

1 September 2021

## Botanix Presentation Corporate Update

### Key highlights

- Botanix has released a corporate presentation being utilised for investor meetings
- Presentation highlights the successful launch of BTX 1702 rosacea clinical study, with recruitment well underway
- Presentation provides an update on the design of the BTX 1204A pilot study of canines with atopic dermatitis which is about to commence as well as the preparation for the BTX 1801 Phase 2b clinical study targeting the nasal decolonisation of Staph aureus in haemodialysis patients
- The Company continues to review a number of opportunities to leverage the unique properties of the Permetrex™ technology platform to deliver other new drugs for dermatology diseases
- Botanix remains in a strong financial position, holding cash balance of A\$21.56m at 30 June 2021

**Philadelphia PA and Perth Australia, 1 September 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 a series of meetings with investors being conducted over the coming few days.

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.

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 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 plans to advance 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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Unlocking the potential of synthetic cannabinoids



# Investor Presentation

September 2021



# World-class 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 4 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 Velicept Therapeutics
- ❖ Senior leadership roles at Iroko Pharmaceuticals, Novartis and GlaxoSmithKline

**Anthony Robinson**

Vice President 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 Ira Lawrence**

Advisor

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

# Botanix: a leader in topical drug development



## Pharmaceutical focus

Leveraging novel skin delivery technology (Permetrex™) and novel drug mechanisms of action, including 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 20-30 years in these indications



## 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 rosacea study, Phase 2b antimicrobial study and assessment of new indications for rapid development

# Corporate overview

## Trading information

Share Price (31 August 2021)	A\$0.080
52 week low / high	A\$0.045 / A\$0.190
Shares outstanding	973,142,074
Market capitalisation	A\$78.8
Cash (30 June 2021)	A\$21.6m
Debt (30 June 2021)	-
Enterprise value	A\$57.2

## Substantial shareholders

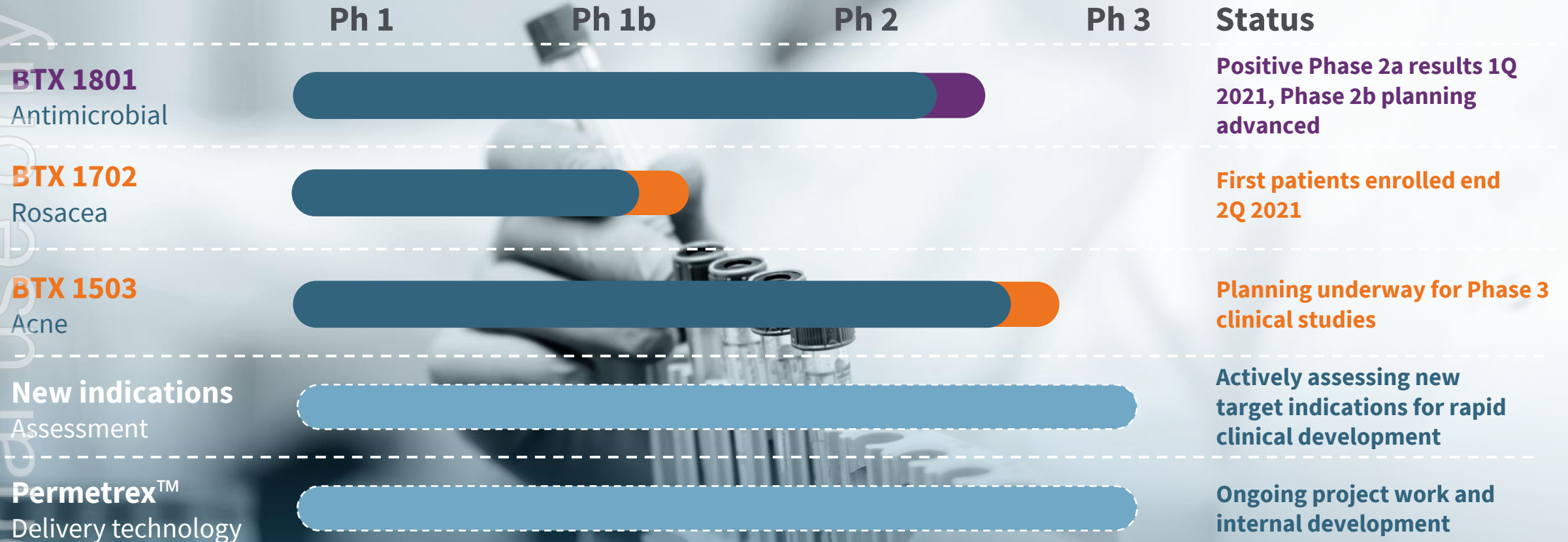
Shareholder	%
Matt Callahan – Founder and Executive Director	7.27%
Caperi Pty Ltd – Co-founder	5.40%

## Share price performance (last 12 months)



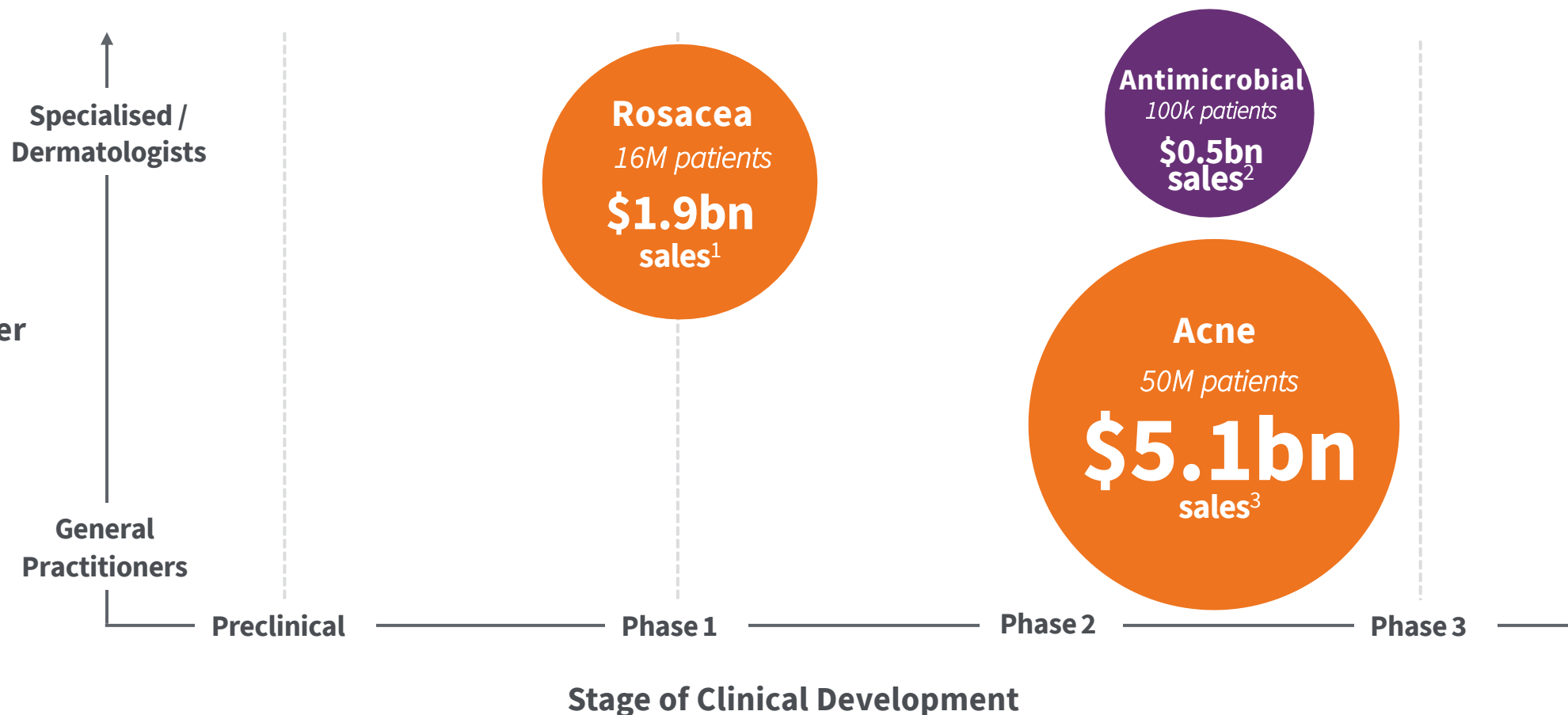


# Advanced pipeline



# Our products target markets with significant annual revenue

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# Permetrex™: unique skin delivery technology fuels pipeline

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

## Initial application

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



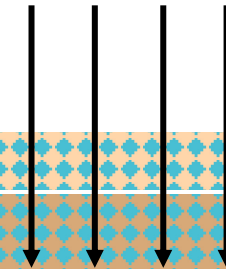
## Evaporation of solvent

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



## Delivery into the skin

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



Epidermis

Dermis

Permetrex™ is utilised in Botanix 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

# 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 lesions**
- ✓ **Kill Staph aureus**
- ✓ **Avoid bacteria from developing resistance**
- ✓ **Have potential for widespread use across human and animal health**





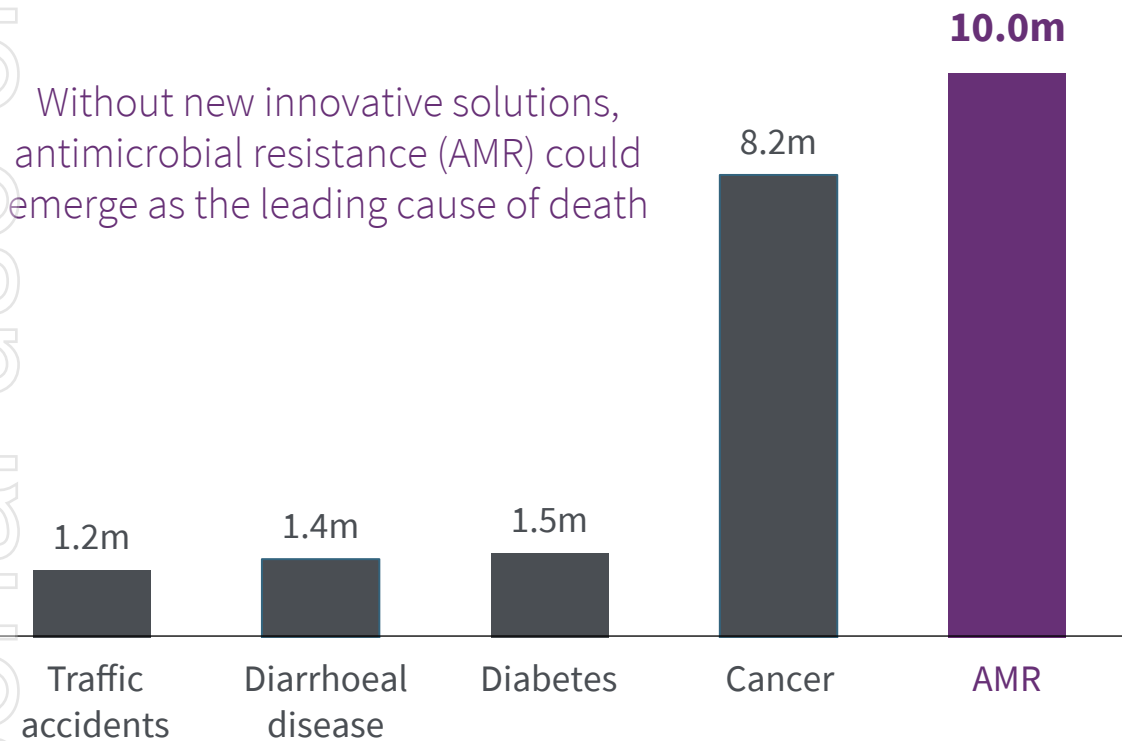
# BTX 1801 development update

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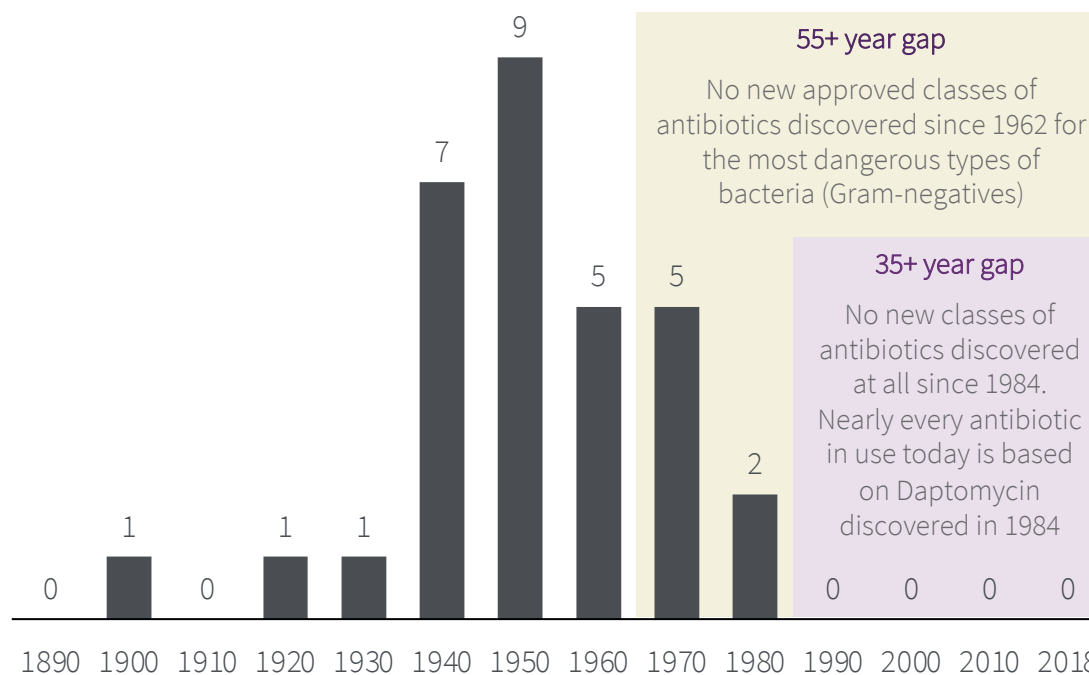


# Antimicrobial resistance is a fast-growing problem, with no innovation in over three decades

## Global forecast deaths by 2050<sup>1</sup> (p.a.)

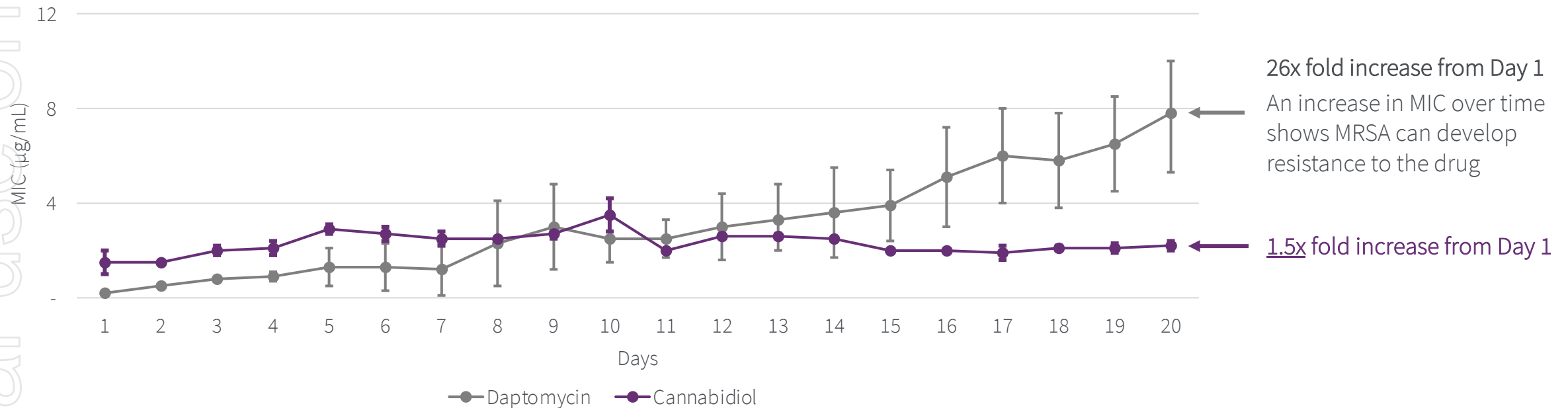


## Number of antibiotic classes discovered or patented<sup>2</sup>



# BTX 1801 has remarkable activity against bacteria without inducing resistance

## MIC daily variability<sup>1</sup>



26x fold increase from Day 1  
An increase in MIC over time shows MRSA can develop resistance to the drug

1.5x fold increase from Day 1

Repeat challenge experiments demonstrate that MRSA bacteria develop resistance to commonly-used antibiotics such as daptomycin, but not easily to synthetic CBD

## BTX 1801 Phase 2a study: clinical efficacy demonstrated



### 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



# 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>
- ❖ Haemodialysis patients infect themselves from their noses



## Significant health risks

- ❖ The central venous catheter patients (approx. 160,000) are responsible for more than 70% of blood infections in the dialysis population<sup>2</sup>

**~US\$32k**

Mean cost (per episode) of treating Staph blood stream infections, including re-admissions and outpatient costs<sup>3</sup>

**US\$1bn**

Estimated annual cost of treating bacteraemia in haemodialysis patients with central venous catheters<sup>4</sup>

**11.8%**

of patients were readmitted within 12 weeks of hospitalisation related to Staph aureus infections<sup>3</sup>

**US\$734m**

Market for nasal decolonisation of haemodialysis patients at risk of blood stream infection<sup>4</sup>



# BTX 1801: rapid clinical development

Phase 1  
Safe and delivers  
synthetic cannabidiol  
effectively

**Next Study**  
Phase 2b  
Effective at killing Staph aureus  
over 2 months, with 2-3 times  
weekly treatment of the nose

Phase 2a  
BTX 1801 effectively kills  
Staph aureus after 5 days of  
continuous treatment

Phase 3  
BTX 1801 is effective at killing  
Staph aureus for up to 12  
months, with three times  
weekly treatment of the nose



## FDA incentives provide accelerated development and increase 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

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# Dermatology clinical programs



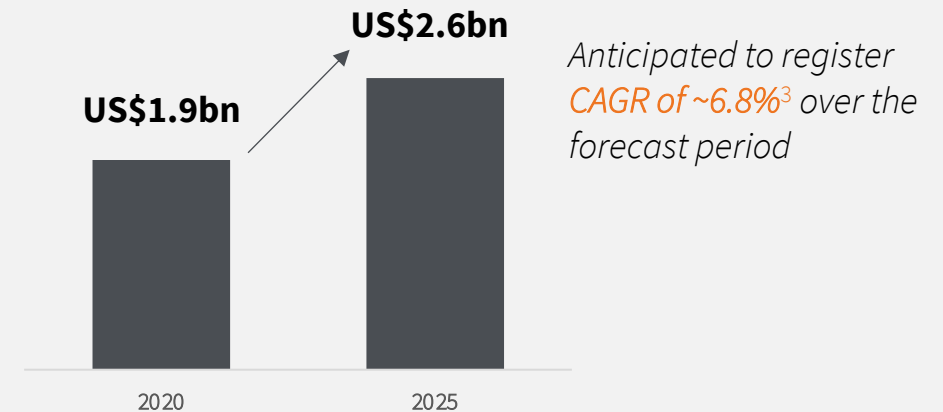
# BTX 1702: impact of rosacea and significant market opportunity

❖ Papulopustular rosacea is a **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

❖ 85% of patients are over 30 years old<sup>5</sup>

❖ There are currently over 16m Americans affected<sup>6</sup> by the illness, with ~5m medical treatment prescriptions<sup>7</sup> in the US alone



# BTX 1702: Phase 1b rosacea study underway



## ❖ 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: ~12 dermatology sites across Australia and NZ

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

## ❖ Treatment period: 8 weeks

## ❖ Screening: facial photos with Canfield imaging

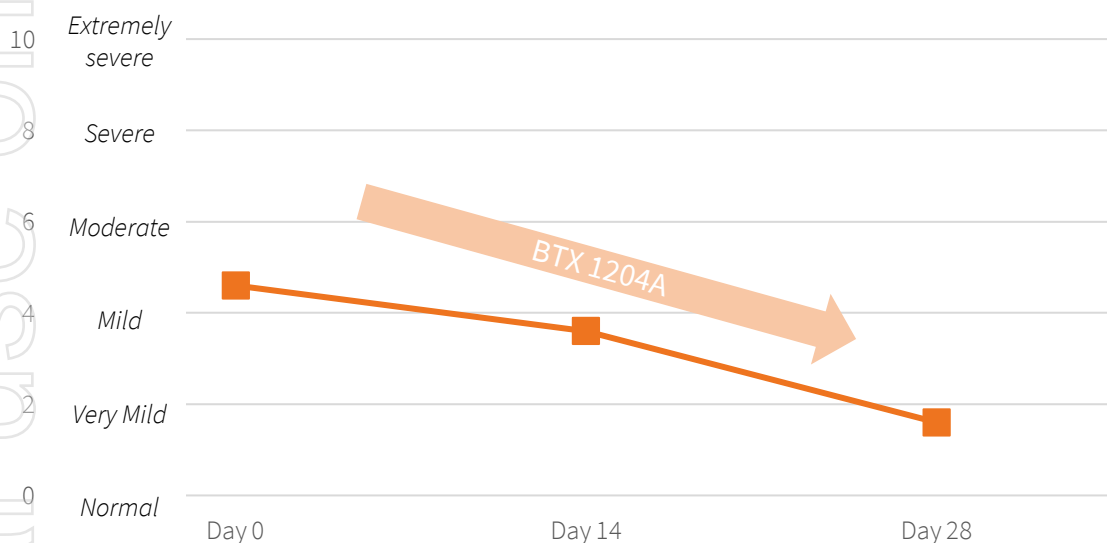
## ❖ Endpoints:

- 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 1204A dermatitis data

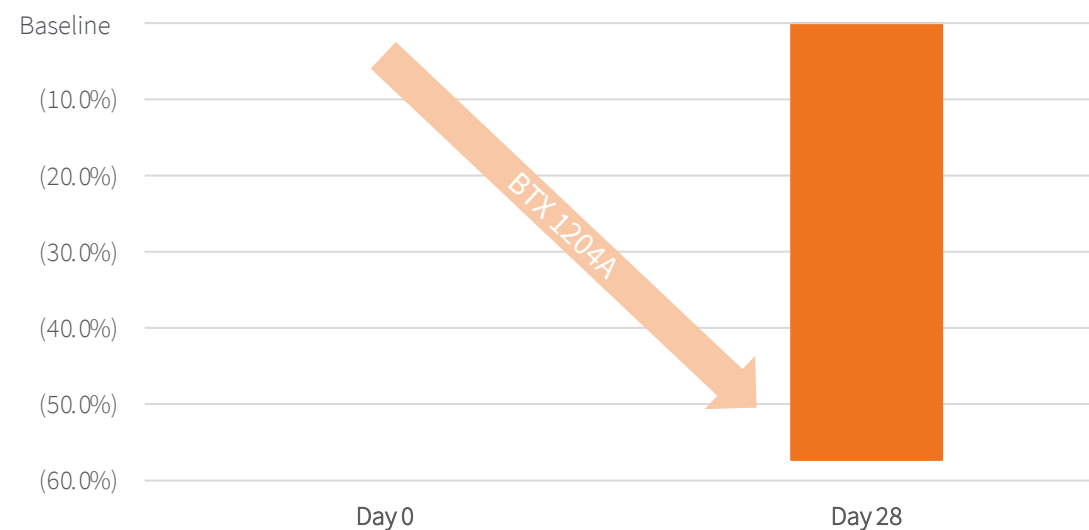
## New animal data supports further development of indication

### BTX 1204A: Pruritus mean ESP scores<sup>1,2</sup>



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

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



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

## BTX 1204A development strategy:

Larger POC canine study commencing - informs licensing program for animal use and potential relaunch of late-stage dermatitis clinical program

### Proposed canine study parameters

#### ❖ Three dose groups ~45 dogs:

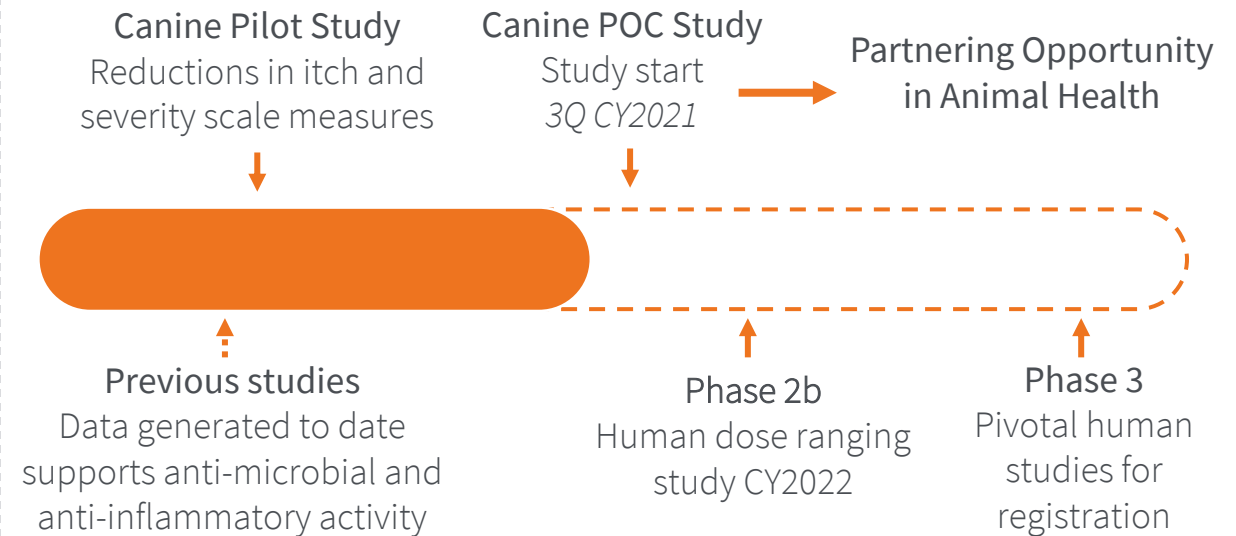
- BTX 1204A high dose: 15 dogs
- BTX 1204A low dose: 15 dogs
- Vehicle: 15 dogs

#### ❖ Sites: 4 Australian sites

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

#### ❖ Endpoints: Enhanced Pruritus Score; Canine Atopic Dermatitis Extent and Severity Scale Index

### Planned pathway to approval



Successful outcome from planned POC canine study opens up partnering opportunity and supports progression to Phase 2b human study in atopic dermatitis

# BTX 1503 Acne: Successful End-of-Phase 2 FDA Meeting and preparation for Phase 3

## Study update

- ✓ End of Phase 2 meeting with FDA successfully completed
- ✓ FDA highlighted excellent safety profile of BTX 1503, and allowed several waivers for studies that are typically required for dermatology drug registration
- ✓ Co-primary efficacy endpoints<sup>1</sup> agreed for Phase 3 studies
- ✓ Confirmed drug development plan to support registration of BTX 1503 for treatment of moderate and severe acne
- ❖ Planning underway for Phase 3 clinical studies to be informed by completion of BTX 1702 Phase 1b study and lifting of COVID-19 restrictions in the USA

## Sizable acne prescription market



**22m** total prescriptions in 2019 growing ~5% year-on-year<sup>2</sup>



**US\$5.1bn** in sales in 2019<sup>2</sup>



**>2m** p.a. active, diagnosed acne patients under HCP care<sup>3</sup>



**~40m to ~50m** acne sufferers<sup>4</sup> (~10m mod-to-severe)



**60%** of acne patients are managed by 5K HCPs<sup>5</sup>



# Executing on key clinical milestones

- ❖ **Antimicrobial: positive BTX 1801 Phase 2a study results**

*Positive results announced and Phase 2b planned start 4Q 2021*

- ❖ **Rosacea: BTX 1702 Phase 1b study enrolling**

*Recruitment currently underway*

- ❖ **Acne: BTX 1503 planning for Phase 3 clinical studies**

*Pending the completion of BTX 1702 Phase 1b clinical study*

- ❖ **New indications: topical treatments**

*Actively assessing new indications for rapid clinical development*

**Strong cash position - A\$21.6m**

*As at 30 June 2021*



# DISCLAIMER

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