

ASX/Media Release

6 June 2019

Botanix at the Jefferies Healthcare Conference

Philadelphia PA and Sydney Australia, 6 June 2019: Medical dermatology company Botanix Pharmaceuticals (“Botanix” or “the Company”) is pleased to announce that its Founder and Executive Director, Matt Callahan, will be presenting the Company’s progress at the 2019 Jefferies Healthcare Conference in New York. Mr Callahan’s presentation is attached to this release.

Jefferies Group is the largest independent full-service global investment banking firm headquartered in the U.S. The conference features company presentations, thematic panel discussions, and one-on-one meetings. Last year, the event attracted more than 2,600 attendees from around the world.

Mr Callahan will provide an update on the progress of Botanix’s late stage clinical programs, including the acne study (Phase 2), atopic dermatitis study (Phase 2) and the psoriasis mechanism of action study (Phase 1b) which remain on track for data read outs in 3Q CY2019, 4Q CY2019 and 2Q CY2020, respectively. The conference will also allow Botanix to establish links with various investors and potential strategic partners.

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 data read-out expected in Q3 2019. The BTX 1204 atopic dermatitis Phase 2 patient study is also underway with enrolment expected to be

completed in 3Q CY2019. Finally, Phase 1b BTX 1308 psoriasis mechanism of action study is nearing completion with data anticipated to be available in 2Q CY2019. Pipeline projects that leverage the anti-microbial properties of cannabidiol are also moving forward and are planned to enter the clinic in 2H 2019.

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

For more information, please contact:

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RESTORING HEALTHY SKIN

Botanix Overview

Jefferies Healthcare Conference

June 2019



Botanix overview

Cannabinoid focused pharmaceutical company, with one of the world's most advanced clinical pipelines, studying CBD in a range of inflammatory and antimicrobial applications



Multiple value
inflection points

Significant clinical inflection points from **completion of funded studies for acne, atopic dermatitis and psoriasis in 2019**



Growing data
support

Recent FDA approval of Epidiolex® **validates the safety profile and therapeutic potential of synthetic cannabidiol** as a novel therapeutic



Validation of
pharma focus

Investment in the sector is moving beyond plants – **Botanix is one of the world's most advanced pharma-focused synthetic cannabinoid companies**



Technology
driven

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



World class
team

Team has significant clinical, regulatory and commercial expertise and has **advanced product candidates into Phase 2 studies within 24 months of commencement**

Corporate overview

Australian Stock Exchange (ASX) listed company showing stable share appreciation and a highly aligned Board and management team

Trading information

Share price (as at 5-Jun-2019)	A\$0.100
52 week low / high	A\$0.180 / A\$0.069
Shares outstanding ¹	765m
Market capitalisation¹	A\$76.5m
Cash (as at 31-Mar-2019)	A\$9.3m
Debt (as at 31-Mar-2019)	-

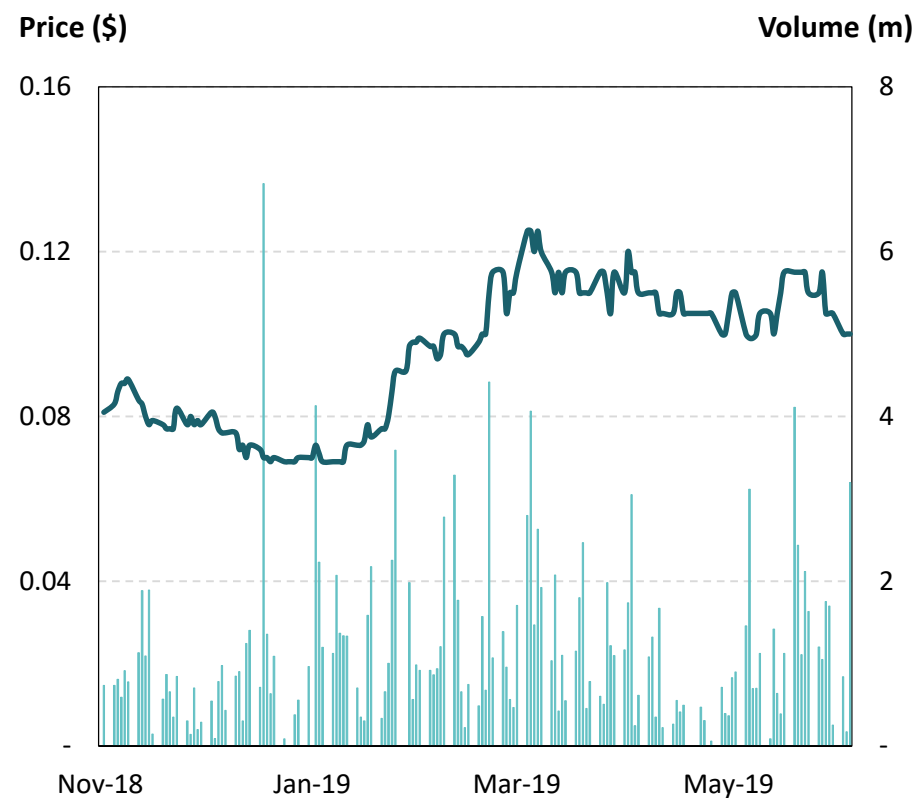
Top shareholders (May 2019)

Shareholder	%
Matthew Callahan – Founder and Executive Director	9.2
Caperi Pty Ltd – Co-founder	9.2
Board and management (excl. shareholders above)	2.6

Source: IRESS

1. Excludes 53.2m options

Share price performance



Significant re-rating potential if data continues to be positive

Botanix has one of the most advanced CBD clinical programs globally, with potential for a significant value inflection points following multiple clinical study completions in 2019



Lead products: BTX 1503, BTX 1204, BTX 1308

Phase 2 acne, Phase 2 atopic dermatitis and Phase 1b psoriasis

Target population: 100m patients p.a.²

Revenue potential: >US\$3bn p.a.³

CBD source: Synthetic (100% pure)

Manufactured at industrial scale, facilitates relatively lower COGS

Technology: Permetrex™ skin delivery platform

Pipeline products:

Multiple clinic-ready products which leverage published efficacy data and target attractive markets (e.g. antimicrobial markets worth >US\$10bn p.a.)

Market cap (US\$m)¹

US\$54m

US\$5.6bn



Lead product: Epidiolex®

FDA Approved for Lennox-Gastaut / Dravet epilepsy

Target population: 43k patients p.a.⁴

Revenue potential: >US\$1.3bn p.a.⁵

CBD source: Naturally extracted

Manufacturing scale up and quality variation challenges, leads to relatively higher COGS

Technology: None – oil based oral delivery

Pipeline products:

Focused on similar CNS markets as Epidiolex® (product cannibalisation risk) or niche markets; other than Rhett's - in early clinical development with limited efficacy data published to date

Significant opportunity for value inflections following successful results

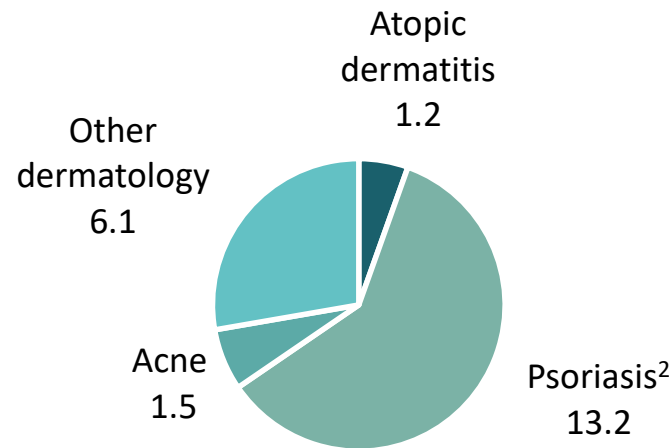
1. Bloomberg
2. GBI Research. *Dermatology Therapeutics Market to 2018; American Academy of Dermatology; British Journal of Dermatology; Expert Review of Dermatology.*
3. Symphony Health Solutions PHAST
4. *Scrip (2018) Gottlieb: Epidiolex Approval Covers One Specific Cannabidiol Medication, Not Marijuana.*
5. Cowen analyst report February 2019



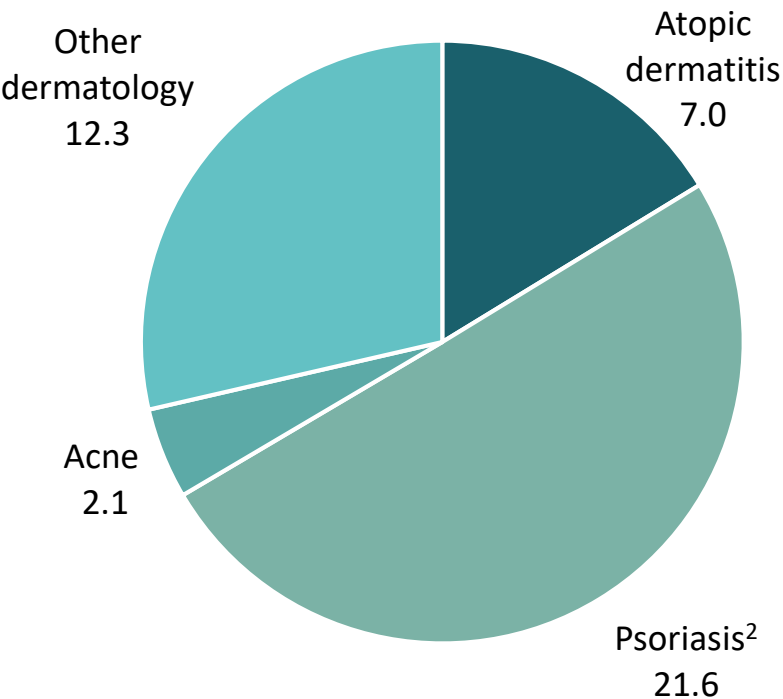
Our focus is on large markets that are poised for growth

Global medical dermatology market is expected to grow to US\$43bn by 2024¹

2017 global dermatology market¹
US\$22bn sales








2024 global dermatology market¹
US\$43bn sales



1. Evaluate Pharma
2. Growth driven by Biologics

Rapidly advancing pipeline targeting large and growing markets

Phase 2 trial completions for acne and atopic dermatitis trial and Phase 1b MOA study due for completion in 2019

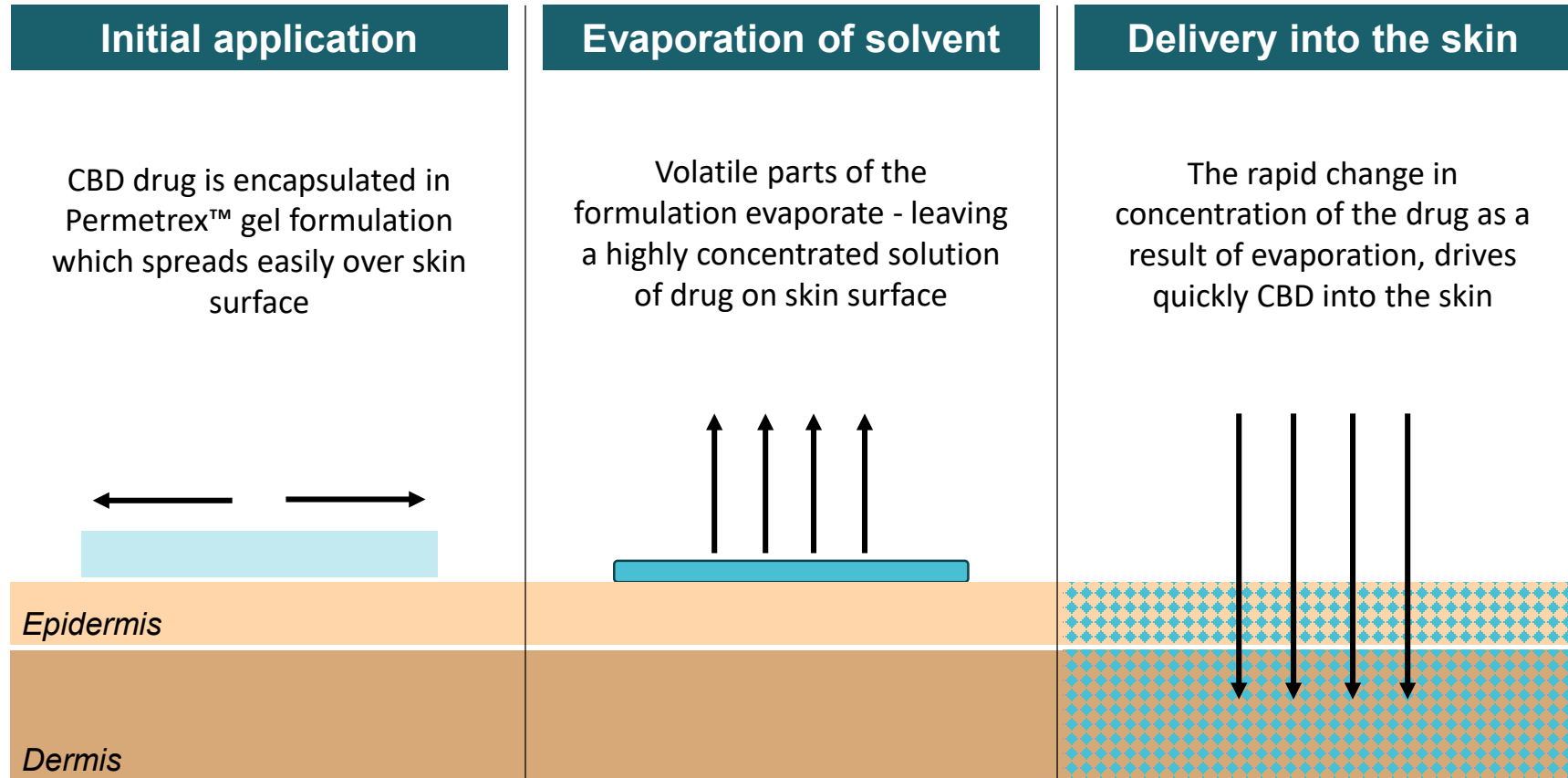
Product candidate		Indication	Pre-clin	Ph 1	Ph 1b	Ph 2	Status
Synthetic CBD with Permetrex™ technology	BTX 1503	Moderate to severe acne					Study complete 3Q 2019
	BTX 1204	Moderate atopic dermatitis					Study complete 4Q 2019
	BTX 1308	Psoriasis					Study complete 2Q 2019
	BTX 1801	Antimicrobial skin infections					Preparing for Phase 1b/2 study
Permetrex™ programs	External	Various					Ongoing collaborations with partners

Overview Permetrex™ Technology



Permetrex™ - proprietary novel skin delivery technology

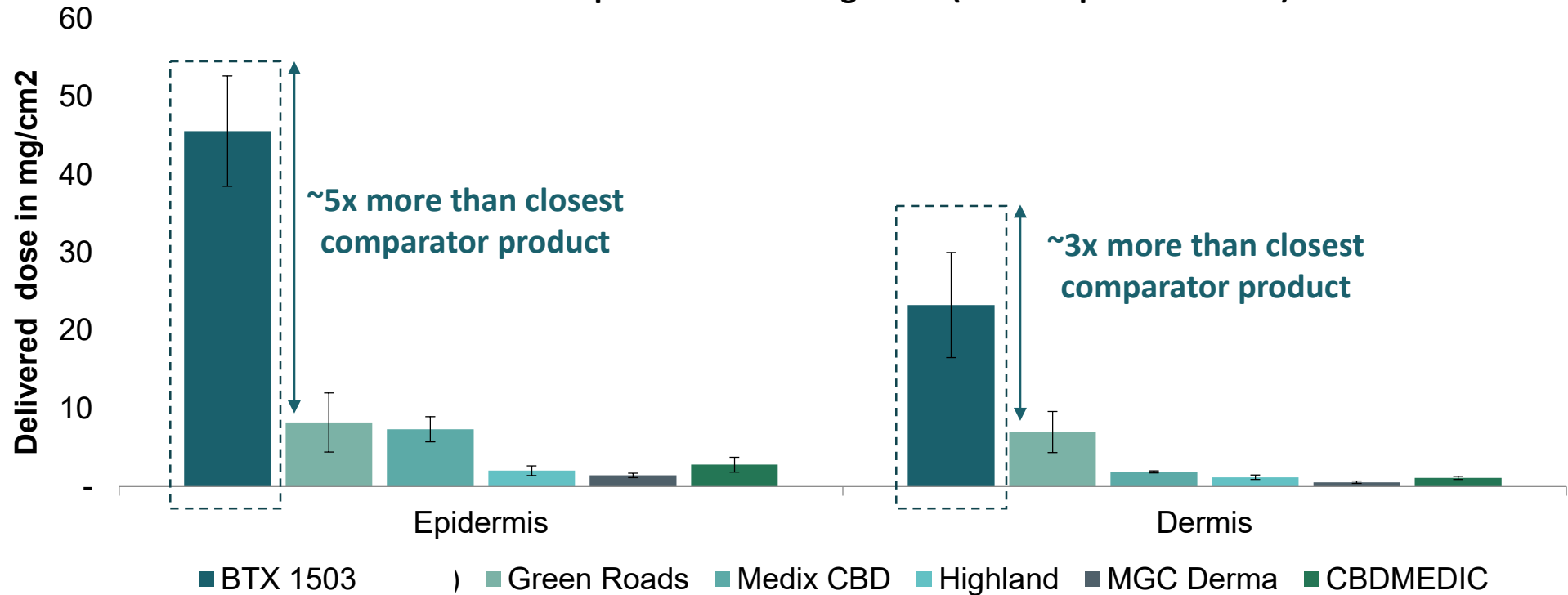
Makes new types of gels, that deliver very high doses of drug into the layers of the skin without using permeation enhancers, preservatives, or irritating levels of alcohol / petrolatum additives



Permetrex™ delivers 3-5 times more CBD into the skin

BTX 1503 (acne) significantly outperformed the other tested CBD products in delivering drug to the targeted layers of the skin¹

Amount of CBD permeated through skin (time elapsed 48 hours)



Relative to the closest comparator, BTX 1503 delivers significantly more CBD to the skin than other OTC creams and gels

1. For further details on these tests – see BOT ASX release on 26/02/19. Skin penetration tested using franz cell human skin vessel with receiver fluid assayed for CBD content at each level (epidermis and dermis). Study conducted by Tiaga Research. Botanix data on file.

Over-the-counter CBD products are not what they seem

Over-the-counter (OTC) or internet purchased CBD products often contain approximately one tenth of labelled CBD content, are not regulated and may come with other quality risks¹

Product name	Manufacturer	Product type	Label claim CBD content (mg/tube)	Tested CBD content
TheraGreen™	Green Roads	Cream	300 →	24.5
Biotech Pain Relief	Medix CBD	Cream	150 →	11.2
Therapy+Hemp Cream	Highland Pharms	Cream	200 →	24.6
CBD Herbal Repair Cream	MGC Derma	Cream	Undisclosed →	8.8
CBDMEDIC™ Back and Neck	CBDMEDIC	Ointment	Undisclosed →	14.9



Dr. Amy Abernethy ✓ @DrAbernethyFDA · 22h

Key questions about product safety need to be addressed. Data are needed to determine safety thresholds for CBD; datasets/information should be objective, of adequate quality and available for transparent review. Lab testing and data analyses need to be replicable.

Dr Amy Abernethy
Principal Deputy
Commissioner and Acting
CIO – FDA²

1. For further details on these tests – see BOT ASX release on 26/02/19. Products purchased from internet websites of respective vendors and tested by independent laboratory testing service Tioga Research. HPLC analysis of CBD content compared labeled CBD or cannabinoid content to Tioga test results.. Botanix data on file.

2. Dr Amy Abernethy Twitter post during FDA Public Hearing “Scientific Data and Information about Products Containing Cannabis or Cannabis Derived Compounds” – 31 May 2019

Botanix Dermatology Development Programs

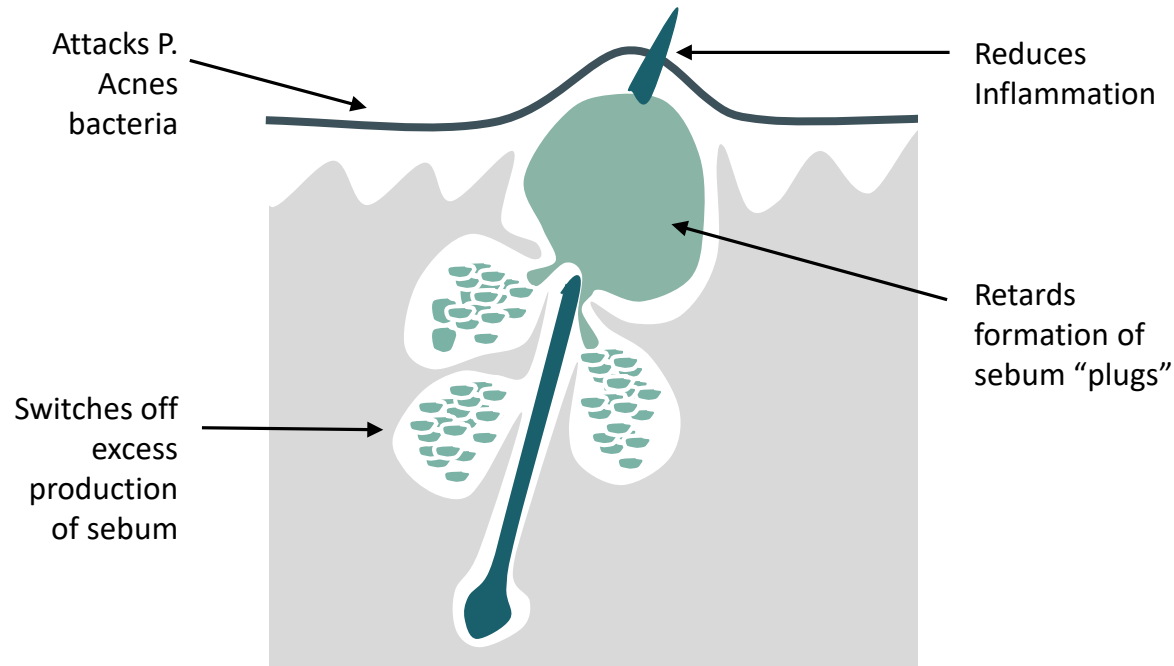
1. BTX 1503: acne
2. BTX 1204: atopic dermatitis
3. BTX 1308: psoriasis
4. BTX 1801: antimicrobial



1. BTX 1503 – moderate to severe acne

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

BTX 1503 potentially addresses 3 key acne pathologies ¹



CBD has been shown in studies to...

- 1 **Exert anti-inflammatory effects** via inhibition of the NF-κB pathway and to **suppress sebocyte proliferation**²
- 2 Have **potent anti-microbial** activity against gram-positive bacteria³
- 3 **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

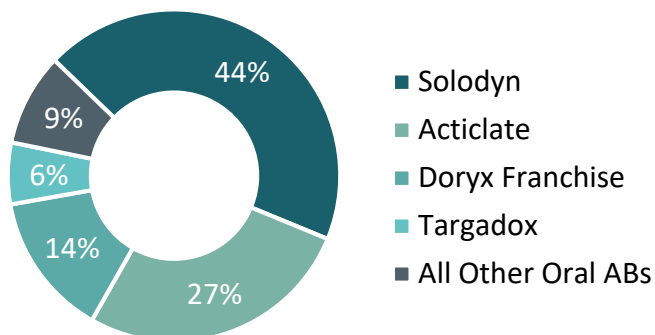
Rank	Brands	Revenue (US\$m) ¹	Scripts ('000)
1	SOLODYN Minocycline, Valeant	\$492	434
2	ACTICLATE Doxycycline, Almirall	\$234	261
3	DORYX FRANCHISE Doxycycline, Mayne	\$65	132
4	TARGADOX Doxycycline, Journey	\$40	63

Top topical brands

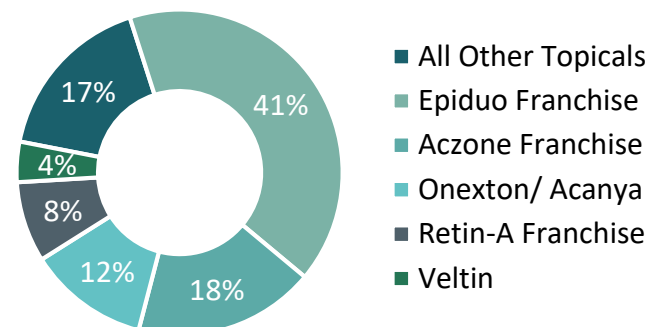
Rank	Brands	Revenue (US\$m) ¹	Scripts ('000)
1	EPIDUO FRANCHISE Adapalene+BPO, Galderma	\$659	1,431
2	ACZONE FRANCHISE Dapsone, Allergan	\$298	625
3	RETIN-A FRANCHISE Tretinoin, Valeant	\$219	304
4	ONEXTON/ACANYA Clindamycin+BPO, Valeant	\$200	410
5	VELTIN Clindamycin+tretinoin, Almirall	\$79	151

Target
market
share
>US\$1.5bn

Prescription market share oral brands²



Prescription market share topical brands²



Source: Symphony Health Solutions PHAST (accessed 1.2018)

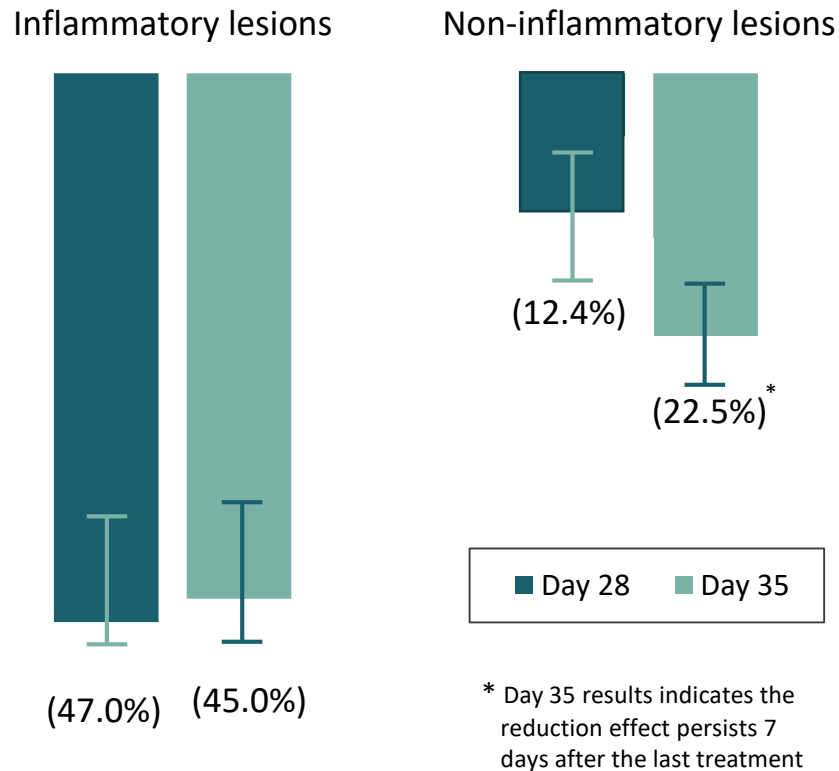
1. US \$ represent SHS metric (TRx MBS) or dollarized prescriptions

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



Phase 1b patient data for BTX 1503 (acne)

4 week Phase 1b study data shows a marked reduction in inflammatory lesions and no serious adverse events

Lesion count reduction (%)¹



Other FDA approved products²

Product	Owner	Lesion count reduction (%) ³	2017 annual revenue ⁴
 Epiduo®	Galderma	~42%	US\$659m
<ul style="list-style-type: none"> ✓ Combination of two drugs – benzoyl peroxide and adapalene ✗ Common side effects include redness, skin peeling mild burning / stinging and dryness 			
 Aczone®	Allergan	~38%	US\$298m
<ul style="list-style-type: none"> ✓ Few side effects ✗ Studies showed large placebo / vehicle effect – i.e. at 12 weeks Aczone reduced inflammatory lesions by 54% while vehicle achieved 48% reduction 			
BTX 1503	Botanix	~47%	-

1. Botanix BTX.2017.002 trial - Botanix data on file

2. Botanix BTX.2017.002 trial with reported 4 week data from Epiduo and Aczone as published Am J Clin Dermatol (2016) 17: 293-303 and Journal of Drugs in Dermatology (2016) Vol 15 Issue 8 P 962.

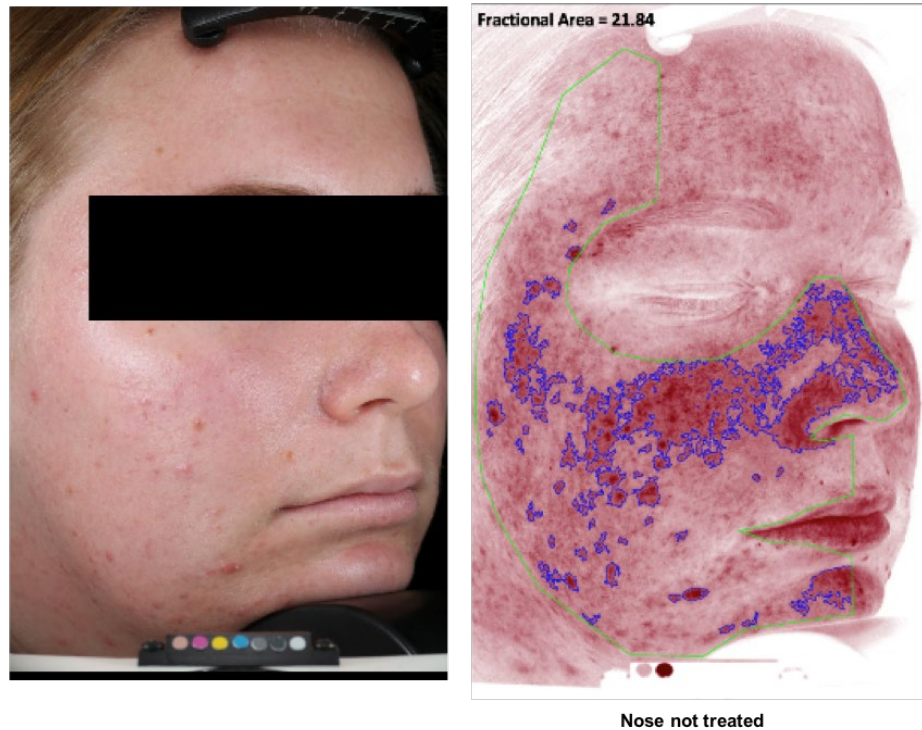
3. Lesion count reduction based on average inflammatory lesion reduction at 4 weeks

4. Symphony Health solutions PHAST 2018

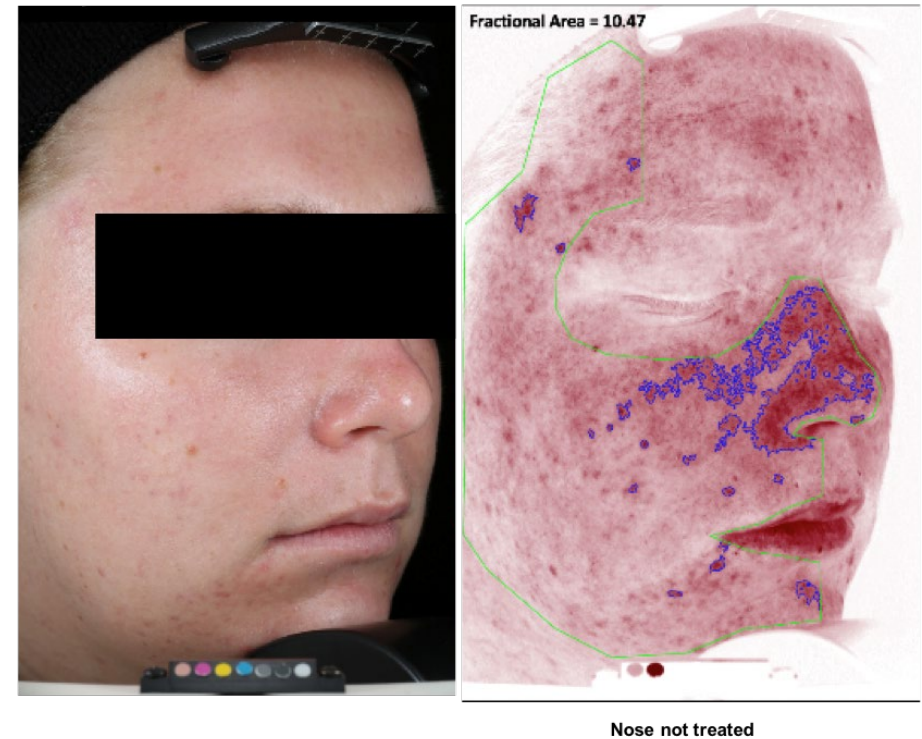
BTX 1503 (acne) - anti-inflammatory effects of CBD

Canfield RBX® images from the Phase 1b acne patient study, demonstrate a clear anti-inflammatory effect over the 4-week treatment course¹

Baseline (day 1)



Visit 4 (4 weeks)



BTX 1503: acne – Phase 2 study well advanced

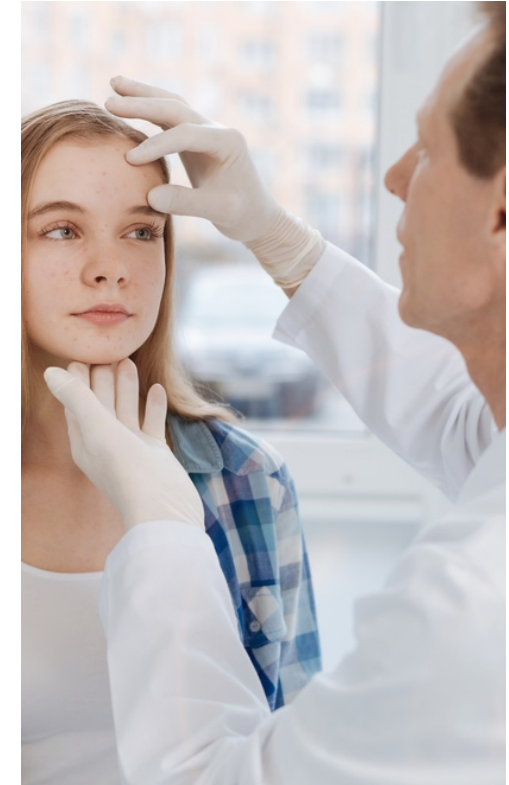
12-week randomised, double-blind, vehicle controlled study to evaluate the safety and efficacy of BTX 1503 in patients with moderate to severe acne

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

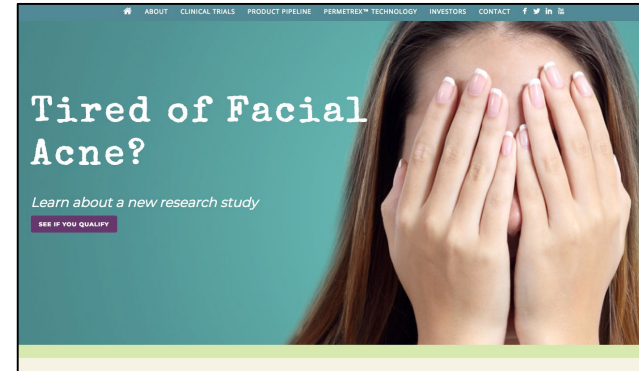


Study completion end 3Q CY2019

BTX 1503 Phase 2 patient study schedule

Recruitment is complete with final subjects completing in-life phase of study

- No serious adverse events / issues arising from treated patients to date
- Positive feedback from dermatologists on study



BTX 1503 indicative clinical timeline (CY)

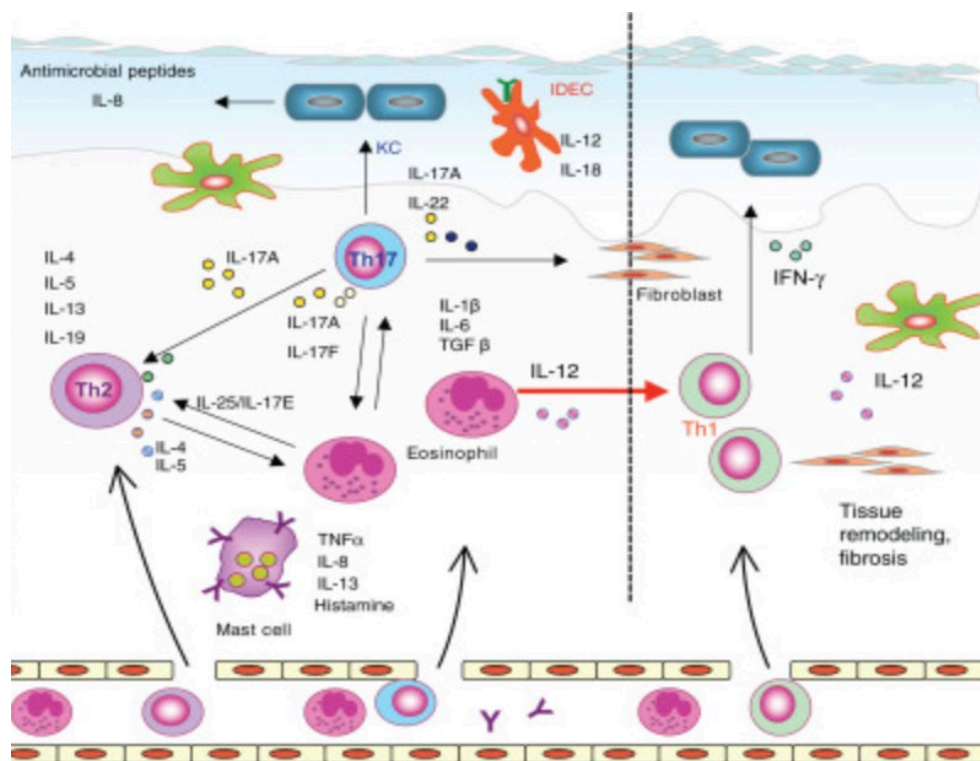


2. BTX 1204: moderate atopic dermatitis

Atopic dermatitis is a T-cell mediated inflammatory disease of the skin

Acute phase

Chronic phase



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 market projected to be ~US\$25bn in 2027

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 diseases¹

- 2% - 3% of adults, 25% of children
- 75% of patients are moderate to severe³

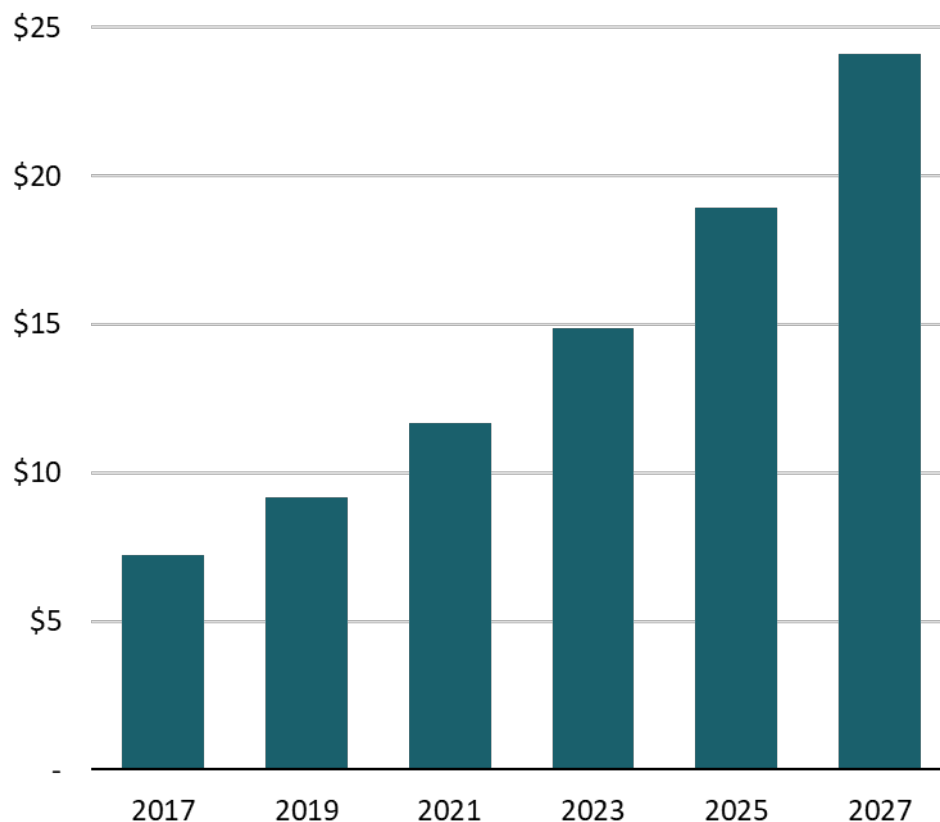
Large unmet needs across the atopic dermatitis population²

- Few safe and effective non-steroidal option for chronic use
- Biologics address only the severe population

Pediatric population particularly has a need for a steroid free alternative¹

- Safety concerns with steroids are high
- Topical Calcineurin Inhibitors (Protopic/Elidel) have a boxed warning
- Current non-steroidal options have been reported to have tolerability concerns

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

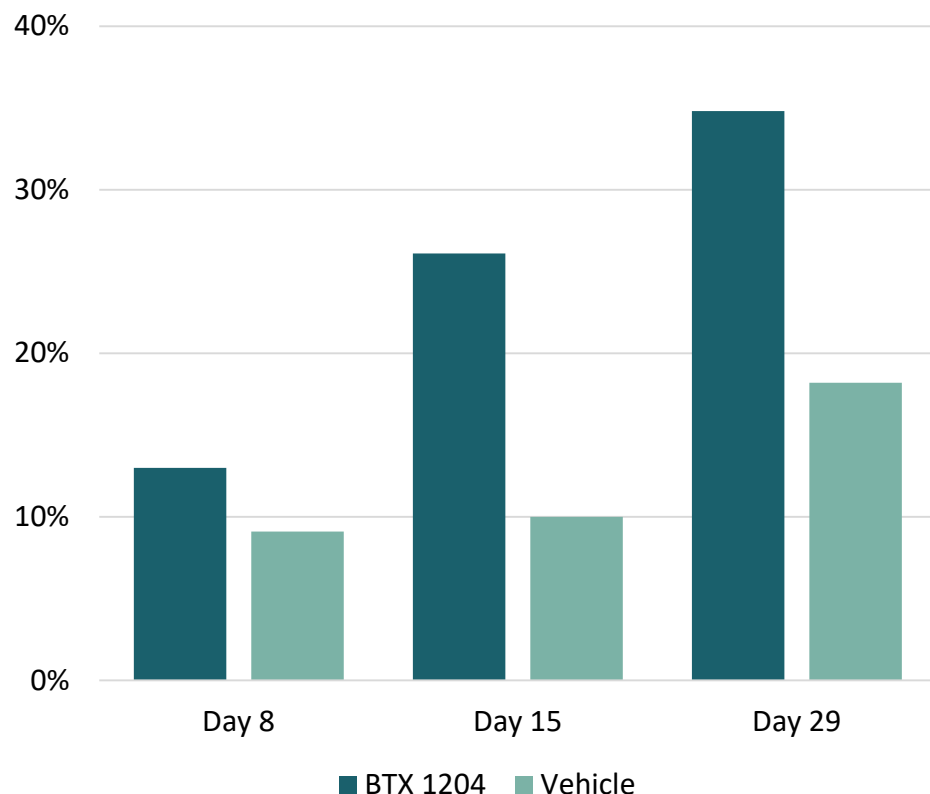


1. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al Guidelines of care for the management of atopic dermatitis, Section 1 diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol* 2014 Feb; 70(2):338-51.
2. Global Data. *Pharmapoint Atopic Dermatitis* Nov 2015.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

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 may allow 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



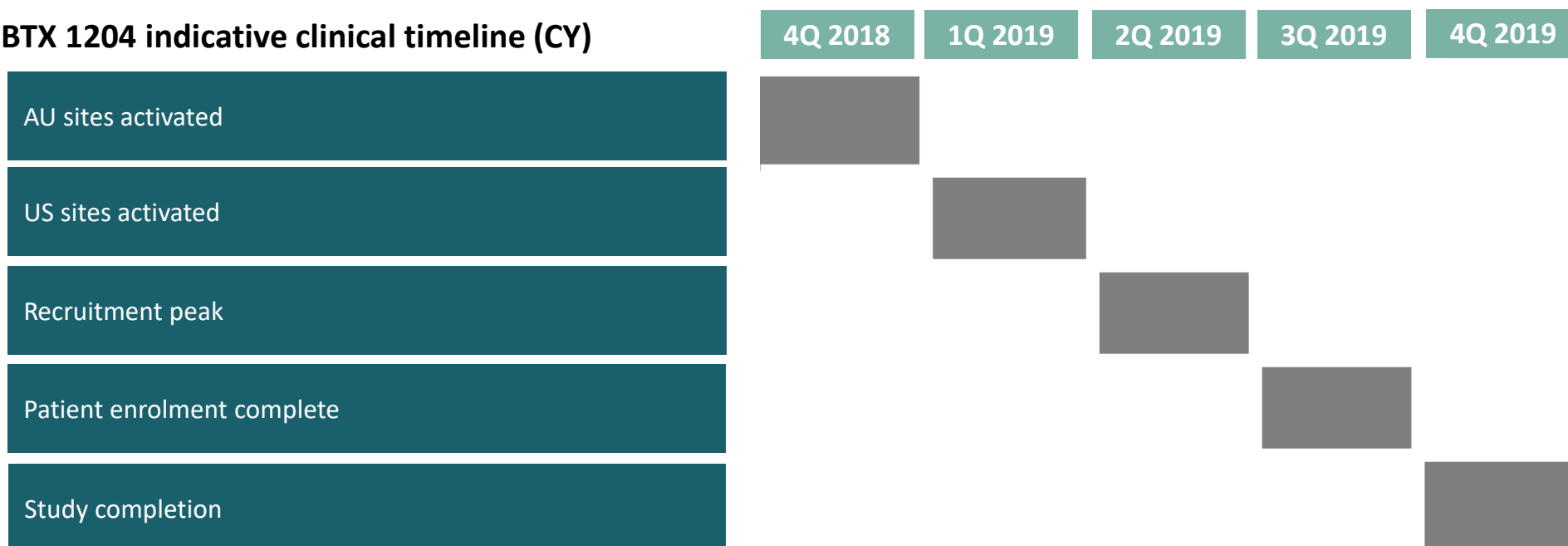
Study completion 4Q CY2019

BTX 1204: atopic dermatitis – Phase 2 study advancing

Randomised vehicle controlled study in 200 moderate patients

- 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)



3. BTX 1308 for psoriasis

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

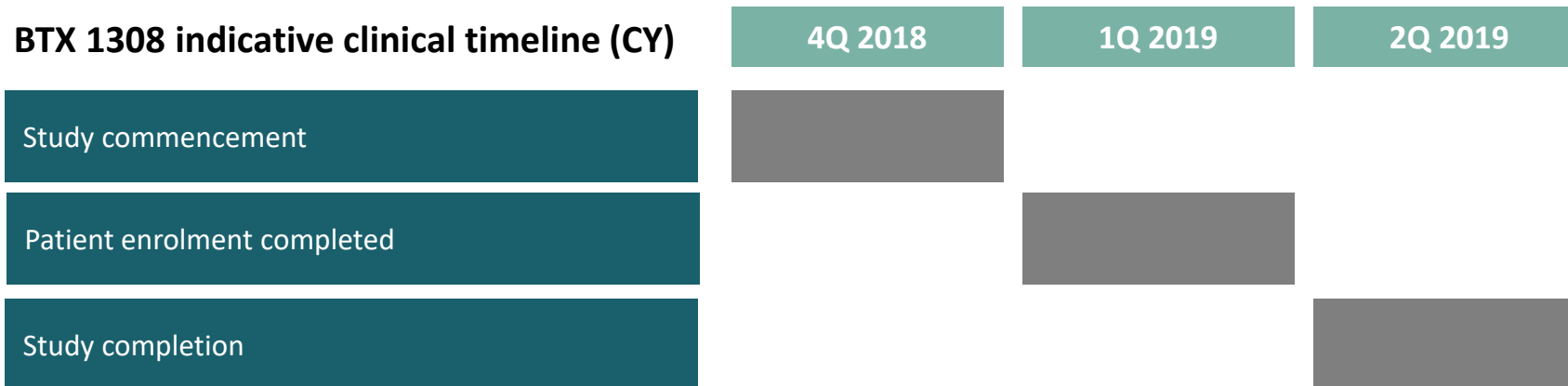
Psoriasis plaque model

Novel multi-drug comparison study format

- ✓ Biopsies of each drug zone and also healthy skin data may help elucidate the mechanism of action
- ✓ Potentially provides insight into pathways and gene targets of interest



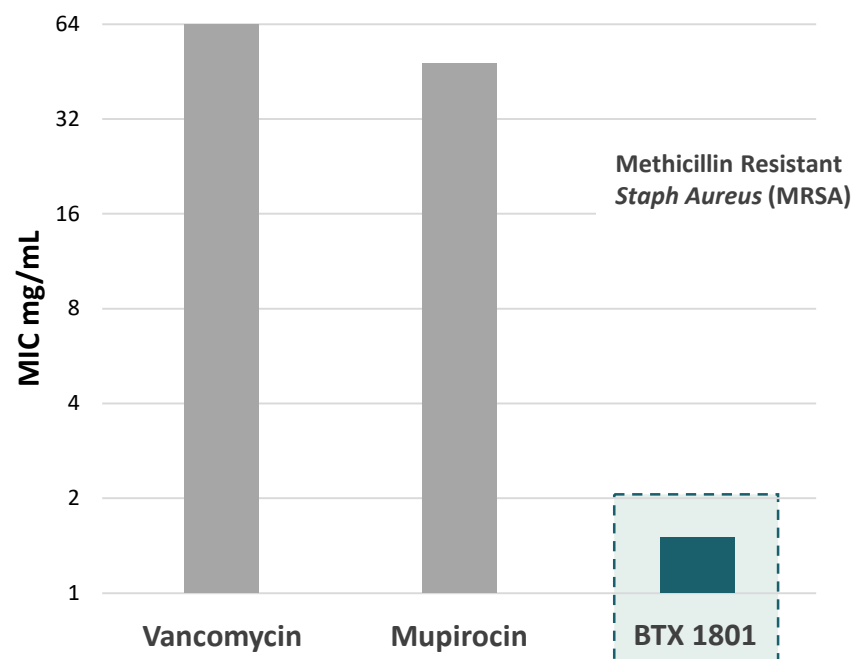
BTX 1308 indicative clinical timeline (CY)



4. 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



Note: 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:²

- ✓ Gram-positive bactericidal effect
- ✓ 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
- ✓ Prevent early use of IV antibiotics (significant side effects)

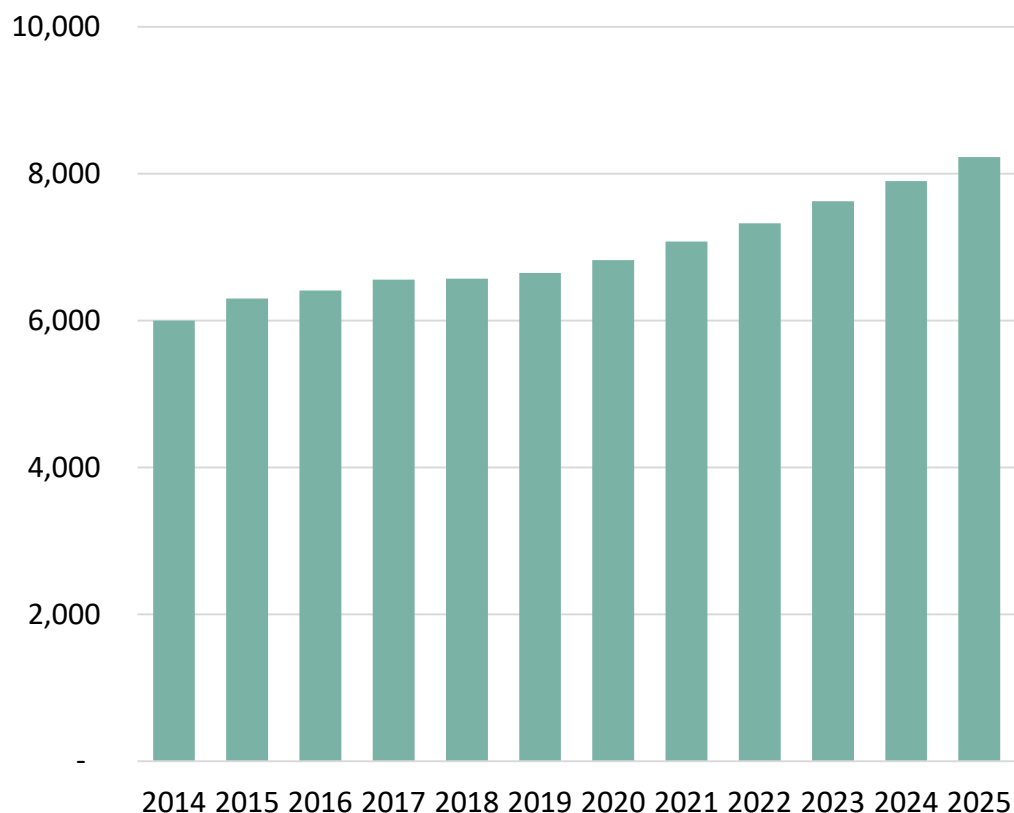
1. Vancomycin used to treat serious infections in many different parts of the body while Mupirocin used to treat certain skin infections

2. Potential benefits based on published literature and independent testing by third party laboratories Botanix data on file

Market for skin infections exceeds US\$6.5bn per annum

The market for skin infection drugs continues to increase with the challenges of resistance driving the price of more effective products higher

Skin infection drugs market forecast 2014-2025 (US\$m)








- Skin infections are the most common healthcare-associated infection (HAIs) **accounting for 31% of all HAIs among hospitalised patients**
- **MRSA accounts for ~59% of skin & soft tissue infections (SSTIs) presenting to the ER**
- Patients with HAI's face **prolonged hospital stays, treatment-associated risks, long-term adverse outcomes and a 2–11 fold increase in mortality risks**



Botanix leads the way in synthetic CBD clinical development

Phase 2 acne trial completion in 3Q and phase 2 atopic dermatitis trial completion in 4Q 2019

Product candidate		Indication	Pre-clin	Ph 1	Ph 1b	Ph 2	Status
Synthetic CBD with Permetrex™ technology	BTX 1503	Moderate to severe acne					Study complete 3Q 2019
	BTX 1204	Moderate atopic dermatitis					Study complete 4Q 2019
	BTX 1308	Psoriasis					Study complete 2Q 2019
	BTX 1801	Antimicrobial skin infections					Preparing for Phase 1b/2 study
Permetrex™ programs	External	Various					Ongoing collaborations with partners

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