ASX/Media Release

28 October 2019

Botanix Pharmaceuticals 2019 Annual General Meeting Presentation

Philadelphia PA and Sydney Australia, 28 October 2019: Clinical stage cannabinoid company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company") is pleased to release the presentation to be made at the Annual General Meeting to be held at 9.30am today (AWST).

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a clinical stage synthetic cannabinoid company based in Perth (Australia) and Philadelphia (US) 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 clinical study and is moving forward with its clinical program with a Phase 2 FDA meeting. A Phase 2 patient study in atopic dermatitis is on target to complete enrolment in 4Q CY2019 with data in 1Q 2020. The Company has 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 2H CY2019.

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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Botanix Pharmaceuticals

AGM October 2019

Botanix overview

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

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 antimicrobial 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 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					Study start 4Q CY2019
BTX 1801 Gel	Antimicrobial					Successful MOA[1] study
BTX 1308 Ointment	Psoriasis					Successful MOA[1] study

1. MOA: Mechanism of Action

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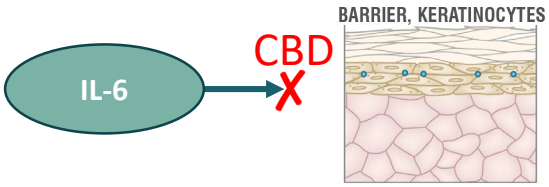
Topical CBD is a well suited to treat skin disease

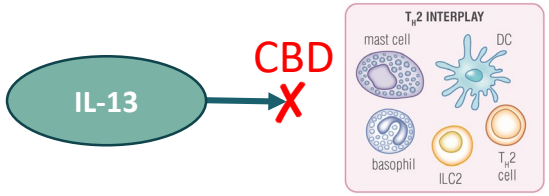
Botanix has generated strong scientific support for synthetic CBD's anti-inflammatory and immune modulation mechanisms of actions, combined with newly identified antimicrobial effects

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



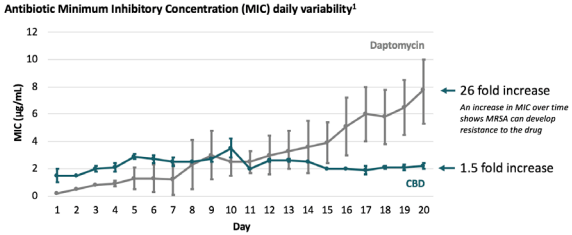
CBD inhibits a pathway which disrupts the signaling driving the body's immune response

CBD antimicrobial effects

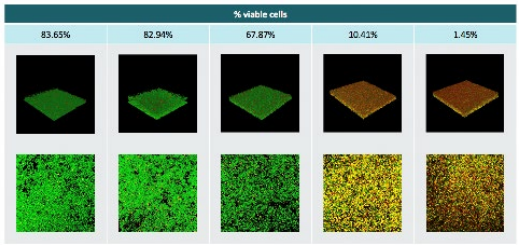
CBD is active against all tested gram +ve bacteria

Antibiotic	*S. aureus* all isolates (µg/mL)			MRSA[1] (µg/mL)		MSSA[2] (µg/mL)	
	MIC_{50}	MIC_{50}	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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BTX 1503 - acne

BTX 1503: Phase 2 top line data

Solid efficacy and safety results show BTX 1503 5% once-a-day 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% 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 compliance and commercial perspective, is the ideal dosing regime

Clinical response

A strong and consistent impact on inflammatory lesions was seen across the entire study with even greater non-inflammatory lesion reductions

Overall trend is clean and Australian data is statistically significant

Overall efficacy trend is positive and Australian sites showed clear separation of BTX 1503 5% once a day vs vehicle - 40.8% vs 26.4% for inflammatory and 38.1% vs 5.1% for non-inflammatory lesions

USA only vehicle response

Patients in the USA that received vehicle had an unusually high vehicle response which skewed the overall primary endpoint

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

BTX 1503: CBD mechanism of action – supported by data

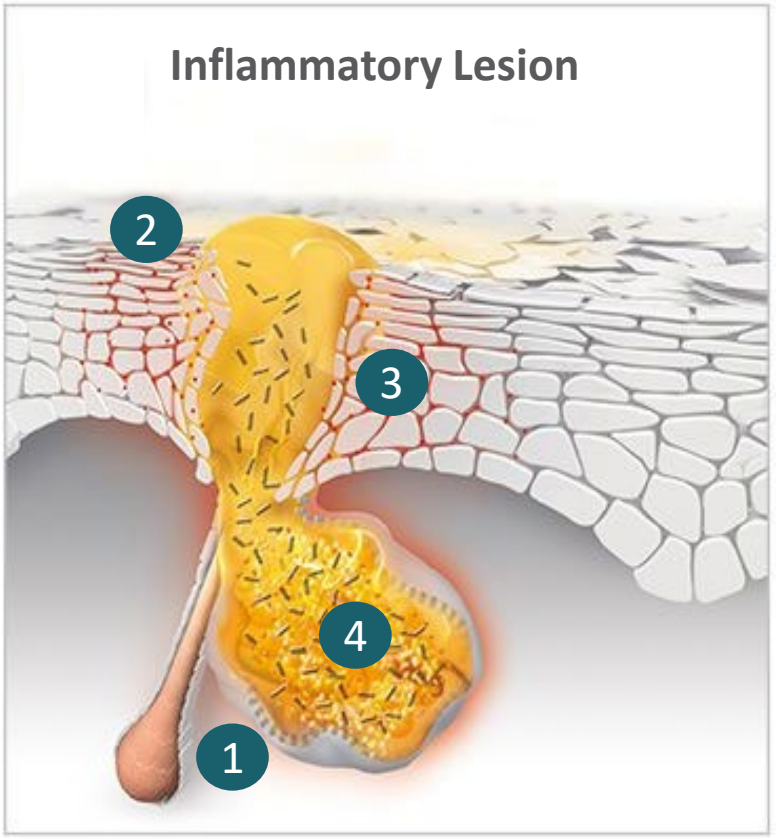
BTX 1503 is a safe and well tolerated topical acne treatment that potentially addresses all the key causes of acne

1 CBD normalises sebum production

- Inhibits lipogenesis and sebocyte proliferation in response to "pro-acne" agents (androgens)[1]

2 CBD inhibits keratinocyte hyperproliferation

- Antiproliferative effects mediate through PPAR agonism[2]



3 CBD exerts a broad anti-inflammatory effect

- Inhibits *P. acnes*[3] induced p38 MAP Kinase-dependent inflammatory responses in keratinocytes[4,5]
- Inhibits *P. acnes* induced inflammation mediated by proinflammatory cytokines TNFα, IL-1, IL-6, IL-8, and IL-12[4,6]

4 CBD is a potent Gram-positive antibiotic

- Potent bactericidal activity against clinical isolates and antibiotic resistant strains of *P. acnes*[7]

1. *Olah et al. J Clin Invest. 2014:124(9):3713-3724*
2. *Wilkinson & Williamson. J Derm Sci. 2007;45:87-92*
3. *Recently renamed Cutibacterium acnes*
4. *Based on BTX 1308 Phase 1b study and BTX 1503 Phase 1b study – BOT data on file*
5. *Li, Wen-Hwa et al. Dermatology and therapy vol. 5,1 2015: 53-66*
6. *Petrosino et al. J Pharmacol Exp Ther. 2018 Jun;365(3):652-663*
7. *Based on University of Queensland testing – BOT data on file*

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Key takeaways and next steps

Overall efficacy and safety and 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 reflects Phase 3 study design

- Study included Phase 3-like population with approximately half of patients under 18 years old
- Endpoints mirror those required in Phase 3 studies for approval

Safety and efficacy data with once a day dose reflects 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 study with FDA to be scheduled alongside preparation for Phase 3 clinical studies

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

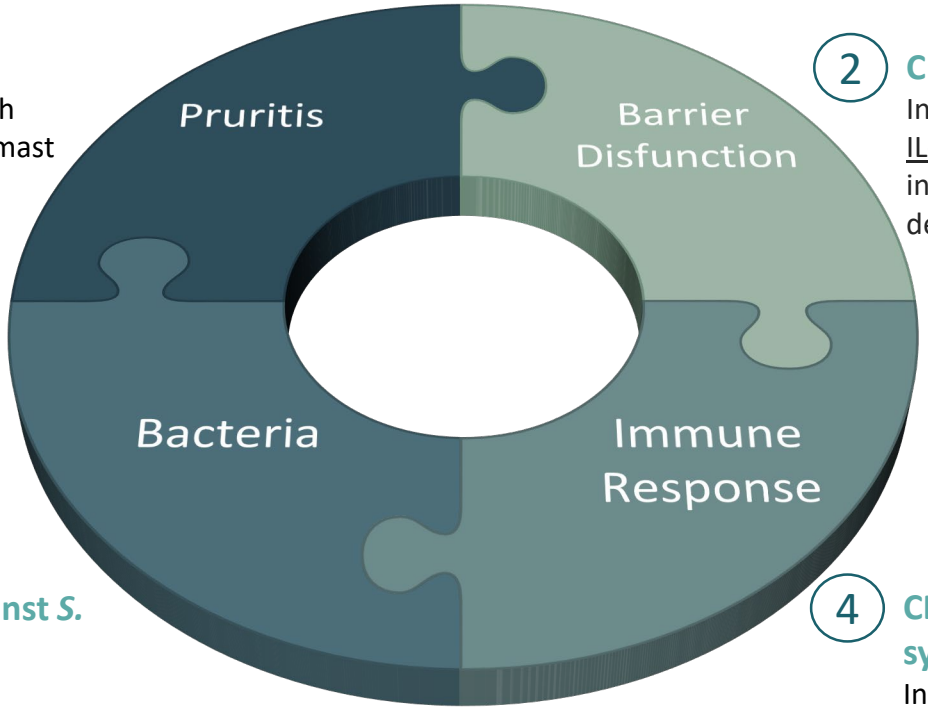
BTX 1204 – atopic dermatitis

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*

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 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
- 90% of patients are mild to moderate[3]

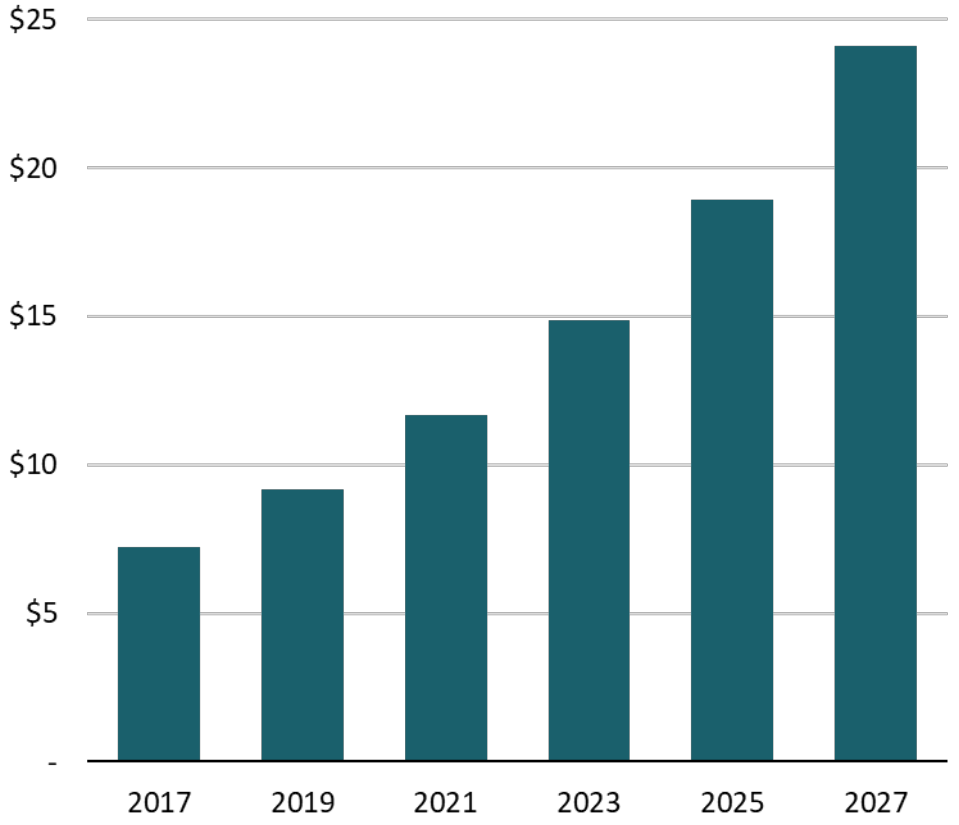
Large unmet needs across the atopic dermatitis population[2]

- No safe and effective non-steroidal option for chronic use
- Biologics are reserved for the severe population

Pediatric population particularly has a need for a steroid free alternative[1]

- 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$b)[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*

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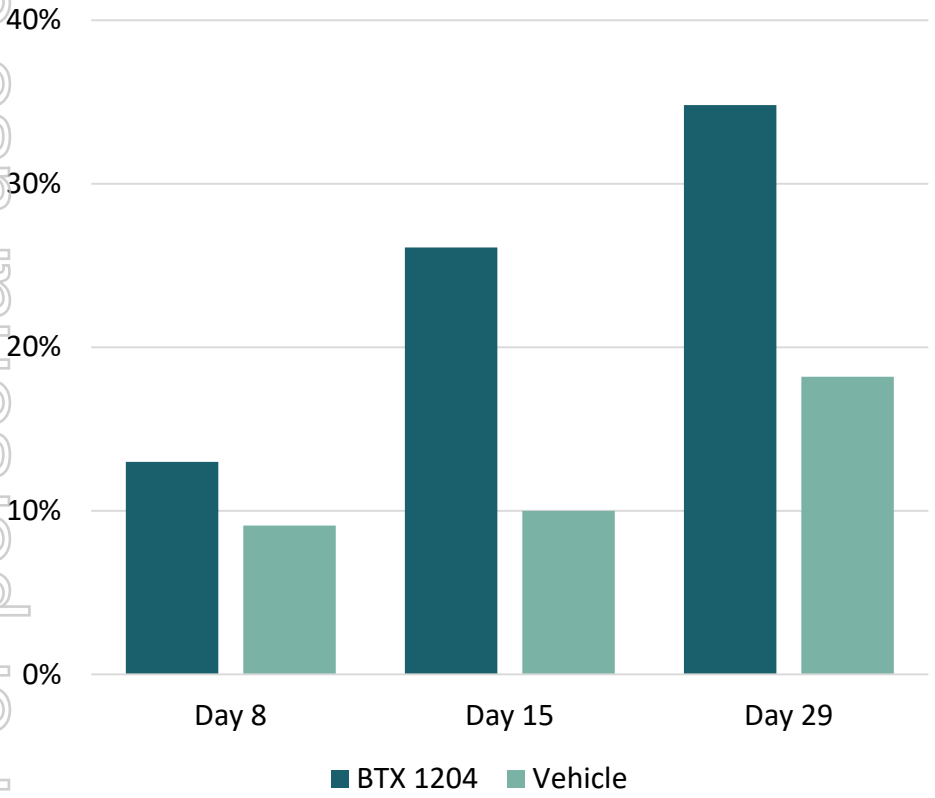
BTX 1204 Phase 1b study results support efficacy and safety potential

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

Treatment success (%)[2]



Efficacy still increasing at 4 week timepoint 9 (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 recruiting

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

Data in 1Q CY2020

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Additional Pipeline programs

1. BTX 1702: rosacea
2. BTX 1801: antimicrobial

BTX 1702: impact of papulopustular rosacea

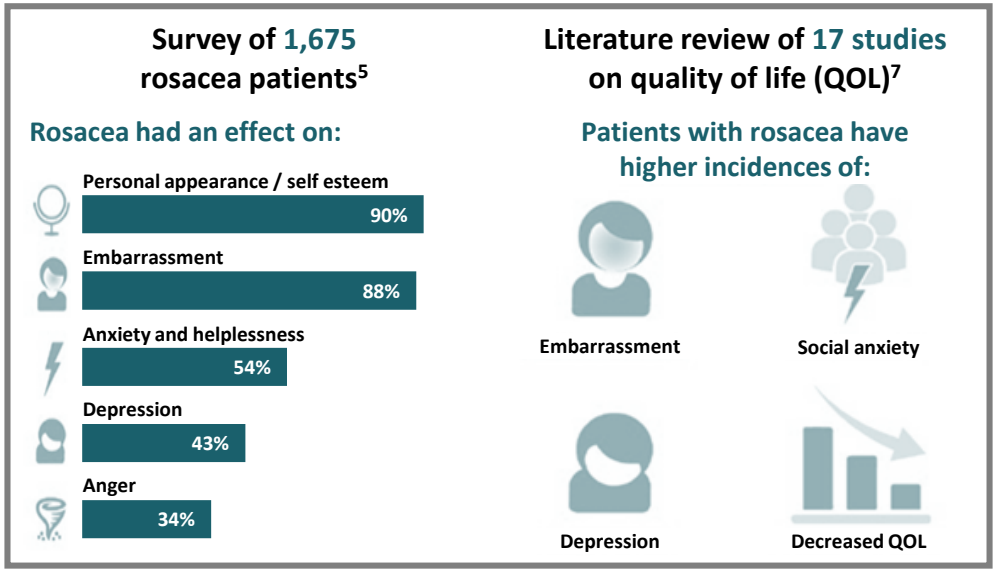
Papulopustular rosacea is a chronic skin disease characterised by redness (inflammation) and acne-like break-outs[1]

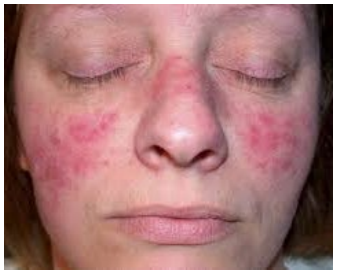
Affects ~16m Americans[3]

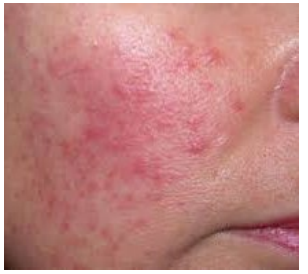
- ~5.5% of the adult population is affected by rosacea[4]
- only 10% seek treatment[2]
- misdiagnosis is common[2,5]
- 85% of patients are over 30 years old and have multiple co-morbidities and sensitivities to treatments[6]

Clearly identified unmet medical need[2]

Very high emotional and psychological impact[7]







1. Blount BW, Pelletier AL. Am Fam Physician. 2002;66:435-440.
2. Prevalence of rosacea. http://www.rosacea.org/rr/index.php.
3. National Rosacea Society. www.rosacea.org.
4. Gether L, et al. Br JDermatol. 2018;179:282-289
5. National Rosacea Society. http://www.rosacea.org/rr/2010/winter/article_1.php.
6. Syneos Health, Treatment Answers Prescriber Audit Data, MAT OCT18
7. Moustafa F. J Am Acad Dermatol. 2014;71:973-980.

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BTX 1702 study

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

Study Design

- 2 dose groups: ~36 patients
  - BTX 1702 twice daily: 24 patients
  - Vehicle twice daily: 12 patients
- 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 & pustules)
  - Proportion of subjects with a clear (0) or almost clear (1) IGA
  - Reduction of erythema severity assessments by patients and by the Investigator

Study start 4Q CY2019

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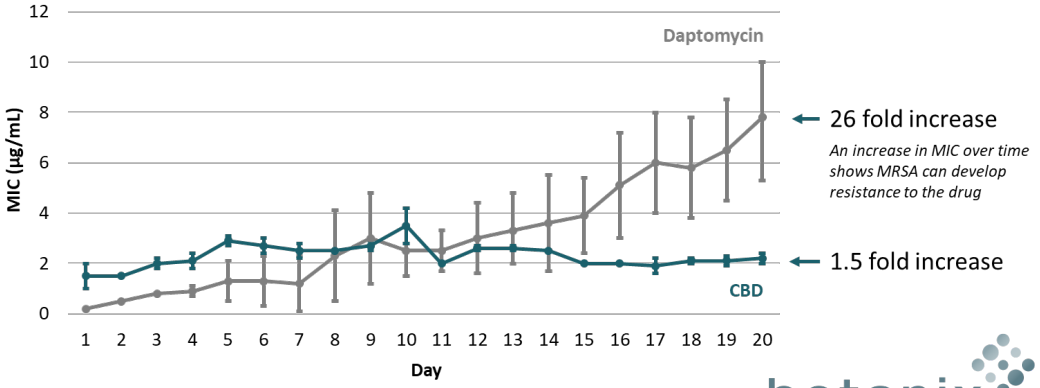
BTX 1801 - antimicrobial

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

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)*

Near term milestones

Key near term milestones combine clinical and other endpoints and provide solid news flow through 2Q CY 2020

Event	Timing
BTX 1702 rosacea study kickoff	4Q CY2019
BTX 1801 antimicrobial study kickoff	4Q CY2019
BTX 1204 atopic dermatitis study data	1Q CY2020

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Operations: 3602 Horizon Drive, Suite 160 King of Prussia PA 19041

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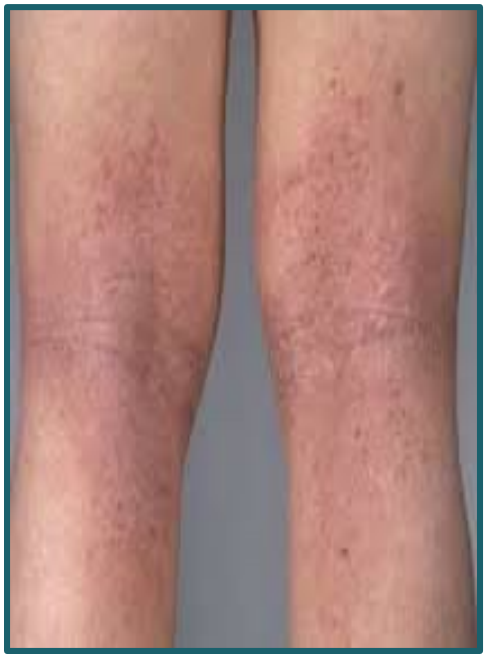
Inflammation + bacterial infection are important to most skin diseases[1]

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

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