

16 March 2021

Botanix presenting at ASX Small and Mid-Cap Conference

Philadelphia PA and Sydney Australia, 16 March 2021: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “the Company”) is pleased to announce Vince Ippolito, President and Executive Chairman, will be presenting at the ASX Small and Mid-Cap Conference, held on 16 to 17 March 2021.

The Company will provide an update on the progress of the key clinical programs, including the BTX 1801 Phase 2a results and the implications of this data on the broader dermatology platform. The event is free to attend, and investors are invited to register [here](#). The conference presentation is attached to this release.

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 nasal decolonization study announcing positive data in early February CY2021. For the dermatology platform, the Company has confirmed a drug development plan for the BTX 1503 acne program to support registration and plans to initiate its Phase 1b rosacea study in 1H CY2021. To learn more please visit: <https://www.botanixpharma.com/>

For more information, please contact:

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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.



Unlocking the potential of synthetic cannabinoids

ASX Small and Mid-Cap Conference

March 2021



Investment Highlights

Pharmaceutically focused

Leading pharmaceutical company leveraging unique delivery technology (Permetrex™) and the properties of synthetic cannabinoids, including cannabidiol (CBD)

Antimicrobial opportunities

Novel antimicrobial platform with positive Phase 2a results that underpin potential of CBD to combat antimicrobial resistance

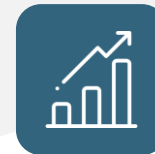


Dermatology opportunities

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 dermatology and antimicrobial drug development expertise



Near-term catalysts

Multiple upcoming key catalysts including launch of Phase 1b rosacea study, progression of 1801 antimicrobial platform and Phase 3 acne study

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
- ❖ Former CSO of iCeutica Inc. and
- ❖ Co-inventor of SoluMatrix™, a 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, Intrommune and Shire Pharmaceuticals

Lynda Berne

Head of Commercial

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

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

Dr Ira Lawrence

MD, FACP

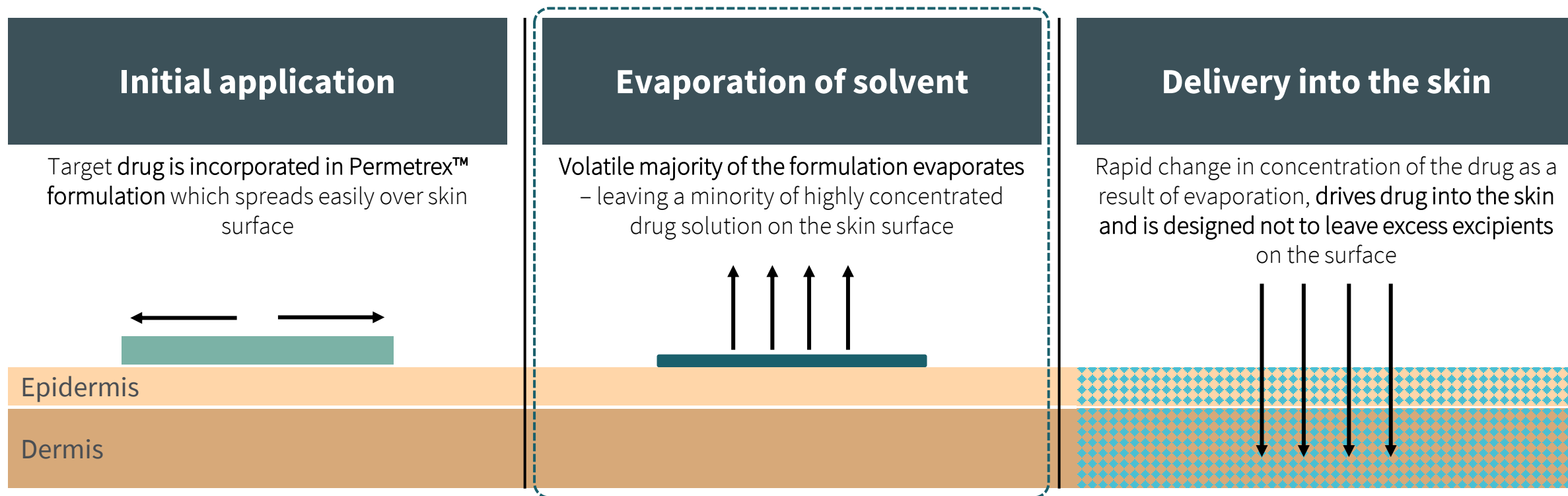
- ❖ 30+ years of senior level leadership experience within the global pharmaceutical and medical device industries

Advanced Pipeline

	Ph 1	Ph 1b	Ph 2	Ph 3	Status
BTX 1503 Acne					Planning underway for Phase 3 clinical studies
BTX 1801 Antimicrobial					Positive Phase 2a results, finalising clinical development plan
BTX 1702 Rosacea					Phase 1b study to commence in 2Q CY2021
Permetrex™ Delivery technology					Ongoing project work and internal development

Permetrex™: Proprietary skin delivery technology

Makes new types of topical products¹ that deliver very high doses of drug into the layer of the skin without using permeation enhancers, preservatives, or irritating levels of alcohol / petrol derivatives



Permetrex™ is utilised in Botanix synthetic CBD pipeline products and to improve delivery of other drugs in development with partners

Synthetic Cannabinoids are well suited to Treat Skin Diseases and Infections

Botanix's studies show synthetic cannabidiol to be:

- ✓ 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* (MRSA - "Superbugs")
- ✓ MRSA bacteria do not develop resistance¹
- ✓ Potential for widespread use across human and animal health

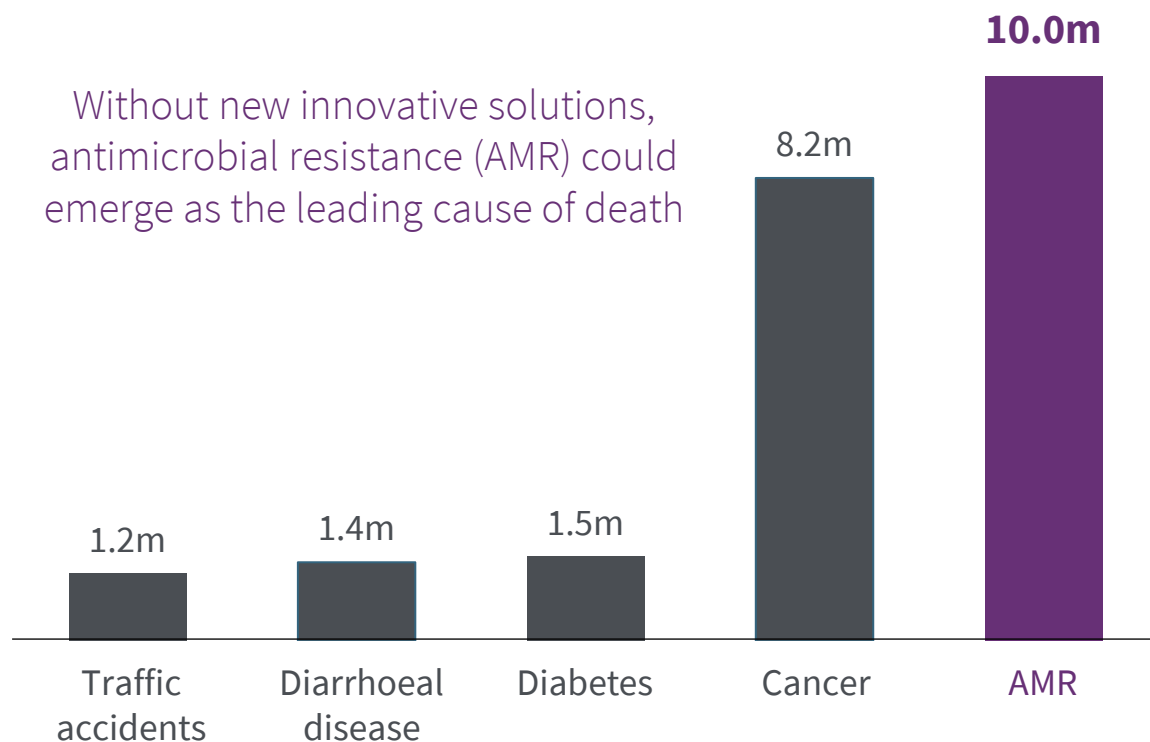
Anti-microbial resistance background and BTX 1801 clinical program



Antimicrobial Resistance is a Fast-Growing Problem...

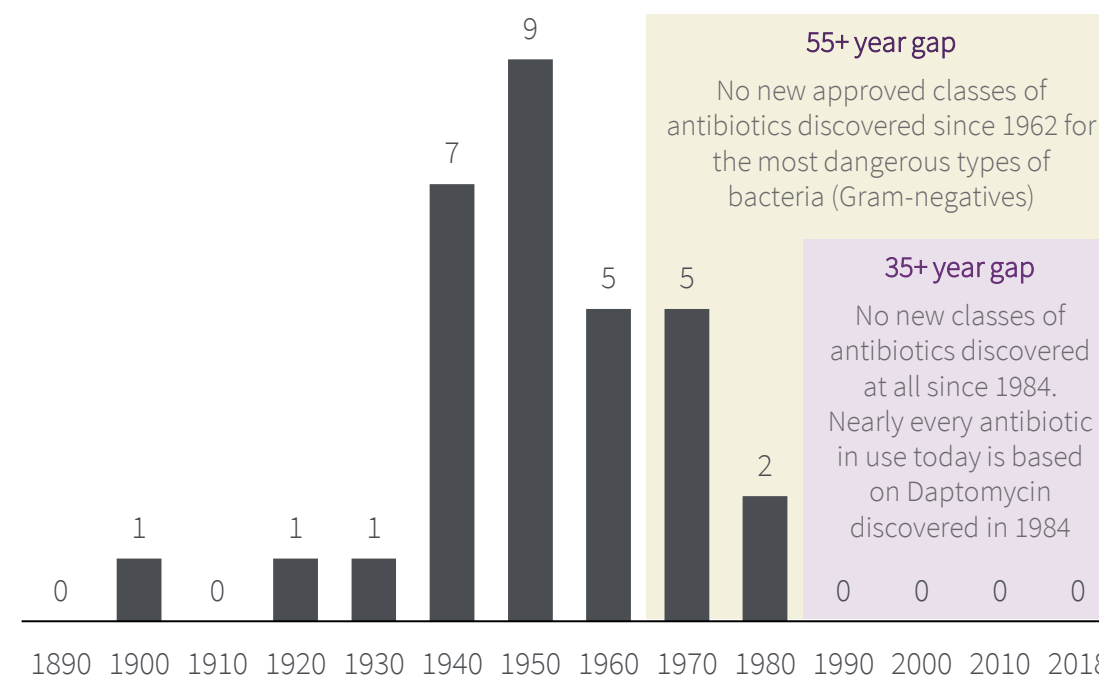
Global forecast deaths by 2050¹ (p.a.)

Without new innovative solutions, antimicrobial resistance (AMR) could emerge as the leading cause of death



...with No Innovation in Over Three Decades

Number of antibiotic classes discovered or patented²



BTX 1801: nasal decolonisation *staph aureus* Phase 2a study



Study design

- ❖ Double-blind, vehicle-controlled Phase 2a clinical study
- ❖ 4 dose groups: 66 healthy volunteers:
 - BTX 1801 Formulation A
 - BTX 1801 Formulation B
 - Vehicle A
 - Vehicle B
- ❖ 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



Safety & tolerability

- ✓ Safe and well tolerated at doses up to 20% drug active
- ✓ All 66 participants successfully completed the BTX 1801 study
- ✓ No severe adverse events reported¹



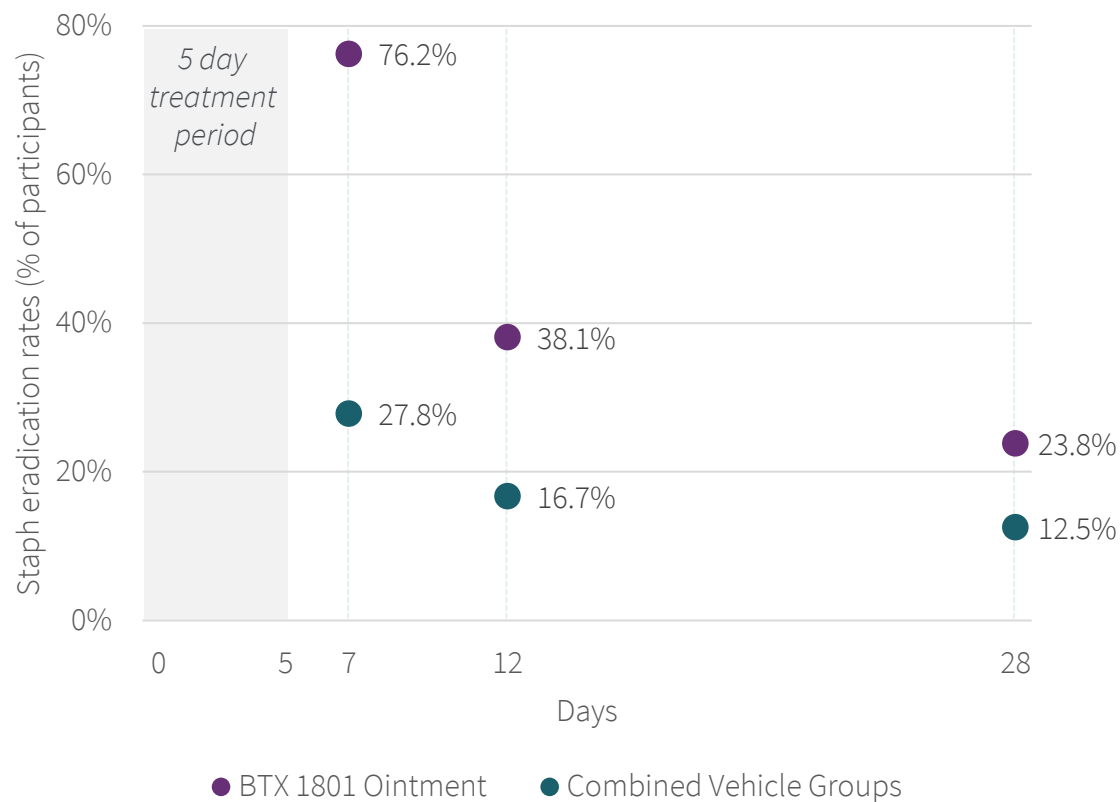
Efficacy

- ✓ Efficacy of ointment and gel formulations demonstrated at primary endpoint of 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

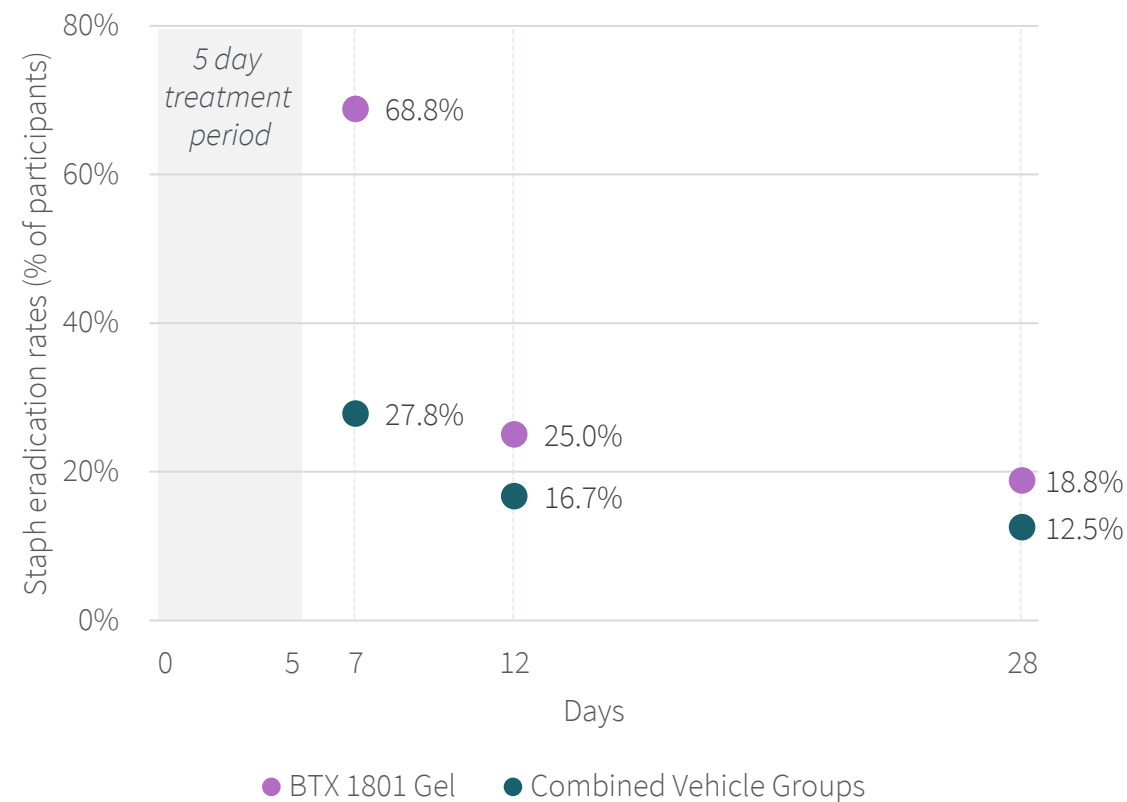
Phase 2a study data: staph eradication

World first human data demonstrating synthetic CBD has clinical utility as an antimicrobial agent

BTX 1801 Ointment: Staph eradication rates (% of participants)¹



BTX 1801 Gel: Staph eradication rates (% of participants)¹



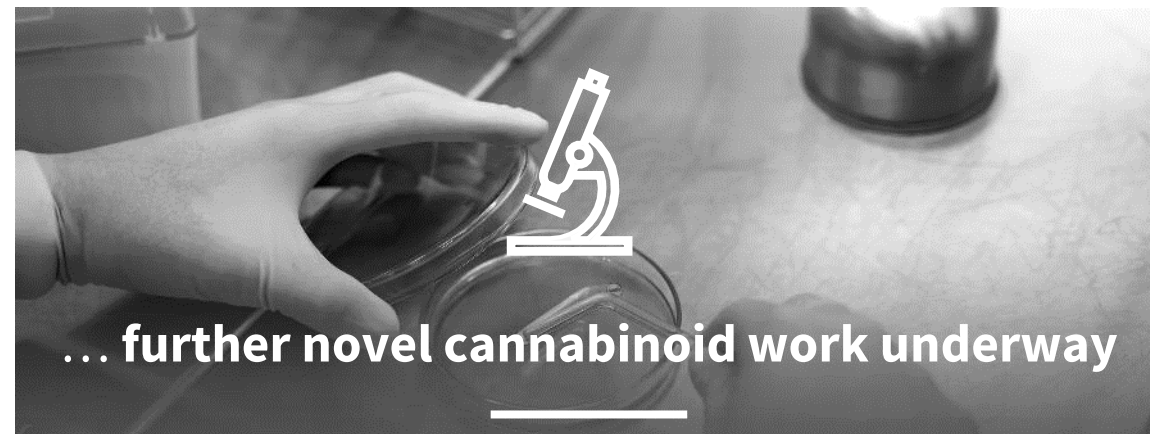
Significant Upside Potential– Multiple AMR Opportunities

- ❖ **Dialysis related infections** - from catheter usage
- ❖ **Skin structure infections** - diabetic ulcers and wounds
- ❖ **Skin infections** – impetigo and bacterial folliculitis
- ❖ ***N. Gonorrhoeae***
- ❖ **Meningitis**
- ❖ **Legionnaires disease**



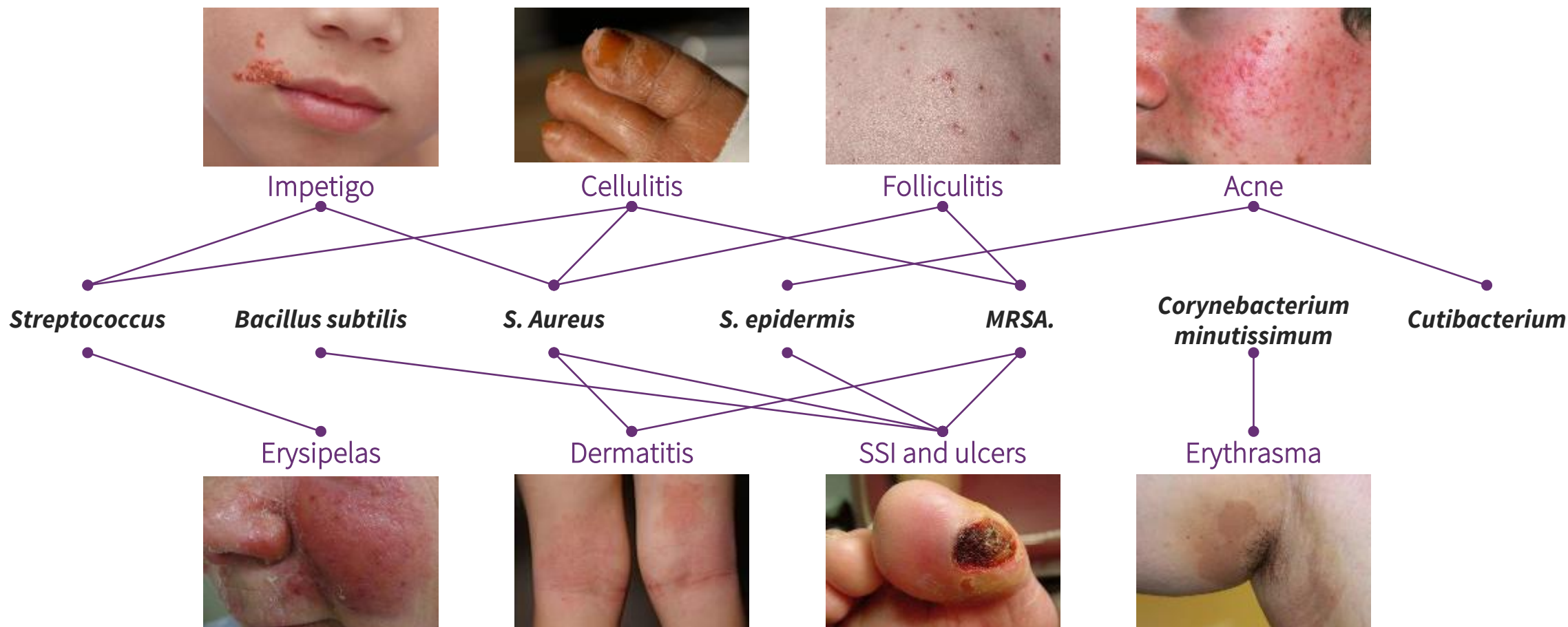
Drug resistant diseases could cause up to **10m deaths each year by 2050¹**

Top-line data and additional information from the BTX 1801 study will further inform development strategies for the antimicrobial platform



- ✓ Awarded Innovation Connection Grant² 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

Implications for Dermatology – Safe and Effective Antimicrobial and Anti-Inflammatory



Dermatology clinical programs

A close-up, monochromatic image of a microscope's objective lens and stage. The lens is labeled 'HI 100/1,25' and '160/0,17'. A hand is visible on the right, adjusting the stage. The image is overlaid with a large orange rounded rectangle containing the text 'Dermatology clinical programs'.



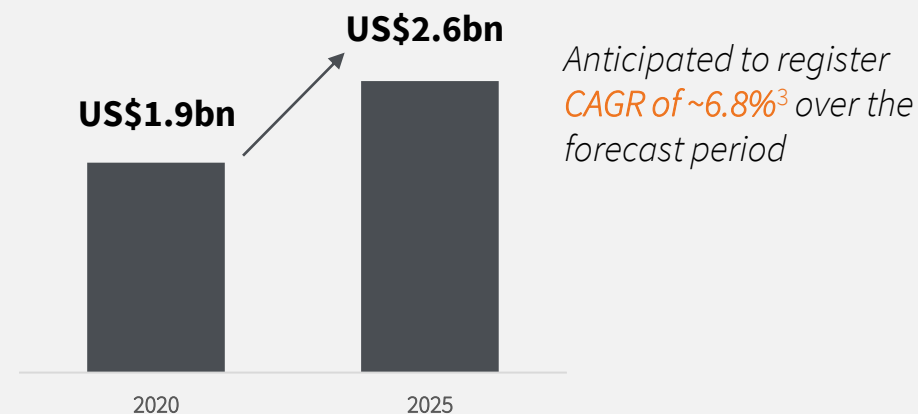
BTX 1702: Impact of Rosacea and Significant Market Opportunity

❖ Papulopustular rosacea is a **chronic skin disease** characterised by **redness (inflammation) and acne-like-break-outs**¹

❖ Patients diagnosed with Rosacea tend to have higher incidences² of:

- Depression
- Social anxiety
- Embarrassment
- Decreased quality of life

A rapidly growing market:
Rosacea market projected to grow to US\$2.6bn by 2025³



❖ Affects ~5.5% of the global population⁴, ~430m individuals

❖ 85% of patients are over 30 years old⁵

❖ There are currently over 16m Americans affected⁶ by the illness, with ~5m medical treatment prescriptions⁷ in the US alone

BTX 1702: Phase 1b Rosacea Study Commencing 2Q CY2021



❖ 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

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 endpoints¹ 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

Large and growing acne market



22m total prescriptions in 2019 growing ~5% year-on-year²



US\$5.1bn in sales in 2019²



>2m p.a. active, diagnosed acne patients under HCP care³



~40m to ~50m acne sufferers⁴ (~10m mod-to-severe)



60% of acne patients are managed by 5K HCPs⁵

Executing on Key Near-Term Milestones

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

Positive results announced and finalising clinical progression plans

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

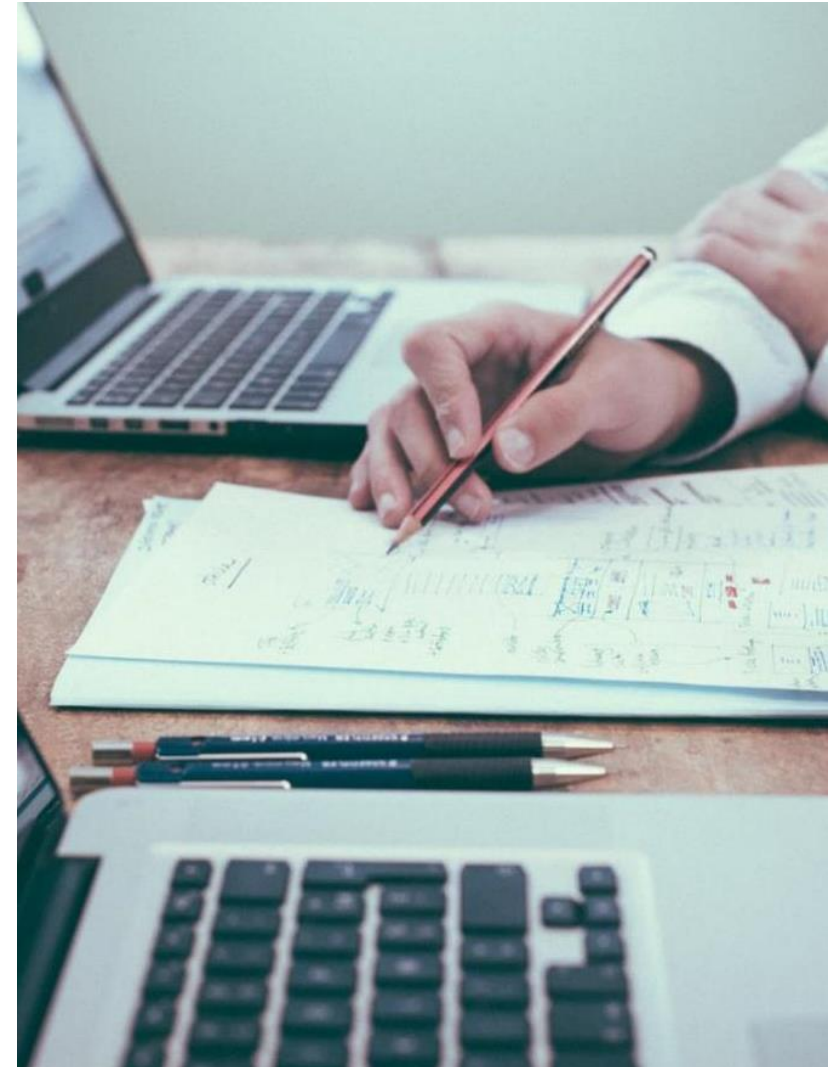
Targeting study commencement in 2Q CY2021

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

Pending the completion of BTX 1702 Phase 1b clinical study

Strong cash position - ~A\$26m

As at 31 December 2020 (including R&D tax return)



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