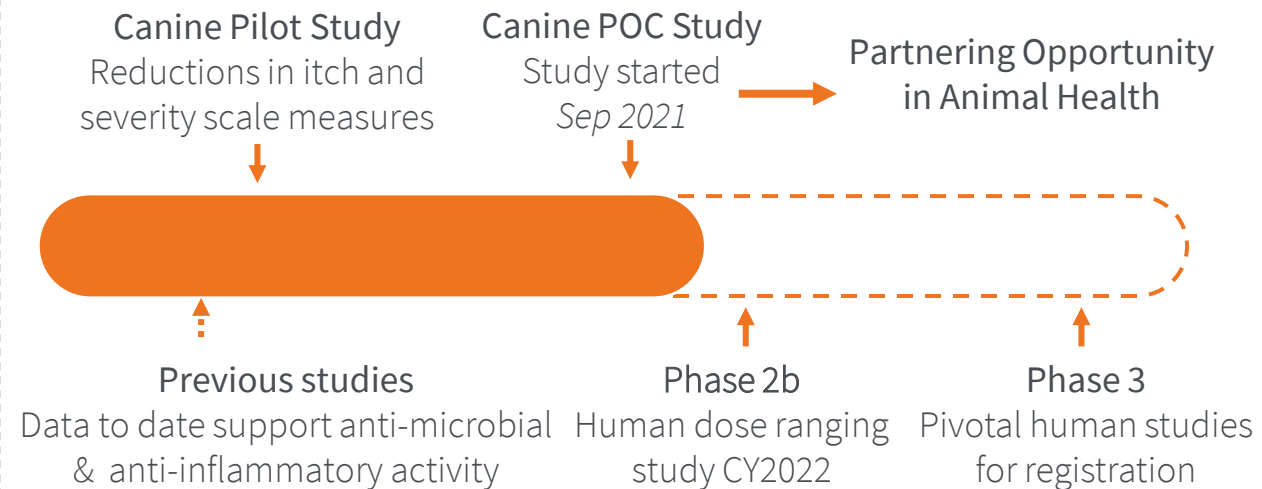
- BTX 1204A high dose: 15 dogs
- BTX 1204A low dose: 15 dogs
- Vehicle: 15 dogs

### ❖ 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.

# BTX 1503: Addresses the 4 underlying causes of acne and meets unmet needs in high growth market



- ❖ Acne is a common chronic skin disease involving blockage and/or inflammation of hair follicles and sebaceous glands
- ❖ Key Acne pathologies<sup>1</sup> include
  - Inflammation
  - formation of sebum plugs
  - production excess sebum
  - P. Acnes bacterial colonisation
- ❖ In US, affects ~80% at some point in life. ~20% have severe acne which can result in scarring and mental health impacts.
- ❖ Patients diagnosed with Acne are much more likely to suffer from anxiety and depression<sup>2</sup>

## Multi-billion dollar growth market

Rank	Brands	Peak gross sales	U.S. peak prescriptions
1	SOLODYN Minocycline	~\$1B	1,295,346
2	DORYX FRANCHISE Doxycycline	~\$900M	983,368
3	EPIDUO FRANCHISE Adapalene+BPO,	~\$700 M	1,208,376
4	ACZONE FRANCHISE Dapsone	~\$300M	896,102

- ❖ Current products with tolerability and safety concerns, and potential anti-microbial concerns have generated significant sales.
- ❖ Physicians seeking safe, topical effective solutions for patients that also help to address these concerns



# 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

# Anti-microbial development update

## BTX 1801

ersonal use only



# 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**

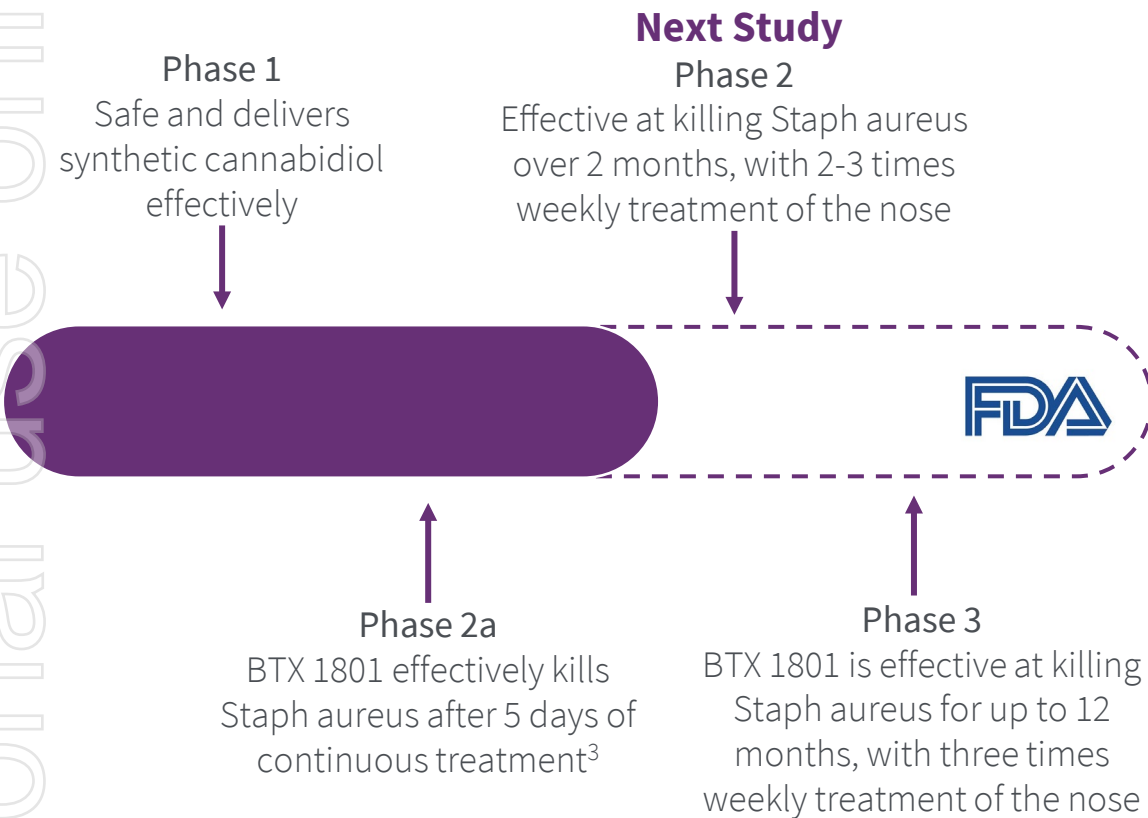
Mean cost (per episode) of treating Staph aureus blood stream infections, including re-admissions and outpatient costs<sup>1</sup>

**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

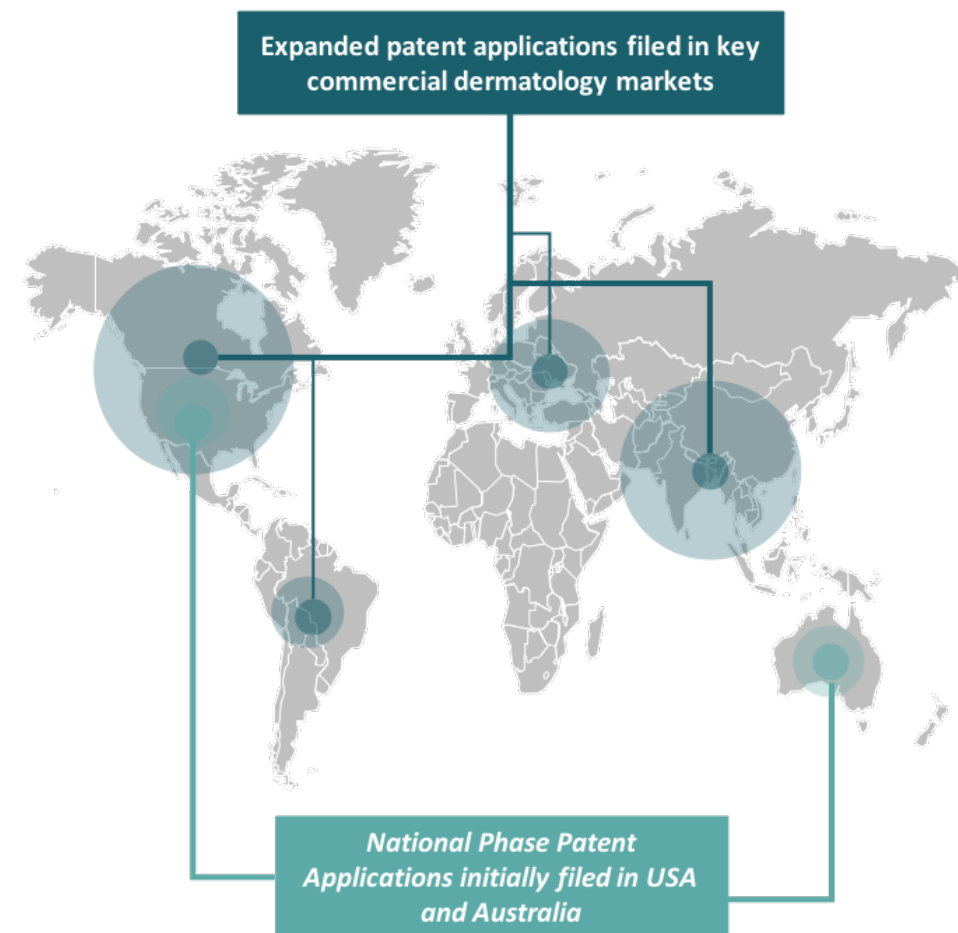
- QIDP<sup>1</sup> status**
  - ❖ Extra 5 years (total of 8 years) exclusivity from generic competition
  - ❖ Attractive economic benefits from FDA approval
- Fast track status**
  - ❖ Following IND submission, allows increased consultation with FDA
  - ❖ De-risks clinical trials and accelerates development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

# Robust IP Portfolio Strategy

Multiple patents filed in key markets including indications, formulation & Permetrex™ technology

- ❖ 12 patent families comprising granted and pending patent applications that cover composition of matter, use patents across Permetrex™, formulations, key diseases and applications such as AMR
- ❖ Key patent protection in targeted regions with established dermatology markets (US, Europe, Japan, Australia, New Zealand, Korea, Singapore, China, Brazil etc).
- ❖ Significant patent protection on commercialisation with patents filed between 2016-2020



# 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*



# DISCLAIMER

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