

5 May 2021

## Updated investor presentation and conference call

**Philadelphia PA and Perth Australia, 5 May 2021:** Clinical dermatology and antimicrobial company, Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “the Company”), is pleased to release an updated investor presentation and provide details for an investor conference call to be held at 11am AEST on Friday, 7 May 2021.

The attached updated investor presentation provides an update on the key clinical development programs, including the progression of BTX 1801 antimicrobial platform and BTX 1702 rosacea study that recently received ethics approval.

Botanix will hold an investor conference call hosted by Vince Ippolito, President and Executive Chairman, and Matt Callahan, Executive Director at 11am AEST on Friday, 7 May 2021. Investors can pre-submit questions to be answered at the end of the call, when registering through the link below.

### Conference call details:

Date: Friday, 7 May 2021

Time: 11:00am AEST

### Registration details:

Participants are encouraged to pre-register for the conference call. Upon registration, participants will receive a unique pin granting fast-track access to the conference call and the opportunity to submit questions to Botanix management team.

<https://s1.c-conf.com/diamondpass/10013700-s0ecot.html>

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. Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin

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diseases, which it utilises in its existing development programs and is being explored with 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 plans for an upcoming Phase 2b study. For the dermatology platform, the Company has received ethics approval to commence its Phase 1b rosacea study and following a successful meeting with the FDA, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration. To learn more please visit: <https://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

May 2021



# Botanix: 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 ( 4 May 2021)	A\$0.084
52 week low / high	A\$0.037 / A\$0.190
Shares outstanding	973,142,074
Market capitalisation	A\$80.8
Cash (31 March 2021)	A\$23.3m
Debt (31 March 2021)	-
Enterprise value	A\$57.5

## Substantial shareholders

Shareholder	%
Matt Callahan – Founder and Executive Director	7.27%
Caperi Pty Ltd – Co-founder	6.12%

## Share price performance (last 12 months)



# 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

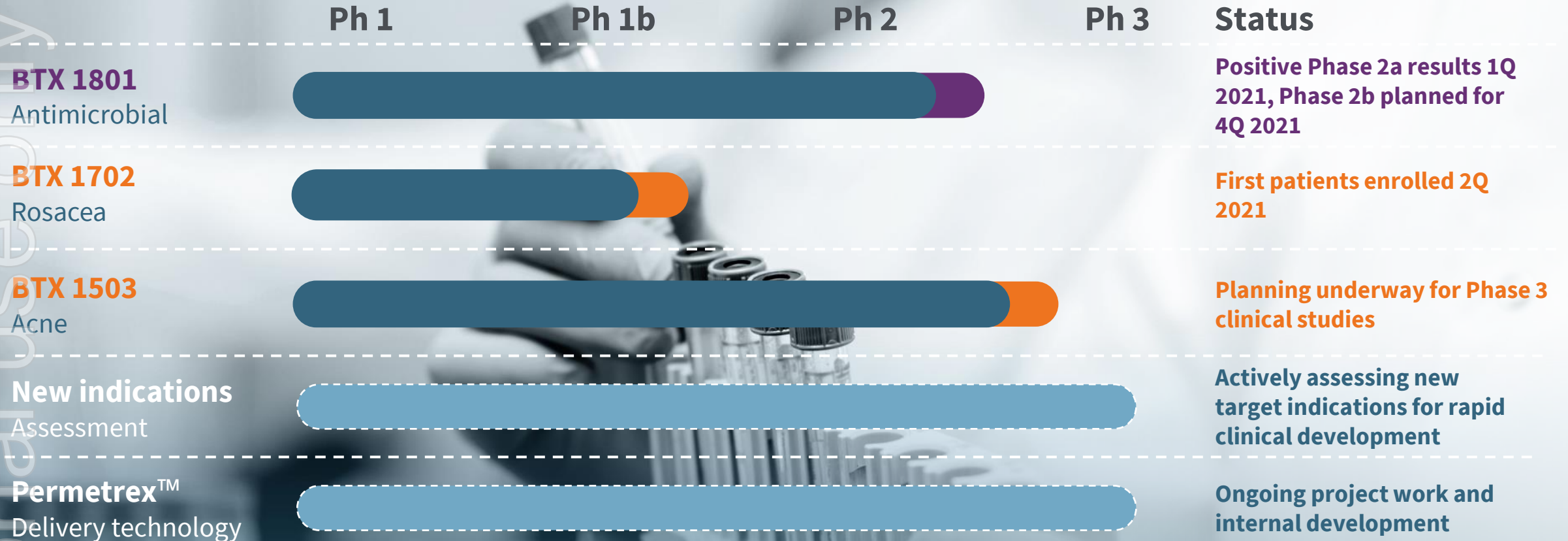
- ❖ Founder of BAL Pharma Consulting
- ❖ 13 years senior leadership roles in pharmaceuticals industry

**Dr Ira Lawrence**

Advisor

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

# Advanced pipeline



# 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



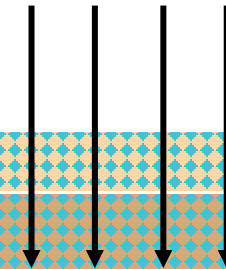
## Evaporation of solvent

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

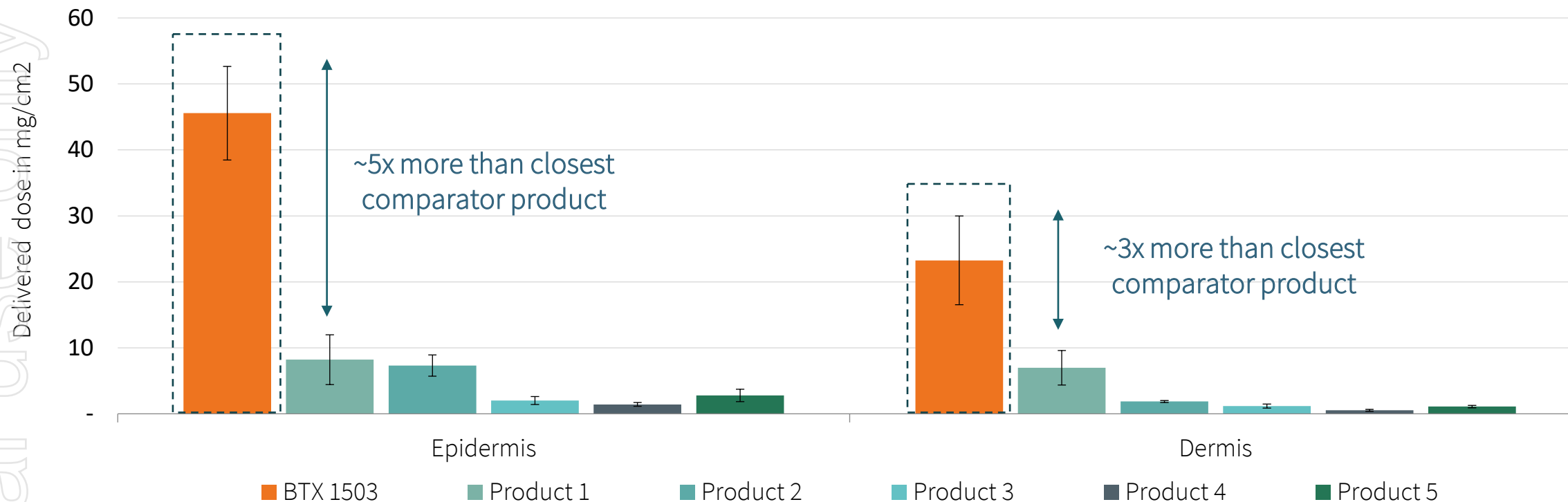
Permetrex™ is utilised in Botanix pipeline products and improves delivery for other drugs in development<sup>1</sup>

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



# Independent comparative analysis of CBD delivered

Amount of CBD permeated through skin (time elapsed 48 hours)<sup>1</sup>



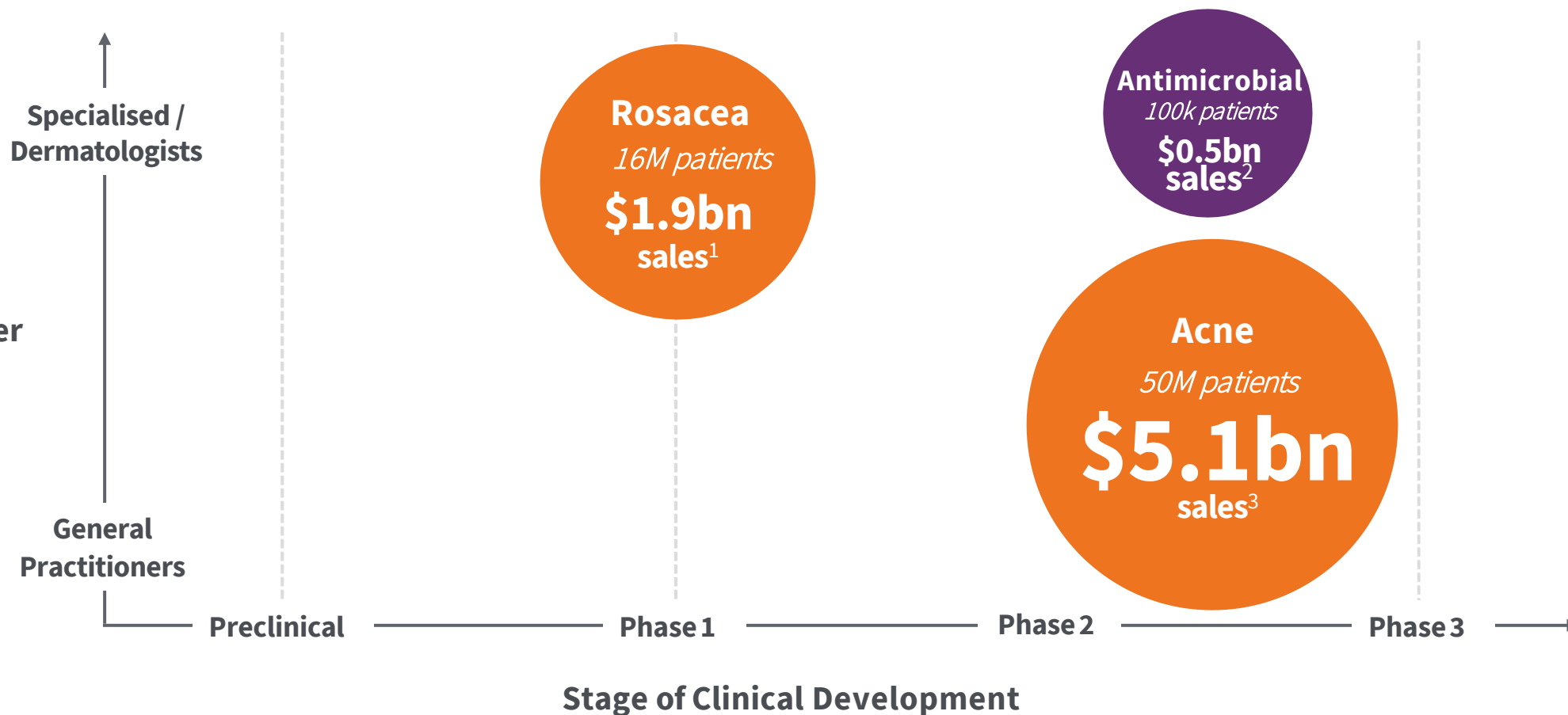
Relative to the closest comparator, Permetrex™ delivers >5 times as much CBD to the epidermis and >3 times as much CBD to the dermis - significantly more than other creams and gels

1. For further details on these tests – see BOT ASX release on 26/02/19. Products purchased from internet websites of respective vendors and tested by independent laboratory testing service Tioga Research. HPLC analysis of CBD content compared labeled CBD or cannabinoid content to Tioga test results.. Botanix data on file.

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# Our products target markets with significant annual revenue

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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

# 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**



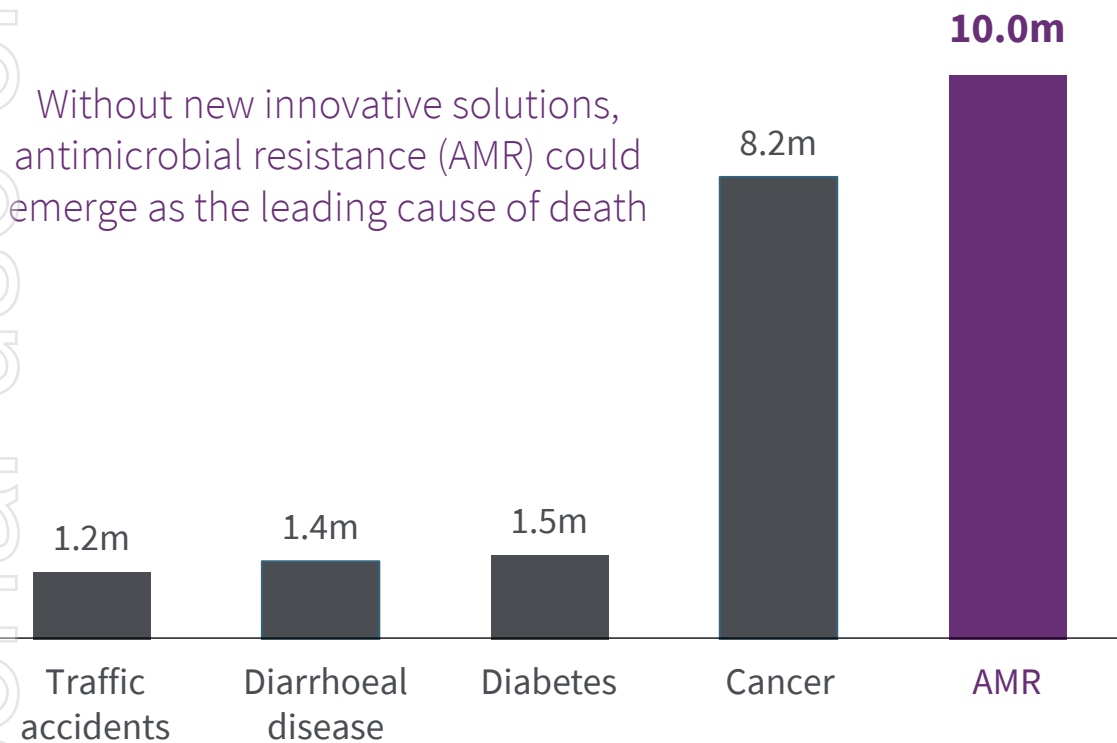
# BTX 1801 development update

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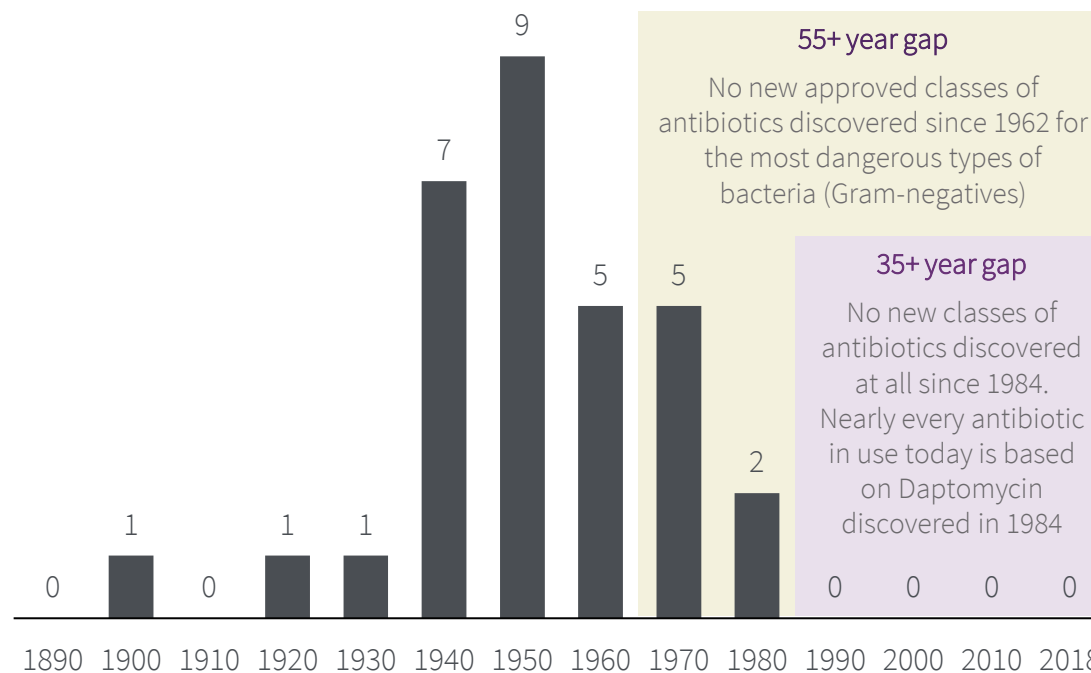


# Antimicrobial resistance is a fast-growing problem, with no innovation in over three decades

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

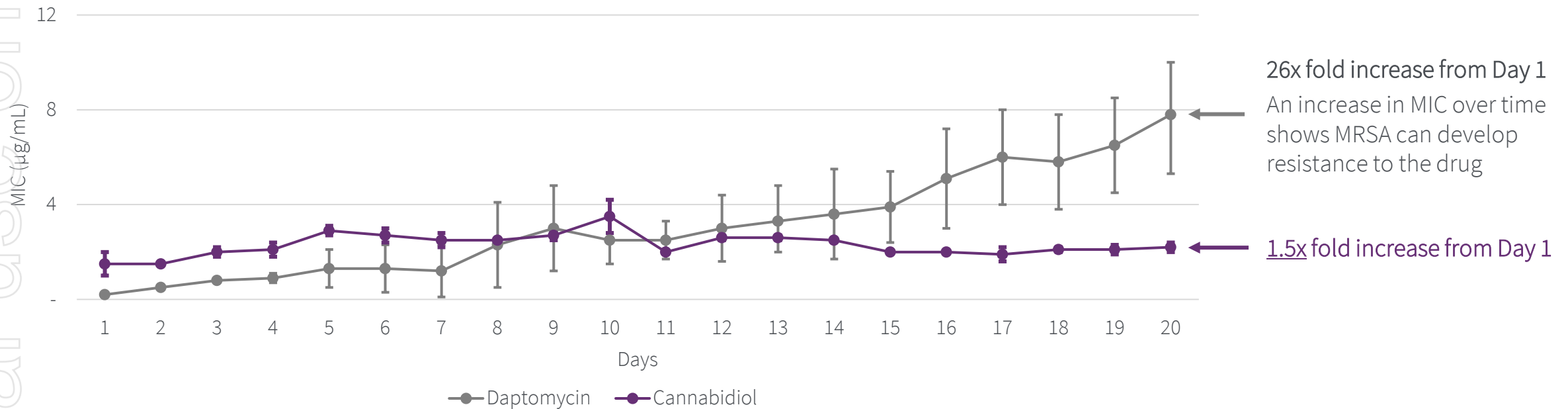


## Number of antibiotic classes discovered or patented<sup>2</sup>



# 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>

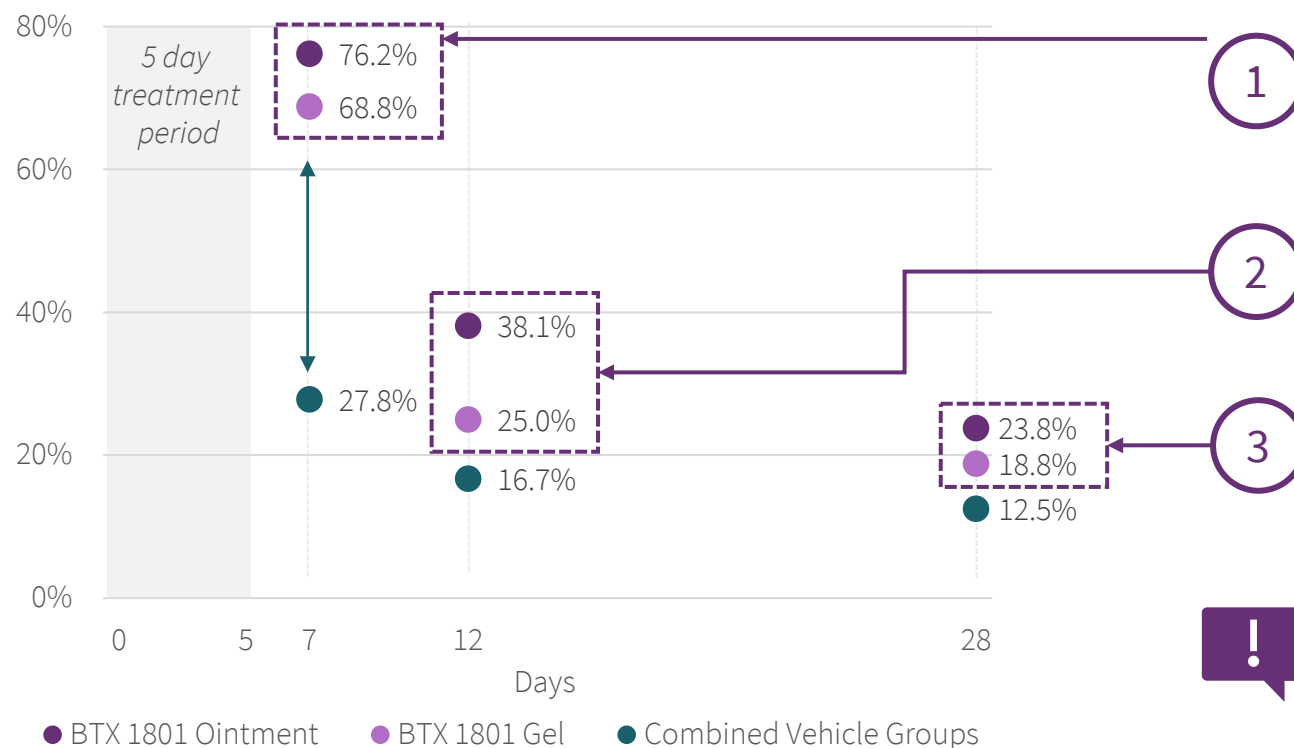


## Efficacy

- ✓ 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

# Phase 2a study data: Staph aureus eradication

## BTX 1801: Staph aureus eradication rates (% of participants)<sup>1</sup>



## Study observations

- ✓ Significant eradication of Staph aureus 2 days after completion of treatment period
  - ✓ Large difference between active groups / vehicle control
  - ✓ After 7 days of no treatment with BTX 1801 – significant % of subjects maintained eradication of Staph aureus
  - ✓ After 23 days of no treatment with BTX 1801 – significant % of subjects maintained eradication of Staph aureus
- ! *The BTX 1801 Phase 2a study did not include a full body chlorhexidine wash, that has been used in other clinical studies to remove bacterial reservoirs in other parts of the body (that recolonize the nose)*
- ! *Bacterial detection was with high accuracy PCR testing rather than less accurate culture methods*

First human data demonstrating clinical utility of synthetic CBD as an antimicrobial agent



# 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

- ❖ Frequent use of catheters or inserting of needles to access the bloodstream puts patients at high risk of bloodstream infections
- ❖ 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

- ❖ Studies have found that risks for central venous catheter-related complications were as high as 30% and 38%, at 1 and 2 years respectively<sup>2</sup>
- ❖ The central venous catheter population (approx. 160,000 patients) is responsible for more than 70% of blood infections in the total dialysis population<sup>2</sup>

# Health system impact of haemodialysis infections



**~60%**

of Staph aureus-related hospital admissions occur within the first year of the initiation of dialysis therapy<sup>1</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>



**13 days**

Average length of stay for the index admission<sup>1</sup>

**11.8%**

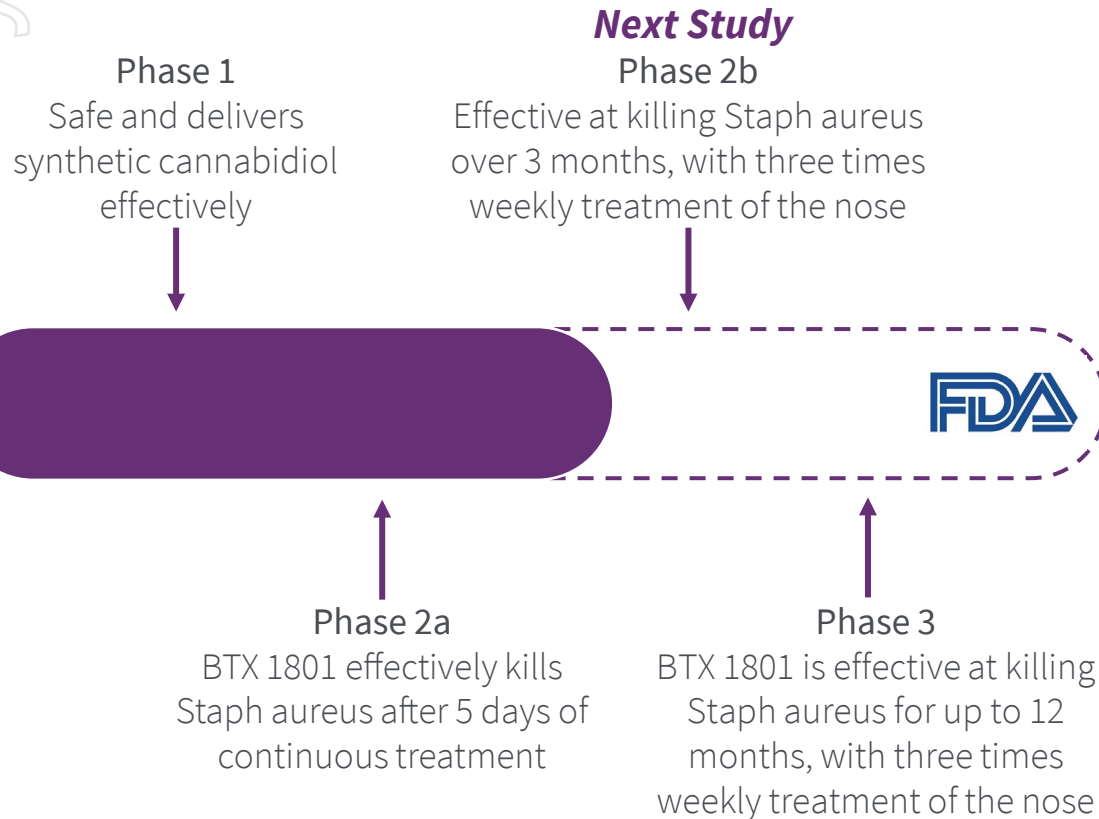
of patients were readmitted within 12 weeks of hospitalisation related to Staph aureus infections<sup>1</sup>

**US\$734m**

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



# BTX 1801: rapid clinical development



## 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



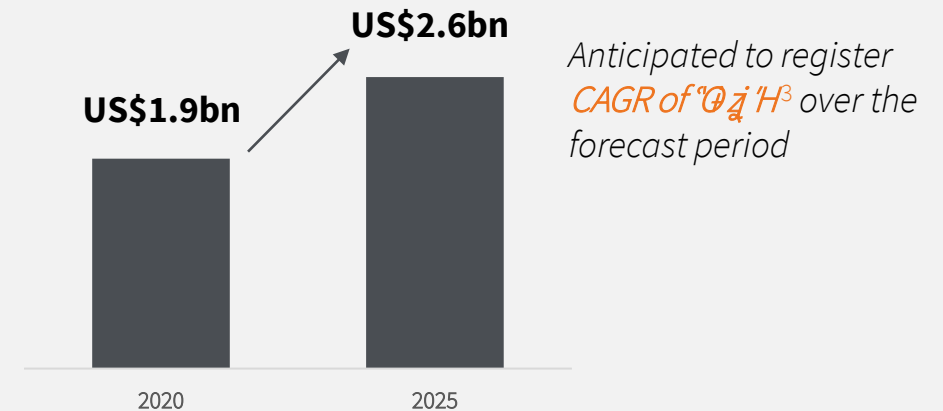
# BTX 1702: impact of rosacea and significant market opportunity

❖ 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 start



## ❖ 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 1503: 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 start**

*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\$23.3m**

*As at 31 March 2021*





# DISCLAIMER

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