

#### ASX/Media Release

#### 18 October 2016

#### Botanix to present at 7<sup>th</sup> Annual Australian Microcap Investment Conference

**Perth, Australia; 18 October 2016:** Medical dermatology company Botanix Pharmaceuticals ("Botanix" or "the Company") has been invited to present today at the 7<sup>th</sup> Annual Australian Microcap Conference in Melbourne.

Botanix Executive Director Matthew Callahan will present the latest information about the Company's investment opportunity, the skin disease product market and lead product BTX1503. The conference is the largest in Australia focused on the microcap sector and is held over two days on Tuesday 18th and Wednesday 19th October 2016.

Mr Callahan's presentation is attached to this press release and available <u>here</u> (under 'Reports and Presentations)'.

#### **About Botanix Pharmaceuticals**

Botanix Pharmaceuticals is dedicated to developing next generation therapeutics for the treatment of serious skin diseases. Our mission is to improve the lives of patients battling acne, psoriasis and atopic dermatitis, by providing new treatment options for conditions that currently are inadequately addressed or are treated with therapeutics that are burdened with side effects profiles. Botanix is harnessing the untapped potential of a synthetic active pharmaceutical ingredient known as cannabidiol, which is currently being studied for the treatment of epilepsy, pain, arthritis and schizophrenia and has a well-established safety profile. Botanix is preparing for the first human trials with synthetic cannabidiol utilising a proprietary drug delivery system (Permetrex<sup>™</sup>) for direct skin delivery of the therapy.

For more information on Botanix, please visit <u>www.botanixpharma.com</u> or follow us on Twitter @Botanixpharma.

#### For more information, please contact:

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restoring healthy skin

ASX:BOT www.botanixpharma.com

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## Botanix Pharmaceuticals

- US based medical dermatology company
- Focused on new treatments for acne, psoriasis, and atopic dermatitis
- Utilising a synthetic form of cannabidiol as the drug active - pharmaceutical grade and commercially scaleable
- Exclusive license to a new skin drug delivery system Permetrex<sup>™</sup>
- Following faster path to market than usual oral drug development pathway
- Experienced team with more than 10 FDA approvals between them



**Drug** active:

**Initial Product:** 

– Permetrex<sup>™</sup>

**Business focus:** 

- acne

– synthetic cannabidiol

**Drug delivery system:** 

– medical dermatology



Directors & management own  $\approx 23\%$  of the new Company

<b>Corporate</b> *	Team*				
ASX	BOT	Chairman	Graham Griffiths	<ul><li>Nearmap</li><li>Pointerra</li></ul>	
Offer Price	\$0.020			• iintegrate	
Cash raised under the Offer	\$3,500,000		Matt Callahan	<ul><li>iCeutica</li><li>Churchill Pharma</li><li>Orthocell</li></ul>	
Share Price (@ close 11/10/16)	\$0.043	Exec Director	Dr Bill Bosch	<ul><li>iCeutica</li><li>Elan Drug Technologies</li><li>Nanosystems</li></ul>	
Market Capitalisation (@close 11/10/16)	\$17.4 million	Director	Rob Towner	<ul><li>bioMD</li><li>Triangle Energy</li><li>Cornerstone Corporate</li></ul>	

#### **Shareholding Structure**\*



### Market opportunity ... medical dermatology

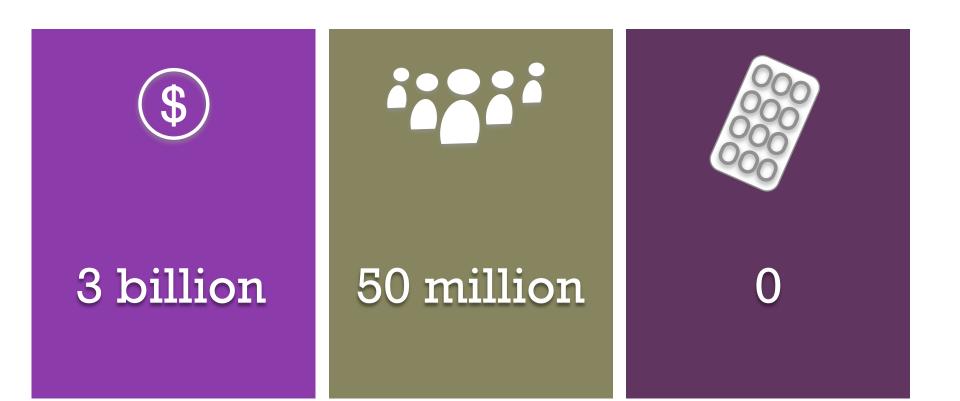
Particularly attractive segment of the pharma industry:

- many drugs with significant side effects
- pipeline of new products is very thin, despite multibillion dollar markets
- development of dermatology products is more cost efficient and faster than oral/injectable

from start-up to first safety and efficacy trials within 12 months for < \$3.5 million invested</p>



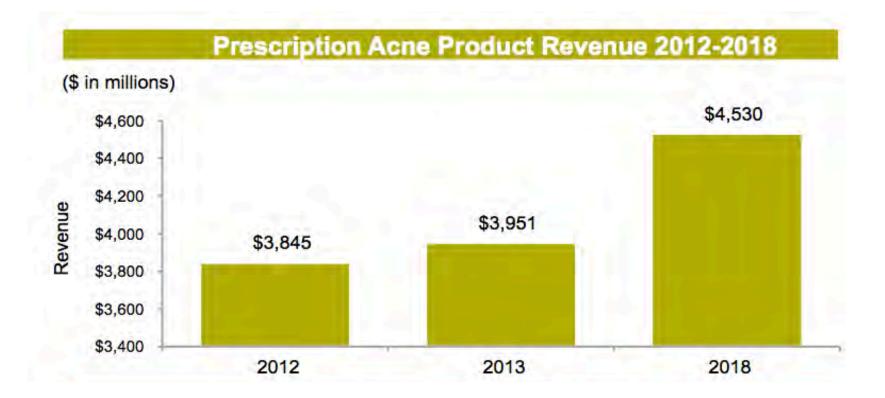
## Market opportunity in acne





Confidential Property of Botanix Pharma

# Acne prescription and OTC markets rapidly growing



#### The non-prescription (OTC) market is worth \$2.4 billion<sup>(3)</sup>

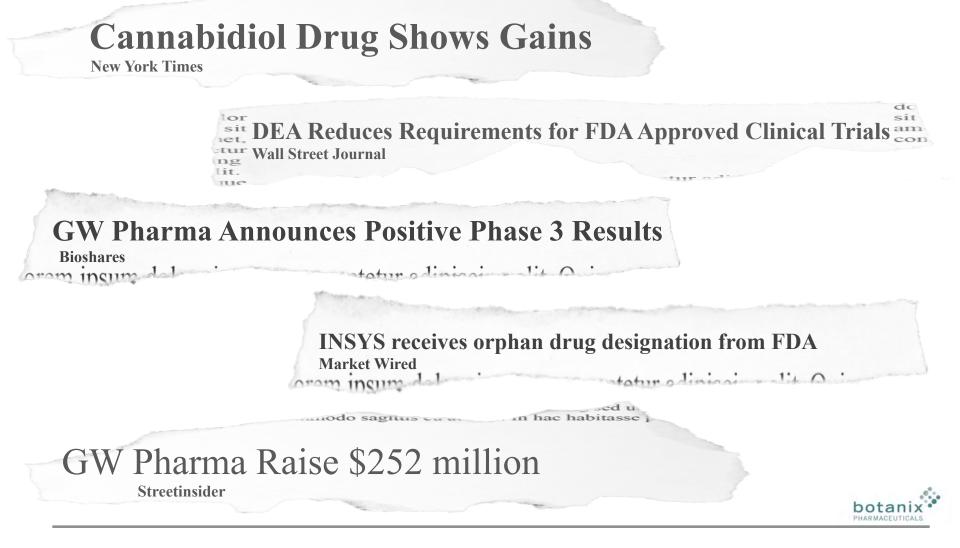
2) Symphony Health Solutions, Pharmaceutical Audit Suite for 2012 as reported in Dermira S1

3) IBIS Research July 2014



# Cannabidiol active drug showing promising results...

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in hac habitasse

## Image: Second content of the source of drug supply is important...



Extracted and purified

100+ chemicals

**Multiple impurities** 

Scaled up to  $\approx 1$ kg

Not registered with FDA

Must comply with FDA's "Guidance on Botanicals"



Synthetically manufactured

l chemical

100% pure

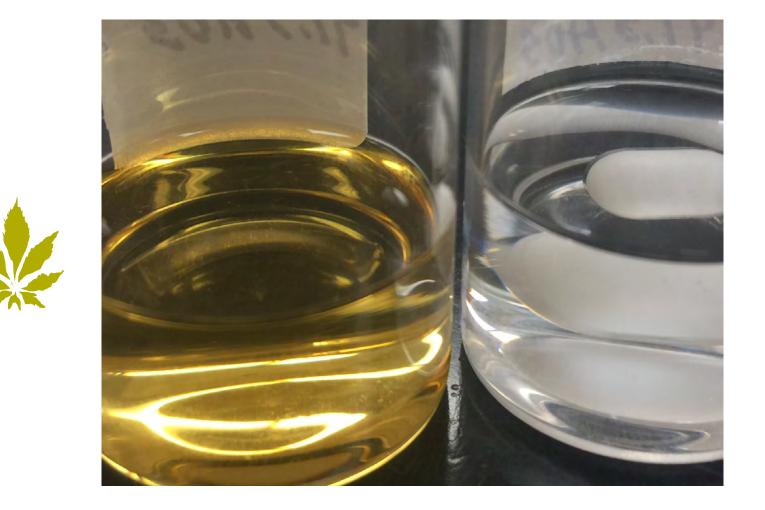
Scaled up to 50kg

**Registered with FDA** 

No additional compliance required



### ...and the difference is clear

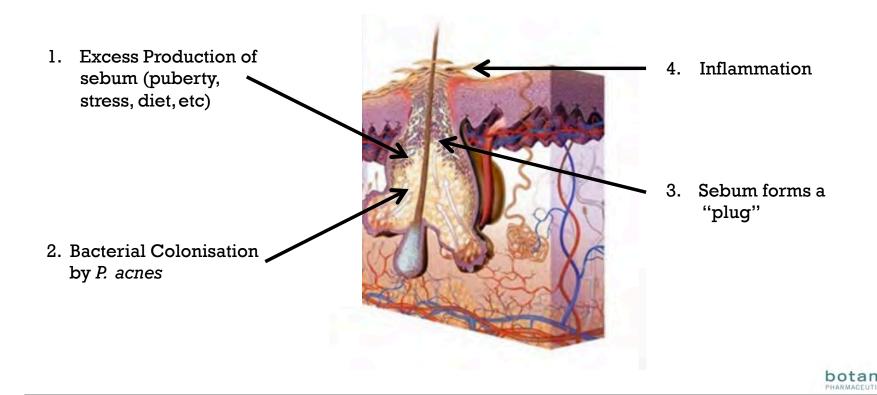






## How does acne happen?

Hair follicles become partially plugged with excess oils (sebum) and cells to form lesions of varying grades of severity



### BTX1503 – novel mechanism of action in acne



Switches off excessive oil or 'sebum' production



Reduces inflammation



Blocks cell proliferation



**Reduces infection** 

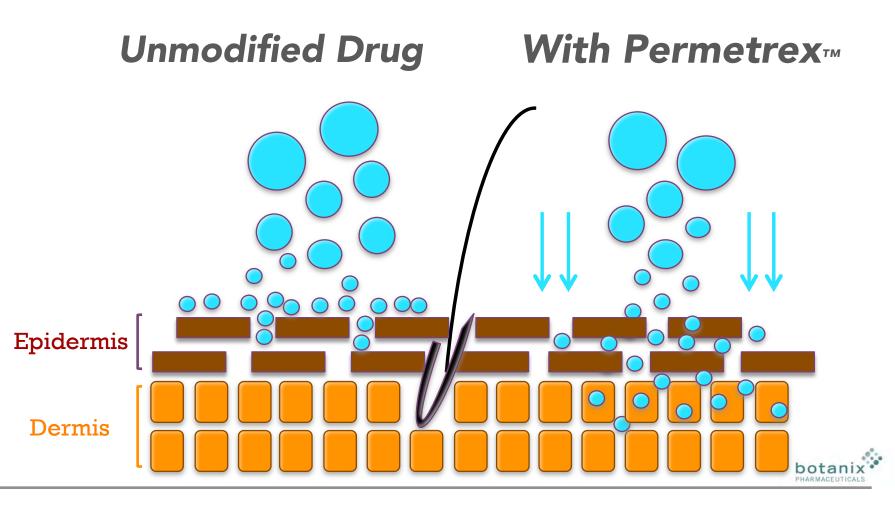
#### **BTX1503 also targeting a benign side effect profile**





# Permetrex<sup>™</sup> - superior skin delivery

Oral delivery of cannabidiol is only 6% bioavailable



Confidential Property of Botanix Pharma

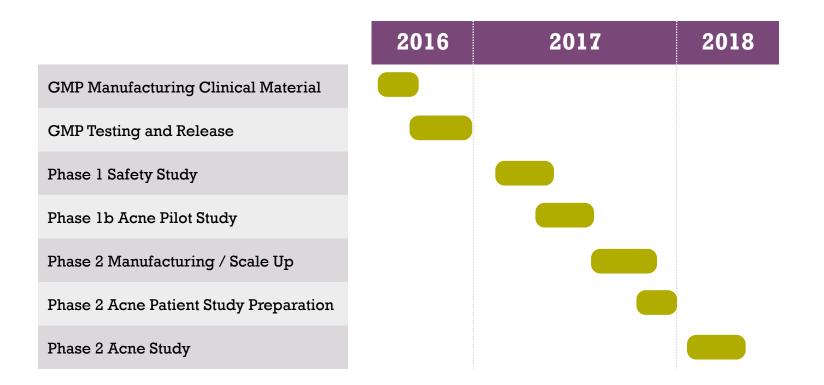
#### BTX1503 - planned positioning versus existing acne products

	BI	A1503	dannycin gopi	cal retino	alene Min	ocycline Fityt	Accutat
Reduces Sebum	1	×	×	×	×	×	
Anti-inflammatory	1	×	1	1	×	×	<b>√</b>
Anti-microbial	1	1	×	×	1	1	<b>√</b>
Topical	1	×	1	1	×	×	×
Minimal side effects	1	×	1	1	×	1	×

"...the 'Holy Grail' of acne treatments would be a topical that can influence sebum production or the physiochemical properties of sebum." Prof Emeritus James Leyden

## BTX 1503 - planned timeline

Accelerated development timetable compared to oral and injectable drugs



Partnering and collaboration opportunities available at each stage of development



## BTX 1503 – activity accelerating

Substantial risk already reduced within first 3 months of listing



- Source of synthetic cannabidiol secured
- Formulation re-manufactured using GMP components
- Pre-clinical testing underway
- Clinical packaging options refined
- Safety/irritation POC study designed and pending
- Clinical site identified and protocol finalized



# Targeted news flow and milestones for first 12 months

- Appointment experienced industry leaders for clinical and manufacturing positions
- Securing synthetic cannabidiol supply
- Formalisation of world class Scientific Advisory Board
- Completion GMP Manufacturing and pre-clinical testing
- Filing TGA, DEA and/or Customs licenses
- Pipeline development progress
- Collaborative research arrangements
- New product addition to pipeline (based on platform)
- Commencement and then completion of first human trials
- Commencement and then completion of patient pilot study
- Conference presentation/attendances



### Pipeline – multiple products leveraging the platform

BTX 1308 (psoriasis)

**BTX 1204** 

(dermatitis)

- 7.5 million Americans have psoriasis (most have *plaque* psoriasis)
- Cost of injectable biologic treatments in 2014 was \$20 billion
- Biologic drugs have serious side effect issues (including lymphoma)
- US patient incidence estimated to be 31 million people 10 -18% of children
- Estimated annual cost of treating Atopic Dermatitis in the US is \$3.8 billion
- Multiple opportunities utilizing Permetrex™ and/or synthetic cannabidiol to treat serious skin disease







### Team with significant FDA success...



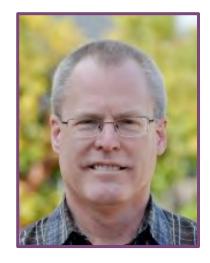
Matt Callahan Director

- 3 FDA approved products
- 15 years pharma experience
- Venture capital partner



**Dr Bill Bosch** Director

- 6 FDA approved products
- 26 years pharma experience
- Co-inventor of drug delivery technologies including Nanocrystal®



Mr Mark Davis Clinical/Regulatory

- Unique experience with cannabidiol with Insys
- 30 years of clinical experience
- Former clinical lead with Medicis and Connetics



Mr Doug Bakan Manufacturing/Quality

- 35 years manufacturing and development experience
- Former senior exec with Medicis
- Project lead for formulation



#### ...and unique experience



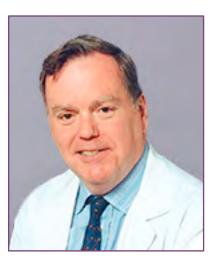
Dr Gene Cooper Consultant

- 5 FDA approved products
- Expert in skin delivery
- Inventor of Permetrex<sup>™</sup>
- 40 years pharma experience



**Dr Joel Gelfand** Medical Director Clinical Studies

- Dermatology A/ Professor at Penn
- Expert in skin disease and clinical trial management



**Prof James Leyden** Scientific Advisor

- E/Professor Dermatology at University of Pennsylvania
- World leading acne and skin specialist



**Prof Diane Thiboutot** Scientific Adviser

- Professor of Dermatology at Penn State University
- Leading researcher in acne and rosacea
- Pre-clinical and clinical trials services provider



### Botanix ...a compelling investment case

- ✓ Significant unmet patient needs in serious skin disease
- ✓ Novel treatment for acne with a growing evidence base
- Proprietary drug delivery system
- Fast and efficient development pathway, relative to usual pharmaceutical development
- Very large markets with few competing products in development
- Experienced team with track record of FDA approvals

