

14 March 2022

## Investor Presentation

### Key highlights

- **Release of updated corporate presentation for Botanix's investor roadshow this week and the Switzer Small and Micro cap Conference on the 23rd of March**
- **The presentation includes updates on the Company's clinical pipeline with near term catalysts and new pipeline opportunities for later stage dermatology assets**
- **Botanix retains a strong cash position of \$16.8 million as at 31 December 2021 with R&D tax concession return pending**

**Philadelphia PA and Perth Australia, 14 March 2022:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to release an updated corporate presentation for its investor roadshow taking place this week as well as the Switzer Small and Micro cap conference on Wednesday 23<sup>rd</sup> March.

The presentation includes an update on the Company's BTX 1801 Phase 2b antimicrobial study which is nearing commencement, the advanced BTX 1702 Phase 1b/2 rosacea study, and the BTX 1204A Phase 1b canine dermatitis study which are completing enrollment in the coming months, as well as new pipeline opportunities for later stage dermatology assets.

The Company's cash position remains strong with \$16.8 million as at 31 December 2021 excluding the pending R&D tax concession return. No capital raising is planned as part of this roadshow.

Release authorised by

**Vince Ippolito**

President and Executive Chairman

### About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology focused 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 separate 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. To learn more please visit: <http://www.botanixpharma.com/>

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[haley@hck.digital](mailto:haley@hck.digital)**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



# Botanix Overview

March 2022

**Operations:**  
3602 Horizon Drive, Suite 160  
King of Prussia PA 19041

**Corporate Office:**  
Level 1, 50 Angove Street  
North Perth W. Australia 6006

# US focused clinical stage dermatology company

Targeting billion-dollar markets with novel products



## Pharmaceutical focus

New treatments for common skin diseases (such as rosacea and acne), and life threatening bacterial infections



## Topically driven

Dermatologists prefer creams and gels as first line treatment and our skin delivery technology (Permetrex™), provides a new and effective solution



## Significant markets

Targeting multi-billion dollar markets, with no new acting products approved by FDA, in more than 20 years for conditions like acne and rosacea



## World-class team

US based clinical development and commercialisation team, with recent billion dollar exits to big pharma



## Near-term catalysts

Upcoming readout of Phase 1b/2 rosacea study, start of Phase 2b antimicrobial study, Phase 1b canine dermatitis data readout and announcement of new pipeline opportunities

# Corporate Overview

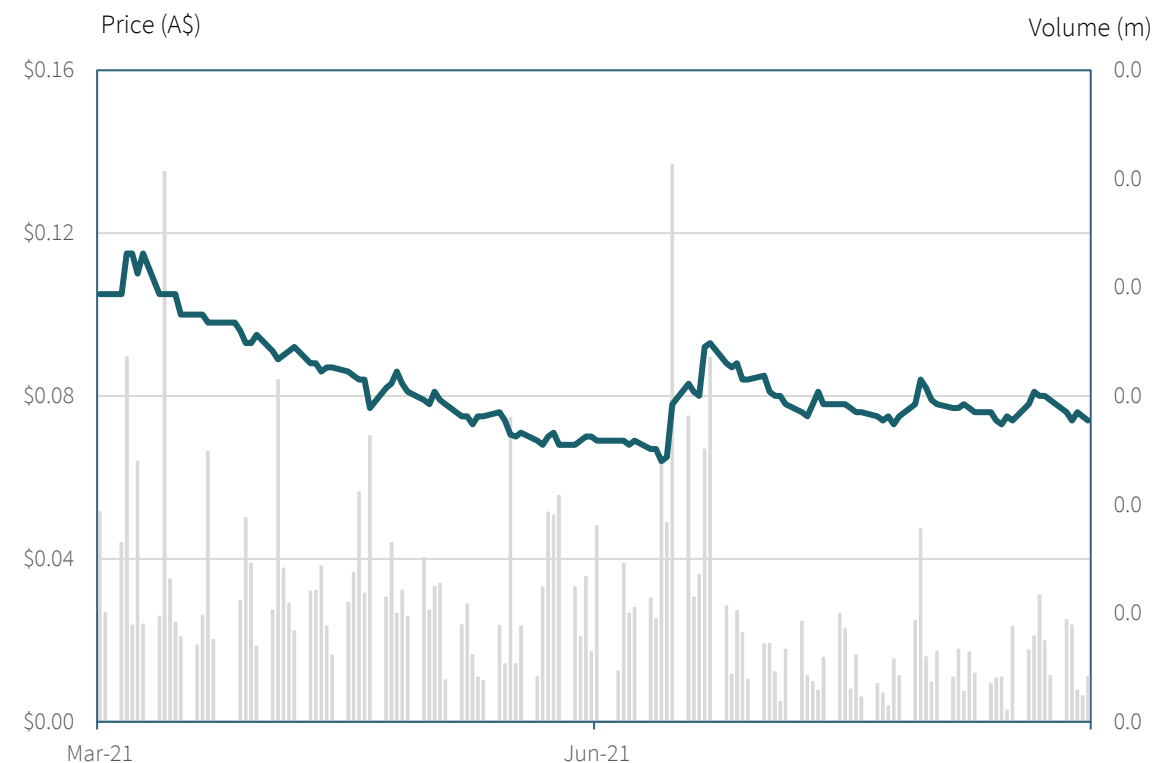
## ASX: BOT Trading Information

Share price	A\$0.061
6-month low / high	A\$0.061/0.115
Shares outstanding	973,142,074
<b>Market Capitalisation</b>	<b>A\$59.36</b>
Cash (31 Dec 2021)	A\$ 16.8m
Debt (31 Dec 2021)	Nil
<b>Enterprise value</b>	<b>A\$ 41.6m</b>

## Substantial Shareholders

Shareholder	%
Matt Callahan, Founder and Executive Director	7.27%
Caperi Pty Ltd, Co-Founder	5.4%

## Share price performance (last 6 months)



# 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**

Senior Medical Adviser

- ❖ 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**

Commercial Adviser

- ❖ 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**

Clinical Adviser

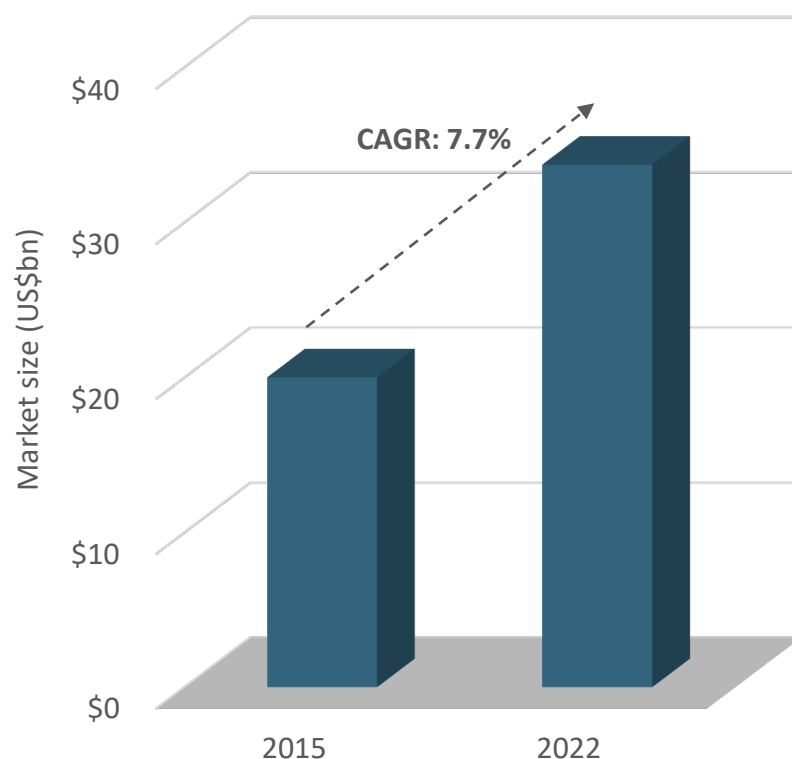
- ❖ 30+ years of senior level leadership experience within the global pharmaceutical and medical device industries

# Botanix team has led multiple successful product development campaigns and launches



# Global dermatology market is worth more than \$33 billion - with little recent innovation

Global dermatology market <sup>1</sup>

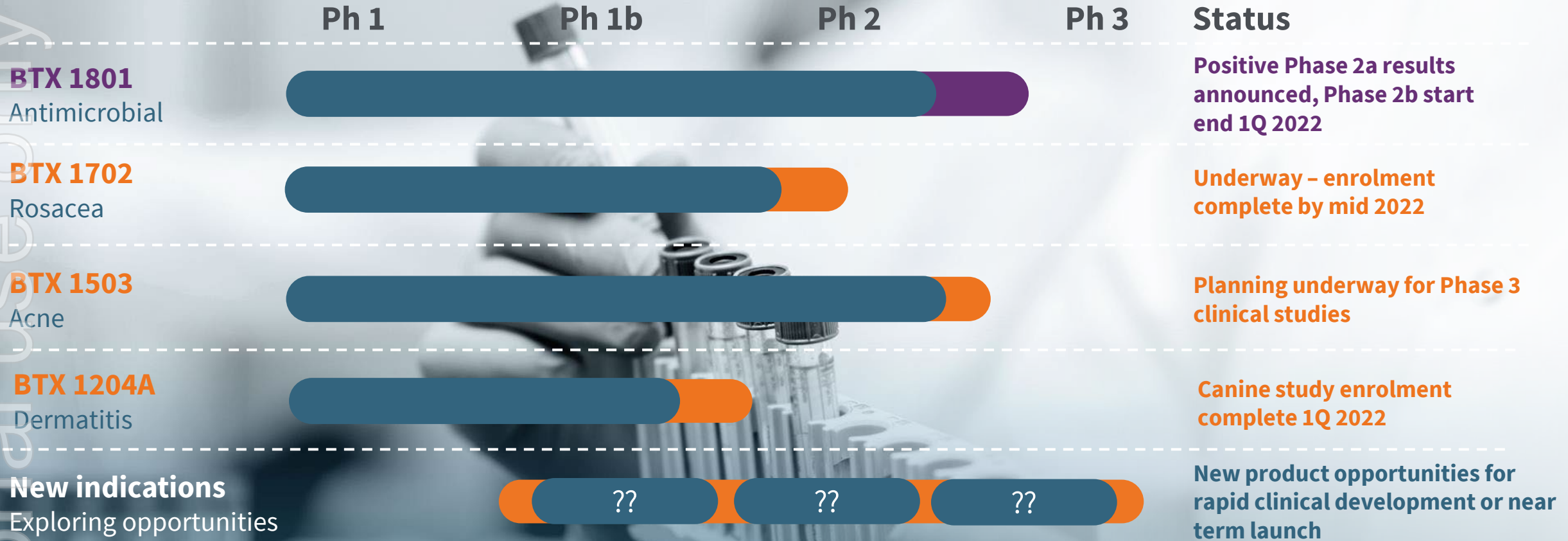


- ❖ More than 3,000 types of dermatological conditions exist, ranging in severity and clinical presentation
- ❖ Approximately 1/3 of the US population suffers from an active skin condition
- ❖ Significant unmet medical needs for treatment options that:
  - are effective via multiple pathways
  - have improved safety/tolerability profiles
  - allow for long-term use especially in kids
- ❖ Most of the smaller dermatology companies have been acquired or pivoted back to early-stage R&D in the last 5 years – significant opportunity exists for novel later stage products

1. Source: Konzept Market Research: Dermatology Market 2018

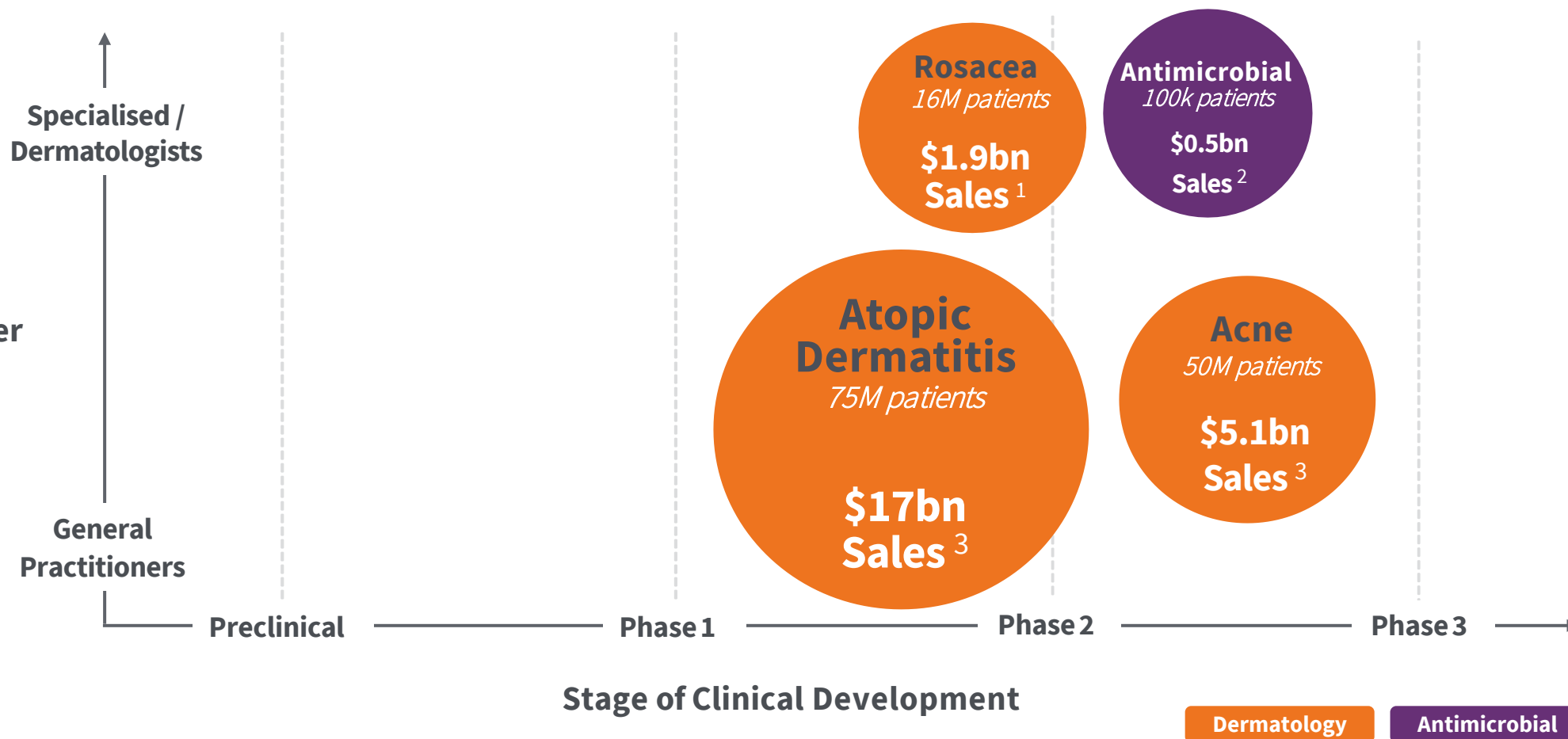


# Advanced late-stage pipeline



# 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

# Permetrex™ skin delivery technology fuels the pipeline

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

## 1. Initial application

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

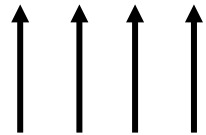


Epidermis

Dermis

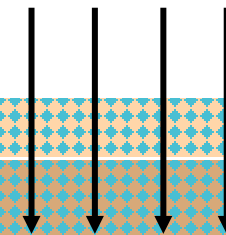
## 2. Evaporation of solvent

Majority of volatile 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 does not leave an excess of sticky gel on the surface



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

# Dermatology programs



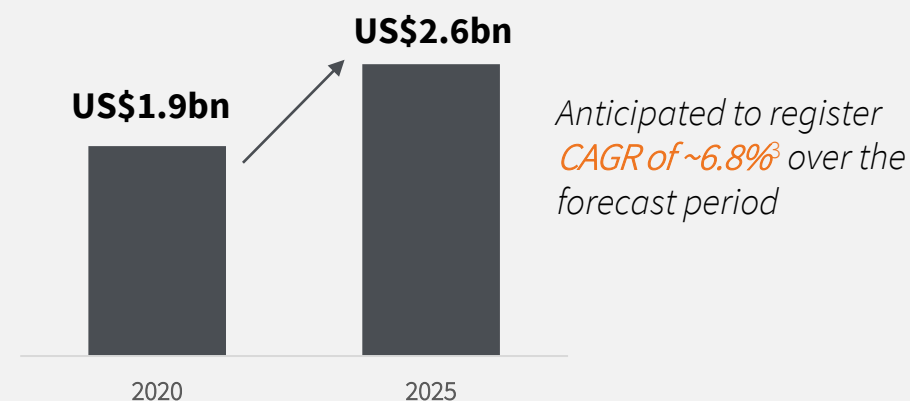
# BTX 1702: high impact of rosacea on patients and significant market opportunity

❖ 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 nearing completion

Randomised controlled study in patients for 8 weeks



- ❖ 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: ~17 dermatology sites across Australia and NZ

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

## ❖ Treatment period: 8 weeks

## ❖ Endpoints:

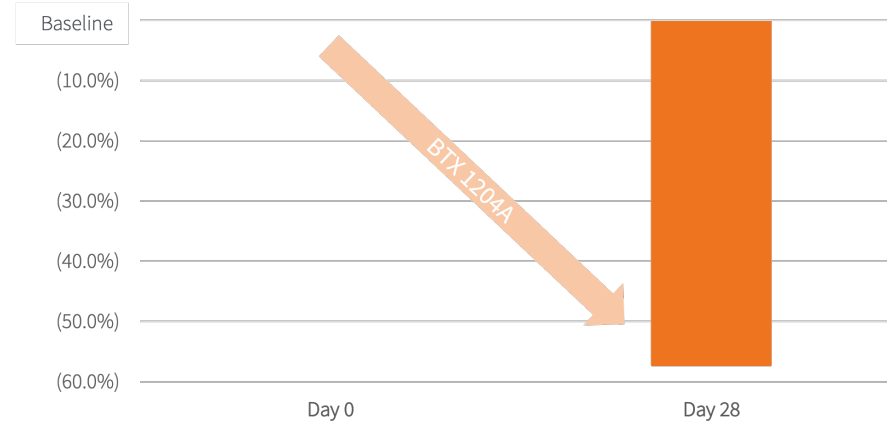
- Safety and tolerability
- Change in inflammatory lesion counts from baseline at days 15, 29 and 57
- Proportion of patients with Investigator's Global Assessment (IGA) treatment success
- Change in Clinician's Erythema Assessment (CEA) scale
- Imaging and patient reported outcomes

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

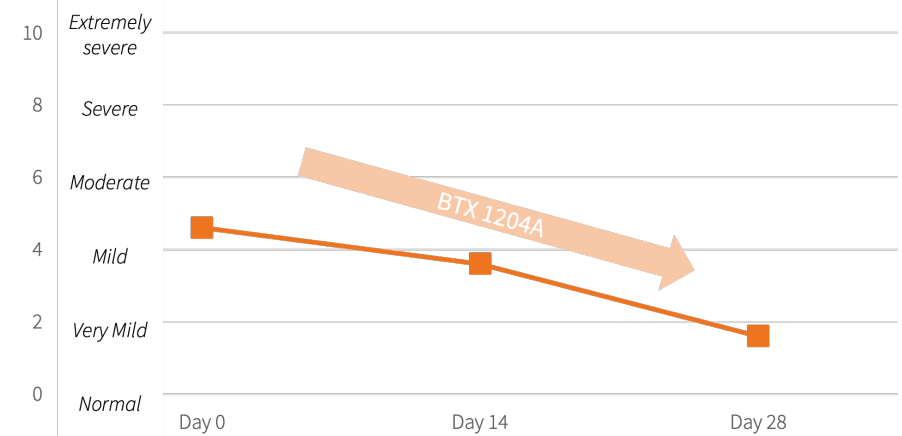


- ❖ Canines naturally develop a form of dermatitis that is extremely similar to human dermatitis<sup>4</sup>
- ❖ Dogs and humans with dermatitis also have similar problems with skin barrier function – which leads to Staph Aureus infections<sup>5</sup>
- ❖ Canine studies are faster and more cost effective than human studies and help de-risk later stage studies

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



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



1. BTX 1204A clinical study data announced 17 May 2021  
 2. EPS: Enhanced Pruritus Score – designed to measure the severity of itching in dogs  
 3. CADESI-04: Canine Atopic Dermatitis Extent and Severity Index –  
 4. Leung. Curr Opin Pediatr. 2016 Aug; 28(4): 456-462  
 5. Hong et al. Semin Cutan Med Surg. 2011;30(2):71-86

# 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:

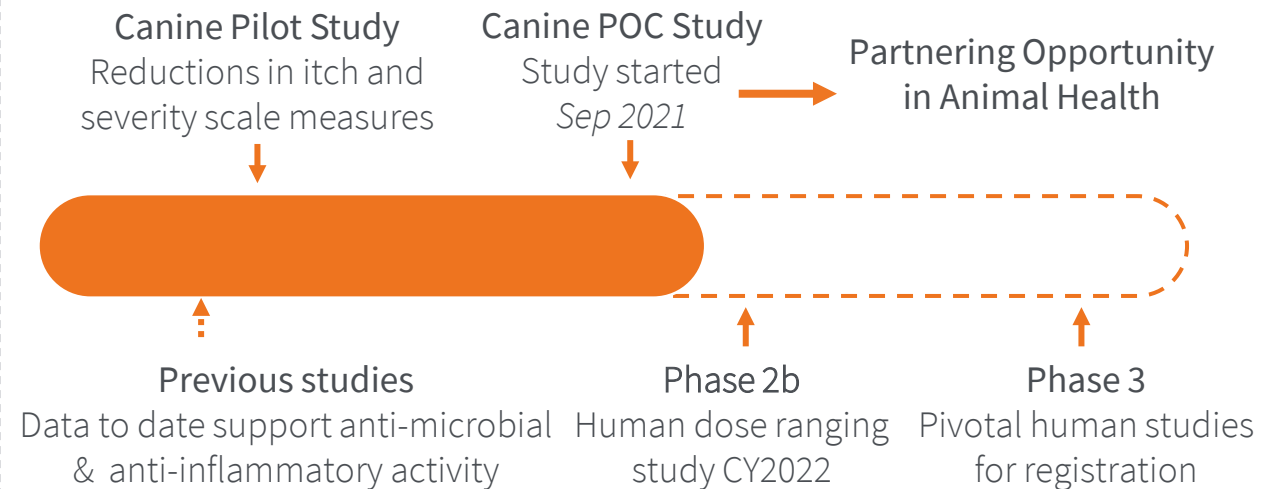
- BTX 1204A high dose: 15 dogs
- BTX 1204A low dose: 15 dogs
- Vehicle: 15 dogs

### ❖ 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: Acne in preparation for Phase 3 and future filing






## Completion of Rosacea BTX 1702 study (with higher dosing) will inform final design for P3 Acne study

### Study update

- ✓ End of Phase 2 meeting with FDA successfully completed<sup>2</sup>
- ✓ FDA highlighted excellent safety profile of BTX 1503, allowing several waivers for studies typically required
- ✓ Co-primary efficacy endpoints<sup>3</sup> agreed for Phase 3
- ✓ Important milestone providing clarification on activity to move forward
- ❖ Planning underway for Phase 3 clinical studies to be informed by completion of BTX 1702 Phase 1b/2 study

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

### 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>

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>

# Executing on key clinical milestones

## ❖ **Antimicrobial: BTX 1801 Phase 2b study**

*Positive Phase 2a results announced, Phase 2b study start end 1Q 2022*

## ❖ **Rosacea: BTX 1702 Phase 1b/2 study**

*Targeting full enrolment mid 2022, with data 3Q 2022*

## ❖ **Acne: BTX 1503 for Phase 3 clinical studies**

*Commencement pending completion of BTX 1702 Phase 1b/2 study*

## ❖ **Dermatitis: BTX 1204A canine proof of concept study**

*Enrolment targeting completion end 1Q CY2022, data 2Q 2022*

## ❖ **Pipeline opportunities**

*Exploring other pipeline opportunities for later stage dermatology assets that are closer to approval and revenue generation*



Dates are calendar years

# DISCLAIMER

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