

ASX/Media Release

4 March 2019

Updated investor presentation

Philadelphia PA and Sydney Australia, 4 March 2019: Medical dermatology company Botanix Pharmaceuticals (“Botanix” or “the Company”) is pleased to release an updated investor presentation. The presentation will be used to update shareholders, investors and strategic partners on the ongoing Phase 1b and Phase 2 clinical trials, pipeline products in development and other key upcoming activities.

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage medical dermatology company based in Perth, Australia and Philadelphia, PA. The Company’s focus is the development of safe and effective topical treatments for acne, psoriasis, atopic dermatitis and other skin conditions. The active ingredient contained in Botanix products is a synthetic form of a widely studied natural compound. Treatment targets include inflammation, deterioration of the skin barrier, skin cell proliferation, pruritus (itch), excess sebum production and bacterial infection.

Botanix has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases. Botanix is working with multiple parties to test the application of Permetrex™ on both a fee-for-service and traditional license basis.

Botanix pursues a rapid clinical development strategy aimed at accelerating product commercialisation. The patient treatment duration of clinical studies is generally completed within a 4 to 12-week timeframe.

The Company completed its first acne patient studies with BTX 1503 in January 2018 and has commenced a Phase 2 clinical study in June 2018 with completion of enrolment expected in mid-2019. The BTX 1204 atopic dermatitis Phase 2 patient study is also underway with enrolment expected to be completed by in 3Q CY2019. Finally, Phase 1b BTX 1308 psoriasis patient study is in late stage enrolment and will be complete by the end of 1Q CY2019 with data available in 2Q CY2019.

To learn more please visit: <https://www.botanixpharma.com/>

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RESTORING HEALTHY SKIN

Botanix Overview

March 2019



2019 outlook

Transformative year ahead, with planned completion of two Phase 2 studies, a Phase 1b patient study, along with milestones for the broader pipeline and the Permetrex™ technology platform



**Multiple value
inflection points**

Data read-outs in 2019 from **fully funded clinical studies** for psoriasis (2Q CY19), acne (3Q CY19) and atopic dermatitis (4Q CY19) **will drive significant value increase**



**Growing data
support**

Recent approval of first cannabidiol product (Epidiolex® for epilepsy) **validates the safety profile and potential of synthetic cannabidiol** as a new skin treatment



**Validation of
pharma focus**

Initial wave of investment in the sector is now moving rapidly to pharmaceutical applications – **Botanix is one of the world's most advanced cannabinoid companies**



**Technology
driven**

Novel skin delivery technology, Permetrex™ is **proven to enhance delivery of cannabidiol** compared to traditional approaches and provides **a novel IP position**



**Growing world
class team**

Experienced team has **advanced product candidates to Phase 2 studies within 24 months** and is adding US capability to **accelerate commercialisation plans**

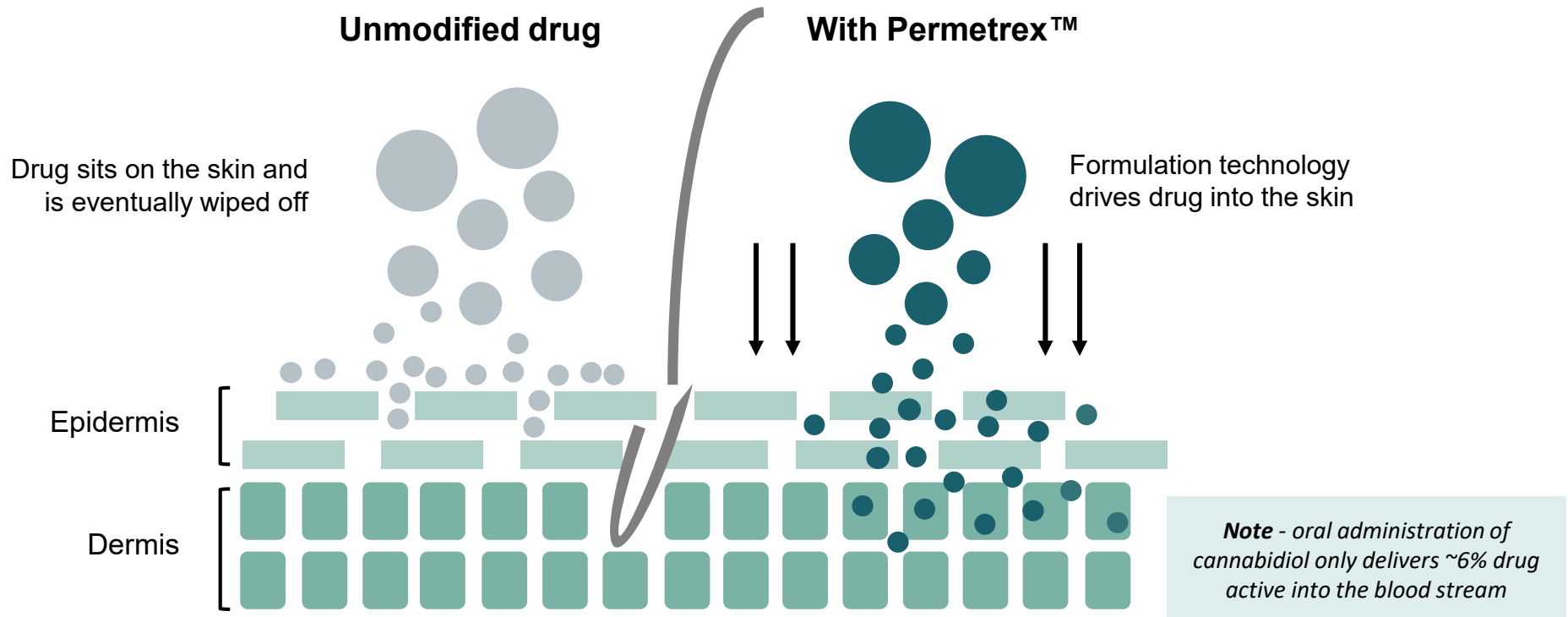
Clinical programs with near term milestones

Well advanced Phase 2 acne and atopic dermatitis programs as well as Phase 1b psoriasis and pending skin infections clinical programs

Product candidate	Indication	Pre-clin	Ph 1	Ph 1b	Ph 2	Status
Synthetic cannabidiol	BTX 1308	Psoriasis				Phase 1b patient study underway
	BTX 1503	Moderate to severe acne				Phase 2 clinical study underway
	BTX 1204	Moderate atopic dermatitis				Phase 2 clinical study underway
	BTX 1801	Skin infections				Preparing for Phase 1b study
Permetrex™ programs	Internal/external	Various	Collaborations			Ongoing studies with partners

Permetrex™ skin delivery technology

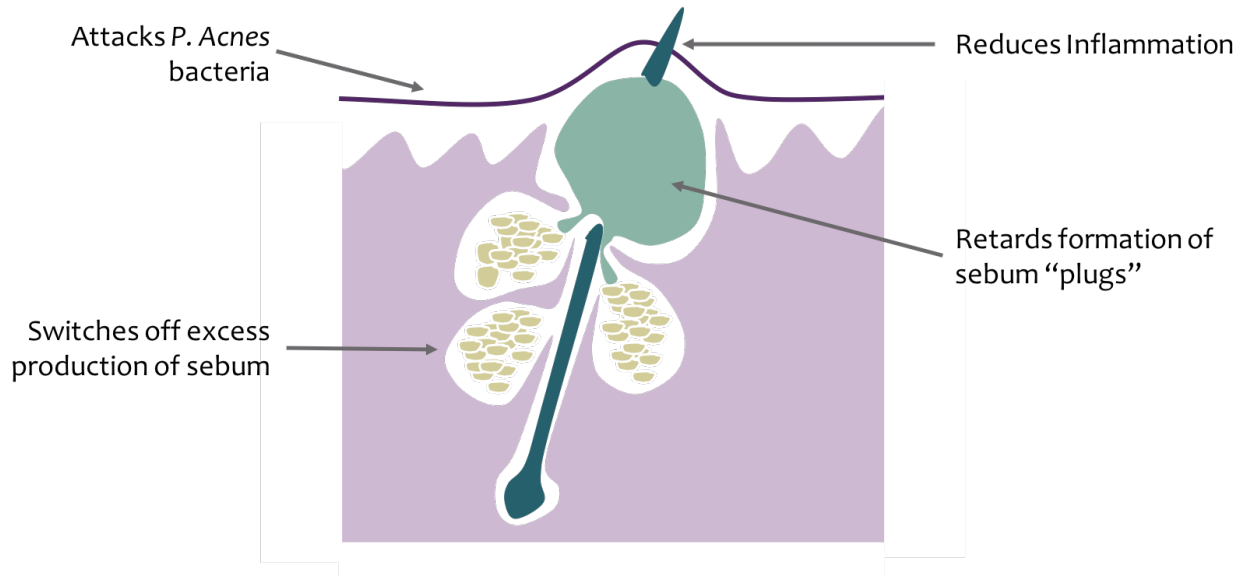
Proprietary Permetrex™ technology delivers high doses of drug into the layers of the skin without use of permeation enhancers, preservatives, or irritating levels of alcohol / petrolatum additives



BTX 1503 – acne mechanism of action

BTX 1503 is a safe and well tolerated topical treatment that potentially addresses all of the 3 causes of acne

BTX 1503 addresses acne pathologies in a CB1/CB2 receptor independent manner¹



Cannabidiol has been shown to...

- ✓ Have anti-inflammatory effects on human sebocytes and to suppress sebocyte proliferation²
- ✓ Have potent anti-microbial activity against gram-positive bacteria³
- ✓ Inhibit human keratinocyte proliferation, through a non CB1/CB2 mediated mechanism⁴

1. Rocha & Bagatin *Acne Vulgaris: an Inflammatory Disease Even Before the Onset of Clinical Lesions* (2014). *Inflammation and Allergy – Drug Targets* June 13(3)
2. Olah et al. *J Clin Invest.* 2014;124(9):3713-3724
3. Appendino et al. *J Natl Prod.* 2008;71:1427-1430
4. Wilkinson & Williamson. *J Derm Sci.* 2007;45:87-92

Botanix's acne target market share exceeds US\$1.5bn p.a.

Competitive products with less ideal safety profiles and potentially poorer efficacy generate more than US\$1.5bn per annum between them in revenue

Top oral brands

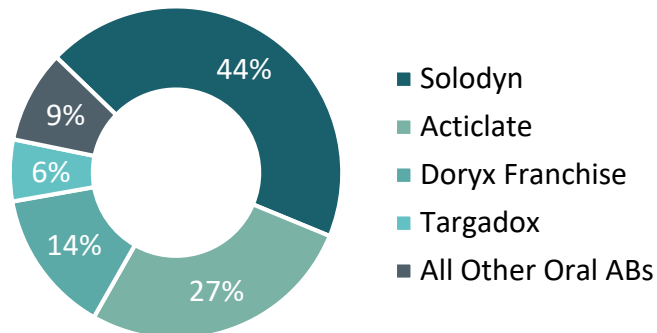
Rank	Brands	Revenue (US\$m) ¹	Scripts ('000)
1	SOLODYN Minocycline, Valeant	\$492	434
2	ACTICLATE Doxycycline, Almirall	\$234	261
3	DORYX FRANCHISE Doxycycline, Mayne	\$65	132
4	TARGADOX Doxycycline, Journey	\$40	63

Top topical brands

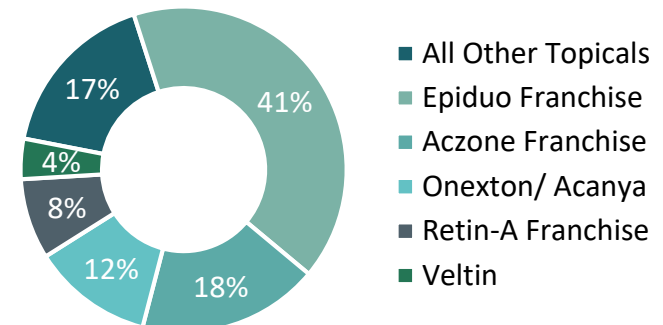
Rank	Brands	Revenue (US\$m) ¹	Scripts ('000)
1	EPIDUO FRANCHISE Adapalene+BPO, Galderma	\$659	1,431
2	ACZONE FRANCHISE Dapsone, Allergan	\$298	625
3	RETIN-A FRANCHISE Tretinoin, Valeant	\$219	304
4	ONEXTON/ACANYA Clindamycin+BPO, Valeant	\$200	410
5	VELTIN Clindamycin+tretinoin, Almirall	\$79	151

Target
market
share
>US\$1.5bn

Prescription market share oral brands²



Prescription market share topical brands²



Source: Symphony Health Solutions PHAST (accessed 1.2018)

1. US \$ represent SHS metric (TRx MBS) or dollarized prescriptions

2. Market shares of the oral branded prescription acne drug market and the topical branded prescription acne drug market according to the total number of prescriptions

BTX 1503: acne – Phase 2 study well advanced

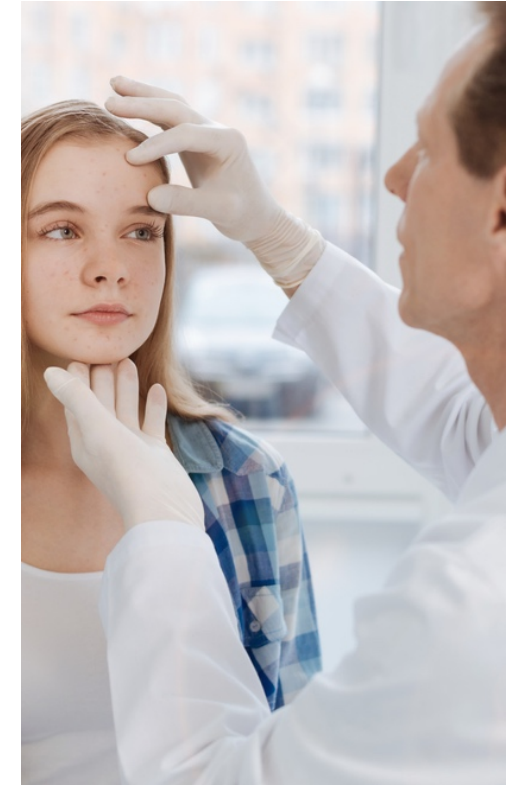
12-week randomised, double-blind, vehicle controlled study to evaluate the safety and efficacy of BTX 1503 in patients with moderate to severe acne

Design

- 5 dose groups: ~360 subjects
 - High Dose twice a day: ~90 subjects
 - High Dose once a day: ~90 subjects
 - Low Dose once a day: ~90 subjects
 - Vehicle/Control: ~90 subjects
- ~28 US and Australian dermatology sites
- Children (> 12 years) and adults
- Moderate to severe acne patients
- Treatment Period 12 weeks

Endpoints

- Primary endpoints:
 - Absolute change from Baseline to Week 12 in inflammatory lesions
- Secondary endpoints:
 - Absolute change from Baseline to Week 12 in non-inflammatory lesions
 - % change from Baseline to Week 12 in inflammatory and non-inflammatory lesions
 - Proportion of patients with at least 2 grade reduction from Baseline IGA at week 12
- Safety
 - Adverse events and local tolerability

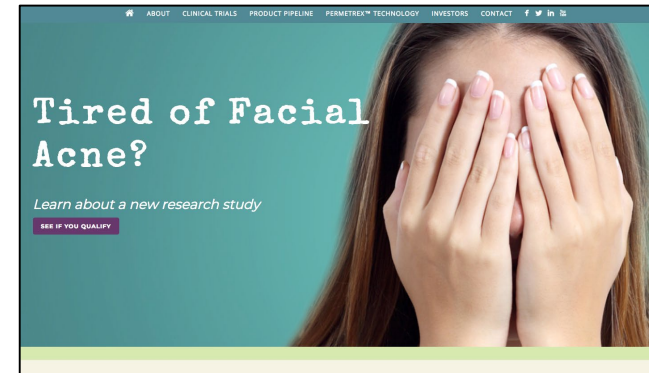


target data read out 3Q CY2019

Phase 2 patient study advancing on schedule

All sites are active and recruiting patients, with some Australian sites already reaching maximum recruitment numbers in early 1Q CY2019

- No safety issues arising from treated patients to date
- Positive feedback from dermatologists on study

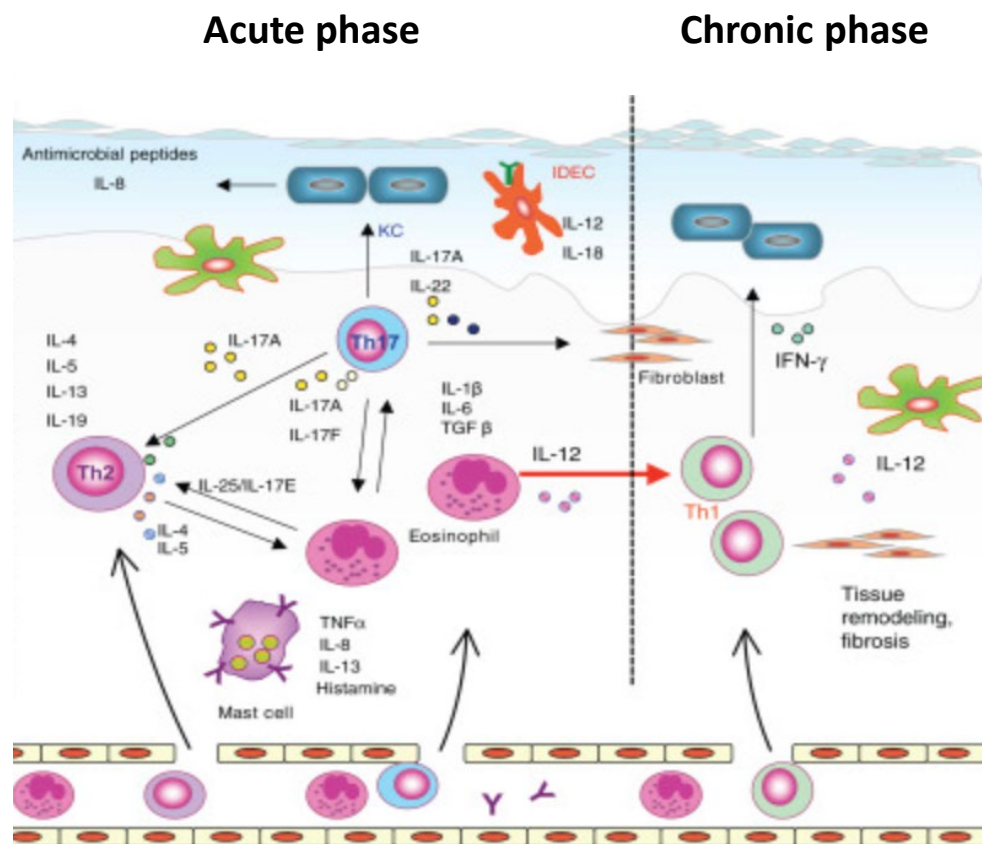


BTX 1503 indicative clinical timeline (CY)



BTX 1204: atopic dermatitis – potential mechanism of action

Atopic dermatitis (and psoriasis) are both T-cell mediated inflammatory diseases of the skin



1. During the “acute phase”, dendritic cells cause excessive Th2 and Th17 cell activation
2. During the “chronic phase”, dendritic cells recruit Th1 cell populations that release Interferon-g

- ✓ Cannabidiol inhibits **Th17 responses (IL17)**, anti-inflammatory effect (in vitro model of IL-17A-induced mucosal inflammation using human cells^{1, 2})
- ✓ Cannabidiol attenuates **Th2 responses (IL4/IL13)**, anti-inflammatory effect (in mouse models of AD^{3,4})
- ✓ Cannabidiol inhibits **Interferon-g production** which prevents deterioration of skin barrier function (in activated lymphocyte cultures¹ and mouse model of autoimmune myocarditis⁵)

1. Harvey et al. *Cytokine*. 2014;65:236-244
2. Kaplan et al. *Biochem Pharmacol*. 2008;76(6):726-737
3. Gaffal et al. *Exp Derm*. 2014;23:401-406
4. Kim et al. *Int J Derm*. 2015;54:e410-e408
5. Lee et al. *Mol Med*. 2016;22:136-146

Atopic dermatitis – large unmet need for topical drugs

BTX 1204 addresses the need for a safe, non steroid topical option for chronic use with multiple mechanisms of action including anti-inflammatory, anti-microbial and immune modulating

One of the most common skin diseases ¹

- 2% - 3% of adults
- 25% of children

Large unmet needs across the atopic dermatitis population ²

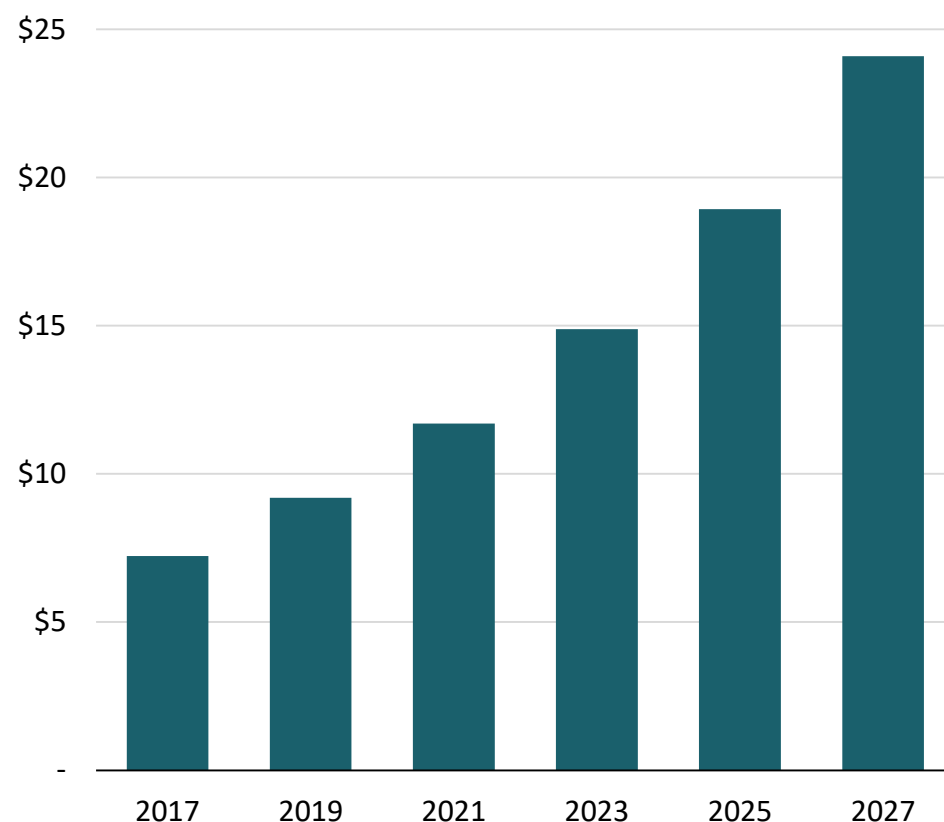
- Few safe and effective non-steroidal options suitable for chronic use
- New biologics address only the more severe populations – 75% of patients have mild to moderate disease ³

Paediatric population particularly has a need for a steroid alternative ¹

- Safety concerns with steroids are very high in the paediatric population (growth inhibition etc)

1. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al Guidelines of care for the management of atopic dermatitis, Section 1 diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol* 2014 Feb; 70(2):338-51.
2. Global Data. Pharmapoint Atopic Dermatitis Nov 2015.
3. Sanofi and Regneron Pharma. Dupixent (dupilumab) injection 300mg. Full Prescribing Information. Jan 2019.
4. Symphony Health Services (PHAST) 2017

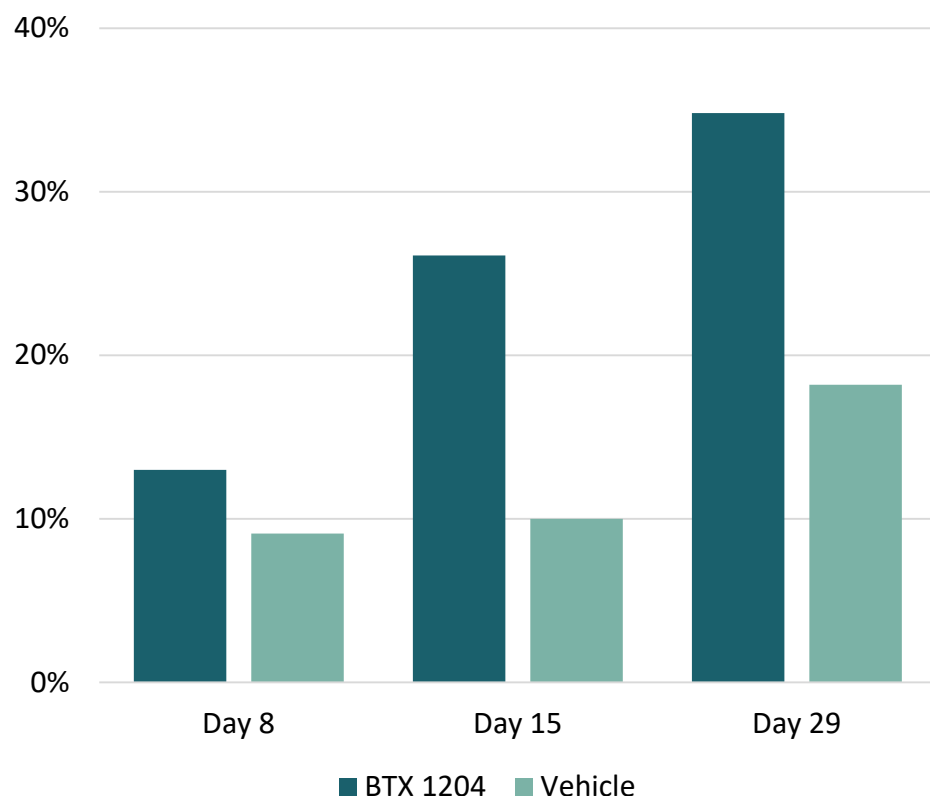
Projected atopic dermatitis market by revenue (US\$bn)⁴



Phase 1b study results support efficacy and safety potential

BTX 1204 was twice as effective as vehicle (with efficacy still increasing) and displayed a substantial improvement in the key signs of atopic dermatitis¹

Treatment success (%)²



Efficacy still increasing at 4 week timepoint

- Achieved treatment success similar to many competitive topical products
- Data suggests longer treatment period for BTX 1204 possible for increased efficacy

Clear separation from vehicle (placebo)

- Despite being a small study, BTX 1204 shows superiority over vehicle, starting at early time points

Excellent safety profile

- Safety and tolerability established with no burning, stinging or application site adverse events
- BTX 1204 profile allows extended dosing which remains a key challenge with most available therapies

1. Botanix data on file. Results indicated substantial reduction in key signs of AD, providing confidence that unmet needs in AD can be addressed

2. Treatment success defined as a greater than, or equal to, a 4 point improvement in the signs and symptoms of AD

BTX 1204: atopic dermatitis – Phase 2 study underway

12 week randomised, double-blind, vehicle controlled study to evaluate the safety and efficacy of BTX 1204 in patients with moderate atopic dermatitis (AD)

Design

- 2 dose groups: ~200 subjects
 - BTX 1204: ~100 subjects
 - Vehicle/Control: ~100 subjects
- ~25 US and Australian dermatology sites
- Children (> 12 years) and adults
- Moderate AD patients
- Treatment period of 12 weeks

Endpoints

- **Primary endpoint**
 - Proportion of subjects with ISGA success defined as an ISGA score of “Clear” (0) or “Almost Clear” (1) with at least a 2 grade improvement from Baseline at Week 12
- **Secondary endpoints**
 - Change from Baseline in the Signs of AD
 - % body surface area (BSA) affected by AD
 - Time to achieve IGA success
- **Safety**
 - Adverse events and local tolerability



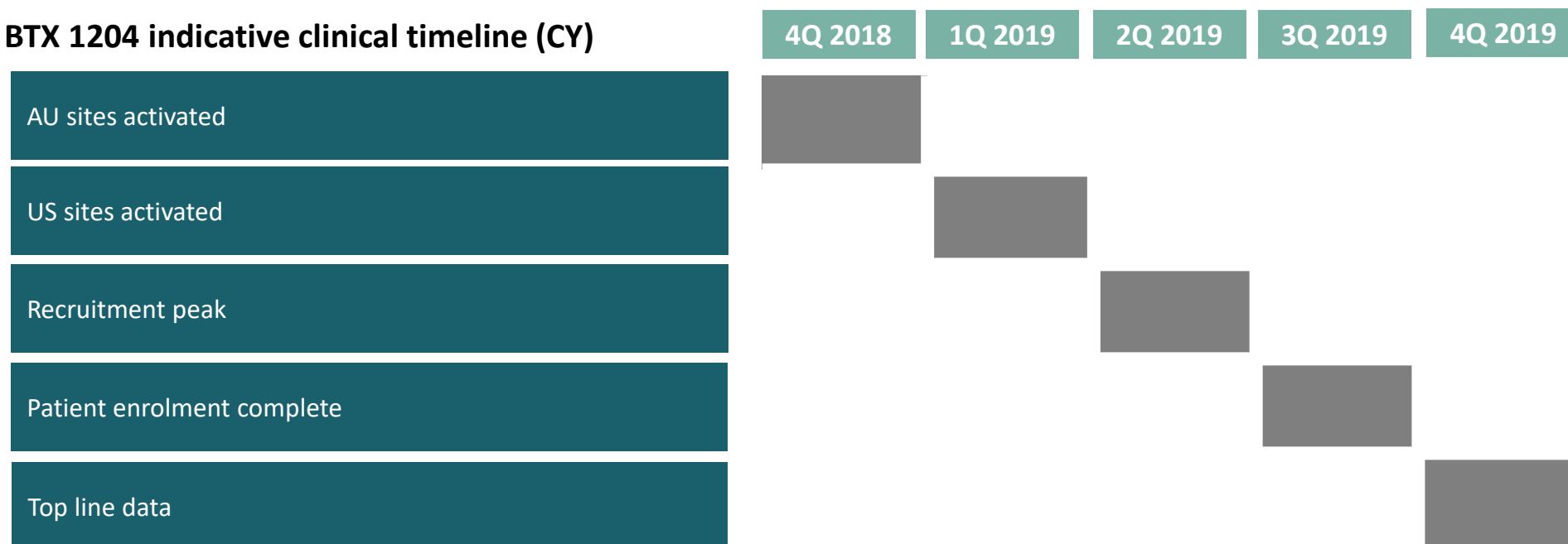
✓ target completion 4Q CY2019

BTX 1204: atopic dermatitis – Phase 2 study advancing

Phase 2 study commenced in late December and targeting top line data in 4Q CY2019

- Program leverages existing data from BTX 1503 acne studies, lowering regulatory and safety hurdles
- Common DEA licensed dermatology clinics from BTX 1503 acne Phase 2 study, reduces cost and start-up timing

BTX 1204 indicative clinical timeline (CY)



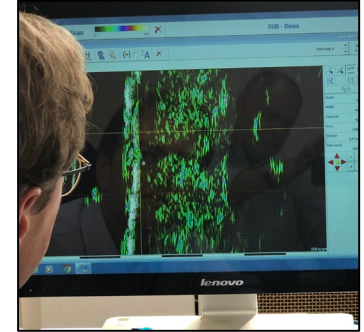
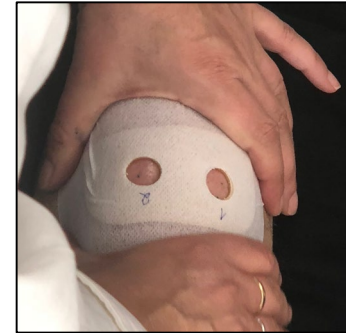
BTX 1308 for psoriasis

Phase 1b patient study is testing BTX 1308 in a model that allows biopsies to be collected which will help validate the cannabidiol mechanism of action in skin diseases

Bioskin GmbH psoriasis plaque model¹

Novel multi-drug comparison study format in the same patient, provides high quality data on BTX 1308 efficacy

- ✓ Biopsies of each drug zone and also healthy skin data will elucidate the mechanism of action
- ✓ For the first time, this biopsy data will inform the proposed anti-inflammatory, skin cell and immune modulation activity



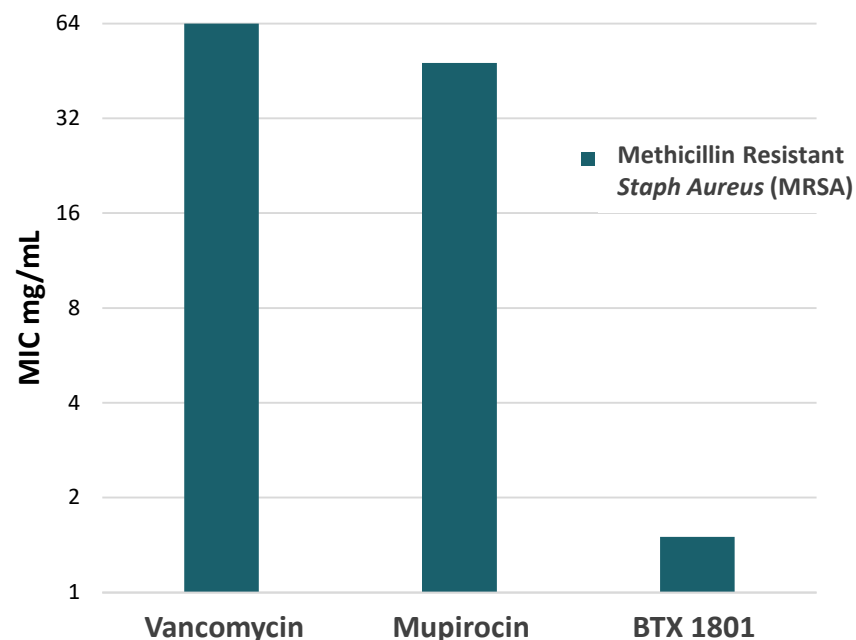
BTX 1308 indicative clinical timeline (CY)

	4Q 2018	1Q 2019	2Q 2019
Study commencement			
Patient enrolment completed			
Biopsy and sonography data analysis			
Top line data available			

BTX 1801: novel antimicrobial for serious skin diseases

Natural potential of cannabinoids is enhanced by delivery with Permetrex™ technology

Minimum Inhibitory Concentration (MIC) effect of BTX 1801 against industry standard antibiotics¹



The lower the MIC – the more effective the drug is at killing the target bacteria and the less drug is required to have the desired effect

BTX 1801 may have the following benefits

- ✓ Gram-positive bactericidal effect
- ✓ New mechanism of action
- ✓ Active against MRSA
- ✓ Topical application suited for skin infections
- ✓ Benign side effect profile based on previous clinical studies
- ✓ Ability to use long term
- ✓ Anti-inflammatory and skin barrier improvement properties
- ✓ Suitable for treatment of children (due to low toxicity)
- ✓ Prevent early use of IV antibiotics (significant side effects)

1. Vancomycin used to treat serious infections in many different parts of the body while Mupirocin used to treat certain skin infections

First two targets - for impetigo and bacterial folliculitis

Impetigo and bacterial folliculitis are two of the most common skin infections caused by *Staph Aureus* bacteria, where bacterial resistance to antibiotics is a growing problem

Impetigo



- Common skin infection in children (school sores)
- Highly contagious, results in rupturable red sores
- Caused by *Staph Aureus* and *MRSA* bacteria
- Approximately 162m children each year suffer from Impetigo
 - 45% of Australian aboriginal children
- **Market size ~US\$446m¹**

Bacterial Folliculitis



- Common skin infection involving inflammation of the hair follicle and pustules that may erupt
- Caused by *Staph Aureus* and *MRSA* bacteria
- Approximately 3m cases in the US alone
 - Incidence in people of African descent estimated to be up to 45%
- **Market size estimated to be ~US\$561m by 2023²**

1. Technavio Global Impetigo Treatment Market 2019-2023.

2. Folliculitis Market Rapidly Growing in Healthcare, Competitor Analysis, Complete Study of Current Trends and Forecast 2018-2023

Key catalysts

Significant clinical and operational milestones across multiple programs expected over the next 12 months

Indicative activities and milestones		1Q CY2019	2Q CY2019	3Q CY2019	4Q CY2019	Upcoming milestones
BTX 1308 Psoriasis	Phase 1b study in psoriasis patients					<i>Top line data 2Q CY2019</i>
BTX 1503 Acne	Phase 2 multi-centre acne clinical study					<i>Recruitment complete 2Q CY2019</i>
BTX 1204 Atopic dermatitis	Phase 2 multi-centre atopic dermatitis clinical study					<i>Recruitment complete 3Q CY2019</i>
BTX 1801 Antimicrobial	Pre-clinical development					<i>Patient study design 2Q CY2019</i>
Permetrex™ collaborations	Research collaborations and partnership discussions					<i>Ongoing studies with partners</i>

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