

Personal use only
Advancing new treatments for skin disease and infection



Investor Presentation

October 2021



Botanix Pharmaceuticals: a leader in topical drug development

Clinical stage dermatology company developing new treatments for common skin diseases and infection, leveraging its novel delivery technology Permetrex™



Pharmaceutical focus

Leveraging novel skin delivery technology (Permetrex™) and novel drug mechanisms of action, including synthetic 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 decades for these indications, with physician and patient demand for new treatments



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/2 rosacea study, commencement Phase 2 antimicrobial study, canine AD data readout and new Permetrex™ opportunities

Botanix: World Class Board and Management 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 four 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 Veliccept Therapeutics
- ❖ Senior leadership roles at Iroko Pharmaceuticals, Novartis and GlaxoSmithKline

Anthony Robinson

VP 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 Jack Hoblitzell

SVP Pharmaceutical Development

- ❖ 30+ years leading world-class technical operations to manufacture and deliver pharmaceuticals
- ❖ Senior leadership roles at Assertio Therapeutics, Pfizer, King, Ivax and Teva

Dr Ira Lawrence

Advisor

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

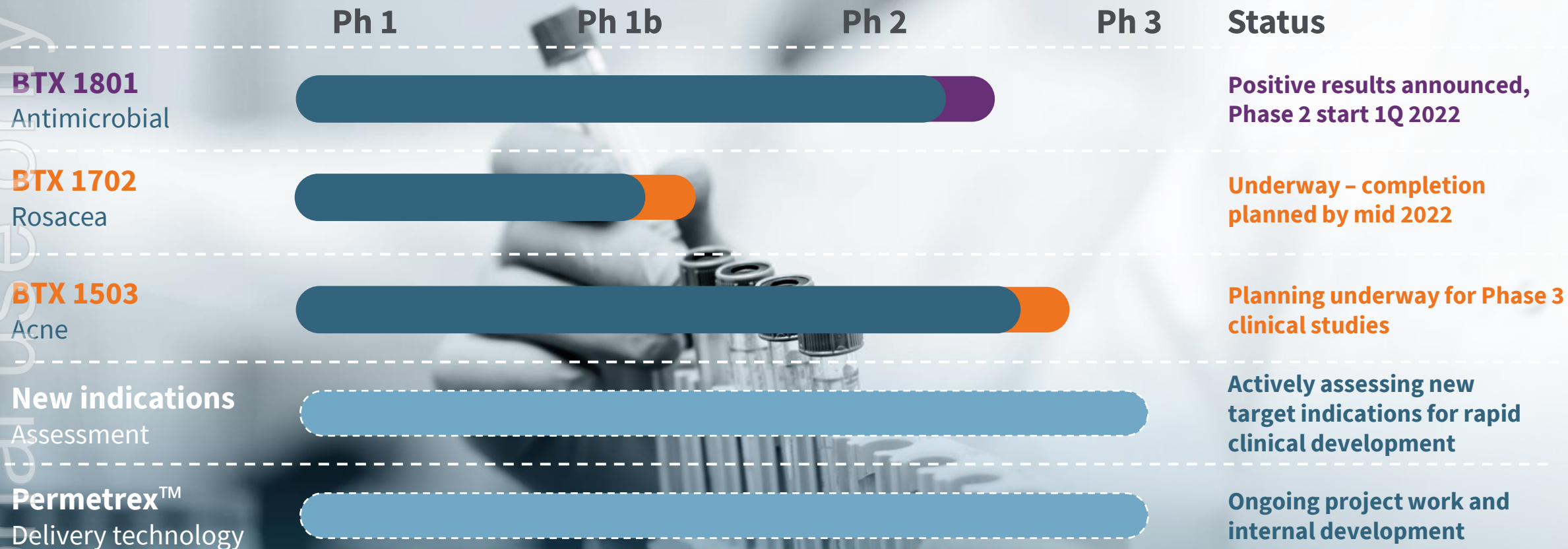
Synthetic cannabinoids are well suited to treat skin diseases and infections

Botanix's studies show synthetic CBD to:¹

- ✓ Be safe and well tolerated
- ✓ Have broad anti-inflammatory properties
- ✓ Have a strong and consistent impact on skin lesions
- ✓ Have anti-microbial properties – kills *Staph aureus*²
- ✓ Have potential for widespread use across human and animal health
- ✓ Have anti-inflammatory and anti-microbial properties important for dermatology conditions including acne, rosacea and dermatitis



Advanced late-stage pipeline

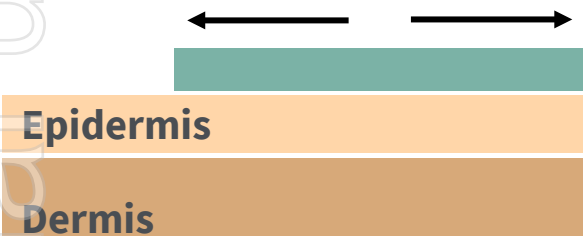


Permetrex™: skin delivery technology fuels pipeline potential

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

1. Initial application

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



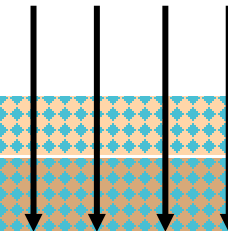
2. Evaporation of solvent

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



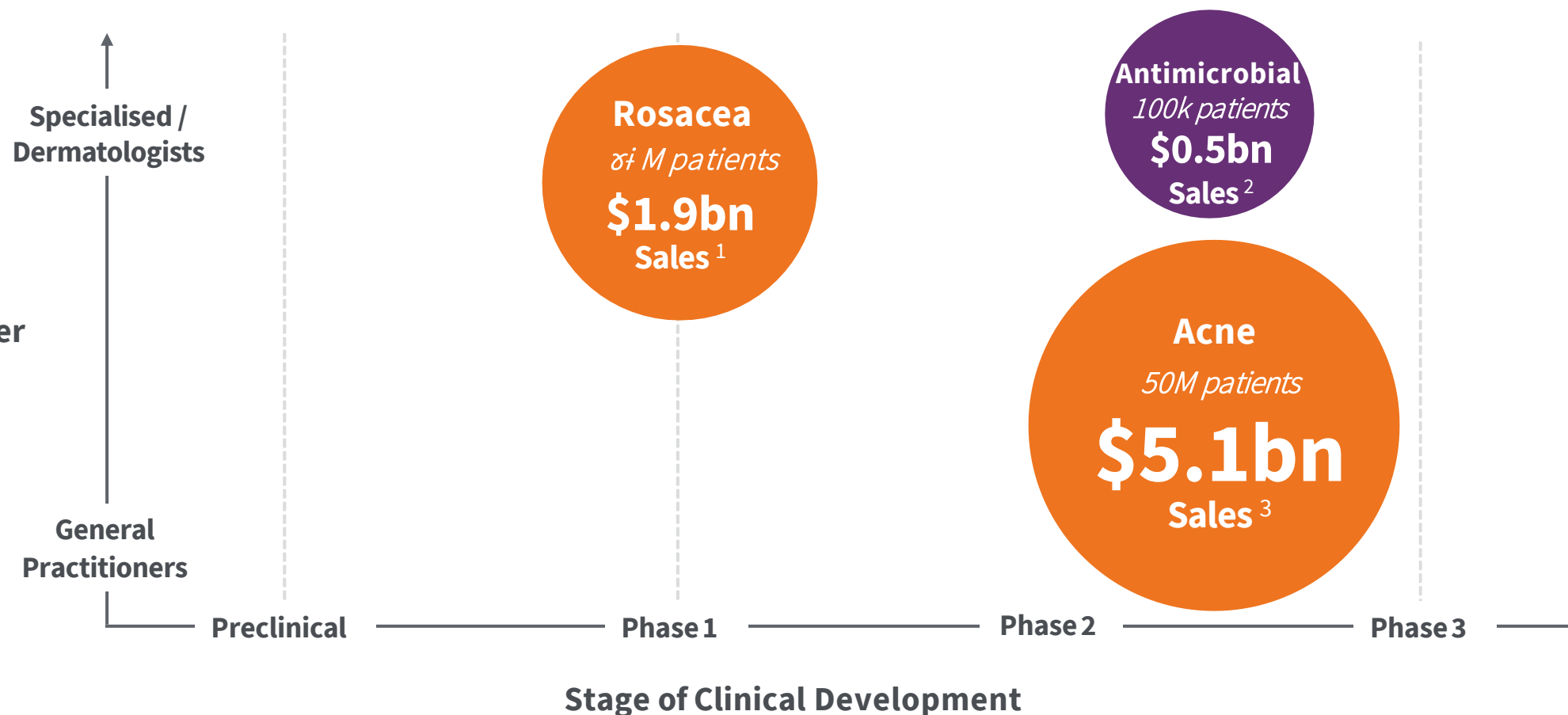
3. Delivery into the skin

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



Permetrex™ is used in Botanix's pipeline products and improves delivery for other drugs in development¹

Target markets with significant annual revenues & unmet needs



Dermatology programs



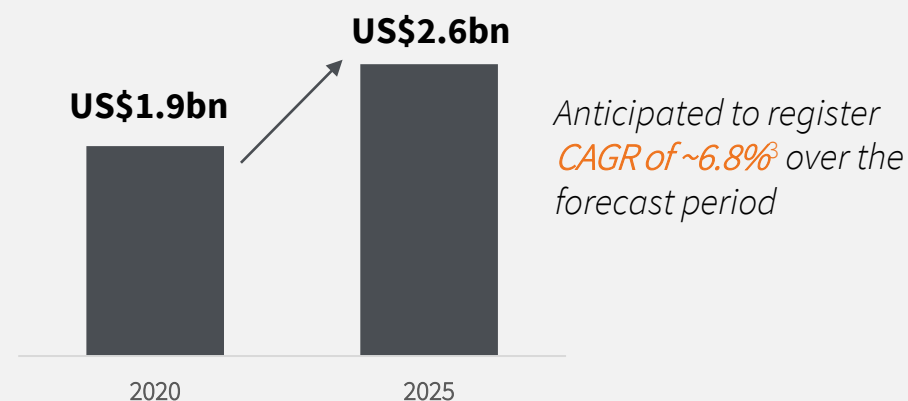
BTX 1702: high impact of rosacea on patients and significant market opportunity

❖ Papulopustular rosacea is a highly visible **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, women are more likely to be affected than men
- ❖ 85% of patients are > 30 years old⁵
- ❖ Currently over 16m Americans affected⁶ by rosacea, with ~5m medical treatment prescriptions⁷ in the US alone
- ❖ Active treatment seekers looking for new solution to rosacea

BTX 1702: Rosacea Phase 1b/2 study is underway

Improved data capture design with dose ranging over 8 week treatment period



- ❖ Study designed to enable increased data capture & provide insights to support broader dermatology program
- ❖ All sites using Canfield imaging technology supporting clinical assessment, tracking & analysis
- ❖ Recruitment going to plan, despite COVID restrictions

❖ 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: ~15 dermatology sites across Australia and NZ

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

❖ Treatment period: 8 weeks

❖ 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: Acne in preparation for Phase 3 and future filing

Successful End-of-Phase 2 FDA meeting and completion of Rosacea BTX 1702 study (with higher dosing and enhanced data capture) will inform final design for P3 Acne study

Study update

- ✓ End of Phase 2 meeting with FDA successfully completed, supported by overall efficacy and safety, and significance of Australian data on further analysis¹ in 2020 of late 2019 P2 study data².
- ✓ FDA highlighted excellent safety profile of BTX 1503, allowing several waivers for studies typically required for dermatology drug registration
- ✓ Co-primary efficacy endpoints³ agreed for Phase 3
- ✓ Important milestone providing clarification on activity to move forward
- ✓ Confirmed drug development plan to support filing and registration for treatment of moderate and severe acne
- ❖ Planning underway for Phase 3 clinical studies to be informed by completion of BTX 1702 Phase 1b/2 study

Sizable acne prescription market



22m total prescriptions in 2019 growing ~5% year-on-year⁴



US\$5.1bn in sales in 2019⁴



>2m p.a. active, diagnosed acne patients under HCP care⁵



~40m to ~50m acne sufferers⁶ (~10m mod-to-severe)



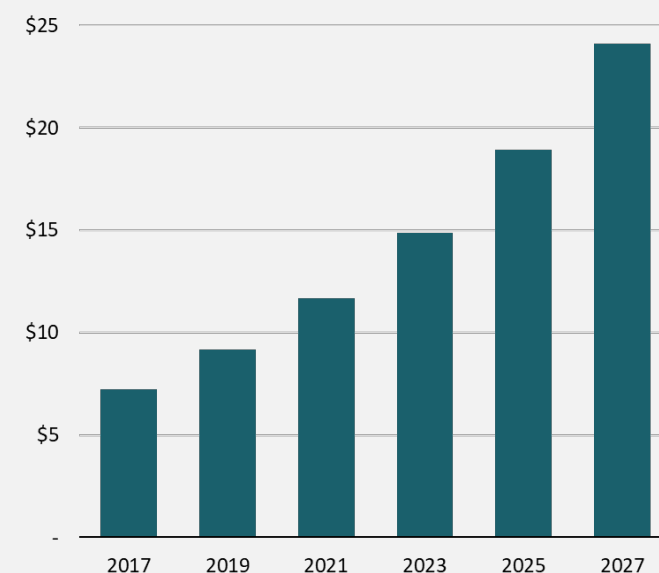
60% of acne patients are managed by 5,000 HCPs⁷

BTX 1204A: Meeting need for safe, non-steroid for chronic use in Atopic Dermatitis



- ❖ Atopic dermatitis is one of the most common skin diseases¹:
 - 2% - 3% of adults, 25% of children
 - 90% of patients are mild to moderate³
- ❖ Patients see flare-ups of itch, red inflamed rash and excessive dryness or scaling
- ❖ Significant unmet need with limited options for safe and effective treatment chronic disease, biologics are reserved for severe population
- ❖ Pediatric population needs tolerable steroid free alternative¹

Atopic Dermatitis Market (\$B)



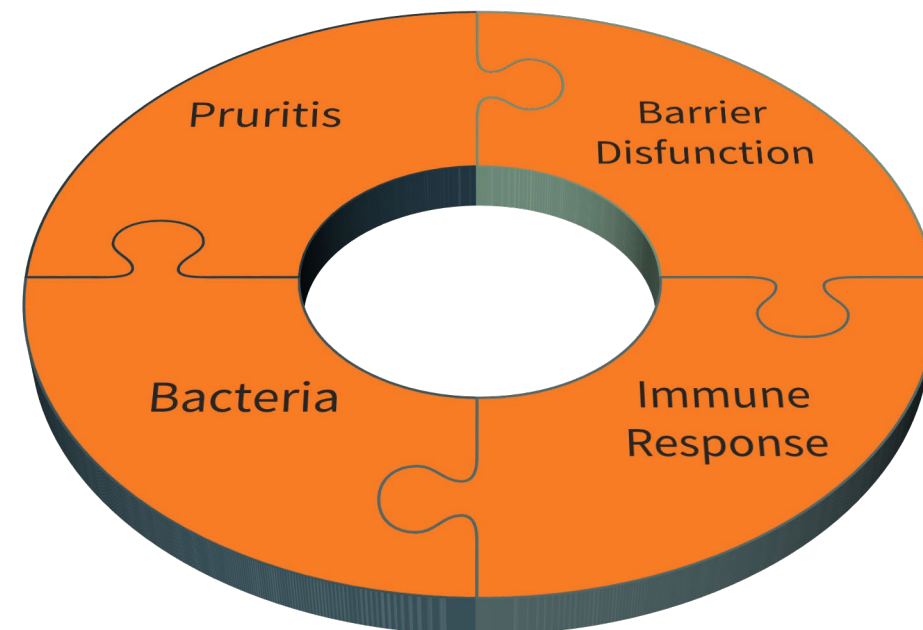
Symphony Health Services (PHAST) 2017

- ❖ Affects 20-25M Americans^{2,3}
- ❖ Almost 85% cases present by the age of 5 years⁶
- ❖ Severe population is ~10% of patients

Atopic dermatitis – chronic inflammatory disease for both canines and humans



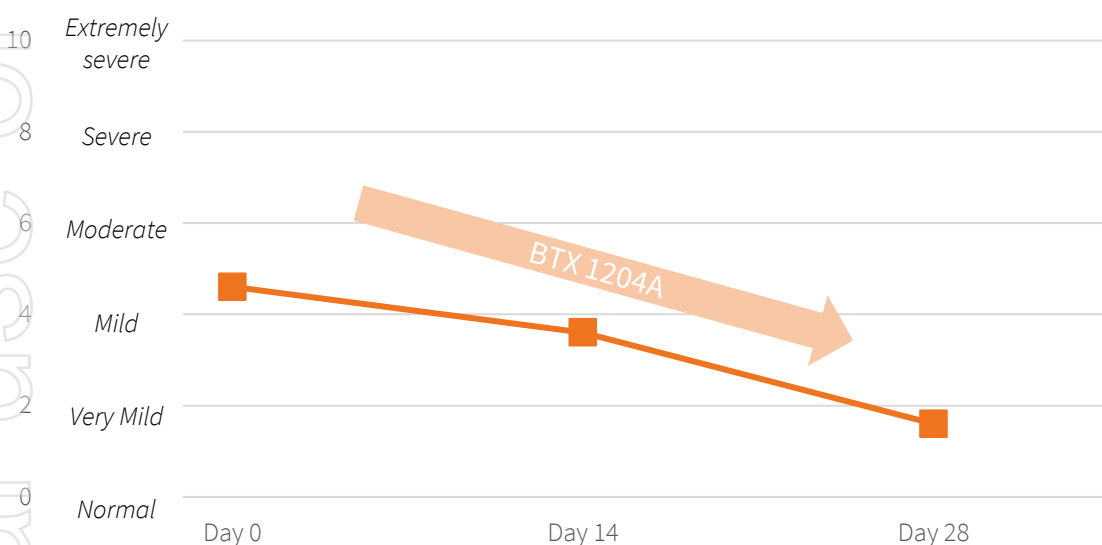
- ❖ Canines naturally and commonly develop a pruritic dermatitis that is clinically and immunologically extremely similar to human AD¹
- ❖ Dogs and humans with AD also have similar problems with skin barrier function – these problems cause the skin to be very dry and prone to Staph Aureus infections²
- ❖ Canine models are increasingly used as screening tools for new therapeutic development, including dose ranging and safety assessments
- ❖ Canine studies are faster and more cost effective than human studies and help de-risk later stage studies



BTX 1204A: Dermatitis data supports further development

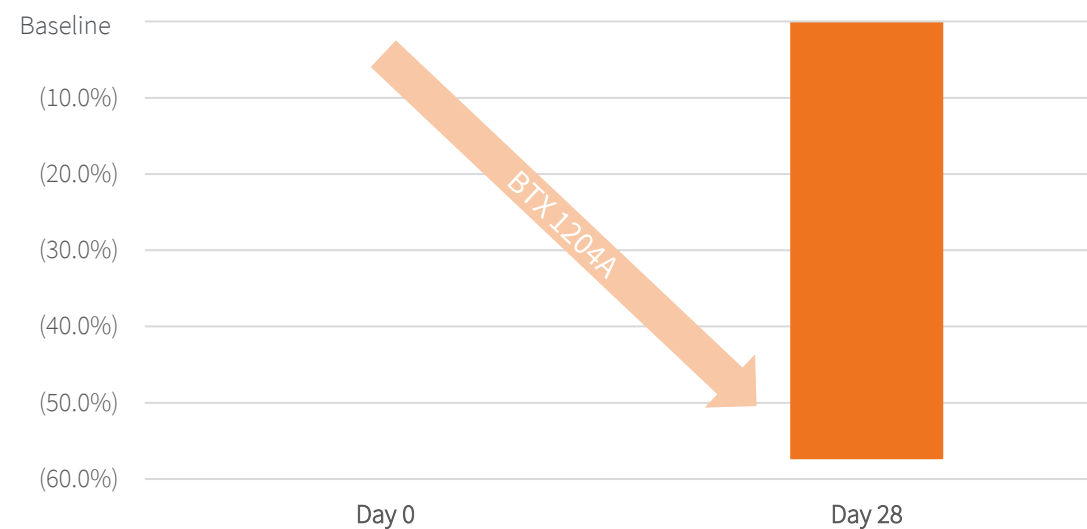
Pilot canine study with higher dose and novel Permatrex™ formulation showed reduction itch and lesions - dermatitis in canines and humans is clinically and immunologically very similar

BTX 1204A: Pruritus (itch) mean ESP scores ^{1,2}



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

BTX 1204A: % reduction from baseline (CADESI-04) ^{1,3}



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

BTX 1204A: Atopic dermatitis development strategy

Larger POC canine study underway¹, will inform licensing in animal health & potential re-launch of late-stage P2b clinical program in 2022

Proof of Concept Canine Study Parameters

❖ Four dose groups, up to 45 dogs:

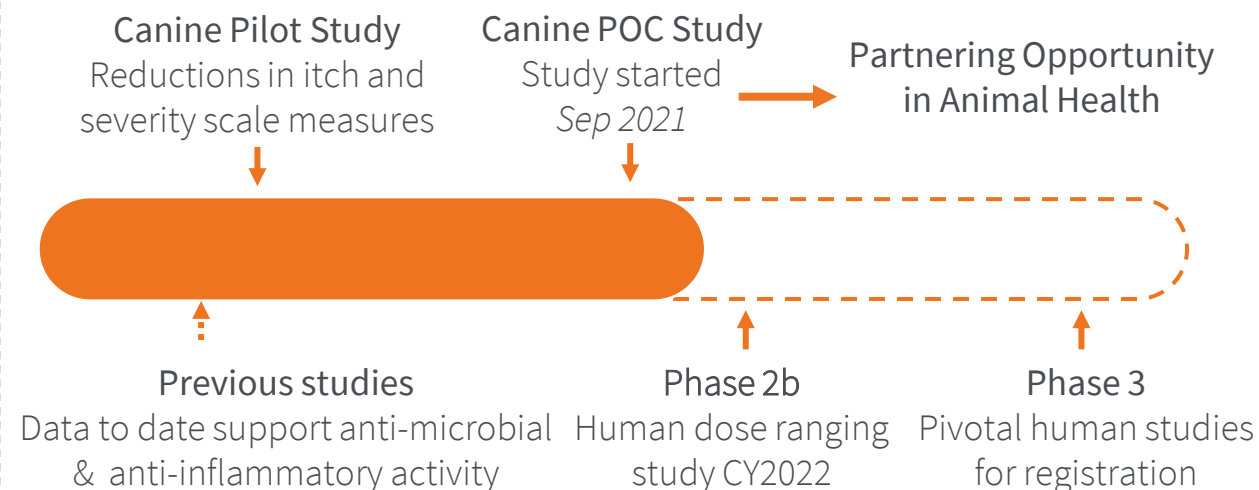
- BTX 1204A high dose: 15 dogs
- BTX 1204A low dose: 15 dogs
- Vehicle: 15 dogs

❖ Sites: 3 Australian sites

❖ Treatment period: Twice daily treatment for 28 days

❖ Endpoints: Treatment effectiveness using Enhanced Pruritus Score²; Canine Atopic Dermatitis Extent and Severity Scale Index³

Planned pathway to approval



Successful outcome opens up partnering opportunity & supports progression to Phase 2b human study in atopic dermatitis.

Anti-microbial development update

BTX 1801

ersonal use only



BTX 1801: Demonstrated clinical efficacy vs *S. aureus* in Phase 2a study

Staphylococcus aureus (*S. aureus* or 'staph') is a common bacterium that lives on skin and in nasal passages. It can cause skin infection and serious or life-threatening blood stream infections, pneumonia or bone and joint infections.



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 reported¹



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



BTX 1801: 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 infection¹



Significant health risks

- ❖ Risks for central venous catheter-related complications were as high as 30% and 38%, at 1 and 2 years respectively²
- ❖ Central venous catheter patients (approx. 160,000) make up more than 70% of blood infections in the dialysis population²

11.8%

of patients were readmitted within 12 weeks of hospitalisation related to Staph aureus infections¹

US\$734m

Market for nasal decolonisation of haemodialysis patients at risk of blood stream infection by 2030³

~US\$32k

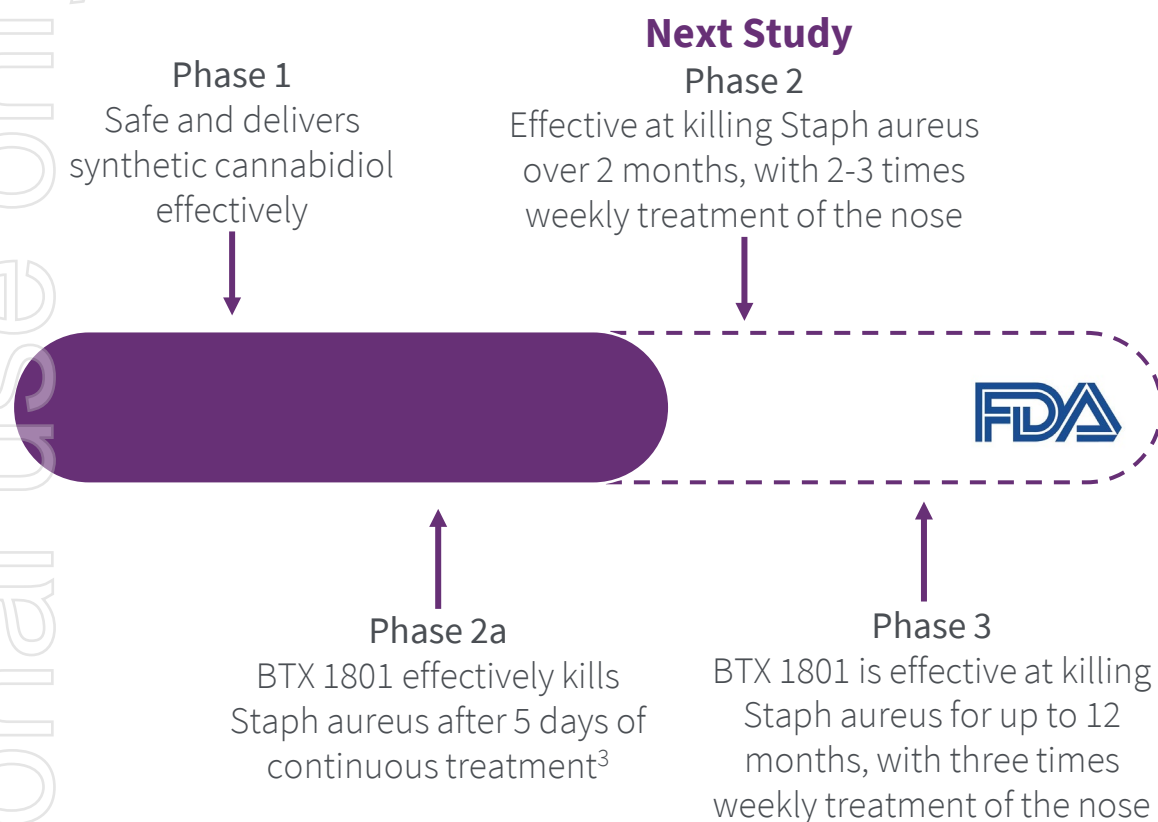
Mean cost (per episode) of treating Staph aureus blood stream infections, including re-admissions and outpatient costs¹

US\$1bn

Estimated annual cost of treating bacteraemia in haemodialysis patients with central venous catheters²

BTX 1801: Clinical development moving quickly to meet need

Targeting nasal decolonisation of Staph in patients undergoing haemodialysis to reduce incidence of life threatening blood stream infections



FDA incentives provide accelerated development and increased market exclusivity

QIDP ¹
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 ²
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

Executing on key clinical milestones

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

Positive results announced, further Phase 2 study start Q1 2022

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

Recruitment currently underway, target completion mid 2022

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

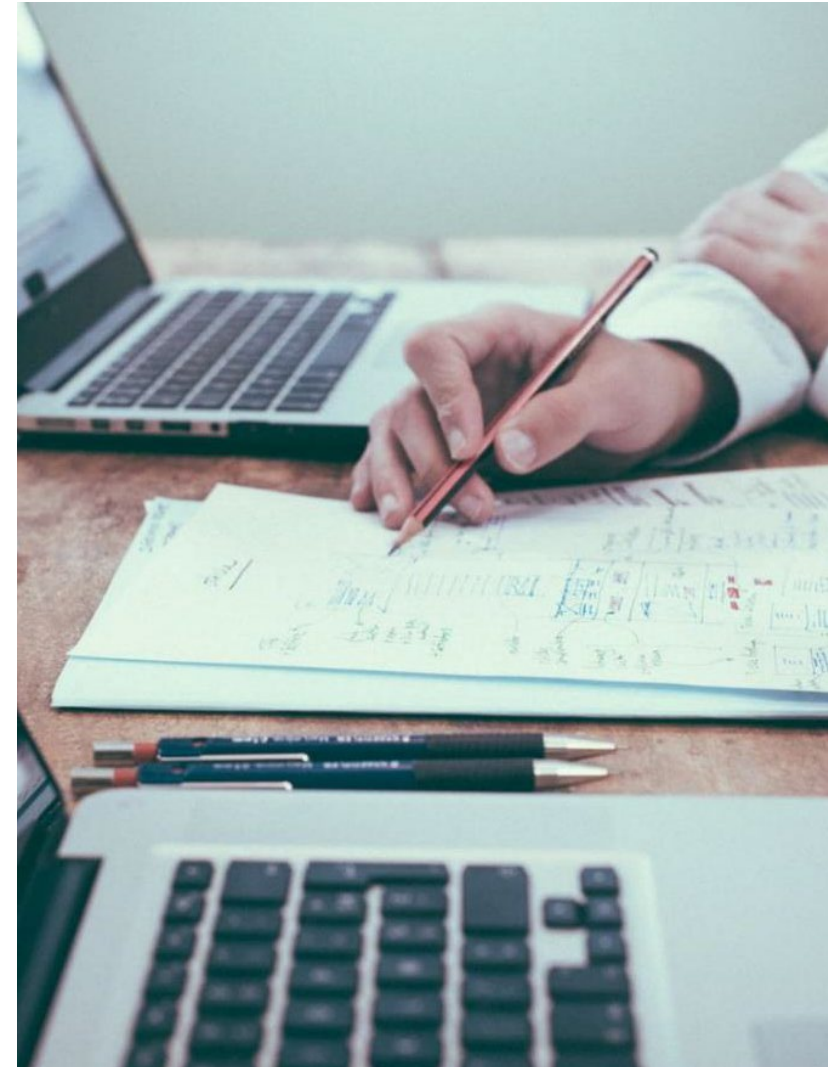
Pending completion BTX 1702 Phase 1b/2 study

❖ **Dermatitis: BTX 1204A canine proof of concept study underway**

To inform potential animal health licensing and re-launch Phase 2b human study - data anticipated 1H 2022

❖ **New indications and Permetrex™ opportunities**

Actively assessing new indications and opportunities for rapid clinical development



Botanix Pharmaceuticals: a leader in topical drug development

Clinical stage dermatology company developing new treatments for common skin diseases and infection leveraging its novel delivery technology Permetrex™



Developing novel skin delivery technology (Permetrex™) and novel mechanisms of action, including synthetic cannabidiol (CBD)



Late stage pipeline targeting dermatology and antimicrobial indications with topical treatments that are safe, well tolerated & clinically validated



Multi-billion dollar growth markets, with demand for new treatments and unmet needs.



Established IP position and protection



World-class , experienced team with significant track record and development expertise



Executing on pipeline across anti-microbial, rosacea, dermatitis and acne indications. Near term catalysts: Ph1b/2 Rosacea and Ph2 antimicrobial studies, new indications for rapid development

DISCLAIMER

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.