ASX/Media Release

13 September 2019

Botanix presents at International Cannabinoid Summit

Key highlights

- Botanix presented at the International Cannabinoid Derived Pharmaceuticals Summit, Boston
- Botanix's presentation is titled *Cannabinoids in dermatology – sorting fact from fiction*
- Shared podium with speakers from GW Pharmaceuticals, Corbus Pharmaceuticals, InMed and other leading clinical stage cannabinoid companies
- The conference highlighted the growing interest in evidence-based cannabinoid therapeutics as the next wave of investment focus

Philadelphia PA and Sydney Australia, 13 September 2019: Clinical stage synthetic cannabinoid company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to announce it presented at the 2nd Annual International Cannabinoid Derived Pharmaceuticals (iCDP) Summit in Boston MA. The presentation titled *Cannabinoids in dermatology – sorting fact from fiction* is attached to this release.

The iCDP Summit is an emerging industry and academic conference focused on profiling leading companies developing cannabinoid-derived pharmaceuticals, through evidence-based clinical research. The iCDP Summit unites key industry leaders and academic researchers who are at the forefront of cannabinoid drug development.

Botanix shared the podium with GW Pharmaceuticals (which received the first FDA approval for an oral cannabidiol product for a form of epilepsy), Corbus Pharmaceuticals, InMed and other leading cannabinoid companies, researchers and service providers to the emerging industry.

Executive Chairman and President of Botanix, Vince Ippolito, commented: "The iCDP Summit was a great opportunity to highlight the solid clinical and scientific data Botanix has generated, examining the efficacy of synthetic cannabidiol for treating skin diseases. Our recent mechanism of action studies, combined with our completed and ongoing clinical studies, provide us with unique insights into the anti-inflammatory, immune-modulating and antimicrobial properties of synthetic cannabidiol."

"It was apparent that outside GW Pharmaceuticals' FDA approved Epidiolex epilepsy product, Botanix has the most mature development pipeline of any other cannabinoid company featured at the iCDP Summit. Our rapid development approach has distinguished us from our peers, many of whom have been in development for 5 to 15 years and are only now starting human studies for the first time."

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 successfully completed its first acne patient studies and has recently completed enrolment of a Phase 2 clinical study which is on target to be completed in 3Q CY2019 with data shortly thereafter. A Phase 2 patient study in atopic dermatitis is also underway with enrolment expected to complete in 4Q CY2019. The Company has successfully completed a mechanism of action study for synthetic cannabidiol in skin disease, with positive interim 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/

For more information, please contact:

General enquiries	**Investor enquiries**	**Media enquiries**
Corporate Communications	Joel Seah	Haley Chartres
Botanix Pharmaceuticals	Vesparum Capital	Hales[2] Communications
P: +61 8 6555 2945	P: +61 3 8582 4800	P: +61 423 139 163
investors@botanixpharma.com	botanixpharma@vesparum.com	haley@h-squared.com.au

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

iCDP Summit: *Cannabinoids in dermatology – sorting fact from fiction*

September 2019

Botanix overview

Botanix is a clinical stage synthetic cannabinoid company focused on developing topical cannabidiol 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 acne data, Phase 2 atopic dermatitis data and commencement of a Phase 1b rosacea study

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Advanced dermatology pipeline with recent successful data read outs

Combination of clinical, safety and mechanism of action data from recent Botanix studies provide support to near term completion of Phase 2 studies in acne and atopic dermatitis

Synthetic CBD with Permetrex™ topical technology

	Indication	Pre-clin	Ph 1	Ph 1b	Ph 2	Status
Pending clinical data						
BTX 1503 Gel	Moderate to severe acne					Study complete 3Q 2019
BTX 1204 Solution	Moderate atopic dermatitis					Study enrolled 4Q CY2019
Recent data						
BTX 1308 Ointment	Psoriasis					Successful MOA[1] study
BTX 1801 Gel	Antimicrobial					Successful POC[1] data

1. POC: Proof of Concept; MOA: Mechanism of Action

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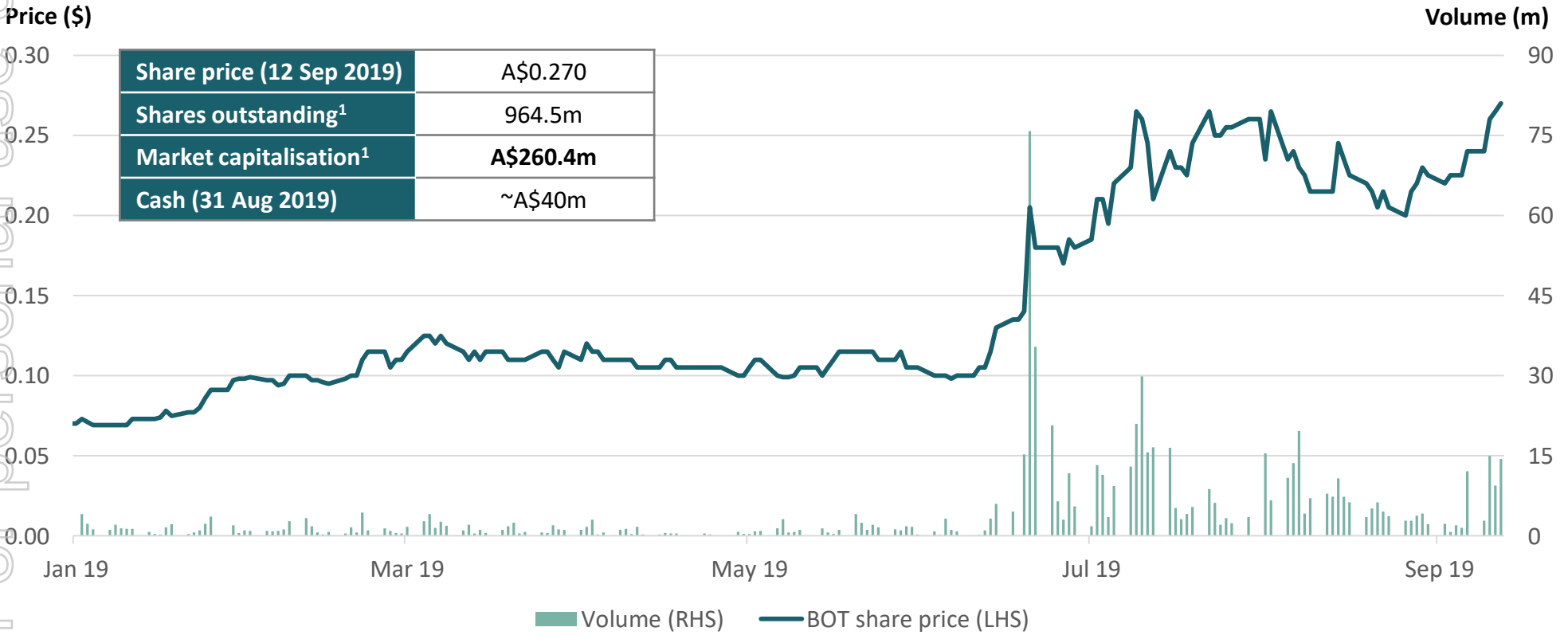
Corporate overview

Botanix share price performance and trading information

Share price (12 Sep 2019)	A$0.270
Shares outstanding[1]	964.5m
Market capitalisation[1]	**A$260.4m**
Cash (31 Aug 2019)	~A$40m



Source: IRESS, company information

1. Excludes 73.0m options

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Fiction

1. Multi-multi drug combo’s are possible today
2. It’s all about CB1/CB2 receptors in the skin
3. OTC products contain [just/much/any] CBD
4. OTC products actually get into the skin

1. Multi-multi drug combo's are developable (or approvable)

✗ The "entourage effect" may well exist – but getting more than three (let alone 100+) actives approved by FDA in a single product is highly challenging (to say the least)

One way of combining different drugs to treat identified diseases

[potentially] =

An alternative way of combining different drugs to treat different diseases

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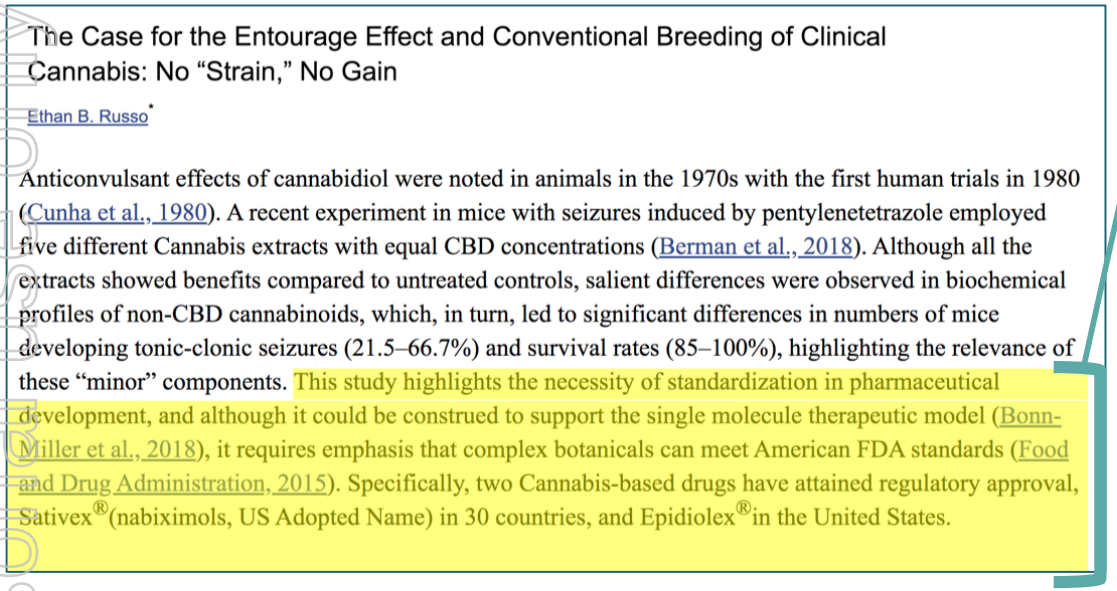
1. Product preferences trump regulatory realities

✗ FDA still wants you to characterise and test each active in the product – the more the not merrier



The Case for the Entourage Effect and Conventional Breeding of Clinical Cannabis: No "Strain," No Gain

Ethan B. Russo*

Anticonvulsant effects of cannabidiol were noted in animals in the 1970s with the first human trials in 1980 (Cunha et al., 1980). A recent experiment in mice with seizures induced by pentylenetetrazole employed five different Cannabis extracts with equal CBD concentrations (Berman et al., 2018). Although all the extracts showed benefits compared to untreated controls, salient differences were observed in biochemical profiles of non-CBD cannabinoids, which, in turn, led to significant differences in numbers of mice developing tonic-clonic seizures (21.5–66.7%) and survival rates (85–100%), highlighting the relevance of these "minor" components. This study highlights the necessity of standardization in pharmaceutical development, and although it could be construed to support the single molecule therapeutic model (Bonn-Miller et al., 2018), it requires emphasis that complex botanicals can meet American FDA standards (Food and Drug Administration, 2015). Specifically, two Cannabis-based drugs have attained regulatory approval, Sativex®(nabiximols, US Adopted Name) in 30 countries, and Epidiolex®in the United States.

However…

- FDA's *Botanical Drug Development Guidance for Industry*:
  - lots of work - GMP for growing and extracting and final product
  - only 2 botanical products ever approved from 600 Pre/IND's [2]
- Epidiolex® was not approved as a "botanical"
- Sativex® is not yet approved by FDA

BEVESPI AEROSPHERE®

budesonide + glycopyrronium + formoterol fumarate versus glycopyrronium + formoterol fumarate versus budesonide + formoterol fumarate

8,500 patients ~$500M cost[1]

Imagine trying to test 5, 10 or more "actives"?

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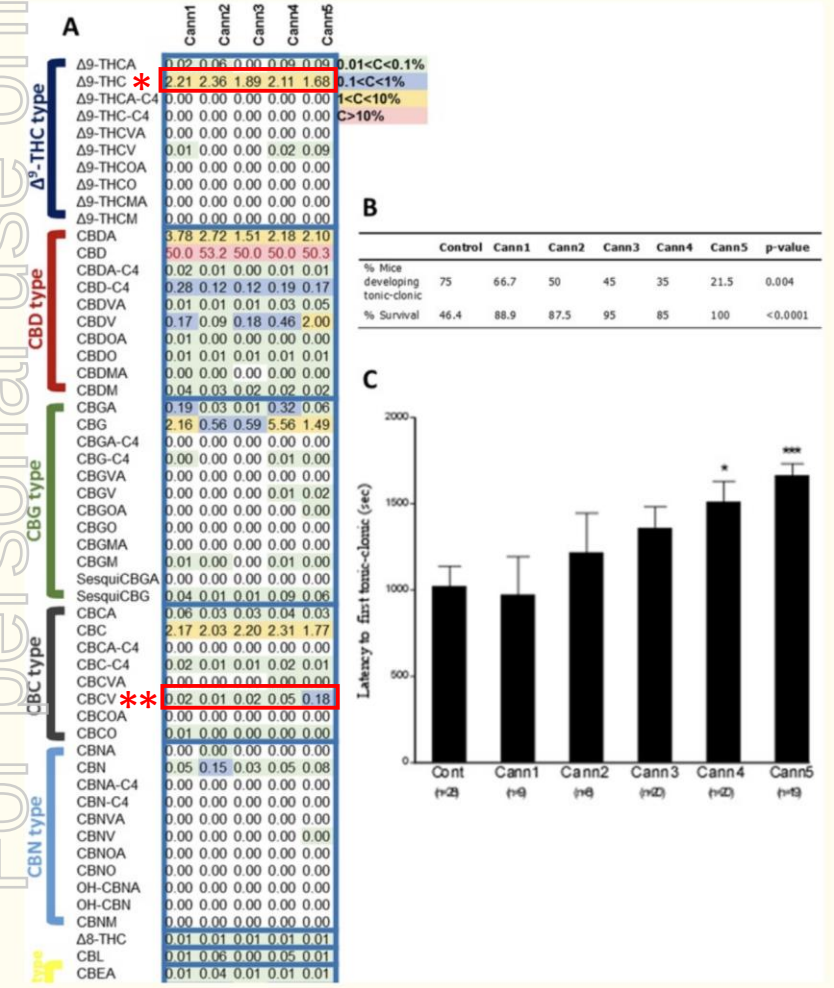
1. https://www.astrazeneca.com/media-centre/press-releases/2019/breztri-aerosphere-phase-iii-ethos-trial-met-its-primary-endpoint-in-chronic-obstructive-pulmonary-disease-28082019.html

1. Case in point - Berman et al 2018[1]

Is it the slightly lower Δ 9-THC* or the slightly higher CBCV ** [or some other miniscule variation in one of the cannabinoids] that creates the significant difference in anticonvulsant properties?



A new ESI-LC/MS approach for comprehensive metabolic profiling of phytocannabinoids in *Cannabis*

Paula Berman,[1] Kate Futoran,[1] Gil M. Lewitus,[1] Dzmitry Mukha,[1] Maya Benami,[1] Tomer Shlomi,[1,2] and David Meiri[1]

These results suggest that not all high-CBD extracts have the same anticonvulsant properties, and that comprehensive phytocannabinoid profiling can enable to evaluate the potential anticonvulsant properties of *Cannabis* extracts

How do you run a clinical study testing variations of each of these permutations [especially if the relative amount of each cannabinoid is also changing each time you make a batch?]

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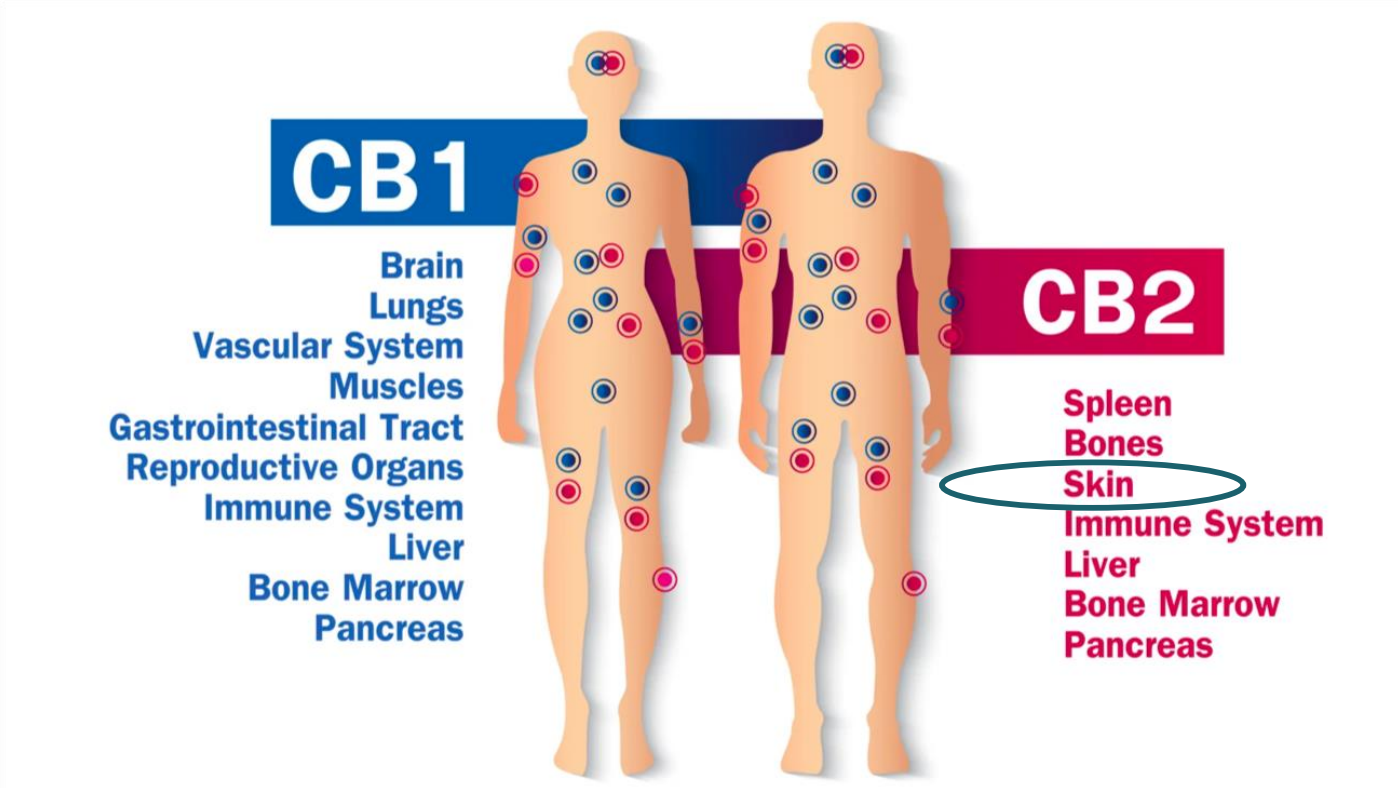
1. Mentioned in the Russo publication on slide 7 (highlighted)– Berman et al 2018 available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6155167/

2. It's all about CB1 and CB2 receptors…

✗ A cannabinoid must act via a cannabinoid receptor huh? Not so fast!



The endocannabinoid system (ECS) of the skin is important, but targeting CB1 and CB2 receptors is probably not the solution[1]

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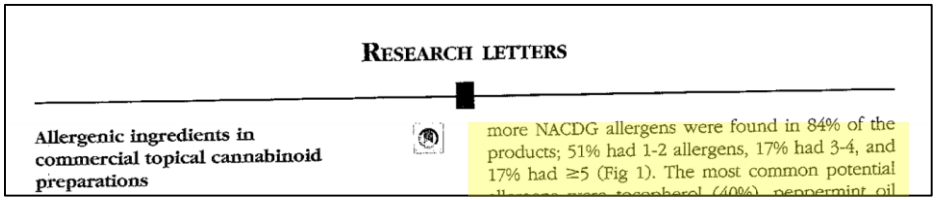
1. See Olah et al. J Clin Invest. 2014:124(9):3713-3724, Wilkinson & Williamson. J Derm Sci. 2007;45:87-92, Botanix synthetic cannabidiol mechanism of action data from BTX 1308 study (data on file)

3. OTC CBD products contain [just/much/any] CBD

✗ Over-the-counter (OTC) or internet purchased CBD products often contain a fraction of labelled CBD content, are not currently regulated and come with other quality and allergenic risks[1]

Product name	Product type	Label claim CBD content (mg/tube)	Tested CBD content
OTC 1	Cream	300	24.5
OTC 2	Cream	150	11.2
OTC 3	Cream	200	24.6
OTC 4	Cream	Undisclosed	8.8
OTC 5	Ointment	Undisclosed	14.9

Dr Amy Abernethey Principal Deputy Commissioner and Acting CIO – FDA[2]



J Am Acad Dermatol Sep 2019 Pp 847-848

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*

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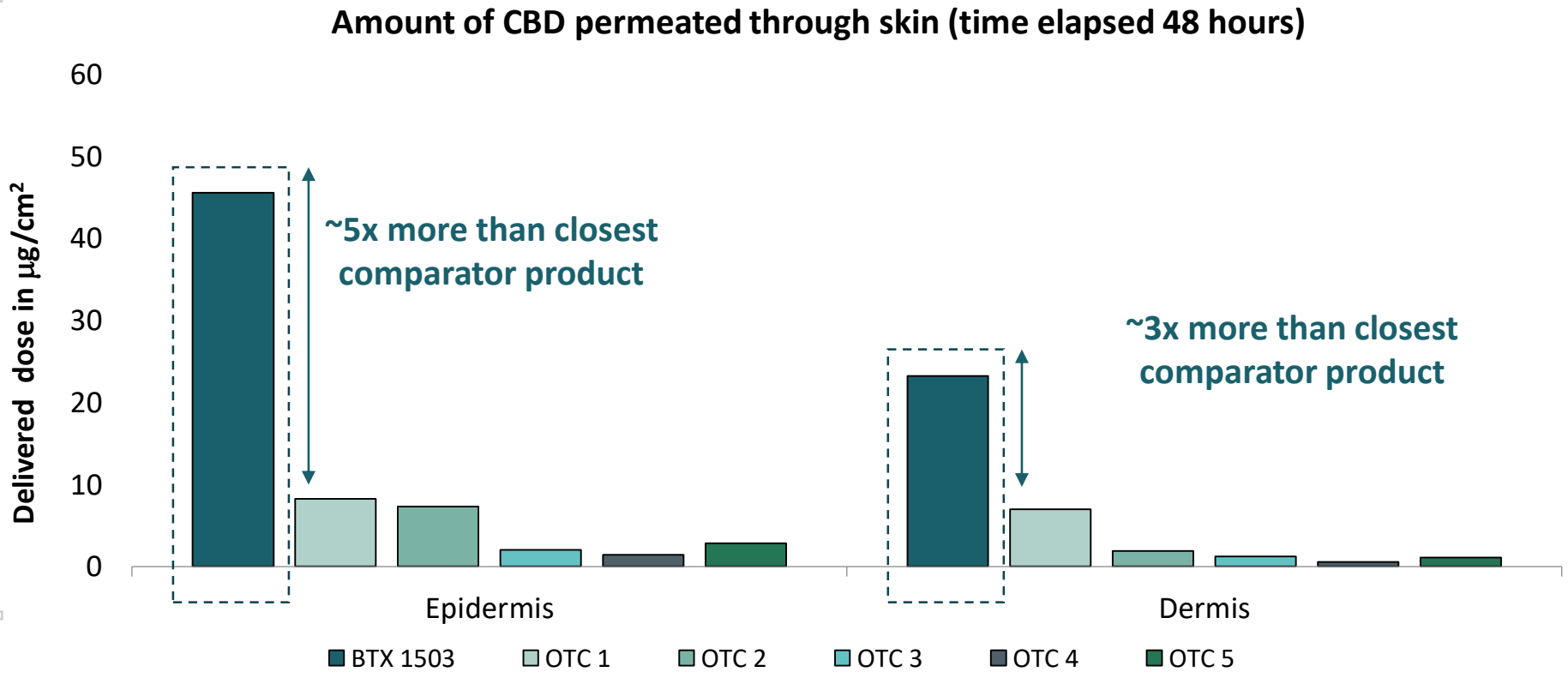
4. The CBD in OTC products goes into the skin

Of the [small amount of] CBD in OTC products, the tested OTC CBD products delivered very little drug into the targeted layers of the skin[1]



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 Tioga Research. Botanix data on file.

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Fact

1. CBD has a unique MOA in skin disease
2. CBD is a unique antimicrobial
3. CBD alone shows efficacy in multiple studies
3. Products can be developed for FDA approval

1. Synthetic CBD's mechanism of action in acne

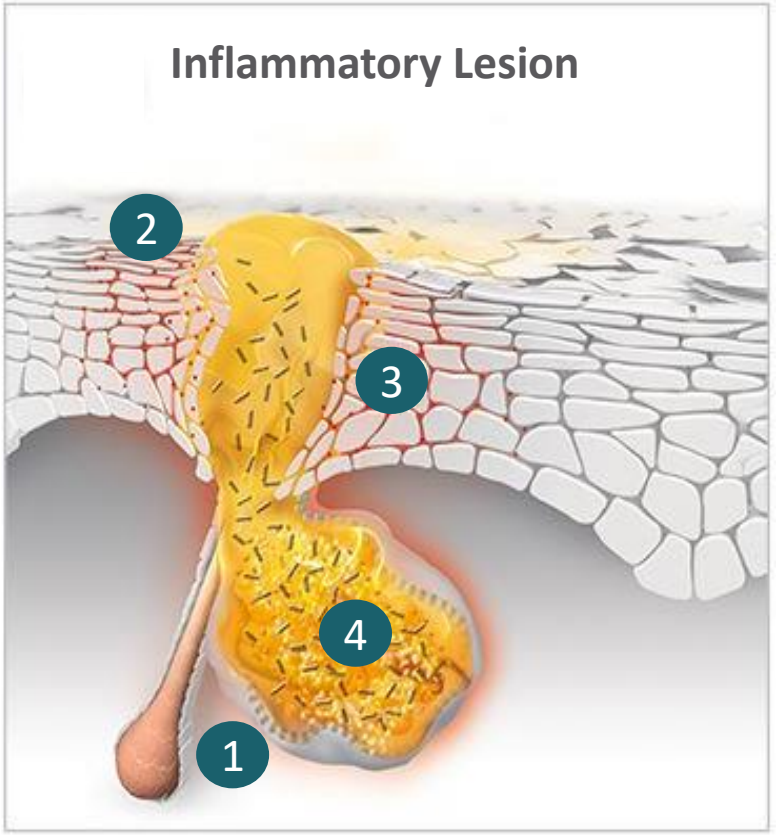
Safe and well tolerated topical acne treatment that potentially addresses all the key causes of acne

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 p38 MAP Kinase[3] -dependent inflammatory responses[4,5]
- Inhibits 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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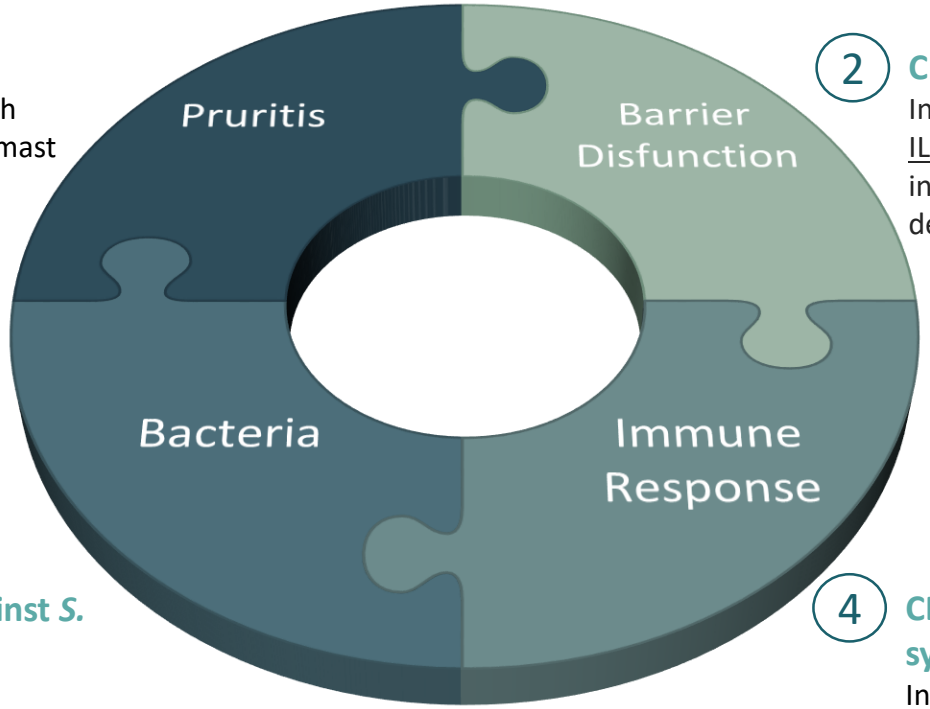
1. Synthetic CBD's mechanism of action in atopic dermatitis

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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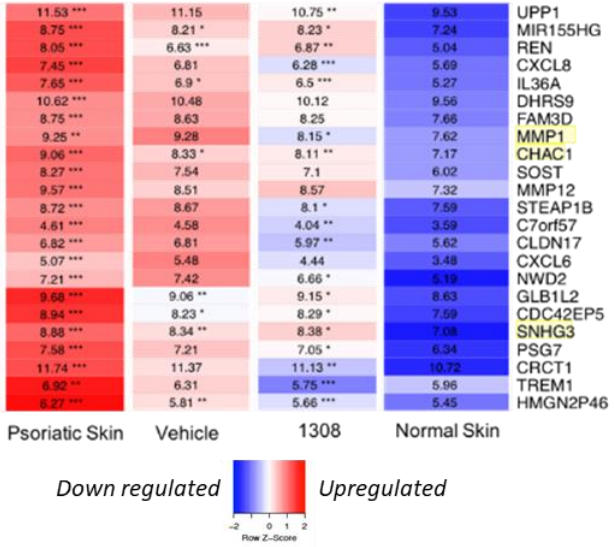
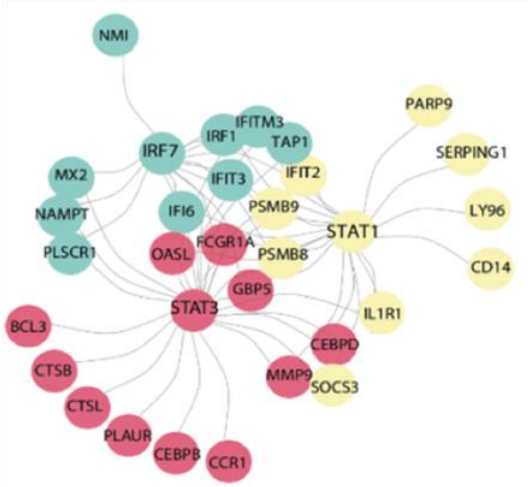
1. CBD's mechanism of action does not depend on CB1/CB2 receptors

Biopsies and gene regulation data from Botanix patient study demonstrated that synthetic CBD triggers significant alterations in inflammatory and immune response pathways

Heat map of genes regulated by treatment with BTX 1308



Ingenuity pathway analysis



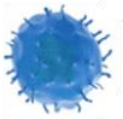
Target pathways identified

Anti-inflammatory pathway

p38 MAP Kinase
Interleukin-6

Keratinocytes

Immune modulating pathway



Interleukin-13

Th2 Helper Cells

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2. Synthetic CBD is a powerful antimicrobial

Broad spectrum, fast acting, biofilm disrupting and bacteria don't form resistance

Target profile	BTX 1801	Antibiotics
Kills *S. aureus* and resistant *S. aureus* (MSRA - "Superbugs")[1]	✓	✗
Shows broad-spectrum Gram-Positive activity[1]	✓	✗
MRSA bacteria do not develop resistance[1]	✓	✗
Disrupts bacterial biofilms[1]	✓	✗
Potential for widespread use across human and animal health[2]	✓	✗
Broad anti-inflammatory properties relevant to infections[3]	✓	✗

1. *Based on University of Queensland testing – BOT data on file*
2. *Based on mouse infection model – Charles River BOT data on file*
3. *Based on BTX 1503 Phase 1b clinical data on inflammation – BOT data on file*

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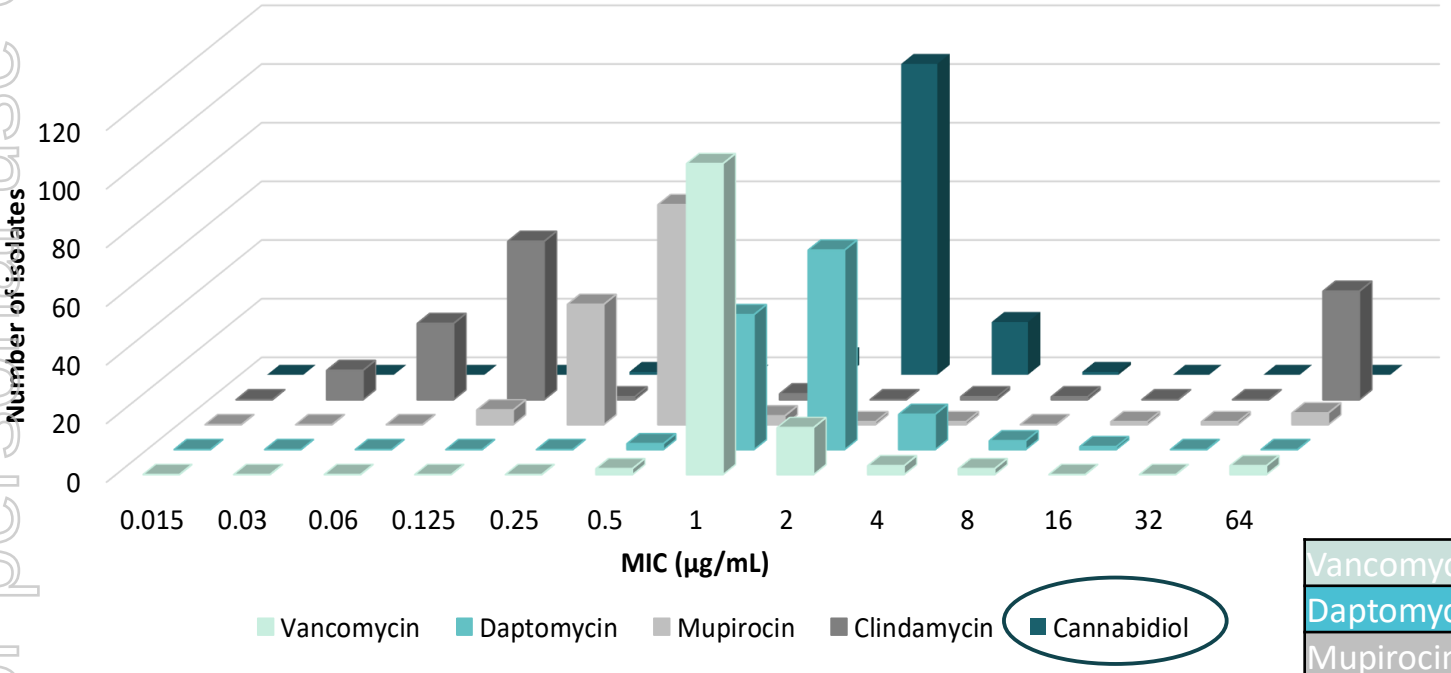
2. Effective against 132 different *S. aureus* isolates

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]

MIC_{90} S.aureus 132 isolates



	MIC 50	MIC 90
Vancomycin	1	2
Daptomycin	2	4
Mupirocin	0.5	0.5
Clindamycin	0.125	64
Cannabidiol	2	4

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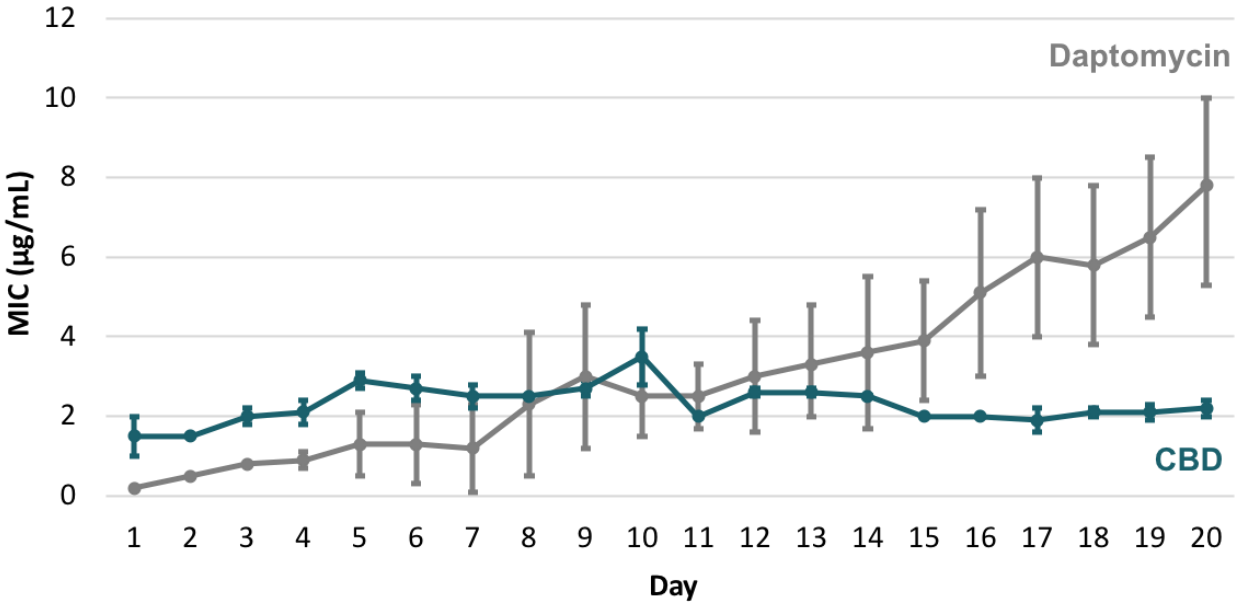
1. Based on University of Queensland testing – BOT data on file

2. MRSA ('golden staph') bacteria do not form resistance to CBD

If the antibiotic does not kill the bacteria quickly and completely, repeated dosing allows bacteria to mutate and form resistance to the drug

Antibiotic Minimum Inhibitory Concentration (MIC) daily variability[1]



← 26 fold increase

An increase in MIC over time shows MRSA can develop resistance to the drug

← 1.5 fold increase

After 20 days passage, average MIC increased from 1.5 to 2.2 µg/mL for cannabidiol (1.5-fold) and from 0.30 to 7.6 µg/mL for daptomycin (26-fold)

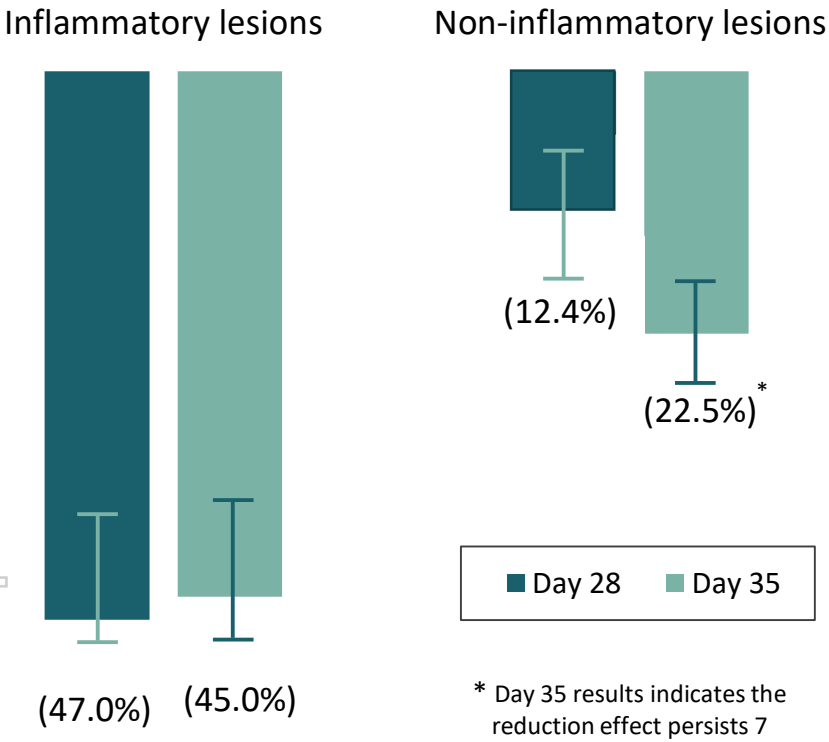
Dr. Mark Blaskovich Principal Investigator and Program Coordinator at The University of Queensland's Institute for Molecular Bioscience: *"The pipeline of new antibiotics in clinical development is way too small to combat the growing threat of antimicrobial resistance. Most of these agents are really only modifications of existing antibiotics and will not provide long-term solutions to the problem."*

1. Based on average of 8 replicates , S. aureus MRSA ATCC 43300 (University of Queensland – BOT data on file)

3. Clinical data reflects proposed MOA in acne

A 4 week Phase 1b open-label study showed a marked reduction in inflammatory lesions and was safe and generally well tolerated

Lesion count reduction (%) [1]



* Day 35 results indicates the reduction effect persists 7 days after the last treatment

Other FDA approved products[2]

Product	Owner	Lesion count reduction (%)[3]	Peak revenue[4]
Epiduo®	Galderma	~42%	~US$700m

✓ Combination of two drugs – benzoyl peroxide and adapalene

✗ Common side effects include redness, skin peeling mild burning / stinging and dryness

Aczone®	Allergan	~38%	~US$300m

✓ Few side effects

✗ Common side effects are site dryness and pruritus

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*

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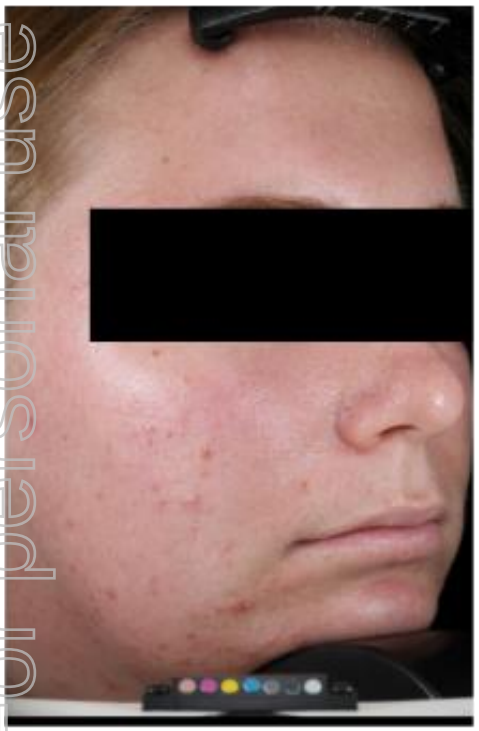
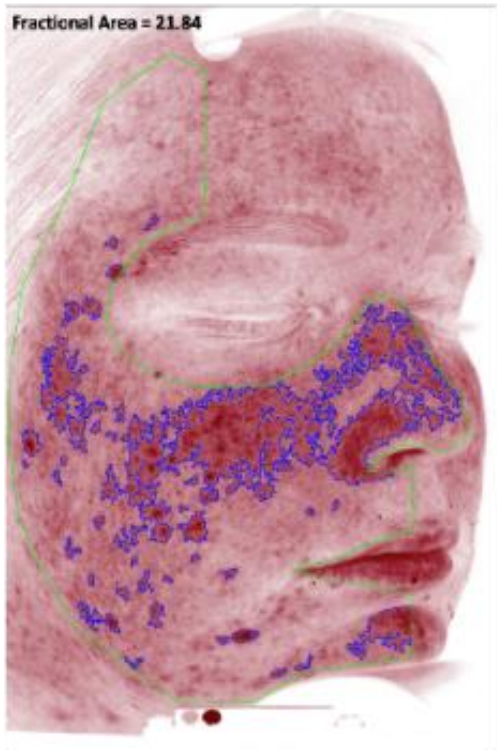
3. Anti-inflammatory effects of CBD are relevant to multiple diseases

Photographic images from the Phase 1b acne patient study, demonstrate a clear anti-inflammatory effect over the 4-week treatment course[1]

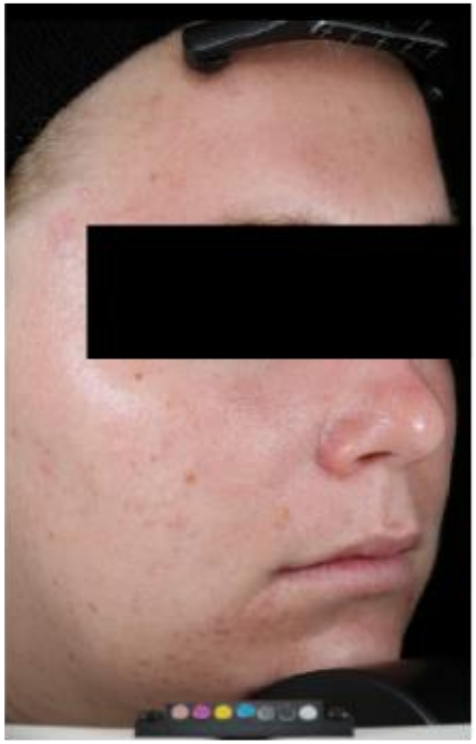
Baseline (day 1)[2]

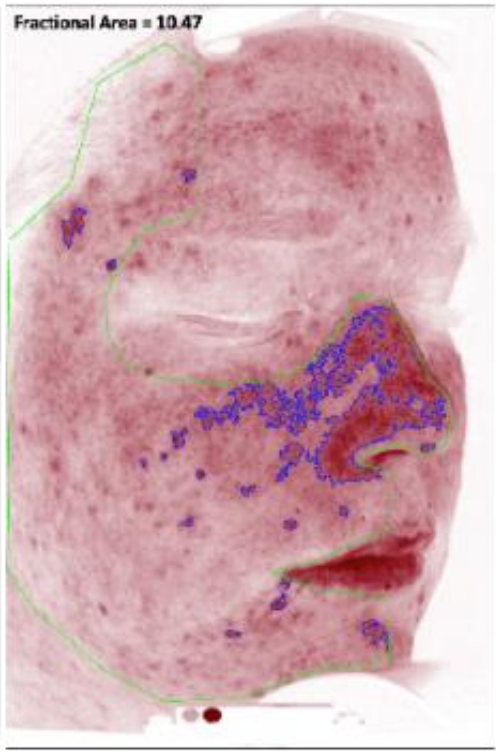




Nose not treated

Visit 4 (4 weeks)[2]





Nose not treated

1. Botanix Pharmaceuticals data on file – Canfield RBX VISIA Complexion Analysis System – Canfield Imaging Systems

2. Nose not treated

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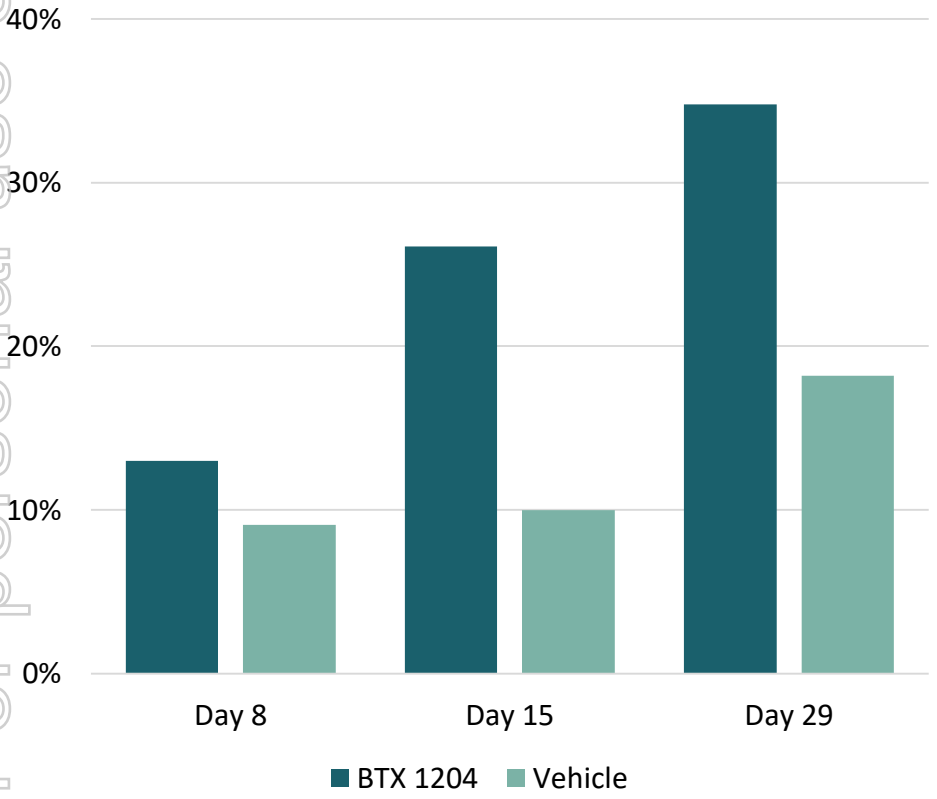
3. Clinical data also reflects proposed MOA in atopic dermatitis

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

- 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 scale*

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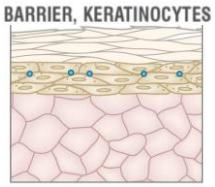
3. Topical synthetic CBD is a well suited to treat skin disease

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

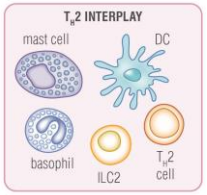
CBD inhibits a key cytokine pathway which affects skin barrier disfunction

IL-6 → CBD ✗



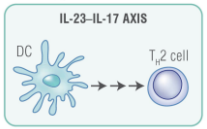
CBD attenuates a well-known cytokine which drives the inflammatory response

IL-13 → CBD ✗



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

P38 MAPK → CBD ✗

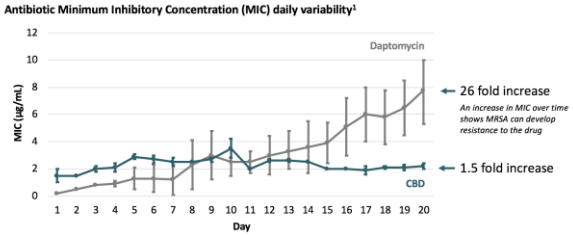


CBD antimicrobial effects

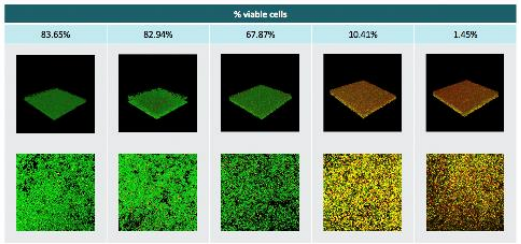
CBD is active against all tested gram +ve bacteria

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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4. Products can be developed rapidly for FDA approval

FDA and DEA are both active and collaborative in the cannabinoid development area and engagement early and often pays dividends

Synthetic CBD with Permetrex™ topical technology

	Indication	Pre-clin	Ph 1	Ph 1b	Ph 2	Status
Pending clinical data						
BTX 1503 Gel	Moderate to severe acne					Study complete 3Q 2019
BTX 1204 Solution	Moderate atopic dermatitis					Study enrolled 4Q CY2019
Recent data						
BTX 1308 Ointment	Psoriasis					Successful MOA[1] study
BTX 1801 Gel	Antimicrobial					Successful POC[1] data

Formulation development to completing Phase 2 studies within 36 months

1. POC: Proof of Concept; MOA: Mechanism of Action

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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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Contact us

Ric Peterson
Botanix Pharmaceuticals
Chief Financial Officer
investors@botanixpharma.com

Visit us
www.botanixpharma.com

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Botanix Pharmaceuticals Limited (ASX:BOT)