19 February 2021

Botanix attends 2nd Dermatology Drug Development Summit Europe

Philadelphia PA and Sydney Australia, 19 February 2021: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to announce Matt Callahan, Executive Director, will be presenting at the 2nd Dermatology Drug Development Conference Europe, held virtually this year.

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 conference attracts industry experts focused on therapeutic innovation in the dermatology space and features company presentations, thematic panel discussions, workshops and one-on-one discussions. 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 CY 2021. 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/

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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 is 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

2nd Dermatology Drug Development Summit Europe

February 2021

Overview of Botanix

Pharma focused

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

Antimicrobial opportunities

Novel antimicrobial platform with positive Phase 2a 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 progression of antimicrobial platform, launch of Phase 1b rosacea study and planning for Phase 3 acne study

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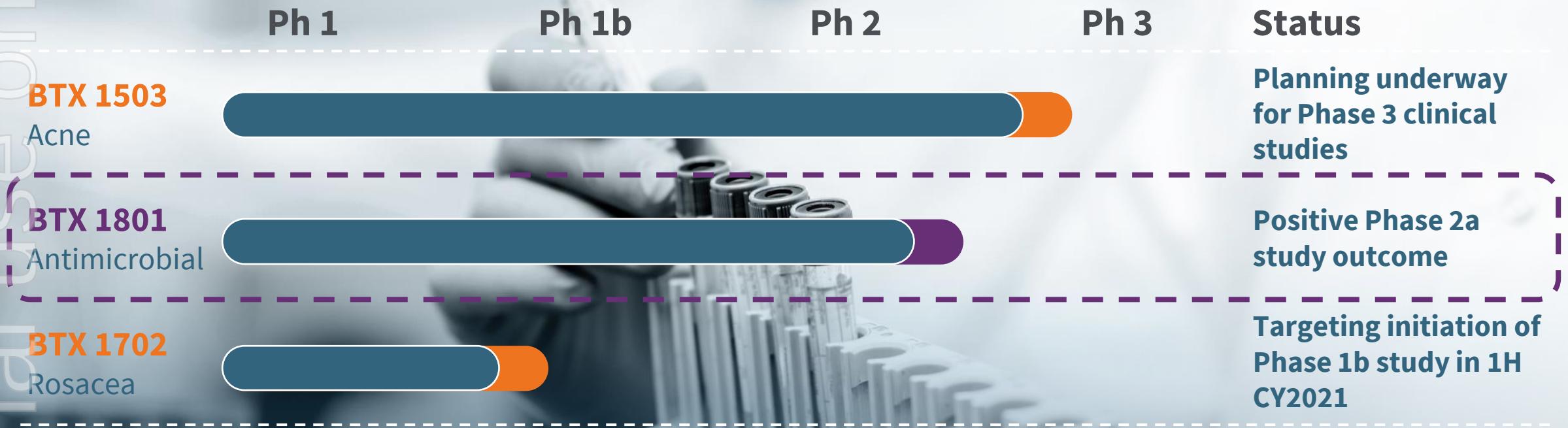
Synthetic Cannabinoids
Advanced Clinical Pipeline



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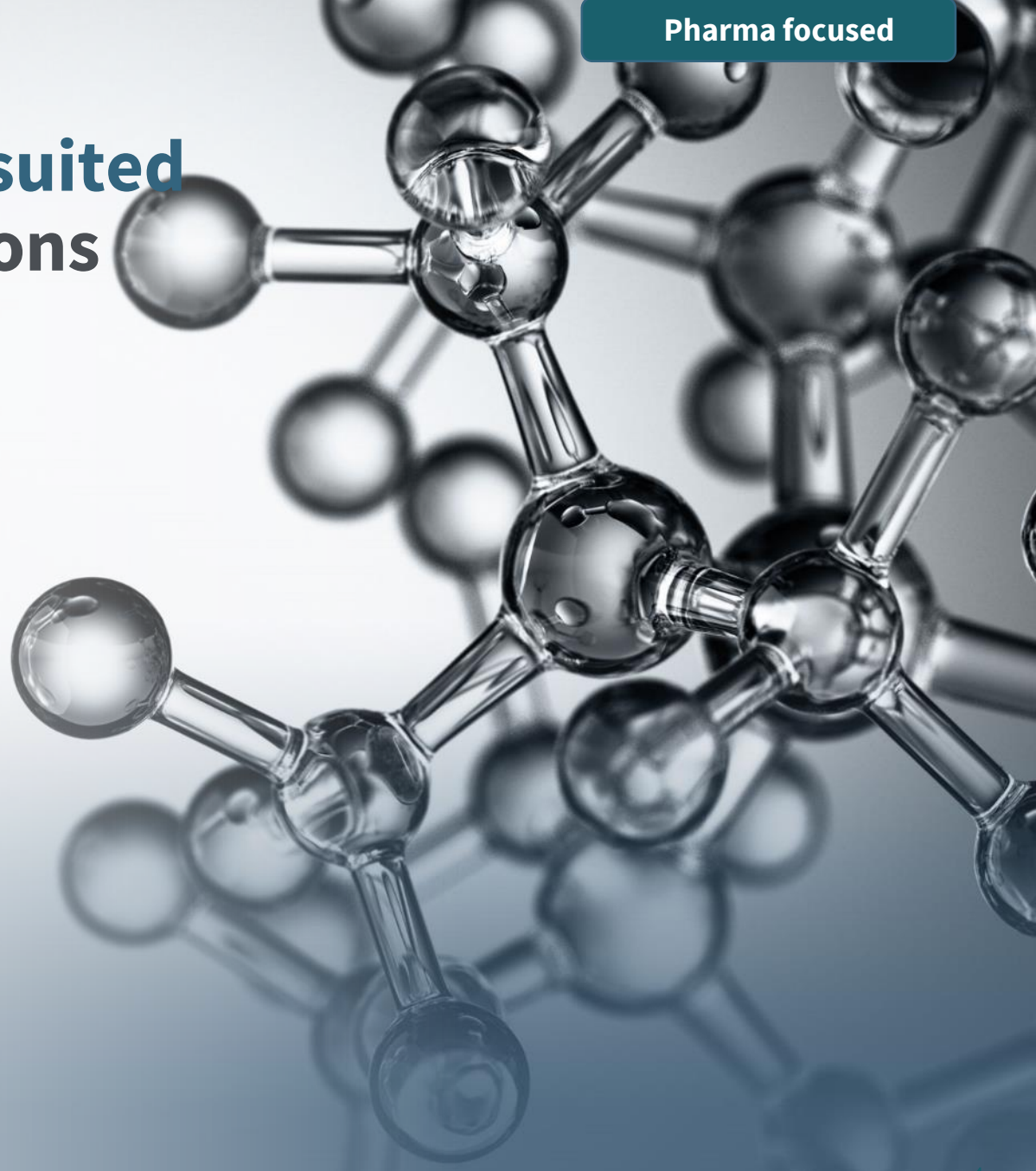
Synthetic Cannabinoids are well suited to treat Skin Diseases and Infections



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 are not prone to develop resistance[1]
- ✓ Potential for widespread use across human and animal health

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1. See ASX announcement "Antimicrobial Platform Update and Launch of BTX 1801 Study" (13 March 2020)

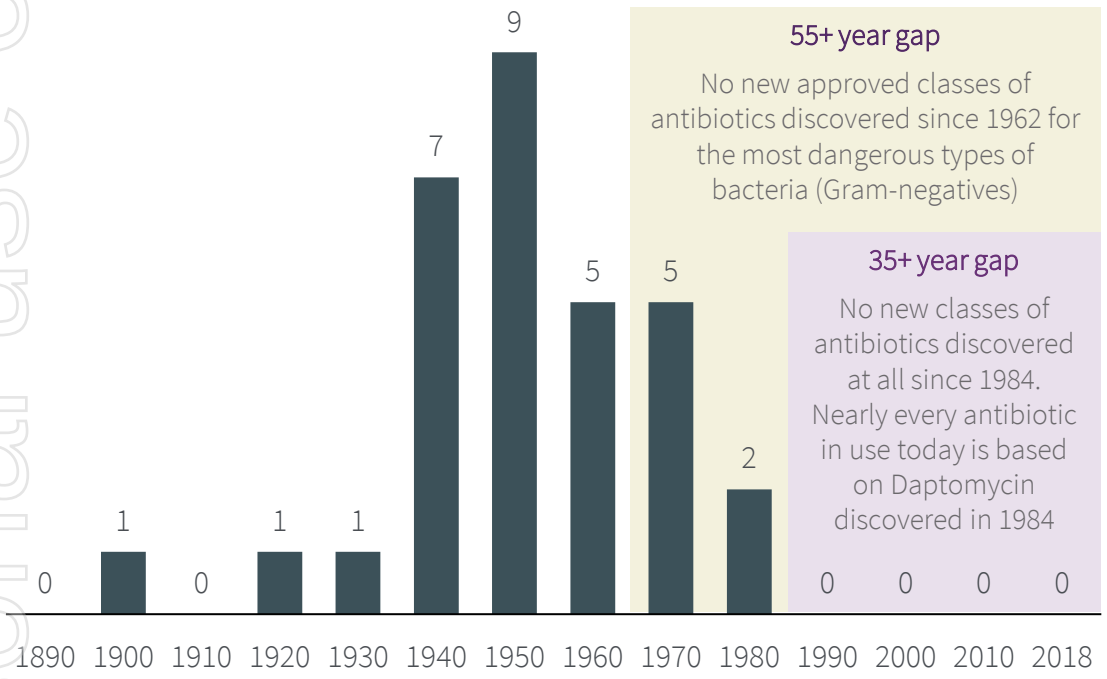
Background

Anti-microbial resistance and cannabinoids

No new antibiotics have been discovered in over three decades

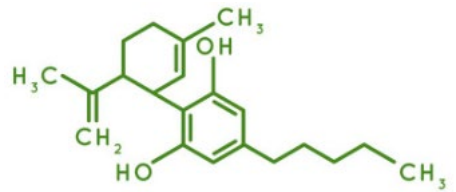
No new approved class of antibiotics has been discovered since 1984 and no new class of antibiotics has been discovered to treat Gram-negative bacteria since 1962

Number of antibiotic classes discovered or patented[1]



Cannabinoids

New class of antibiotics



Structural activity characterized by Botanix
(IP Position secured)

Examples

Cannabidiol (CBD), Cannabigerol (CBG), CBD analogs

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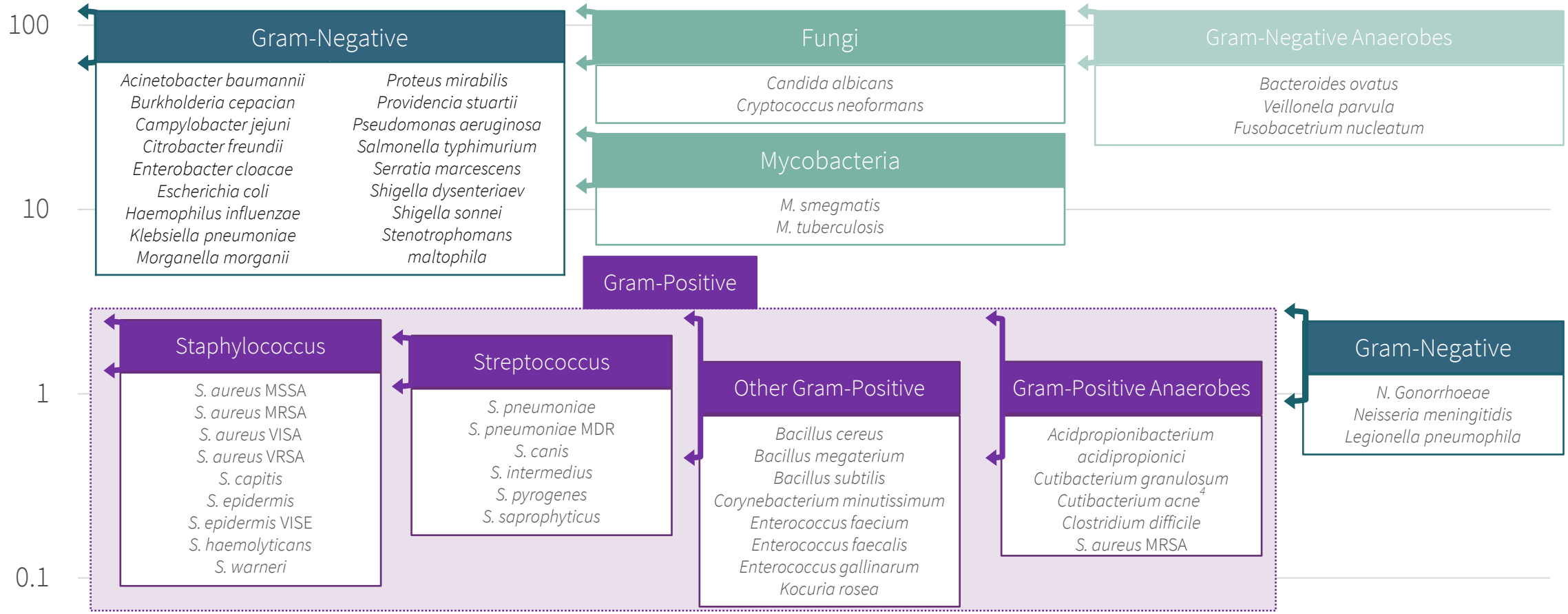
1. Pew Charitable Trusts; Deak et al. Progress in the Fight Against Multidrug Resistant Bacteria?; A Review of FDA Approved Antibiotics 2010-2015. 31 May 2016. DOI: 10.7326/M16-0291

CBD is a broad-spectrum Gram-positive antibiotic

CBD is a powerful new antibiotic that is effective against a range of problematic Gram-positive bacteria at MICs comparable to currently approved antibiotics[1,2,3]



1. Based on testing conducted by the University of Queensland – BOT data on file
2. Based on testing conducted by the Micromyx – BOT data on file
3. Based on testing conducted by Monash University – BOT data on file
4. Formerly known as *Propionbacteria acnes*

Remarkable activity against MRSA without inducing resistance

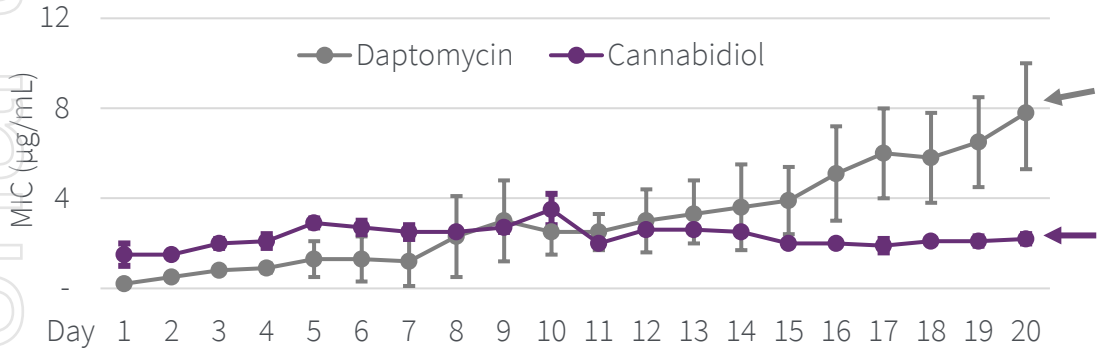
CBD shows remarkable activity against 132 isolates of S. aureus and MRSA[1]

Antibiotic Minimum Inhibitory Concentration (MIC) comparison[1]

Antibiotic	*S. aureus* all isolates (mg/mL)			MRSA (mg/mL)		MSSA (mg/mL)	
	MIC_{50}	MIC_{90}	Range	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}
CBD	2	4	0.25 - 8	2	2	2	4
Mupirocin	0.5	0.5	0.125 – 64	0.5	0.5	0.5	0.5
Vancomycin	1	2	0.5 – 64	1	1	1	2
Daptomycin	2	4	0.5 – 16	2	2	2	4
Clindamycin	0.125	64	0.03 – 64	0.125	0.1875	0.125	64

MIC_{50} = min conc to inhibit growth of 50% of isolates. **MIC_{90}** = min conc to inhibit growth of 90% of isolates. **MRSA** = methicillin resistant *S. aureus*. **MSSA** = methicillin susceptible *S. aureus*

MIC daily variability[2]



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

1.5x fold increase

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

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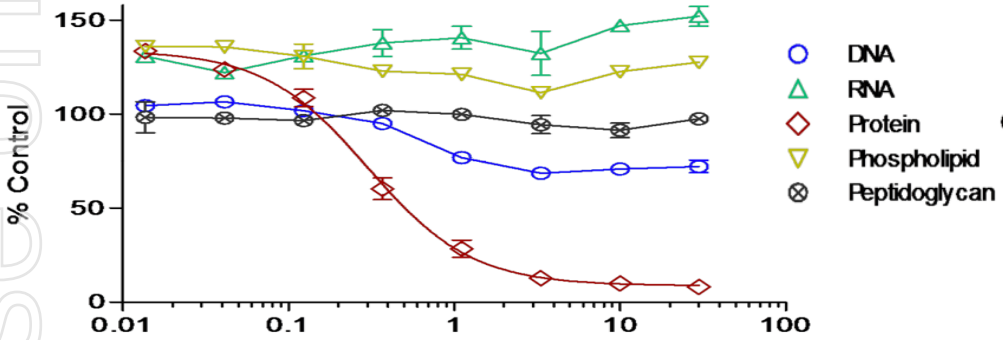
1. Based on testing conducted by the University of Queensland – BOT data on file
2. Based on an average of 8 replicates (University of Queensland – BOT data on file)

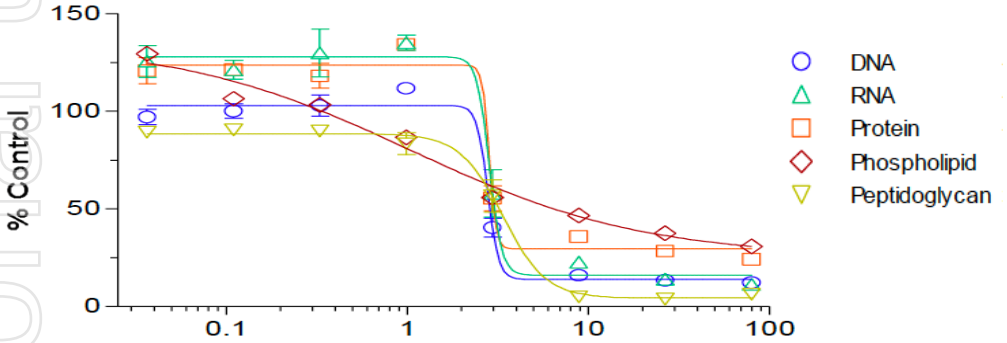
Unique mechanism of action – bactericidal

Novel mechanism of action with unique ability to rapidly kill bacteria without allowing resistance to develop

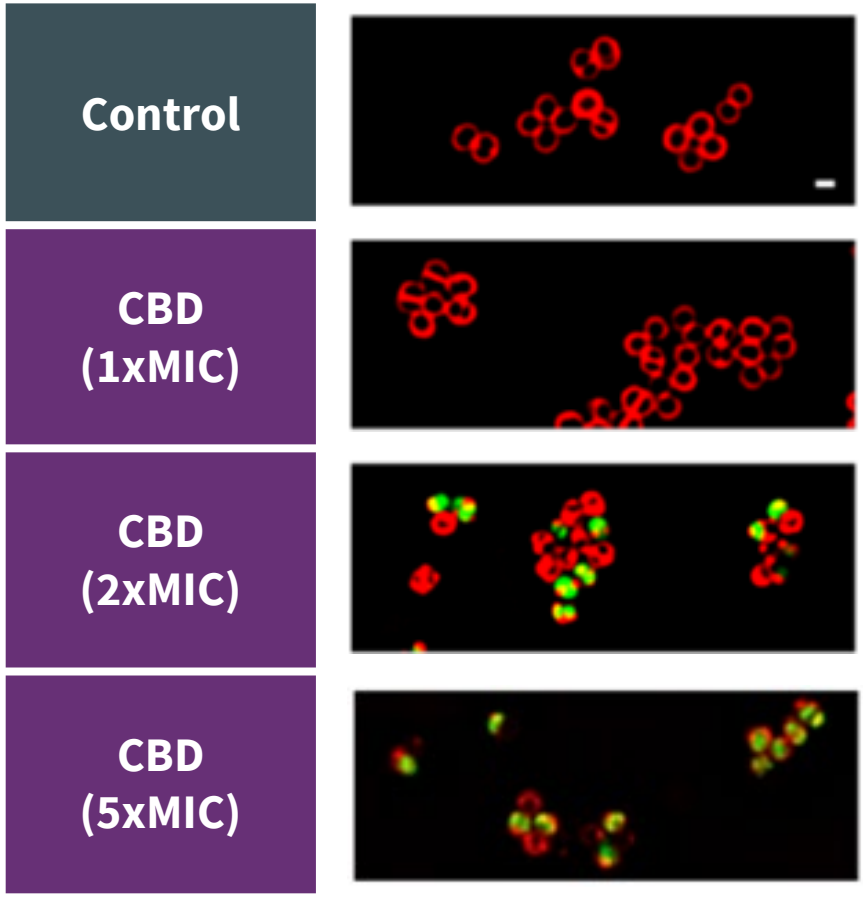
Mupirocin – targets only protein synthesis[1]



CBD – affects all macromolecular pathways[1]



CBD – MRSA bacteria dead within 10 minutes[2]

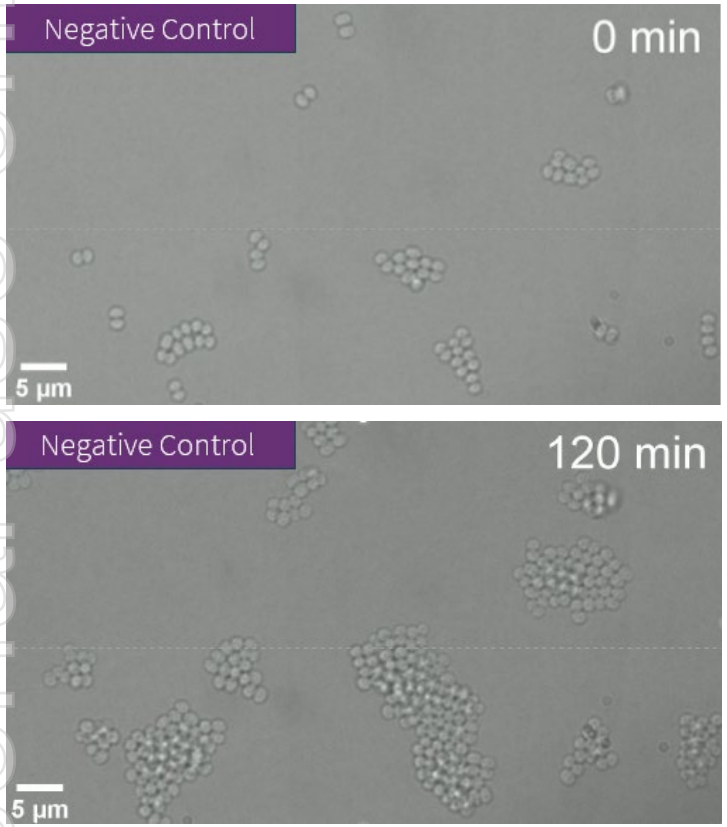


1. Based on testing conducted by HD Biosciences – BOT data on file
2. Based on testing conducted by Linnaeus Bioscience – BOT data on file

Novel Mechanism of Action Confirmed

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

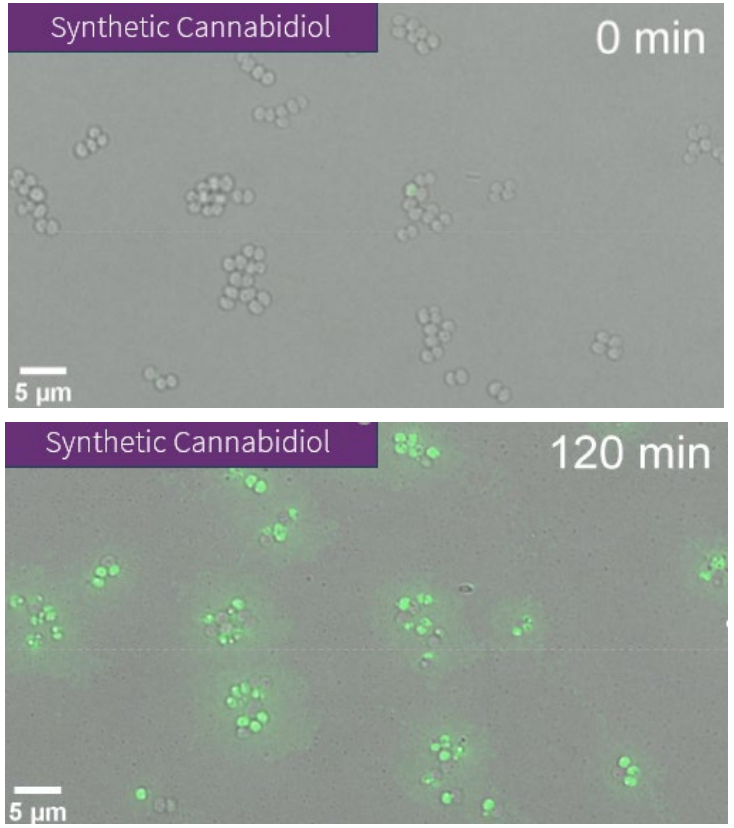
***S.aureus* treated with 2.5% methanol (negative control)[1]**



Staph bacteria treated with negative control

Bacteria are not affected over 120 mins

***S.aureus* treated with synthetic cannabidiol[1]**



Staph bacteria treated with synthetic CBD

Green staining indicates uptake of dye and disintegration of bacteria

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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

Clinical data for BTX 1801 and implications for dermatology

BTX 1801 – First CBD-based program to receive QIDP

FDA QIDP creates multiple commercial benefits

Exclusivity	Priority	Fast track
5 additional years of regulatory exclusivity on top of the standard 5 years	Eligible for an expedited six-month review period (rather than 12 months)	Enables more frequent communication with the FDA during development
Up to 10 years of sales where generics cannot enter the market	Accelerating the FDA review process reduces time to market	FDA guidance throughout development de-risks clinical trials

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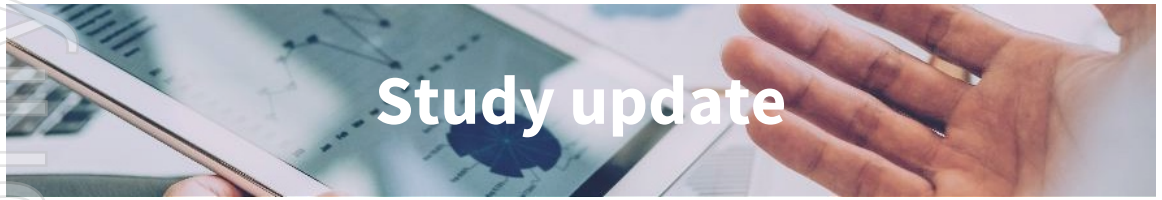
BTX 1801: Phase 2a Clinical Study Successfully Completed



Study update

- ✓ Phase 2a study completed in 4Q CY20
- ✓ Positive top-line data announced 1Q CY21
- Study evaluated safety and local tolerability of 2 formulations to decolonise *Staph* 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

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

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Phase 2a study: Successful at eradicating *Staph*[1]

BTX 1801 met study end points

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 reported[2]

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

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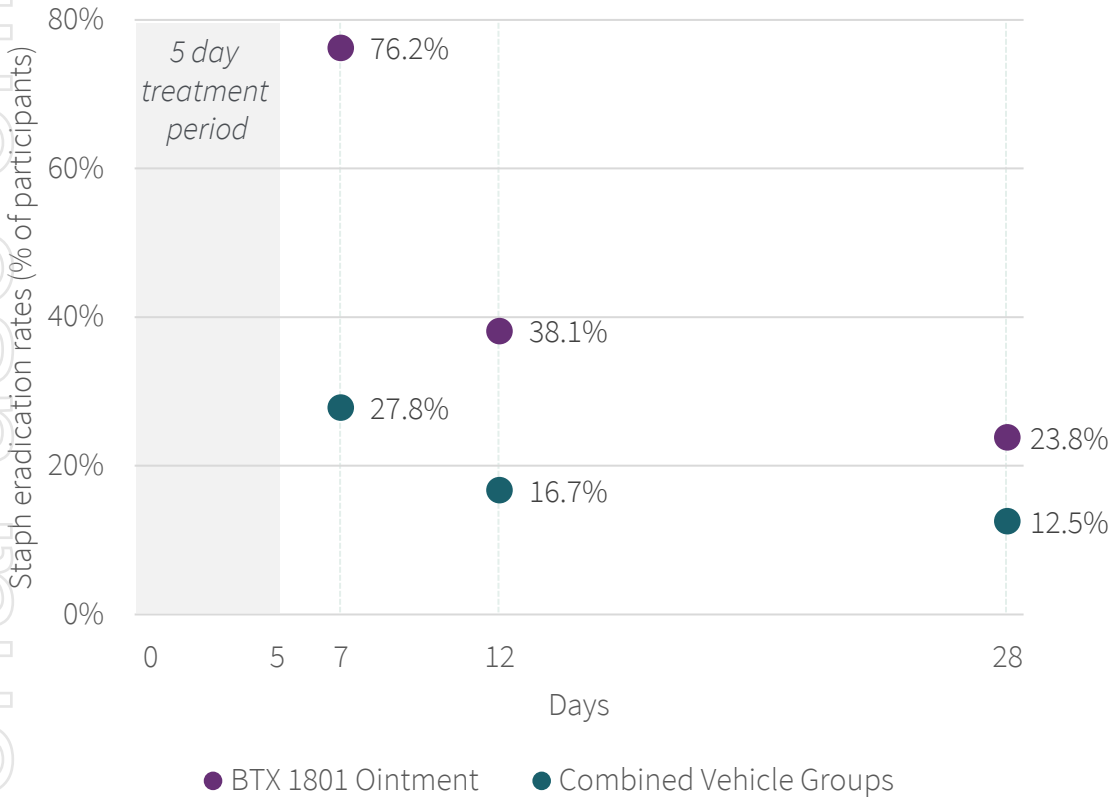
1. Data announced 3 February 2021
2. The incidence of adverse events was low, mild in severity and occurred at similar rates across the different treatment groups with no severe events reported

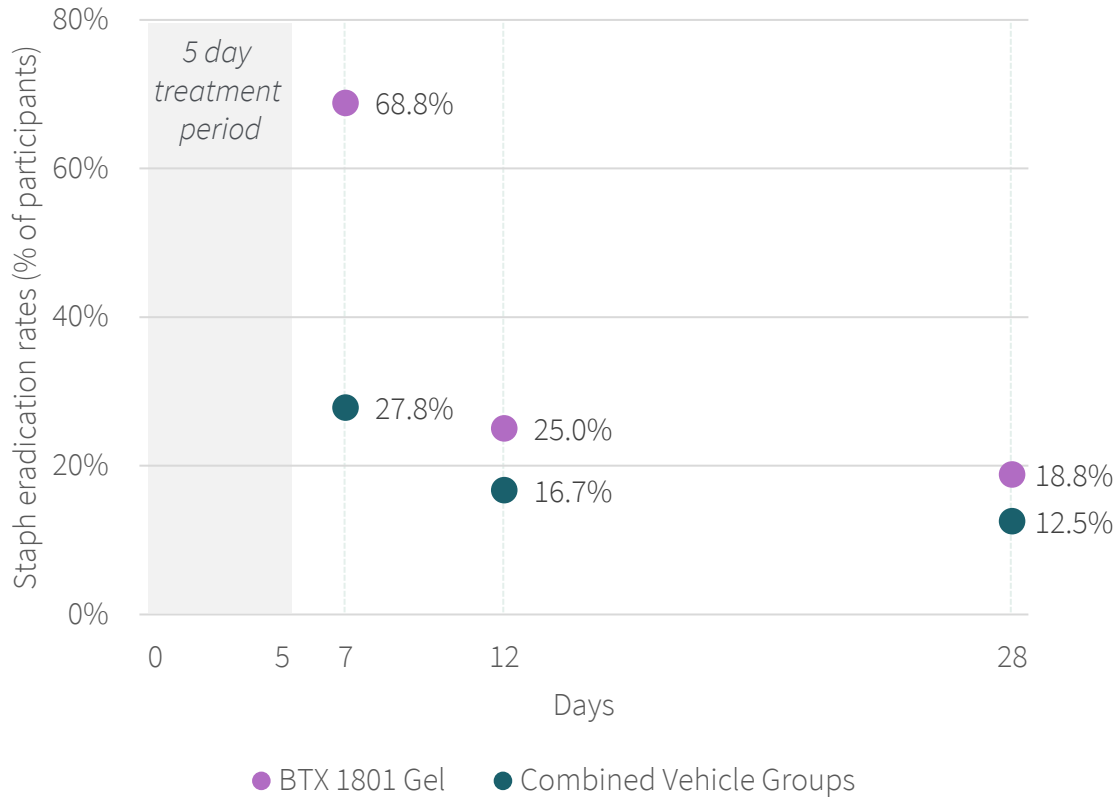
Phase 2a study data: staph eradication

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]



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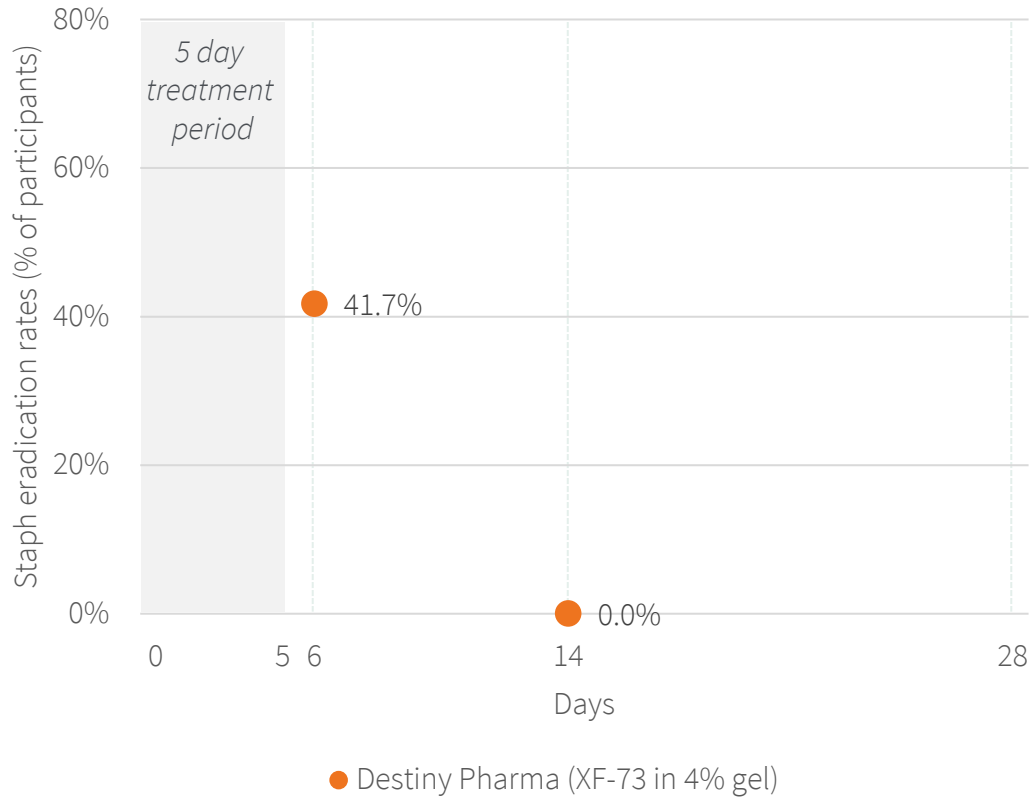
1. Data announced 3 February 2021

Phase 2a study data: context

Destiny Pharma (XF-73): *Staph* eradication rates (% of participants)[1]



- Destiny XF-73 study examined eradication at day 6 (i.e 1 day after treatment period) and Day 14 (9 days after treatment period)
- Like most comparative studies, Destiny XF-73 study included full body chlorhexidine wash during the 5-day treatment period to remove reservoirs of bacteria (helps prevents recolonisation)
- BTX 1801 Phase 2a study did not include this wash protocol

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1. Yendewa et al. A two-part phase 1 study to establish and compare the safety and local tolerability of two nasal formulations of XF-73 for the decolonisation of Staphylococcus aureus: A previously investigated 0.5mg/g viscosified gel formulation versus a modified formulation. Journal of Global Antimicrobial Resistance 2020; 21: 171-180

Significant upside potential– Multiple AMR Opportunities

- **Dialysis related infections**
  from catheter usage
- ***C. Diff* (Clostridium Difficile)**
  causes diarrhea and colitis
- ***N. Gonorrhoeae* (Gonorrhea)**
  re-emerging STD with significant AMR challenges
- ***N. meningitidis* (Meningitis)**
  particular risk for infants
- ***Legionella pneumophila* (Legionnaires disease)**
  severe form of pneumonia

- ✓ Awarded Innovation Connection Grant[2] 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

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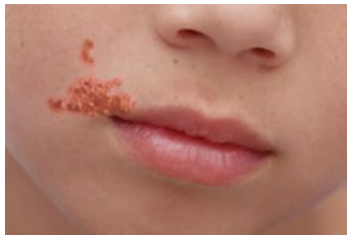
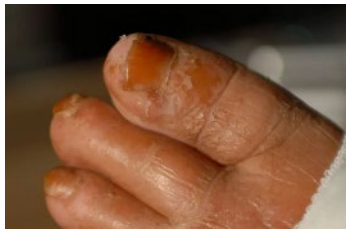
1. No Time to Wait: Securing the future from drug-resistant infections. Report to the Secretary-General of the United Nations (2019) available at https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1
2. See ASX announcement 'Botanix receives grant for synthetic cannabidiol analog program', October 2019

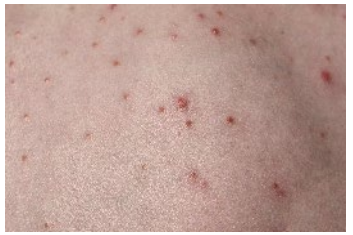
Potential for synthetic CBD in dermatology – Safe and effective antimicrobial and anti-inflammatory



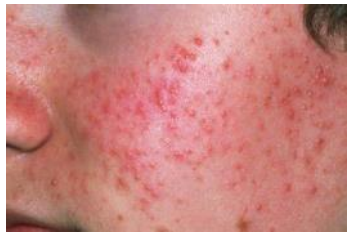
Impetigo



Cellulitis



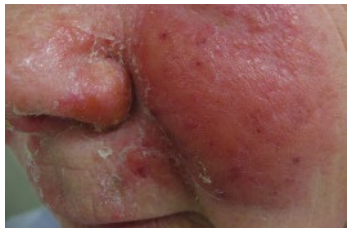
Folliculitis



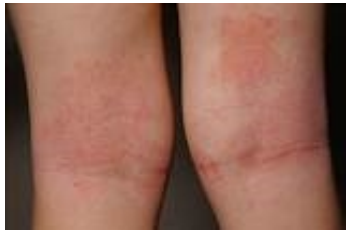
Acne

Streptococcus ***Bacillus subtilis*** ***S. Aureus*** ***S. epidermis*** ***MRSA.*** ***Corynebacterium minutissimum*** ***Cutibacterium***

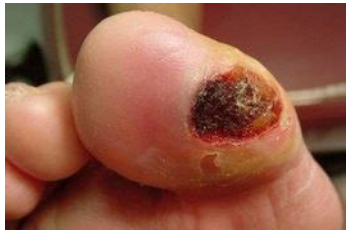
Erysipelas



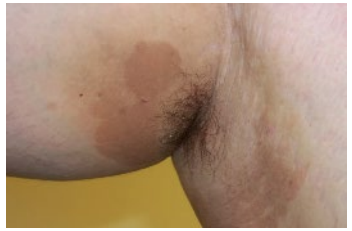
Dermatitis



SSI and ulcers



Erythrasma



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Other clinical programs for synthetic CBD in dermatology

BTX 1702: Phase 1b Rosacea Study: commencing 1H 2021

- **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

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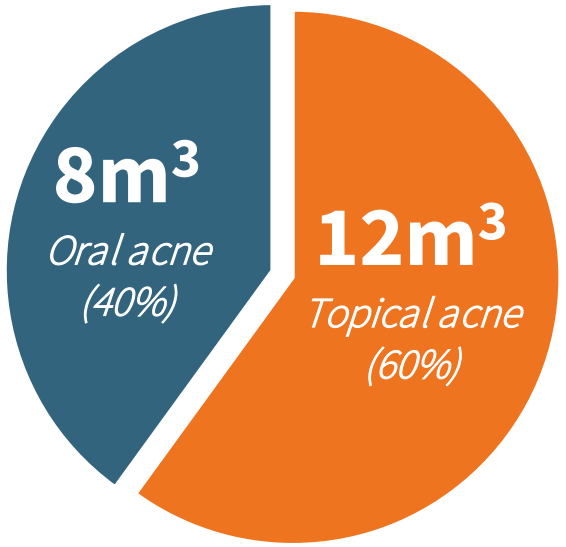
BTX 1503: Successful End-of-Phase 2 FDA Meeting

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[1] 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[2]



BOT US$4.2bn focus market

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1. 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
2. Global Market Insights
3. Number of prescriptions

Executing on Key Near-Term Milestones

- **Antimicrobial: BTX 1801 Phase 2a study completion**
  Positive results announced

- **Rosacea: BTX 1702 Phase 1b study start**
  Targeting study start in 1H CY2021

- **Acne: BTX 1503 planning for Phase 3 clinical studies**
  Pending completion of BTX 1702 Phase 1b clinical study

Strong cash position - ~A$26.0m
As at 31 December 2020 (including R&D tax return ~A$6. 9m)

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DISCLAIMER

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