ASX/Media Release

9 December 2019

Investor Presentation

Philadelphia PA and Sydney Australia, 9 December 2019: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "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 clinical trials, pipeline products in development and other key upcoming activities.

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's focus is the development of safe and effective topical treatments for serious skin diseases, leveraging the unique anti-inflammatory, immune modulating and antimicrobial properties of 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 has announced data from its Phase 2 acne patient study and is preparing for the end of Phase 2 meeting with the FDA. A Phase 2 patient study in atopic dermatitis is now fully recruited with data planned for 1Q CY2020 and its new Phase 1b rosacea study recently received ethics approval. The Company has also successfully completed a mechanism of action study for synthetic cannabidiol in skin disease, with positive data announced in June 2019 and is developing a pipeline of product candidates that leverages the antimicrobial properties of cannabidiol, with first products planned to enter the clinic in Q1 CY2020.

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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RESTORING HEALTHY SKIN

Botanix Pharmaceuticals

Australian Non-Deal Roadshow
December 2019

World class team

Global team with proven experience and an unrivalled track record

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

Dr Michael Thurn

COO and Board Director

Operations + Regulatory

- Extensive start up life sciences experience in dermatology
- Previous MD of Spinifex Pharmaceutical, which sold to Novartis for A$700m

Howie McKibbon

Chief Commercial Officer

- SVP of Commercial at Anacor and Medicis
- More than 20 years dermatology and pharma commercial experience

Matt Callahan

Founder and Consultant

- Developed 4 products through FDA approval and launch
- Serial founder and ex-investment director of 2 venture capital firms in life sciences

Dr Stephane Levy

Chief Medical Officer

Medical + Clinical

- Ex-CMO of Almirall US operations and VP Clinical with Sanofi and Novartis
- Broad commercial and clinical development experience

Ric Peterson

Chief Financial Officer

Finance + Strategy

- Former CFO of Sienna, Novan and Medicis
- Unrivalled dermatology experience across multiple companies for more than 30 years

Jack Lawler

VP Development

Development + Clinical

- 20 years clinical trial and development experience
- Most recently VP at Egalet Corporation and Director at Viropharma (Shire)

Dr Joyce Rico

Strategic Advisor

Medical, Research & Development

- Recent CMO for Novan Pharmaceuticals
- Prior experience as a Board Member for the Society of Investigative Dermatology, VP, Medical Affairs at Astellas and dermatology faculty at Duke, NYU and Northwestern

Dr Judith Plon

VP Regulatory Affairs

Regulatory

- 30 years regulatory experience with multiple FDA approved dermatology products
- Ex-AVP Global Regulatory Affairs at Sanofi

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Botanix overview

Botanix is a clinical stage synthetic cannabinoid company, focused on developing topical products for the treatment of skin diseases and bacterial infections

Pharma focused	One of the world's **most advanced pharmaceutically focused synthetic cannabinoid (CBD) companies**
Technology driven	Proprietary Permetrex™ technology **enhances topical delivery of synthetic cannabinoid** and provides **novel IP position**
Clinical data	Lead dermatology indications validated by **robust clinical efficacy and safety data** with mechanistic **support for expansion into other diseases**
World class team	Experienced and growing team with **significant dermatology and cannabinoid drug development expertise**
Near-term catalysts	**Multiple near-term catalysts** including Phase 2 atopic dermatitis data and commencement of rosacea and bacterial infection studies

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Advanced dermatology pipeline with near term milestones

Combination of clinical, safety and mechanism of action data from recent Botanix studies provide support for ongoing clinical programs, including near term completion of Phase 2 AD study

Synthetic CBD with Permetrex™ topical technology

Product	Indication	Ph 1	Ph 1b	Ph 2	Ph 3	Status
BTX 1503 Gel	Moderate to severe acne					Preparing for FDA end of Phase 2 meeting
BTX 1204 Solution	Moderate atopic dermatitis					Study data 1Q CY2020
BTX 1702 Solution	Rosacea					Ethics approval received for Phase 1b study
BTX 1801 Ointment	Antimicrobial					Preparing for Phase 2 study
BTX 1308 Ointment	Psoriasis					Successful MOA[1] study

1. MOA: Mechanism of Action

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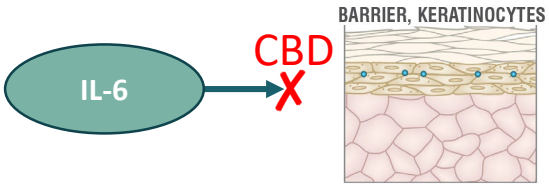
Topical CBD is well suited to treat skin disease and infections

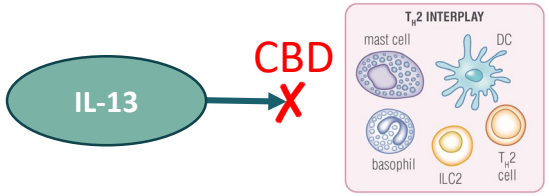
Botanix has generated strong scientific support for synthetic CBD's anti-inflammatory and immune modulation mechanisms of actions, combined with newly identified antimicrobial effects[1]

CBD anti-inflammatory / immune modulating effects

CBD inhibits a key cytokine which affects skin barrier disfunction



CBD attenuates a well-known cytokine which drives the inflammatory response



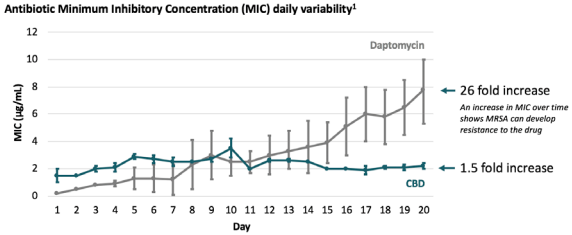
CBD inhibits a pathway which disrupts the signaling driving the body's immune response

CBD antimicrobial effects

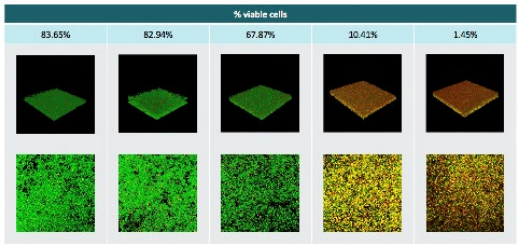
CBD is active against all tested gram +ve bacteria

Antibiotic	*S. aureus* all isolates (µg/mL)			MRSA[1] (µg/mL)		MSSA[2] (µg/mL)	
	MIC_{50}	MIC_{90}	Range	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}
Cannabidiol	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

Bacteria cannot form resistance to CBD's rapid killing power



CBD disrupts the bacteria's biofilm protective cover



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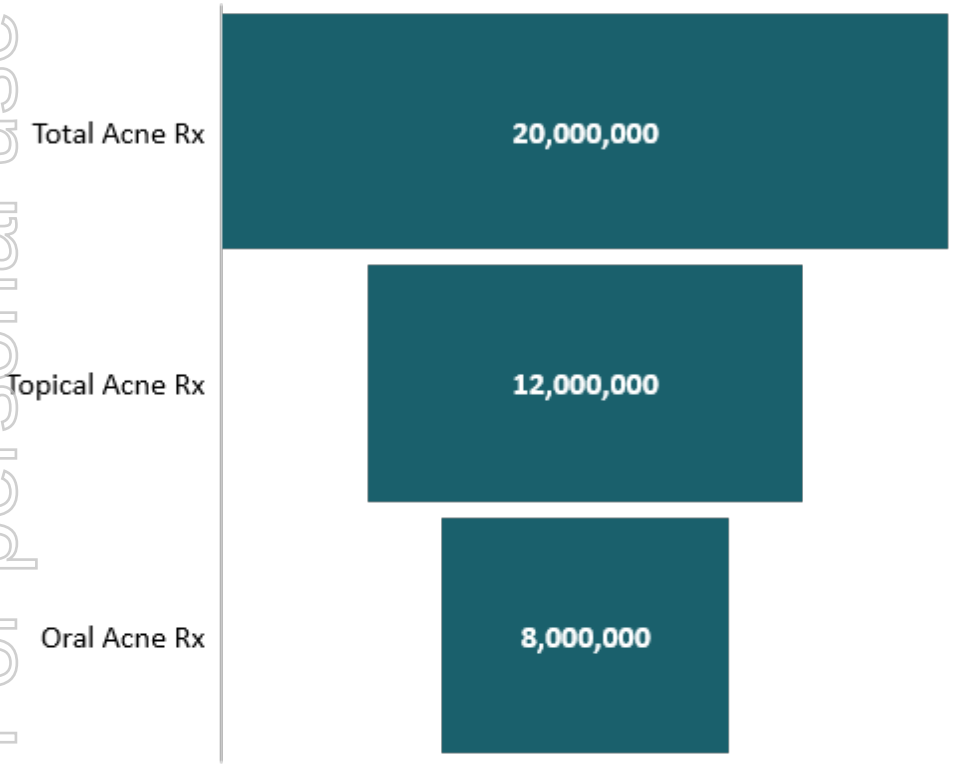
1. Botanix data on file, see slides 9, 10, 14, 19, and 23 of this deck for further data

BTX 1503 – acne

Sizable acne market with a clear unmet medical need

Competitive products with tolerability and safety concerns, as well as antimicrobial resistance challenges, have generated significant annual sales

Acne prescription market



Top brands at peak sales

Rank	Brands	Peak gross sales	US peak prescriptions
1	**SOLODYN** Minocycline	~$1B	1,295,346
2	**DORYX FRANCHISE** Doxycycline	~$900m	983,368
3	**EPIDUO FRANCHISE** Adapalene+BPO	~$700m	1,208,376
4	**ACZONE FRANCHISE** Dapsone	~$300m	896,102

Source: IQVIA NPA

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BTX 1503: Phase 2 top line data

Solid efficacy and safety results show BTX 1503 5% once-a-day (QD) dose is the best treatment to take forward into Phase 3 studies

BTX 1503 is safe and effective	All doses of BTX 1503 were very safe – no serious adverse events or treatment related discontinuations in BTX 1503 5% once a day (QD) group, while achieving positive effects on acne lesion reductions
BTX 1503 once a day is the dose	BTX 1503 as a once daily application had the best performance, which from a patient compliance and commercial perspective, is the ideal dosing regime
Clinical response	A strong and consistent impact on inflammatory lesions was seen with an even greater effect on non-inflammatory lesions
Positive efficacy and Australian data is statistically significant	Overall efficacy outcome is positive and Australian sites showed clear separation of BTX 1503 5% once a day (QD)
USA only vehicle response	Patients in the USA that received vehicle had an unusually high vehicle response which skewed the overall primary endpoint

Source: BTX 1503 Phase 2 Study Results released 22 October 2019

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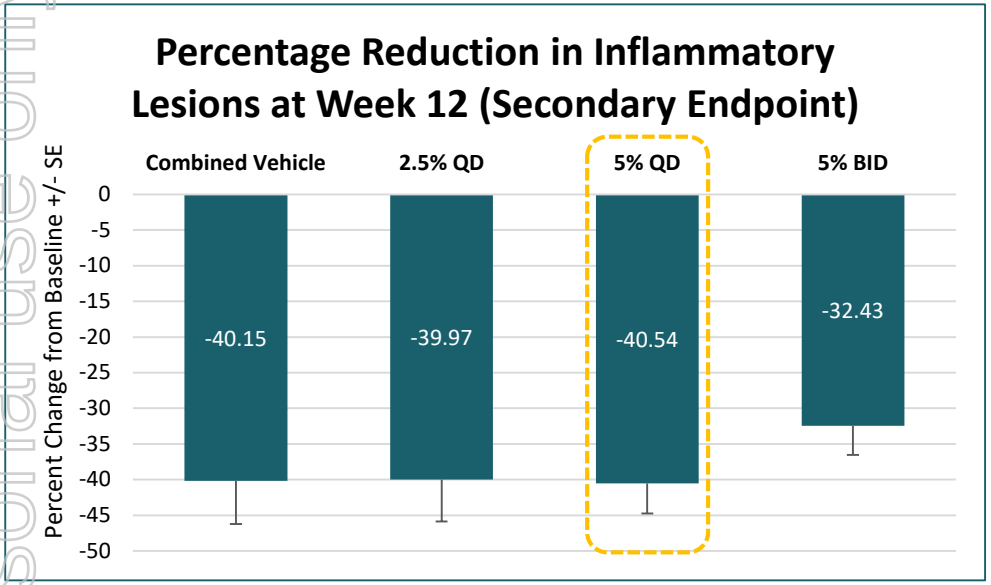
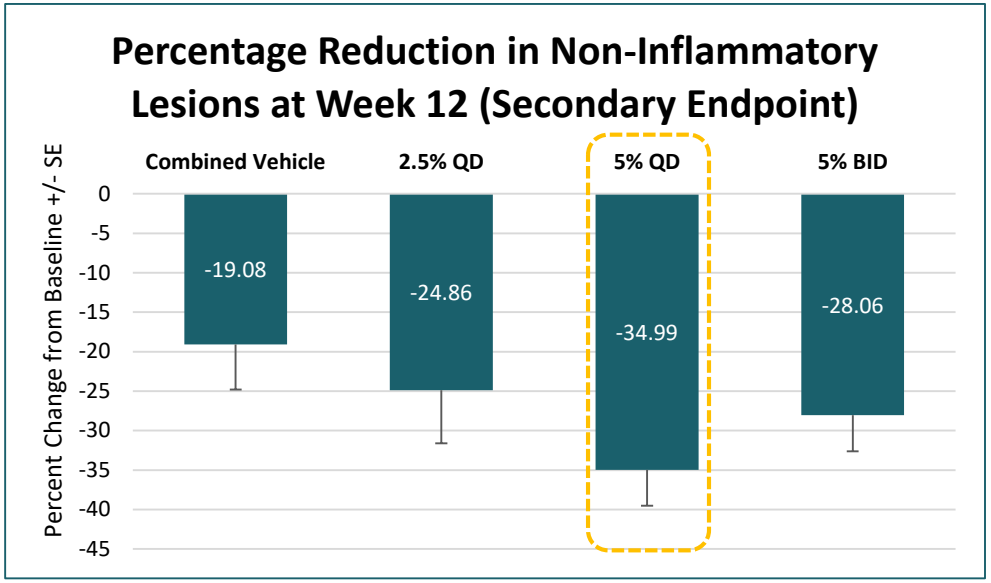
Combined results: Inflammatory and Non-Inflammatory Lesions

BTX 1503 5% once-a-day (QD) was the best performing active dose, but statistical significance was not reached for this primary endpoint, due to the very high vehicle response from the USA sites





- BTX 1503 5% QD effect on inflammatory lesions was in line with target product profile at 12 weeks
- Vehicle response from USA sites was significantly greater than seen in Australia (see next slide for geographic break out)
- Efficacy in line with leading topical acne prescription products

Source: BTX 1503 Phase 2 Study Results released 22 October 2019 – Botanix data on file

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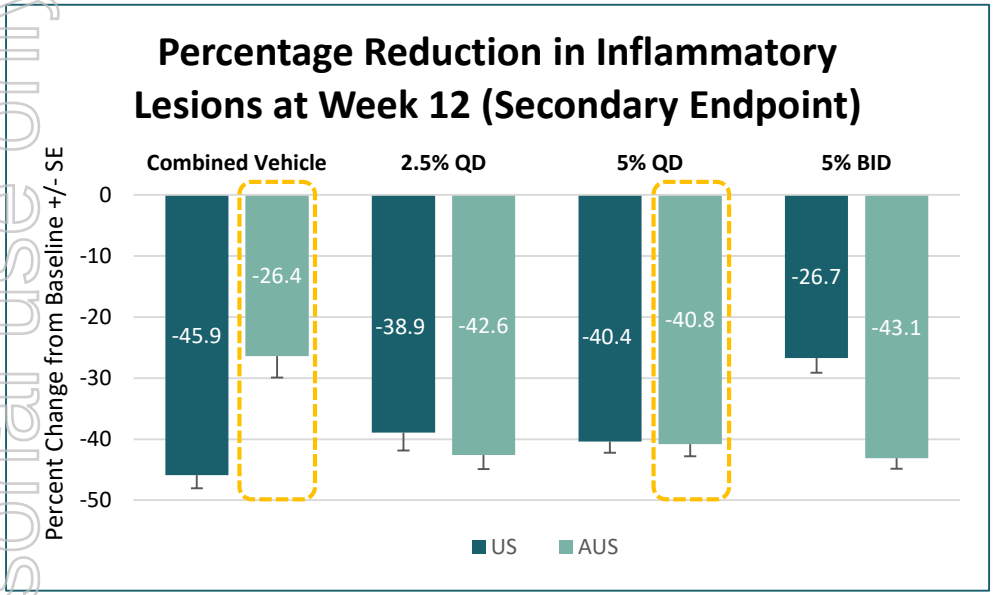
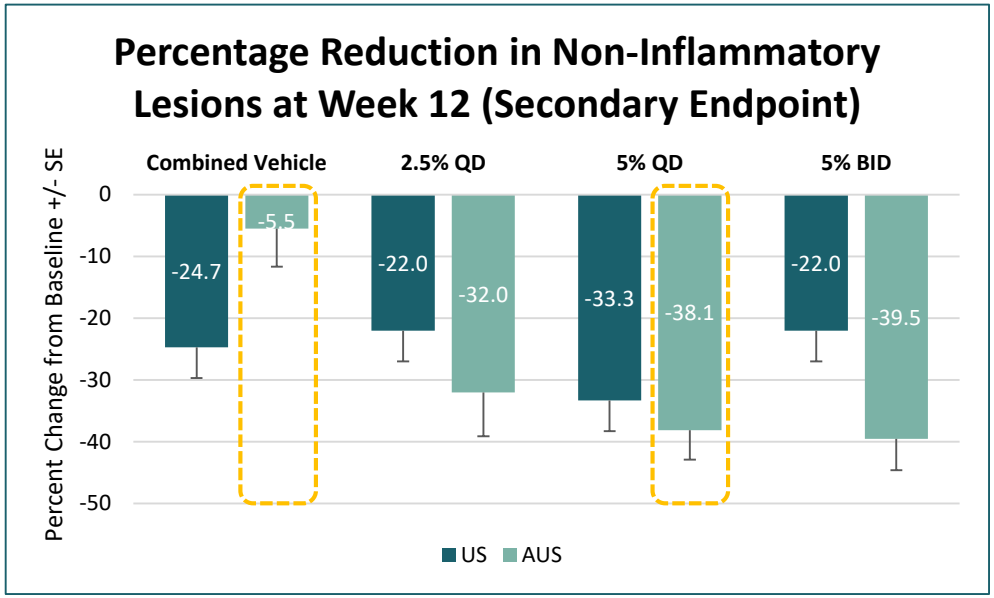
Australia & USA results: Inflammatory and Non-Inflammatory Lesions

Australian data highlights the efficacy and separation expected from vehicle





- Australian clinical sites showed statistically significant improvements in reduction in inflammatory lesions with BTX 1503 BID - 43.1% reduction ($p<0.05$) with BTX 1503 QD showing a 40.8% reduction
- Non-inflammatory lesions were reduced in Australia and the USA following treatment with BTX 1503 – with the Australian BTX 1503 5% QD group showing a 38.1% reduction vs a 5.5% reduction for Vehicle ($p<0.002$)
- Vehicle group response in USA was almost <u>two</u> to <u>four</u> times the response seen in Australia

Source: BTX 1503 Phase 2 Study Results released 22 October 2019 – Botanix data on file

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Next steps

Overall efficacy and safety combined with statistical significance of Australian data provide confidence to proceed with end of Phase 2 FDA meeting and preparation for Phase 3 clinical studies

Outcomes support and expand on Phase 1b results

- Overall safety and efficacy is positive and Australian data shows strong separation from vehicle and excellent safety profile
- Non-inflammatory lesion reduction performance exceeds expectations across geographies

Phase 2 patient population reflects Phase 3 study design requirements

- Approximately half of patients included in the Phase 2 study were under 18 years old which have traditionally been the lowest responders in acne studies
- Endpoints mirror those required in Phase 3 studies for approval

Safety and efficacy data with once a day dose reflects optimal patient compliance and commercial target product profile

- Exceptionally clean safety profile positions BTX 1503 on top of comparative products
- Efficacy in inflammatory and non-inflammatory lesion reduction in line with target profile

End of Phase 2 meeting with FDA to be scheduled alongside preparation for Phase 3 clinical studies

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Source: BTX 1503 Phase 2 Study Results released 22 October 2019 – Botanix data on file

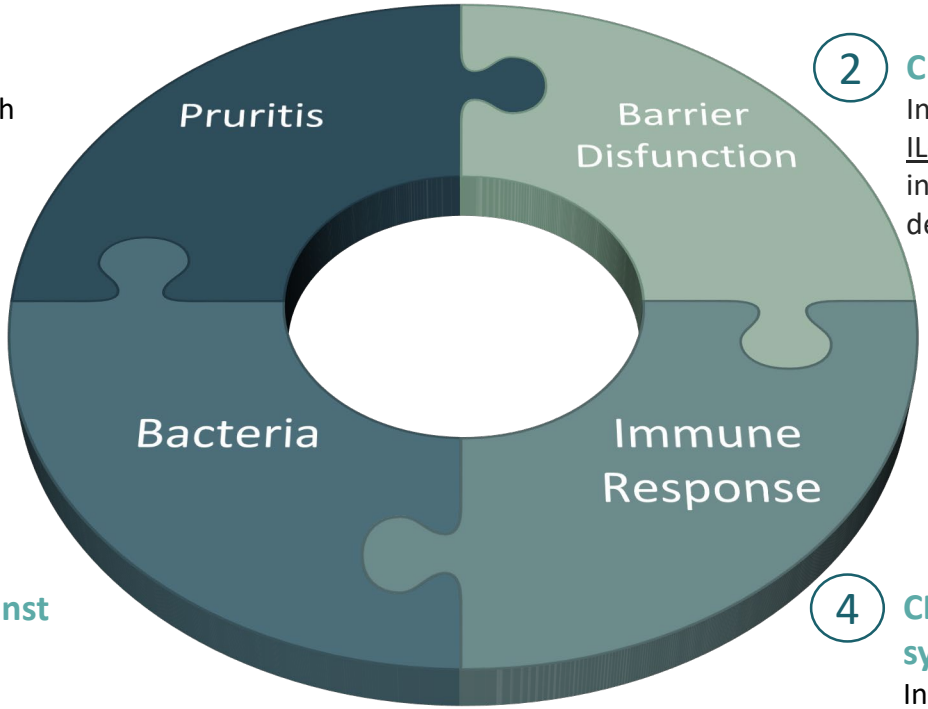
BTX 1204 – atopic dermatitis

BTX 1204: CBD mechanism of action in atopic dermatitis

Ideal therapy that addresses multiple factors of disease pathology

1 CBD inhibits itch

Suppresses itch by interacting with VR / TRPV-1 receptors present on mast cells and keratinocytes[3]



2 CBD repairs barrier dysfunction

Inhibits p38 MAP Kinase activation and IL-6 production in keratinocytes which interrupts the signaling process to dendritic cells and Th2 helper cells[1,2]

3 CBD is potent antibiotic against *S. aureus* bacteria

Reduces *S. aureus* and *MRSA* colonisation responsible for triggering skin inflammation and secondary skin infections[4]

4 CBD modulates the immune system

Inhibits Th17 (IL-17) and Th2 responses (IL-13) responses limiting the release of pro-inflammatory cytokines (TNFα, IL-1, IL-6, IL-8, and IL-12)[1,5]

1. *BTX 1308 Phase 1b clinical study – BOT data on file*
2. *Tan et al. Mol Med Rep 2017:16((6) 8883-8867*
3. *Eagelston et al. Dermatol Onlin J. 2018 Jun 15;24 (6)*
4. *Based on University of Queensland testing – BOT data on file*
5. *Petrosino et al. J Pharmacol Exp Ther. 2018 Jun;365(3):652-663*

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Atopic dermatitis market projected to be ~US$25B in 2027

BTX 1204 is being developed to address the need for a safe, non-steroid option for chronic use with multiple mechanisms of action including anti-inflammatory, anti-microbial and immune modulation

One of the most common skin diseases[1]

- Characterised by flare-ups of itch, red / inflamed rash and excessive dryness or scaling
- Affects 20-25m Americans[2,3] of which 90% are mild to moderate[4,5]
- ~85% of cases present by the age of 5 years[6]

Large unmet need across the atopic dermatitis population[7]

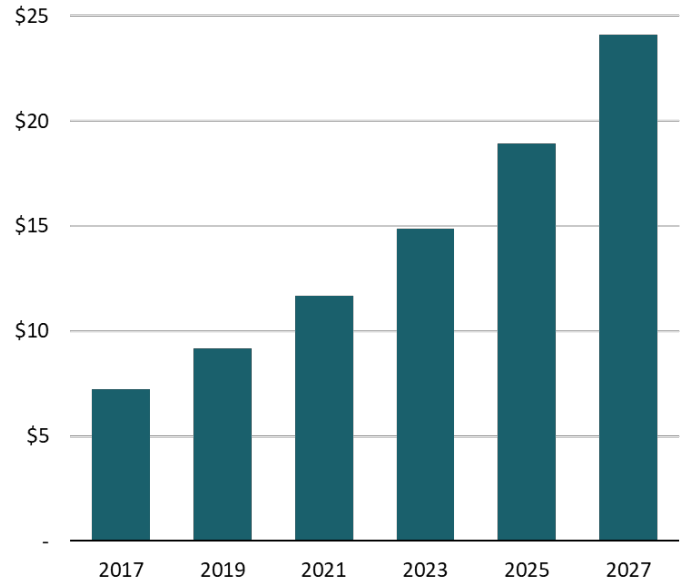
- Limited options for safe and effective treatment of chronic disease
- Biologics are reserved for the severe population (~10% patients)

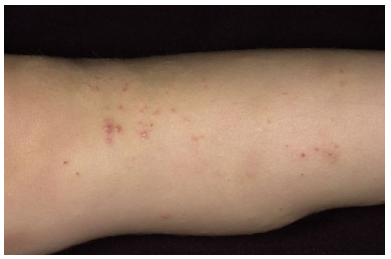
Pediatric population particularly needs a steroid free alternative[1]

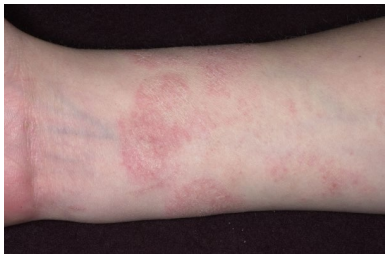
- Safety concerns with chronic use of high potency steroids
- Topical Calcineurin Inhibitors (Protopic / Elidel) have a boxed warning
- Current non-steroidal options have been reported to have tolerability concerns

Projected atopic dermatitis market by revenue (US$B)[8]

(includes 44m topical corticosteroids prescriptions)





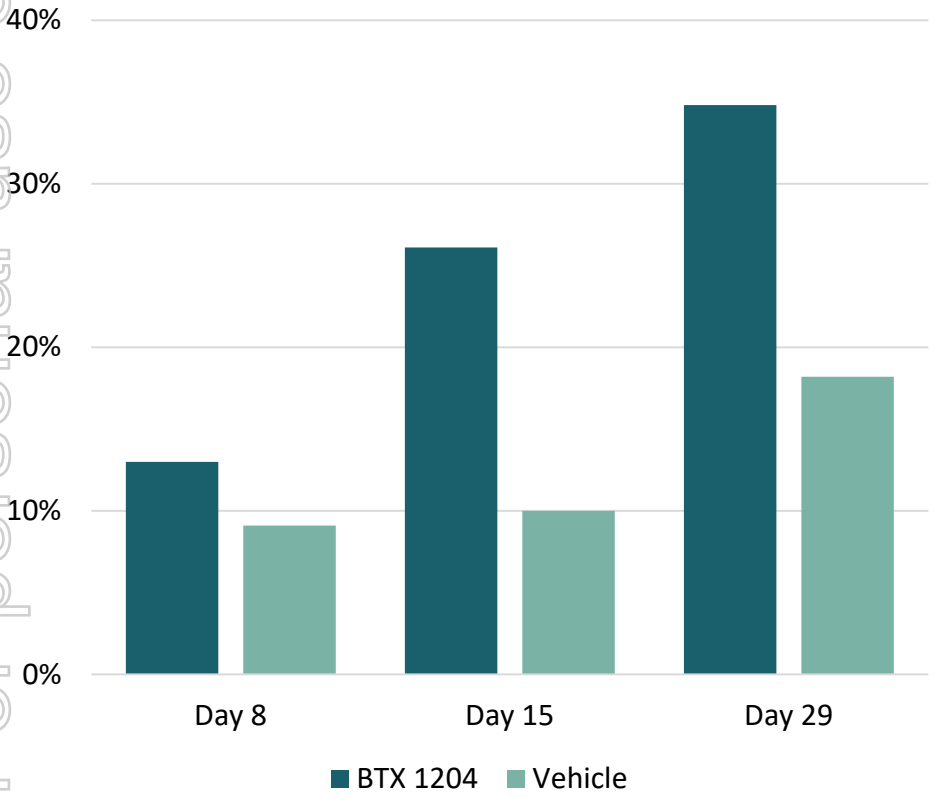


1. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al Guidelines of care for the management of atopic dermatitis, Section 1 diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol 2014 Feb: 70(2):338-51.
2. Hanfin, J.M. et al. Dermatitis, 2007, 82(2): 82-91
3. Silverberg, J.I. & Hanifin, J.M. J Allergy Clin Immunol, 2013, 132(5): 1132-1138
4. Silverberg, J.I. & Simpson, E.L. Dermatitis, 2014, 25(3): 107-114
5. Barbarot et al. Allergy, 2018, 73:1284-1293
6. https://www.aad.org/media/stats-numbers
7. Global Data. Pharmapoint Atopic Dermatitis Nov 2015
8. Symphony Health Services (PHAST) 2017/IQUVIA

BTX 1204 Phase 1b study results support efficacy and safety potential

BTX 1204 was twice as effective as vehicle (with efficacy still increasing at study completion) and displayed a substantial improvement in the study endpoints (key signs of atopic dermatitis)[1]

Treatment success (%)[2]



Efficacy still increasing at 4 week timepoint (n=36)

- 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

- Safe and well tolerated with no SAE's
- 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. Signs of AD score and Investigators Static Global Assessment (ISGA) score on target lesion. Treatment success based on greater than, or equal to, a 4 point improvement

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BTX 1204: atopic dermatitis – Phase 2 fully recruited

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

Study 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

On track to report top line data in 1Q CY2020

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Additional Pipeline programs

1. BTX 1702: rosacea
2. BTX 1801: bacterial infections

BTX 1702: impact of papulopustular rosacea

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

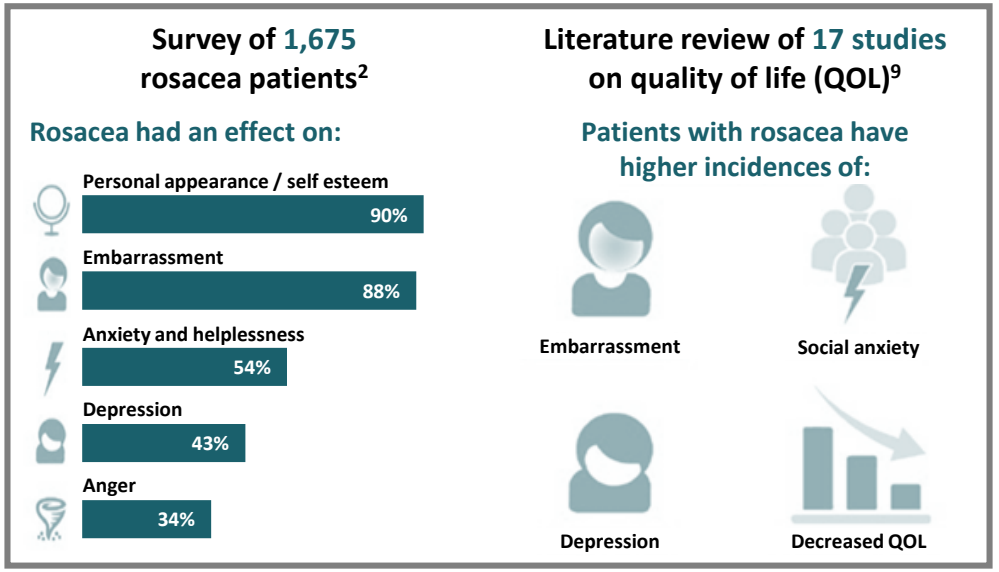
~16M Americans affected by rosacea[2]

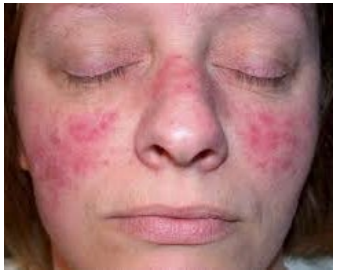
- Affects 5.5% of the world-wide population[3]
- 85% of patients are over 30 years old[4]
- Most common in middle aged women with light skin[5]
- Side effects associated current options affect treatment preferences, satisfaction, and QOL[6]

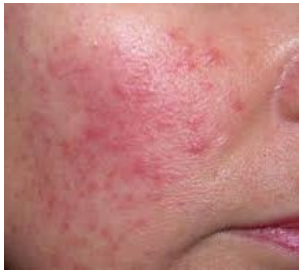
Clearly identified unmet medical need[2]

- Market is projected to grow to $2.6B by 2025[7]
- 5M prescriptions in the US alone[8]

Very high emotional and psychological impact[2]







1. Blount BW, Pelletier AL. Am Fam Physician. 2002;66:435-440.
2. National Rosacea Society. www.rosacea.org
3. Gether L, et al. Br JDermatol. 2018;179:282-289
4. Aimee Two, et al, JAAD, Volume 72, Issue 5, May 2015
5. Mayo Clinic. www.mayoclinic.org
6. Todd Williamson, et al. Am Drug Benefits, 2018 Apr; 11(2): 97–106
7. Grandview Research. www.grandview research.com
8. Symphony Health Solutions, PHAST
9. Moustafa F. J Am Acad Dermatol. 2014;71:973-980.

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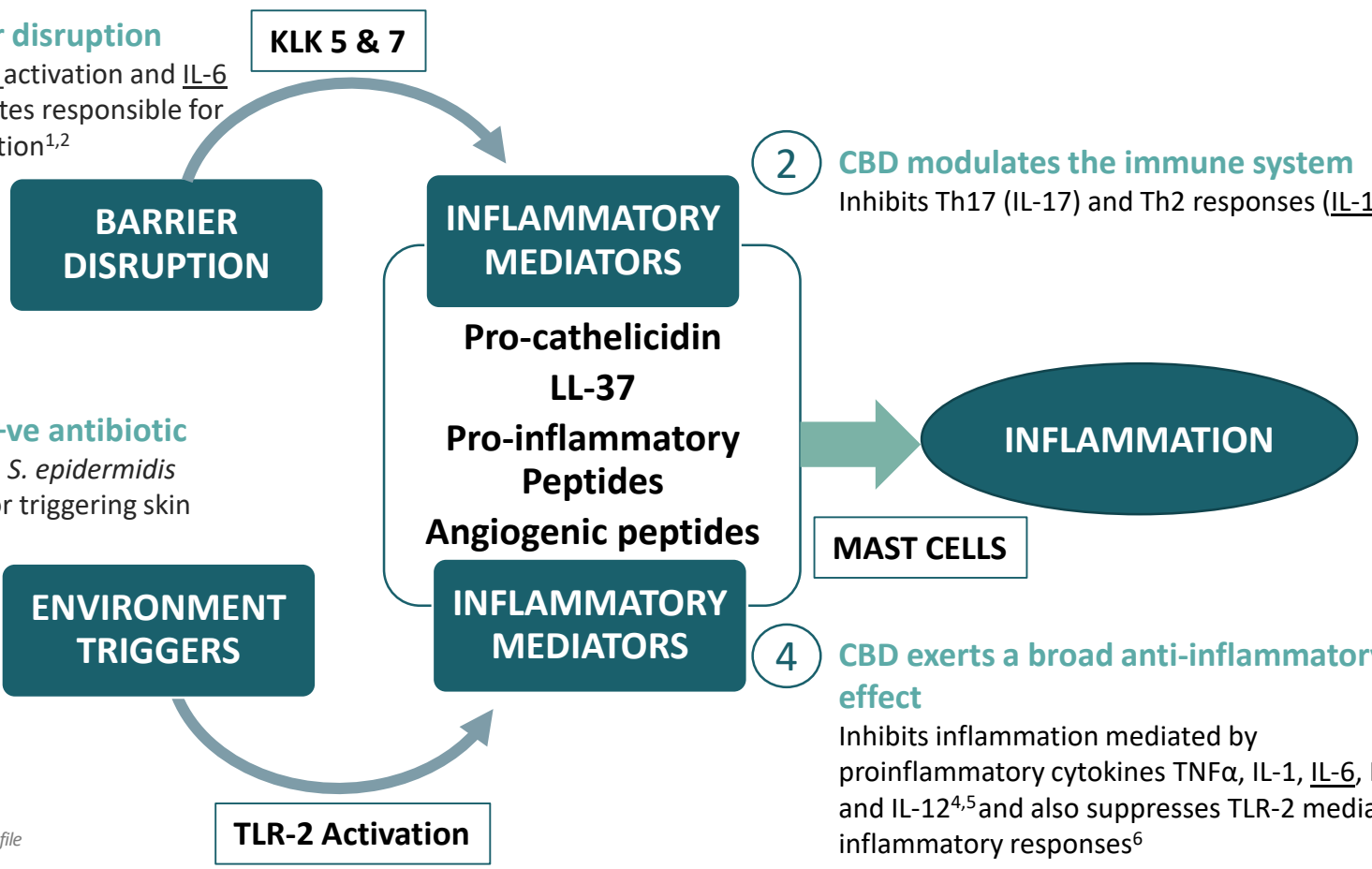
BTX 1702: CBD mechanism of action in rosacea

CBD has the potential to target multiple points in the rosacea inflammatory cascade and other mediators[3]

1 CBD prevents barrier disruption

Inhibits p38 MAP Kinase activation and IL-6 production in keratinocytes responsible for triggering skin inflammation[1,2]



2 CBD modulates the immune system

Inhibits Th17 (IL-17) and Th2 responses (IL-13)[1,5]

3 CBD is potent Gram +ve antibiotic

Reduces *B. oleronius* and *S. epidermidis* bioburden responsible for triggering skin inflammation[4]

4 CBD exerts a broad anti-inflammatory effect

Inhibits inflammation mediated by proinflammatory cytokines TNFα, IL-1, IL-6, IL-8, and IL-12[4,5] and also suppresses TLR-2 mediated inflammatory responses[6]

1. *BTX 1308 Phase 1b clinical study – BOT data on file*
2. *Tan et al. Mol Med Rep 2017:16((6) 8883-8867*
3. *Eagelston et al. Dermatol Onlin J. 2018 Jun 15;24 (6)*
4. *Based on University of Queensland testing – BOT data on file*
5. *Petrosino et al. J Pharmacol Exp Ther. 2018 Jun;365(3):652-663*
6. *McCoy Mediators Inflamm. 2016;2016:5831315*

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New BTX 1702 Phase 1b study design

6 week randomised, double-blind, vehicle-controlled study to evaluate the safety and tolerability of BTX 1702 in patients with papulopustular rosacea

Study Design

- 4 dose groups: ~120 patients
  - BTX 1702 Formulation A - twice daily: 30 patients
  - BTX 1702 Formulation B - twice daily: 30 patients
  - Vehicle A - twice daily: 30 patients
  - Vehicle B - twice daily: 30 patients
- Approx 6 Australian dermatology sites
- Adults: 18 years and older
- Moderate to severe papulopustular rosacea
- Treatment period of 6 weeks
- Facial photos with Canfield imaging

Endpoints

- **Primary endpoint**
  - Safety and local tolerability assessment
- **Exploratory endpoints**
  - Absolute change and percentage change in Inflammatory lesion counts (papules and pustules)
  - Proportion of subjects with a clear (0) or almost clear (1) IGA
  - Reduction of erythema severity assessments by patients and by the Investigator

Ethics approval received 4Q CY2019

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BTX 1801: prevention of post-surgical bacterial infections

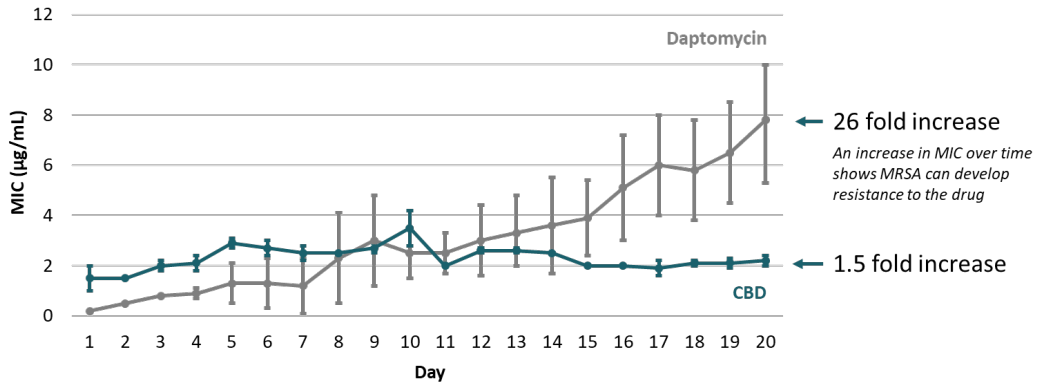
Cannabidiol is a powerful new antibiotic that is effective in tests against *Staphylococcus aureus* ("staph'") and *methicillin resistant Staphylococcus aureus* ("MRSA or golden staph")[1]

Antibiotic	*S. aureus* all isolates (μg/mL)			MRSA[1] (μg/mL)		MSSA[2] (μg/mL)	
	MIC_{50}	MIC_{90}	Range	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}
Cannabidiol	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 concentration to inhibit growth of 50% of isolates
MIC_{90} = min concentration to inhibit growth of 90% of isolates
MRSA = methicillin resistant *S. aureus*
MSSA = methicillin susceptible *S. aureus*

Repeat challenge experiments demonstrate that MRSA bacteria form resistance to commonly used antibiotics such as daptomycin, but cannot form resistance to synthetic cannabidiol

Antibiotic Minimum Inhibitory Concentration (MIC) daily variability[2]



1. *Based on University of Queensland testing – BOT data on file*
2. *Based on average of 8 replicates (University of Queensland – BOT data on file)*

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Near term milestones

Key near term milestones combine clinical and other meaningful study endpoints providing solid news flow through CY2020

Event	Timing
BTX 1702 rosacea study ethics approval	4Q CY2019
BTX 1801 antimicrobial study kickoff	4Q CY2019
BTX 1204 atopic dermatitis study data	1Q CY2020
Dermatology Summit and JP Morgan Conferences	1Q CY2020

Cash Position	
End Sep 2019 - excludes potential R&D tax concession receipt of ~$6m	A$37.3m

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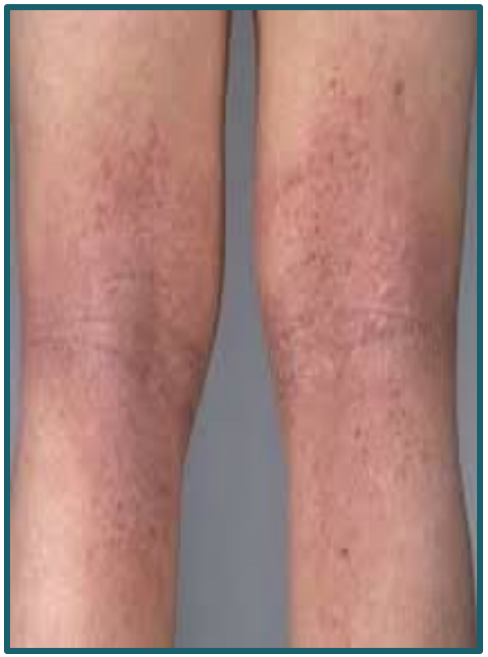
Inflammation + bacterial infection are important to most skin diseases[1]

Newly announced data provide scientific support for synthetic CBD's mechanism of action (MOA), which is highly relevant to all Botanix pipeline products

Acne

Relevance	CBD mechanism of action	Relevance
✓	Kills relevant bacteria (*P. Acnes* and *Staph/MRSA*)[2]	✓
✓	Anti-inflammatory effect[3]	✓
	Immune modulating[3]	✓
✓	Skin barrier protectant[3]	✓
✓	Safe and non-irritating[4]	✓

Atopic dermatitis



Recent Phase 2 acne data supports synthetic cannabidiol MOA

1. Dainichi et al 2014 JDS Vol 76 Iss 2 81-86
2. Based on BTX1801 data (University of Queensland and Charles River testing) – BOT data on file
3. Based on BTX 1308 Phase 1b biopsy data – BOT data on file
4. Based on 3 Phase 1b studies for BTX1503, 1204 and 1308 respectively – BOT data on file

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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 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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