

23 November 2020

## Botanix Annual General Meeting Presentation

**Philadelphia PA and Sydney Australia, 23 November 2020:** Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “the Company”) is pleased to release the presentation to be made at the Annual General Meeting to be held at 9:00am today (AWST).

Release authorised by

**Vince Ippolito**

President and Executive Chairman

### About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage synthetic cannabinoid 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 cannabinoid development platforms, dermatology and antimicrobial products, both of which 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 diseases.

The Company is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabinoids, with the BTX 1801 Phase 2a study for the prevention of surgical site infections fully enrolled. For the dermatology platform, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration and plans to progress its BTX 1702 rosacea study in the near future.

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

# AGM Presentation

23 November 2020



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# Investment Highlights

## Pharma focused

Leading pharmaceutical company leveraging unique properties of synthetic cannabinoids, including cannabidiol (CBD)

### Antimicrobial opportunities

Novel antimicrobial platform with positive pre-clinical results that underpin potential to combat antimicrobial resistance



### Dermatology opportunities

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

### World-class team

World-class and experienced team with significant cannabinoid, dermatology and antimicrobial drug development expertise



### Near-term catalysts

Multiple upcoming key catalysts including Phase 2a antimicrobial study completion, launch of Phase 1b rosacea study and planning for Phase 3 acne study

# Key Achievements

March 2020

Launch of BTX 1801 Phase 2a clinical study

April 2020

FDA grants a Qualified Infectious Disease Product designation for BTX 1801

July 2020

Successful completion of the End of Phase 2 meeting for BTX 1503 with FDA

August 2020

Initiation of recruitment for BTX 1801 Phase 2a study

September 2020

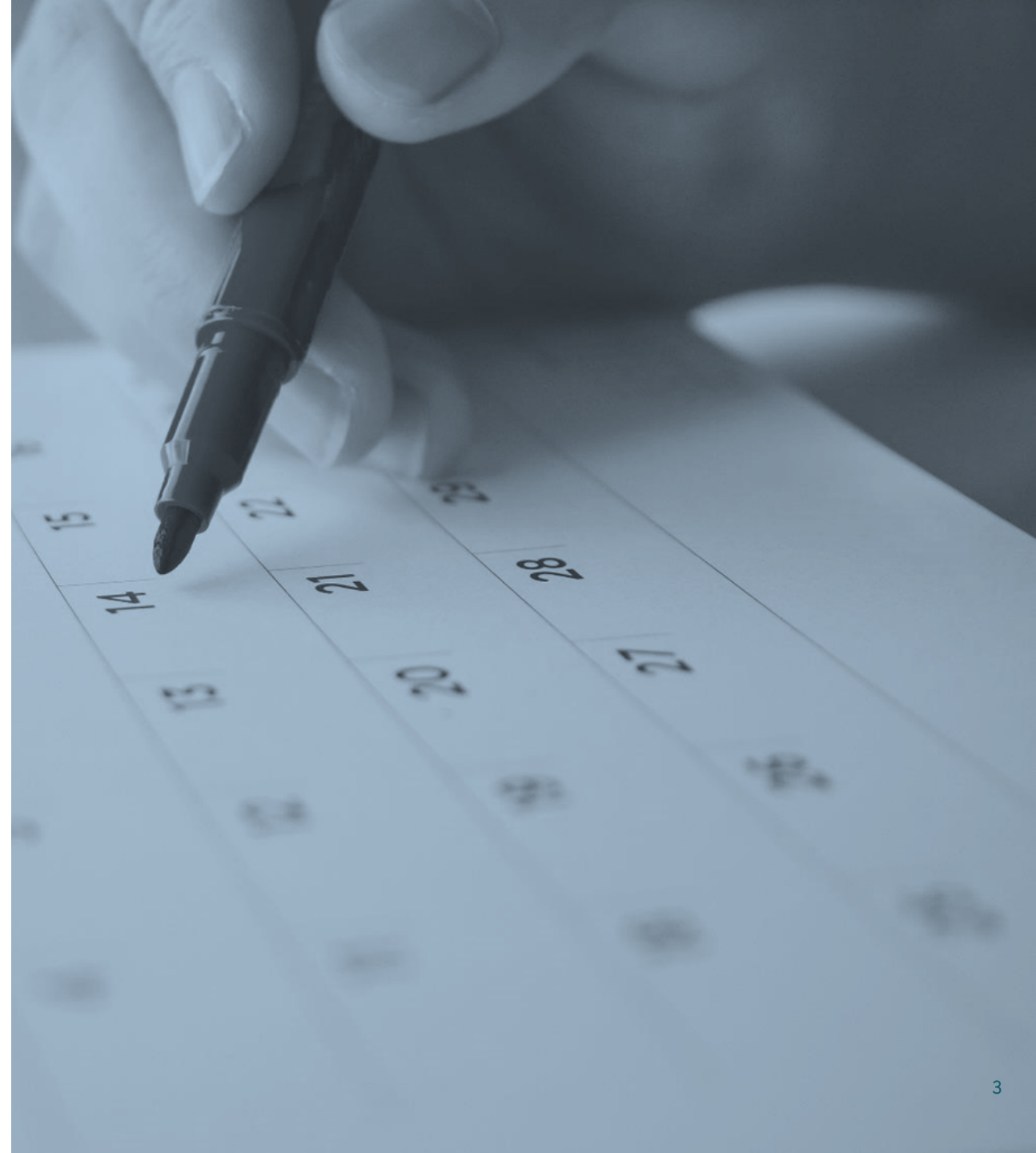
Release of new pre-clinical data supportive of the antimicrobial program and BTX 1801 clinical study

November 2020

Completed successful Pre-IND meeting with FDA for BTX 1801 clearing development in US towards a New Drug Application

November 2020

BTX 1801 Phase 2a clinical study achieves full enrolment

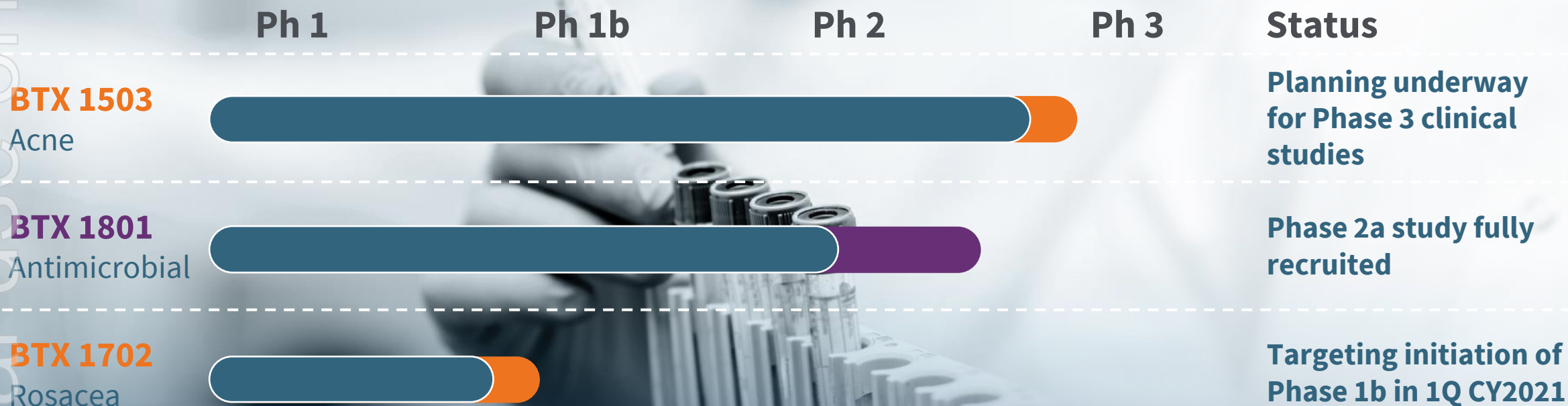


# Synthetic Cannabinoids are well suited to treat Skin Diseases and Infections

## Botanix's studies show synthetic cannabinoids:

- ✓ Safe and well tolerated
- ✓ Broad anti-inflammatory properties relevant to infections
- ✓ Strong and consistent impact on inflammatory lesions
- ✓ Kill *S. aureus* and resistant *S. aureus* (MSRA - "Superbugs")
- ✓ MRSA bacteria do not develop resistance<sup>1</sup>
- ✓ Potential for widespread use across human and animal health

# Synthetic Cannabinoids Advanced Clinical Pipeline



# BTX 1801 – First CBD-Based Program To Receive QIDP

## Strict QIDP criteria:

- ✓ Requires provision of a **detailed package of data**
- ✓ Must be a **novel product**
- ✓ Must treat a **serious or life threatening illness**

## FDA QIDP creates multiple commercial benefits

### Exclusivity

5 additional years of regulatory exclusivity on top of the standard 5 years

Up to 10 years of sales where generics cannot enter the market

### Priority

Eligible for an expedited six-month review period (rather than 12 months)

Accelerating the FDA review process reduces time to market

### Fast track

Enables more frequent communication with the FDA during development

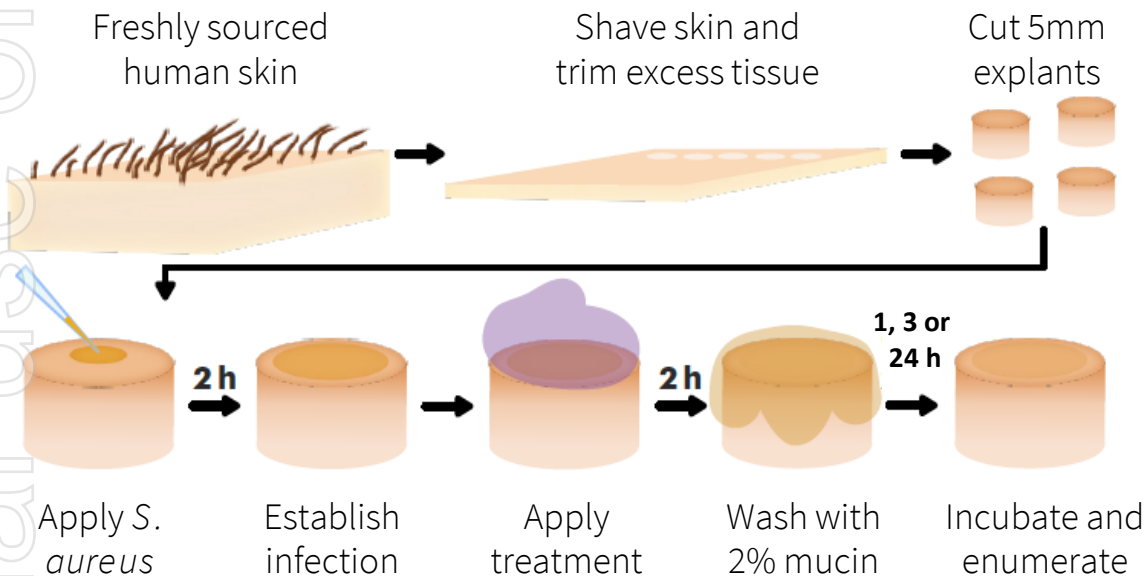
FDA guidance throughout development de-risks clinical trials



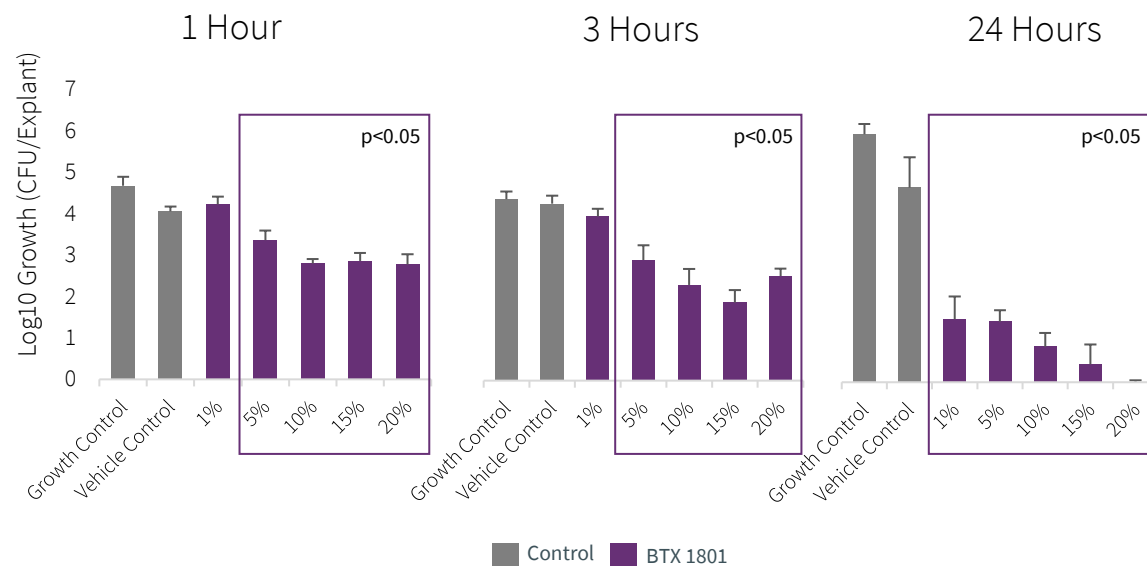
# Encouraging new pre-clinical data

Human explant data demonstrates BTX 1801 eliminates MRSA from infected human skin

## Human Skin Explant Model



## Efficacy of different concentrations of BTX 1801 in MRSA infected human skin explants

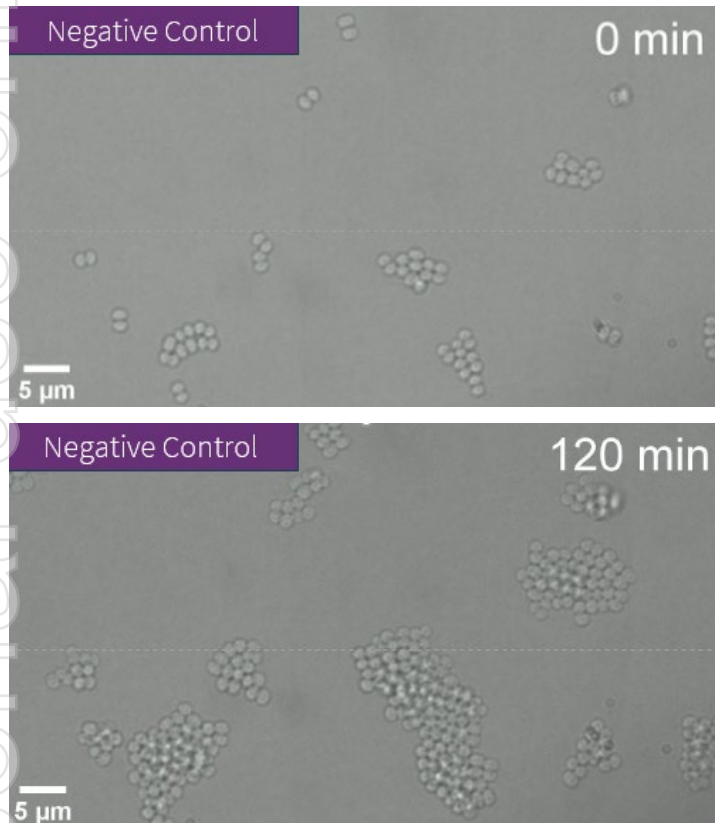


Complete eradication of MRSA from human skin explants was evident with the high dose BTX 1801 to be used in the Phase 2a clinical study

# Novel Mechanism of Action Confirmed

The time-lapse shows CBD causes rapid permeabilization of the bacterial membrane and cell death

*S. aureus* treated with 2.5% methanol (negative control)<sup>1</sup>

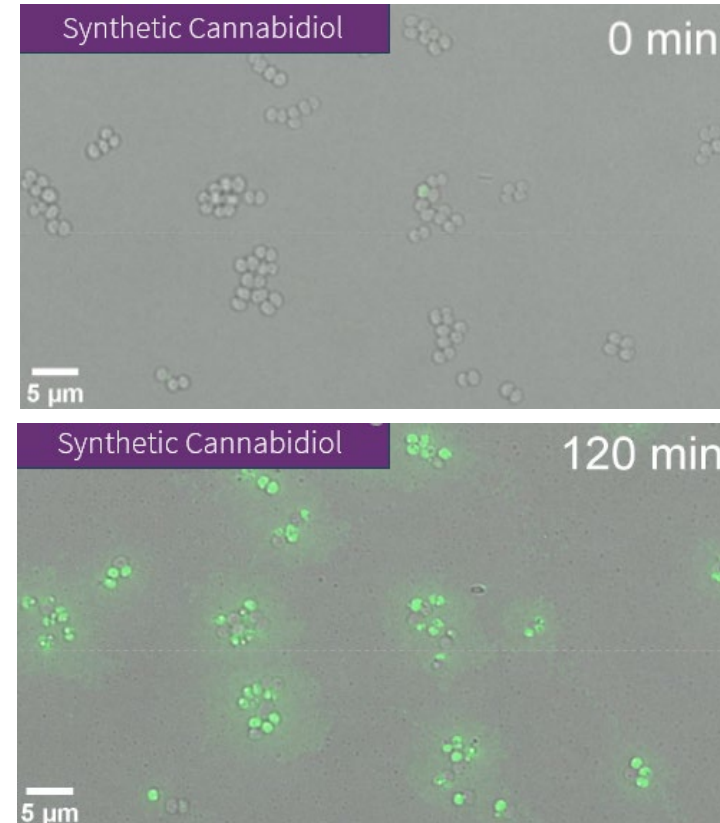


Staph bacteria treated  
with negative control



Bacteria are not  
affected over 120  
mins

*S. aureus* treated with synthetic cannabidiol<sup>1</sup>



Staph bacteria treated  
with synthetic CBD



Green staining indicates  
uptake of dye and  
disintegration of  
bacteria

1. *S. aureus* grown at room temperature on an agarose pad containing 0.25µM SYTOX-Green. Phase images were collected every five minutes for 120 minutes

# Initial Target – Surgical Site Infections

## Surgical site infections (SSIs) – significant health care challenge

- ❖ SSIs are caused by bacteria that get in through incisions made during surgery
- ❖ SSIs threaten the lives of millions of patients each year
- ❖ *Staphylococcus aureus* (SA) remains the most common agent for SSIs<sup>1</sup>
- ❖ SA commonly live **inside the nose** and are usually harmless, however SA can spread to other areas on the skins surface and **contaminate the surgical incisions**
- ❖ Mupirocin is the common antibacterial agent for nasal decolonisation, however widespread use had led to the emergence of Methicillin resistant SA (MRSA)

Screening patients for **SA nasal carriage and decolonising carriers** prior to surgery decreases the risk of SSIs<sup>1</sup>



### 1 PERSON IN 3

Carry SA on their skin or in their nose<sup>2</sup>



### 80% OF WOUND INFECTIONS

Traced to bacteria in the patients own nose<sup>1</sup>



### NASAL SA DECOLONISATION

Reduces post surgical infection by 60%<sup>3</sup>



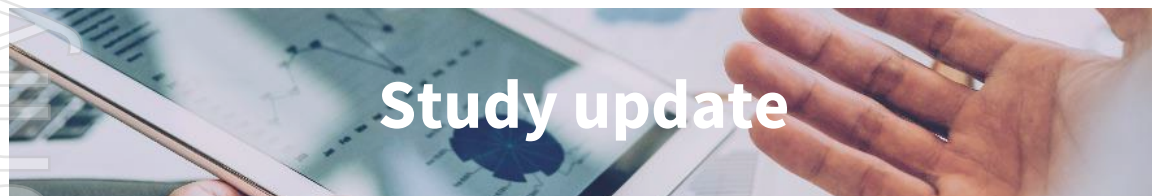
### US, EU AND WHO

Endorse treatment prior to high risk surgeries<sup>4</sup>

# BTX 1801: Clinical Development Strategy

## Study update

- ✓ Phase 2a study is well advanced and being conducted wholly in Western Australia
- ✓ On target for study completion in 4Q CY20
- ❖ Study evaluates safety and local tolerability of 2 formulations to decolonise *Staph / MRSA* from the nose of healthy adults
- ❖ Phase 2a study supports rapid progression into pivotal studies for FDA registration
- ❖ FDA 'fast-track' status application for BTX 1801 to be pursued post IND filing following recent grant of QIDP designation



## Study design

- ❖ Double-blind, vehicle-controlled Phase 2a clinical study
- ❖ 4 dose groups: ~60 healthy volunteers:
  - BTX 1801 Formulation A: 20 healthy volunteers
  - BTX 1801 Formulation B: 20 healthy volunteers
  - Vehicle A: 10 healthy volunteers
  - Vehicle B: 10 healthy volunteers
- ❖ Sites: single Australian site
- ❖ Patients: adults: 18 years and older with positive nasal SA
- ❖ Treatment: twice daily treatment for a 5-day period
- ❖ Primary endpoints: safety and local tolerability, proportion of volunteers carrying *Staph/MRSA* at Day 12



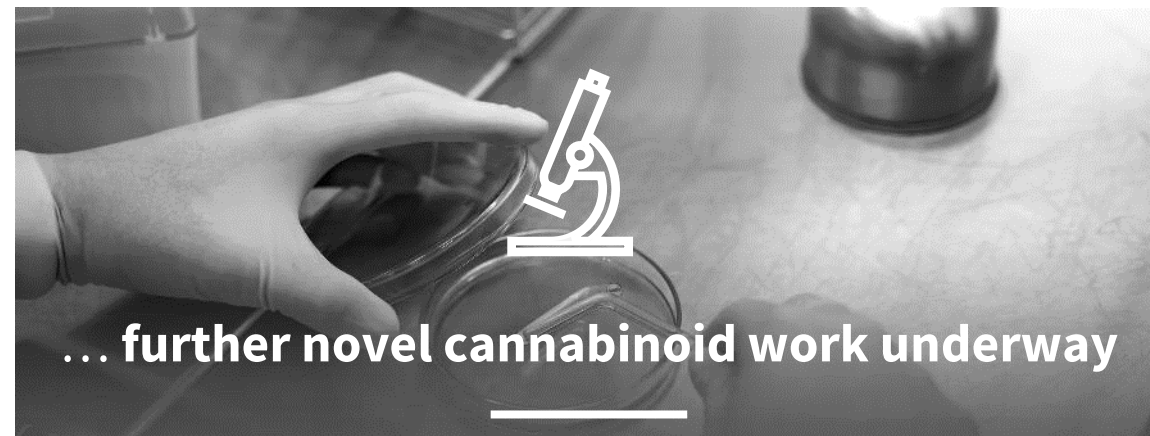
# Significant upside potential – Multiple AMR Opportunities

## Multitude of potential applications...

- ❖ **Dialysis related infections**- from catheter usage
- ❖ **Skin infections** – impetigo and bacterial folliculitis
- ❖ **Skin structure infections** - diabetic ulcers and wounds
- ❖ **Systemic infections** – utilising next generation synthetic cannabinoids
- ❖ **Ocular infections** – utilising next generation synthetic cannabinoids



AMR is projected to cost between **US\$300bn to US\$1tn annually** by 2050<sup>1</sup>



## ... further novel cannabinoid work underway

- ✓ Awarded Innovation Connection Grant<sup>2</sup> to accelerate the medicinal chemistry program
- ✓ Medicinal chemistry program being conducted in collaboration with the University of Queensland
- ✓ Targeting creation of new synthetic analogs to improve the efficacy and bioavailability of “natural” cannabinoids
- ✓ New analogs have a unique structure and activity profile and are patentable as new chemical entities
- ✓ Potential in multiple human and animal health applications

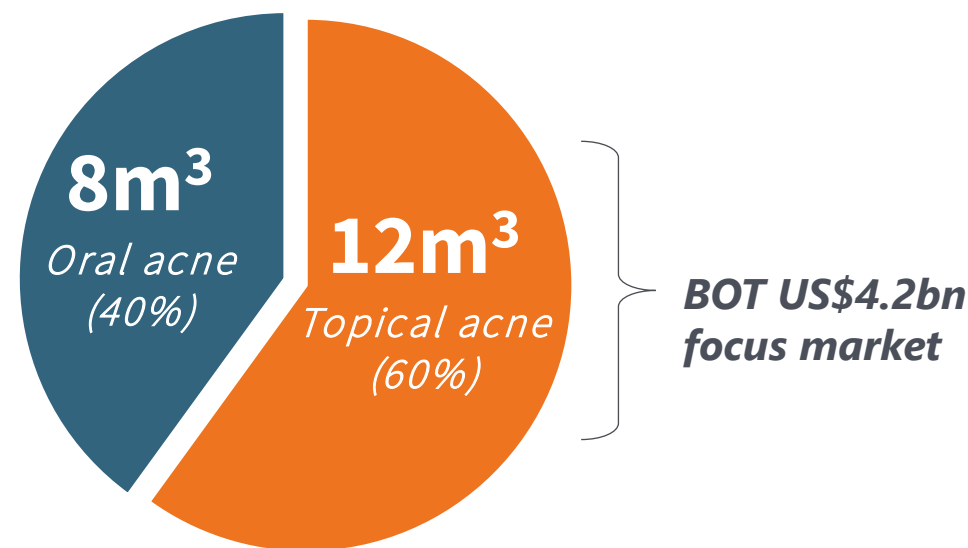
# BTX 1503: Successful End-of-Phase 2 FDA Meeting

## 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

## Sizable acne prescription market

The global acne market expected to reach US\$7bn by 2024<sup>2</sup>



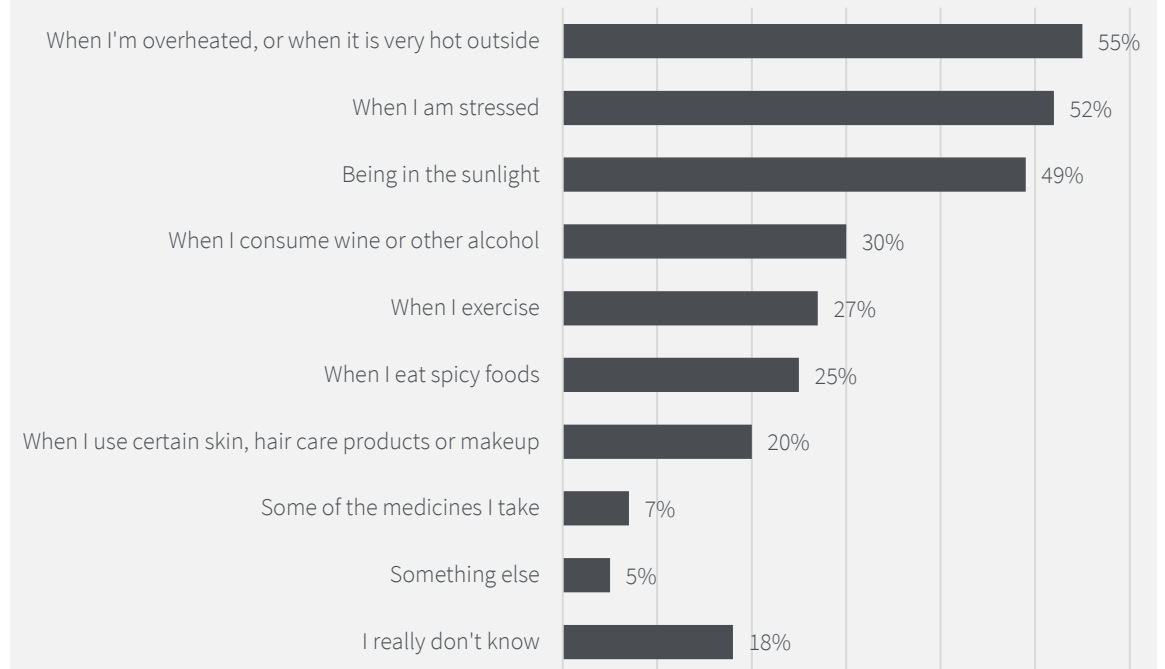
## BTX 1702: Impact of Rosacea and Triggers

❖ 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

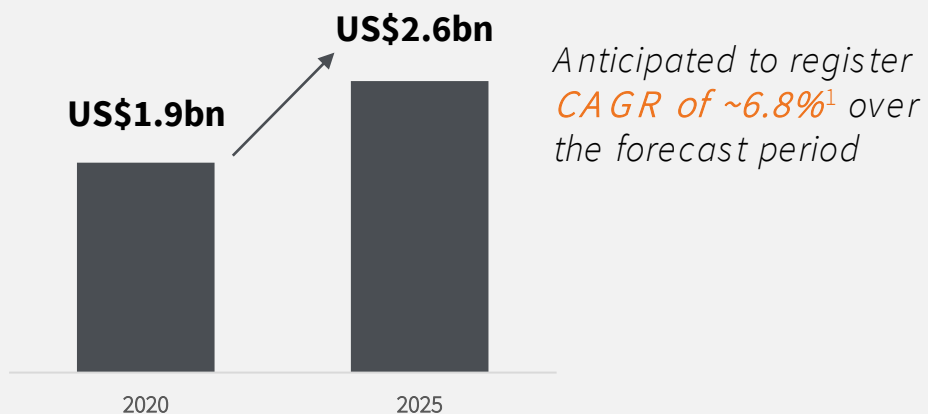
### Rosacea triggers<sup>3</sup>



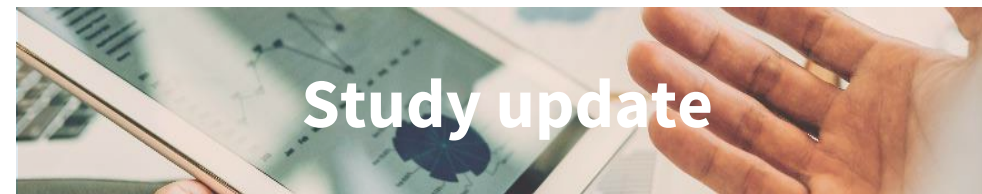
1. Blount BW, Pelletier AL. Am Fam Physician. 2002;66:435-440., 2. Moustafa F. J Am Acad Dermatol. 2014;71:973-980, 3. Vyne Therapeutics: FMX103 Demand Study, Consumer Arm June 2019 Q11 – Which of the following things, if any, do you feel makes your rosacea worse or triggers it? Select all that apply (N=100)

# BTX 1702: Significant Market Opportunity and Study Primed to Kick Off in the New Year

A rapidly growing market:  
Rosacea market projected to grow to US\$2.6bn by 2025<sup>1</sup>



- ❖ Affects ~5.5% of the global population<sup>2</sup>, ~430m individuals
- ❖ 85% of patients are over 30 years old<sup>3</sup>
- ❖ There are currently over 16m Americans affected<sup>4</sup> by the illness, with ~5m medical treatment prescriptions<sup>5</sup> in the US alone



- ✓ Phase 1b clinical study poised to re-start as COVID-19 restrictions eased across Australia and New Zealand early in the New Year
- ❖ Ethics submission updated and site initiation for clinical sites recommenced
- ❖ Study design aimed at providing high quality efficacy and safety data to inform late stage in both rosacea and acne



# BTX 1702: Phase 1b Rosacea Study Updated Design



## ❖ 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: ~10 dermatology sites across Australia and NZ

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

## ❖ Treatment period: 6 weeks

## ❖ Assessment: facial photos with Canfield imaging

## ❖ Endpoints:

- Safety and tolerability
- Change in inflammatory lesion counts from baseline at days 8, 22 and 43
- Proportion of patients with Investigator's Global Assessment (IGA) treatment success
- Change in Clinician's Erythema Assessment (CEA) scale
- Imaging and patient reported outcomes

# World-Class Team

## Board



**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 Michael Thurn**

Executive Director

- ❖ Previous MD of Spinifex Pharmaceuticals which sold to Novartis for A\$700m
- ❖ Extensive start up life sciences experience in dermatology



**Dr Stewart Washer**

Director

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



**Dr Bill Bosch**

Executive Director

- ❖ 20+ years of experience in the pharma industry
- ❖ Former CSO of iCeutica Inc. and
- ❖ Co-inventor of SoluMatrix™, a drug delivery technology and NanoCrystal® Technology

## Advisors

**Dr Ron Dolle**

CMC and Medicinal Chemistry

- ❖ Accomplished drug discovery executive with a record of innovation and success, team leadership, candidate selection, preclinical development, and registration

**Dr Joyce Rico**

MD, MBA, FAAD

- ❖ Recently CMO for Novan Pharmaceuticals
- ❖ Experience as Board Member for the Society of Investigative Dermatology, VP Medical Affairs at Astellas and faculty member at Duke, NYU and Northwestern

**Dr Ira Lawrence**

MD, FACP

- ❖ 30+ years of senior level leadership experience within the global pharmaceutical and medical device industries
- ❖ Currently serves as a senior-level consultant, with numerous clients worldwide

# Executing on Key Near-Term Milestones

❖ **Antimicrobial: BTX 1801 Phase 2a study completion**

*Fully recruited - study completion on target for 4Q CY2020*

❖ **Rosacea: BTX 1702 Phase 1b study start**

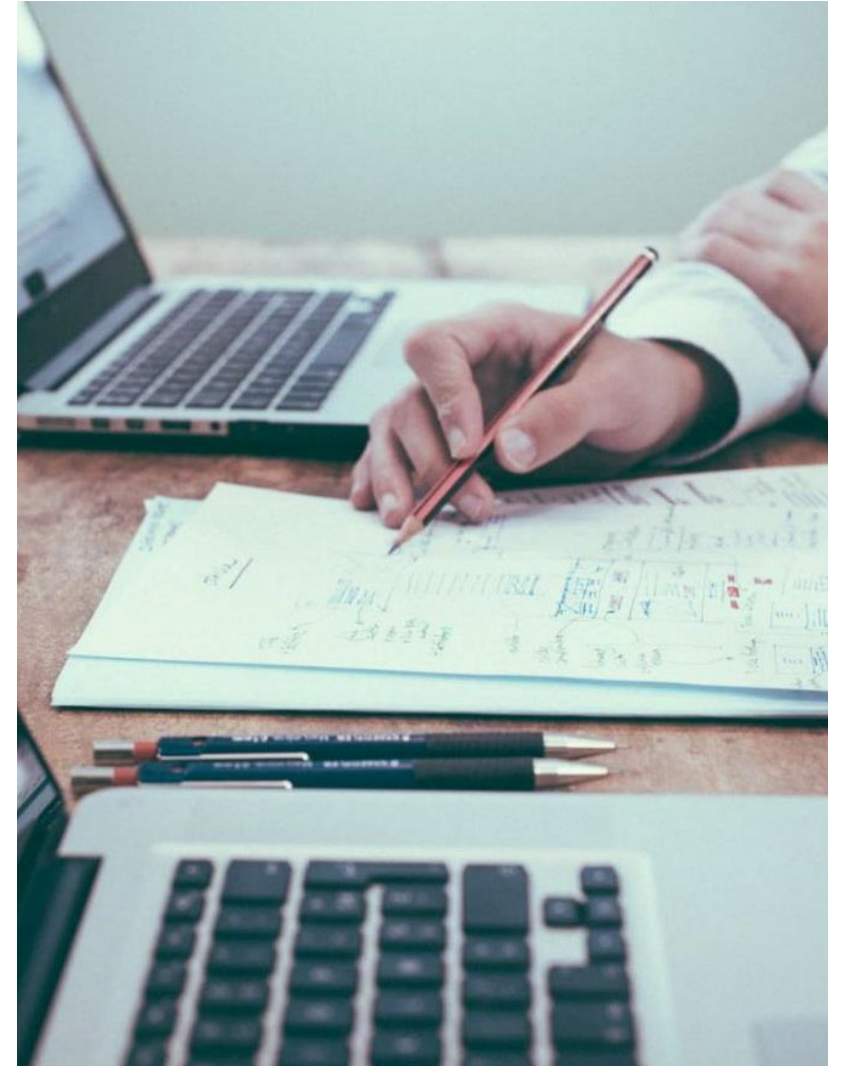
*Targeting study initiation in 1Q CY2021*

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

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

**Strong cash position - A\$22.1m**

*As at 30 September 2020 (not including R&D tax return)*



# DISCLAIMER

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PHARMACEUTICALS