

### **ASX/Media Release**

### 9 April 2018

### **Investor Presentation**

Philadelphia PA and Sydney Australia, 9 April 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") is pleased to release an updated investor presentation to be used in meetings with investors and brokers as part of a non-deal roadshow across Australia in the coming weeks. This investor presentation is being used to provide an update on the Company's key activities including its acne clinical program (BTX 1503), atopic dermatitis clinical program (BTX 1204) and key milestones over the near to medium term.

#### **About Botanix Pharmaceuticals**

Botanix Pharmaceuticals is a clinical stage medical dermatology company, which 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, atopic dermatitis and other skin diseases, 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 potential of a synthetic form of a natural compound, which has a well-established safety profile and has been studied successfully in a range of other therapeutic areas. Botanix has now successfully completed its first acne patient studies with BTX 1503 and is preparing for a Phase 2 study in Q2 2018, while concurrently completing a Phase 1b study for BTX 1204 in atopic dermatitis patients. The Company has an exclusive license to use a proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases and plans to progress the development of BTX 1503, BTX 1204 and its pipeline of other Permetrex<sup>™</sup> enabled products alone, or in collaboration with partners.

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

### For more information, please contact:

**General enquiries** 

Matt Callahan **Botanix Pharmaceuticals Executive Director** P: +1 215 767 4184

E: mcallahan@botanixpharma.com

**Investor Relations** 

Joel Seah Vesparum Capital P: +61 3 8582 4800

E: botanixpharma@vesparum.com

### Media

Julia Maguire The Capital Network P: +61 419 815 386

E: julia@thecapitalnetwork.com.au





## Investment highlights

Botanix is an emerging global dermatology company with advanced clinical programs



Dermatology Focused

Targeting multi-billion dollar prescription markets for acne (with no new products approved in the last 20 years) and atopic dermatitis



**Clinical Stage** 

**Successful clinical data** from acne patient study shows industry leading reduction in inflammatory lesions, after 4 weeks of treatment



Novel Approach Products use a synthetic form of a widely studied natural product, **greatly enhances the probability of clinical and regulatory success** 



Experienced
Team

Predominantly US based leadership team with 20+ FDA approvals between them and extensive dermatology industry experience



## Corporate overview

Medical dermatology company with a clear path to commercialisation and a highly aligned Board and management team

## **Trading information**

Share price (as at 6-Apr-2018)	A\$0.125
52 week low / high	A\$0.04 / A\$0.16
Shares outstanding <sup>1</sup>	681.9m
Market capitalisation <sup>2</sup>	A\$85.2m
Cash (as at 31-Jan-2018)	A\$17.1m
Debt (as at 31-Jan-2018)	-
Enterprise value	A\$68.1m

## Top shareholders (April 2018)

Shareholder	%
Matthew Callahan – Executive Director	10.4
Caperi Pty Ltd – Co-founder	10.4
Board and management (excl. shareholders above)	3.0

### 1. Includes 156.5m full paid ordinary shares subject to escrow until 15 July 2018 and excludes 44.5m options

### Share price performance





<sup>2.</sup> Cash includes A\$14.9m (before costs) received from capital raising announced in February 2018

## Clinical programs with near term milestones

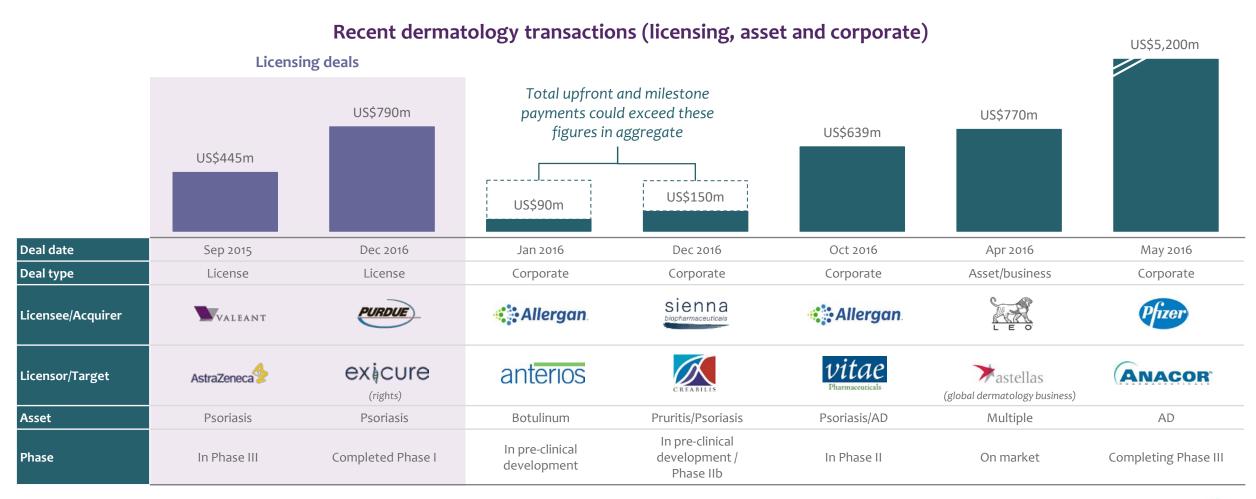
Rapidly advancing acne and atopic dermatitis programs, with deeper pipeline in development and Permetrex™ collaborations to augment revenue and news flow

Product candidate		Indication	Pre-Clin	Ph 1	Ph 1b Ph 2		Next milestones
Synthetic form of natural product extract – cannabidiol	BTX 1503	Moderate to Severe Acne				••••	IND filing for Phase 2 2Q CY2018
	BTX 1204	Atopic Dermatitis			>		Phase 1b patient data available 2Q CY2018
	BTX 1308	Psoriasis		····>			Patient study 3Q CY2018
	BTX 1801	Undisclosed	<b>→</b>				Pre-clinical testing 2Q CY2018
Permetrex <sup>™</sup> programs	Internal/ External	Various		Collabo	rations		Ongoing



## Botanix's product portfolio value considerations

Licensing and partnering transactions are potential monetisation options before FDA approval



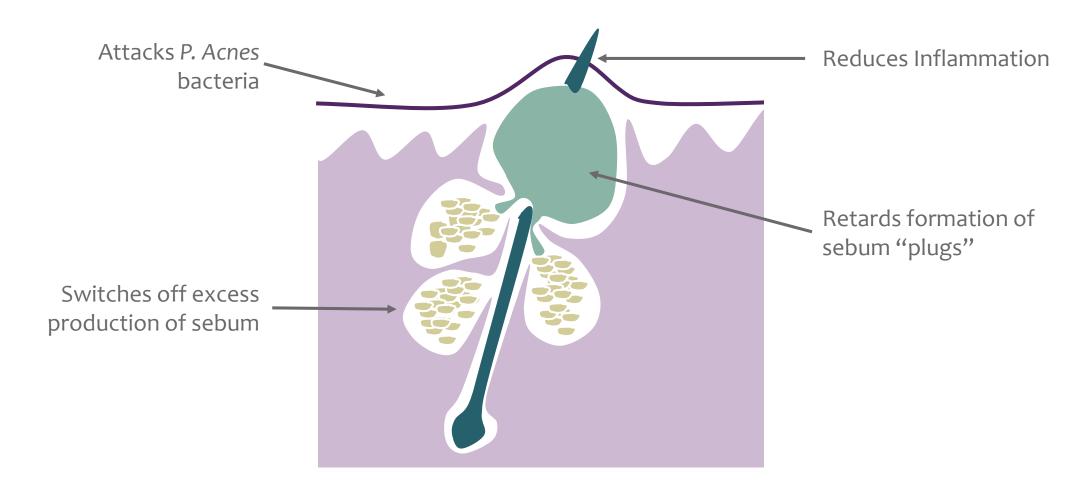


BTX 1503 moderate to severe acne



## How does BTX 1503 work to treat acne?

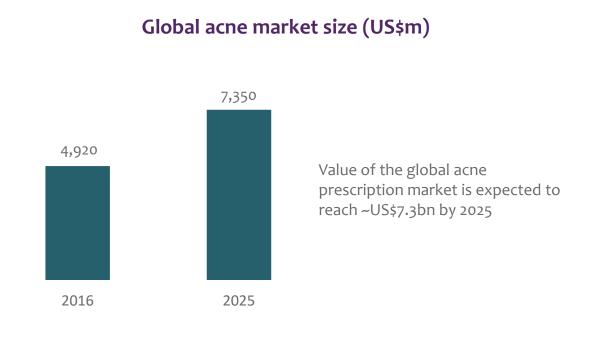
BTX 1503 potentially address all 3 key pathologies of acne with a very safe side effect profile

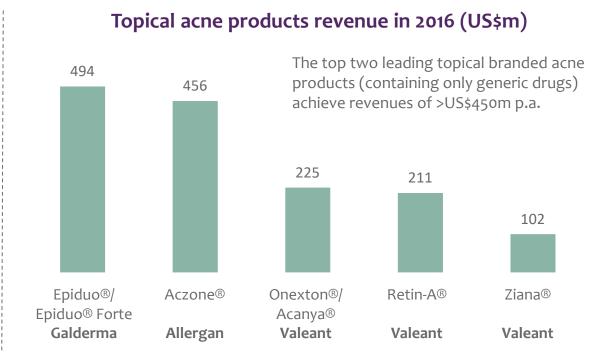




## Why are we focused first on acne?

In 2016, the global acne prescription market was worth ~US\$4.9bn, with the potential to grow to ~US\$7.3bn by 2025





### Large demand with limited recent product development

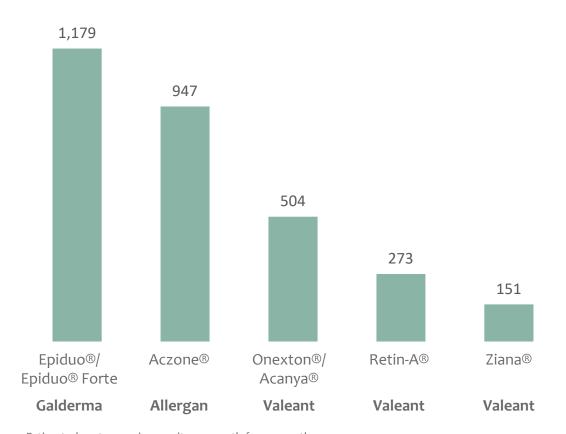
No new chemical entities have been approved by the FDA in the last 20 years for the treatment of acne Only "new" products launched were combinations of old drugs in new formulations or packaging



# Leading US branded topical acne products

Leading topical branded acne products generated ~3m prescriptions in 2016

## Topical acne products prescriptions in 2016 ('000s)



## 2016 list price and cost of topical acne products

	Drug	List price (US\$)	Annual cost (US\$)¹		
Branded / Branded Generic	Epiduo® / Epiduo® Forte	\$398.10	\$3,185		
	Aczone®	Aczone® \$258.90			
	Onexton® Acanya®	\$444.00	\$3,197		
	Retin-A®	\$249.20	\$1,994		
	Azelex®	\$344.70	\$4,136		
Generic	Clindamycin / Benzoyl Peroxide	\$162.80 (low strength) \$340.30 (high strength)	\$1,302 (low strength) \$4,900 (high strength)		
	Tretinoin	\$128.00 (low strength) \$158.50 (high strength)	\$1,024 (low strength) \$1,268 (high strength)		



<sup>1.</sup> Estimated cost assuming 1 unit per month for 12 months Source: Symphony Health Services (PHAST) 2017; The Medical Letter Vol. 58 (1487)

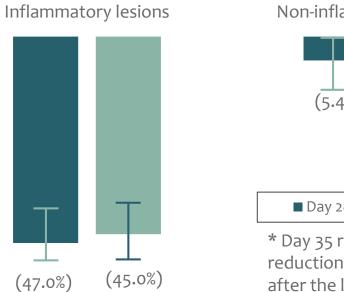
# BTX 1503 outperformed leading acne products

Study data resulted in a reduction in inflammatory lesions greater than any other FDA approved topical acne product at 4 weeks

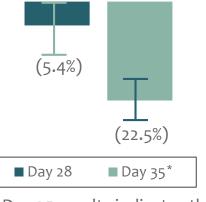
BTX 1503

**Botanix** 

### Lesion count reduction (%)



### Non-inflammatory lesions



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

### Comparison of other FDA approved products

Product	Owner	Lesion count reduction (%)1	2016 annual revenue²				
<b>Epiduo</b> ®	Galderma	~42%	US\$494m				
Epiduo series se	adapalen * Common	<ul> <li>Combination of two drugs – benzoyl peroxide and adapalene</li> <li>Common side effects include redness, skin peeling mild burning / stinging and dryness</li> </ul>					
<b>Aczone</b> ®	Allergan	~38%	US\$456m				
Accorde deputed of the control of th	<ul> <li>✓ Few side effects</li> <li>✗ Studies showed large placebo / vehicle effect – i.e. at 12 weeks Aczone reduced inflammatory lesions by 54% while vehicle achieved 48% reduction</li> </ul>						

~47%

- 1. Lesion count reduction based on average inflammatory lesion reduction at 4 weeks
- . Based on 2016 annual revenue in the US



## Phase 1b acne patient study data

Patient satisfaction high due to the rapid onset of improvement and significant effect on inflammatory lesions

### Photographs of acne study patient before and after treatment<sup>1</sup>



Baseline



Day 28

### **Patient result**

57% reduction in inflammatory lesions

15% reduction in non-Inflammatory lesions

Patient satisfaction report was "Much Better"



## BTX 1503 Phase 2 study design

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

## Design

- 5 dose groups: ~360 subjects
  - High Dose twice a day: ~90 subjects
  - High Dose once a day: ~90 subjects
  - Low Dose once a day: ~90 subjects
  - Vehicle/Control: ~90 subjects
- ~25 US and Australian dermatology sites
- Moderate to severe acne patients

### **Endpoints**

- Primary endpoints:
  - Absolute change from Baseline to Week 12 in <u>inflammatory</u> lesions
- Secondary endpoints:
  - Absolute change from Baseline to Week 12 in noninflammatory lesions
  - Percent change from Baseline to Week 12 in inflammatory and non-inflammatory lesions
  - Proportion of patients with IGA success
- Safety
  - Adverse events and local tolerability

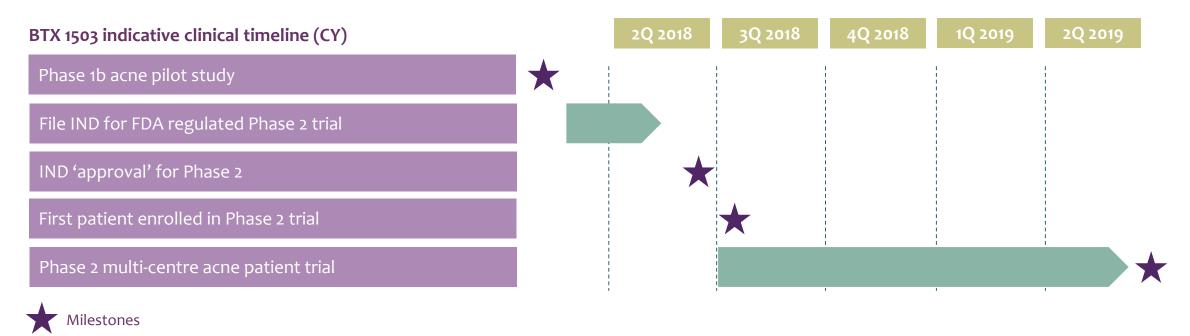
Commences mid-CY2018 (~12 months duration)



## BTX 1503 development timeline overview

Botanix is pursuing a rapid clinical development strategy to accelerate product commercialisation and timing to first revenues

- IND in final stages of preparation for filing with FDA to enable commencement of Phase 2 clinical trial in the US and Australia
- Phase 2 clinical trial to commence late 2Q CY2018 and take approximately 12 months to complete
- Trial designed to deliver data that allows licensing and other corporate opportunities





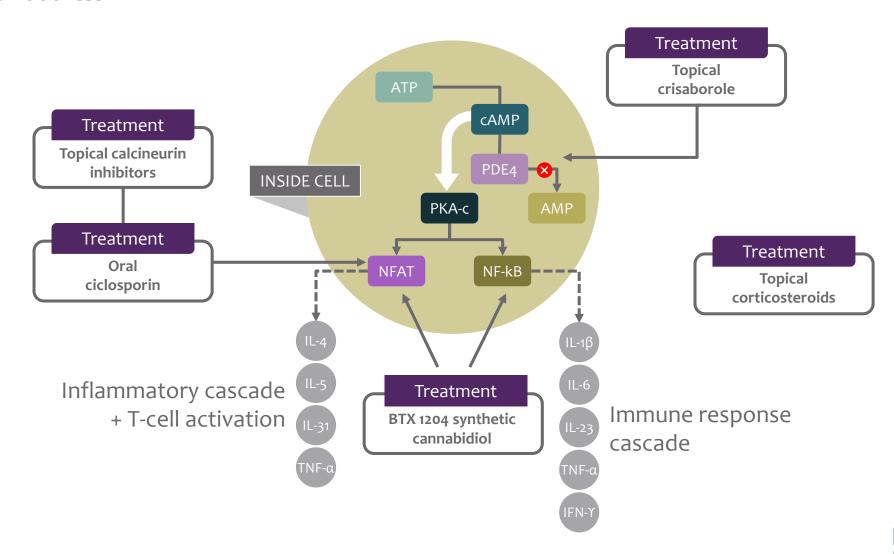


BTX 1204 mild to moderate atopic dermatitis



## BTX 1204 for atopic dermatitis

Atopic dermatitis shares many of the same pathologies as acne, but has an immune response element and itch side effect that cannabidiol can address



## BTX 1204 for atopic dermatitis

Atopic dermatitis (severe eczema) shares many of the same pathologies as acne, but has an immune response element and itch side effect that cannabidiol can address

### Market overview BTX 1204: atopic dermatitis

- Target market: US patient incidence estimated to be 25m people (10% to 18% of children)
- Market size: estimated annual cost of treating atopic dermatitis in the US is ~US\$8bn p.a.
- **Current issues:** steroids only address the symptoms and biologics are expensive and carry safety risks
- Unmet needs: safe and effective topical products



**Atopic dermatitis** 



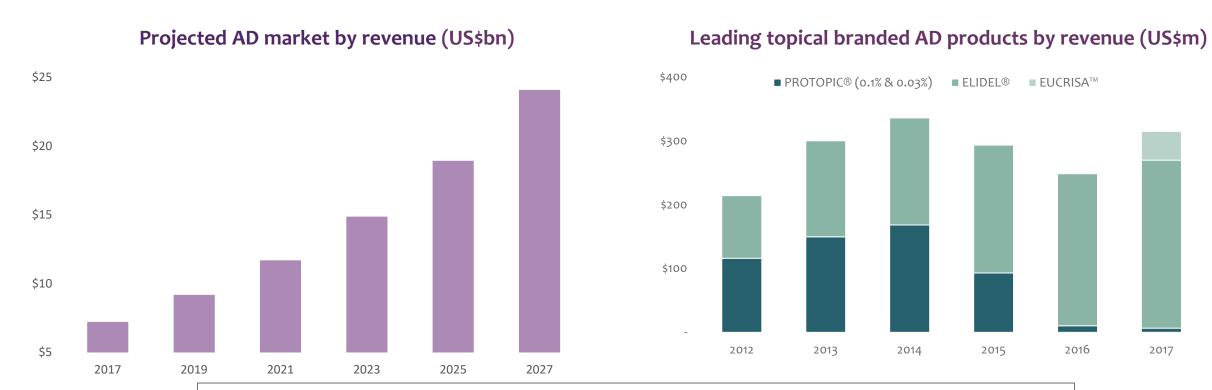
# Cannabidiol is prospective for atopic dermatitis, and has potential to:

- Reduce inflammation
- Prevent deterioration of skin barrier
- Attack staphyloccus aureus bacteria
- Reduce pruritus (itch)
- Reduce skin cell proliferation



## Global atopic dermatitis market

The global atopic dermatitis market is forecasted to grow at a CAGR of 12.8% from ~US\$7bn in 2017 to ~US\$24bn by 2027



## Limited innovation and significant remaining unmet needs

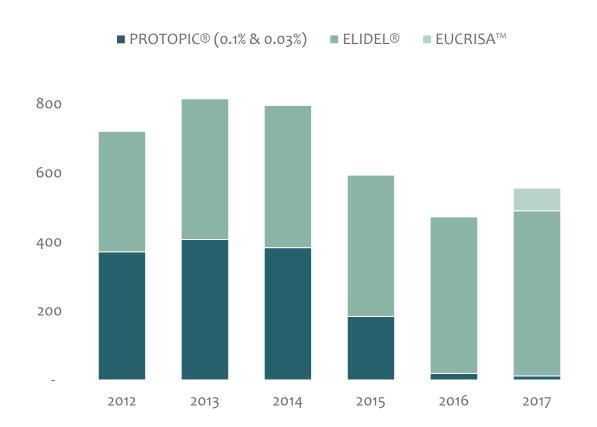
Minimal innovation in atopic dermatitis for 15 years before the 2016 approval of Eucrisa® Eucrisa® does not affect itch and has been a launch failure



# Leading US branded atopic dermatitis products

Leading topical branded atopic dermatitis products generated >550k prescriptions in 2017

### Leading topical AD products by prescription ('ooos)



### 2016 list price and cost of topical AD products

	Drug	List price (US\$)	Annual cost (US\$)¹			
Branded / Branded Generic	Topicort®	\$540	\$9,720			
	Protopic®	\$850	\$10,200			
	Elidel®	\$275	\$3,300			
	Eucrisa®	\$580	\$6,955			
Generic	Triamcinolone	\$24	\$384			
	Hydrocortisone	\$22	\$405			
	Desoximetasone	\$120	\$2,160			
	Clobetasol	\$170	\$3,056			



<sup>1.</sup> Estimated annual cost Source: Symphony Health Services (PHAST) 2017; The Medical Letter Vol. 58 (1487)

## BTX 1204 Phase 1b atopic dermatitis study

4-week randomised, double-blind, vehicle controlled patient study – **NOW FULLY ENROLLED** 

### Design

- ~36 subjects 18 years and older (24 active / 12 vehicle)
- 4 Australian dermatology sites
- At least 1 lesion (25 to 200 cm2), on the trunk upper or lower extremities
- Signs of AD score ≥6 and ≤ 12
- Investigator's Static Global Assessment (ISGA) of mild (2) or moderate (3)

## **Endpoints**

- Primary endpoints: safety AEs, labs, local tolerability and signs of atopic dermatitis
- Exploratory endpoints:
  - ISGA
  - Target lesion size



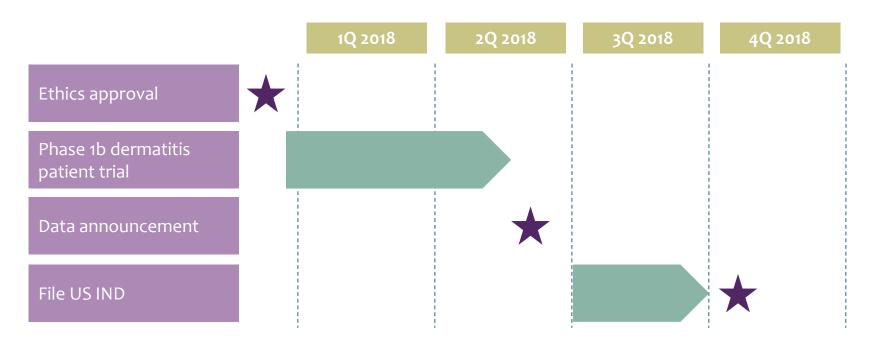
## Data available in 2Q CY2018



## BTX 1204 for atopic dermatitis

Phase 1b patient study commenced in 4Q CY2017, with expected study completion and data planned for 2Q CY2018

### BTX 1204 indicative clinical timeline (CY)



- Expected study completion and data announcement in 2Q CY2018
- Opportunity to accelerate into Phase 2 FDA regulated study in 2018

Easy to accelerate the addition of clinical programs by leveraging previous clinical data from acne program







## Development pipeline

Development pipeline also includes other synthetic cannabidiol and Permetrex™ enabled products targeting key dermatology markets

### BTX 1308: psoriasis

- Target market: ~7.5m Americans have psoriasis (note: most have plaque psoriasis)
- Market size: estimated annual costs of injectable biologic treatments in the US is ~US\$20bn p.a.
- Current issues: biologic drugs are very expensive and have serious side effect issues (including lymphoma)
- Unmet needs: safe and effective topical product



**Psoriasis** 

Botanix expects pre-clinical skin Data in 2Q CY2018



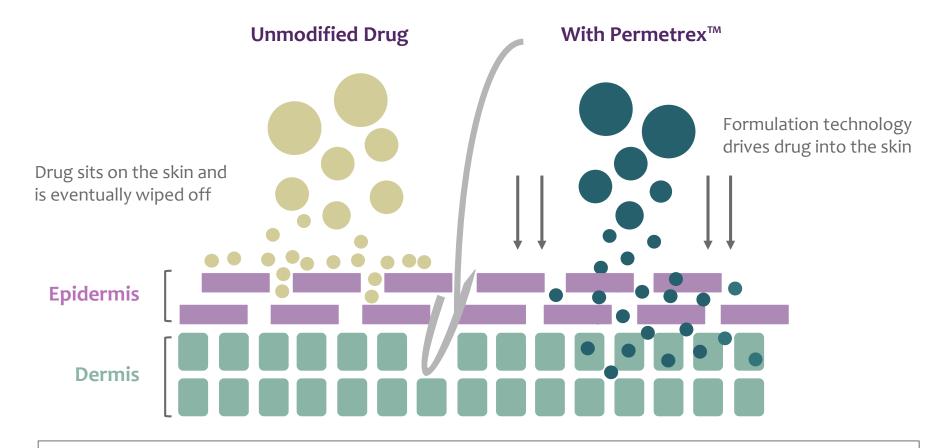
## BTX 1308 leverages prior data from:

- BTX 1503 acne clinical program
- Permetrex<sup>TM</sup> delivery system studies
- With no need to repeat early studies



## Permetrex<sup>™</sup> skin delivery technology

Permetrex<sup>™</sup> delivers high doses of drug into the layers of the skin – oral administration only delivers ~6% to the blood stream and even less to the skin



Botanix holds the **exclusive rights** to utilise Permetrex<sup>TM</sup> for all drugs that treat skin diseases



## Permetrex<sup>™</sup> opportunities

Range of opportunities to utilise Permetrex™ technology for internal product development and partnered programs

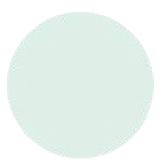
### Early collaborations leading to license discussions

- Botanix is working with multiple parties to test application of Permetrex<sup>™</sup> to solve formulation problems
- Engagement generally starts as fee-for-service by Botanix
- License trigger is generally successful proof of concept human study
- Traditional license structure likely (upfront payments, milestones, royalties)

### Other pipeline products can be developed

• Due to the safety and growing efficacy data for Permetrex<sup>™</sup>, new pipeline products can be added without repeating pre-clinical safety







# Upcoming milestones

Significant clinical and operational milestones expected over the next 12 months

Indicative activities and milestones			2Q CY2018	3Q CY2018		4Q CY2018	1Q CY2019		2Q CY2019	
BTX 1503 Acne	Phase Ib acne study data announcement	*		 						
	IND (FDA) submission for Phase 2 trial		*		 					
	First patient enrolled in Phase 2 trial			*	1			1		
	Phase 2 multi-centre acne patient study	 								*
BTX 1204	Phase 1b study in dermatitis patients			 						
Atopic Dermatitis	Phase 1b study data announcement		*	1 						
BTX 1308 Psoriasis	Pre-clinical studies									
	Phase 1b study in psoriasis patients					<b>*</b>		1		
BTX 1801	Pre-clinical studies			! ! ! !				1		
Permetrex™	Research collaborations and partnership discussions				ı			·		









# Senior leadership: proven track record of success

Proven industry professionals with experience in rapid development of pharmaceuticals



Mr Matthew Callahan Executive Director

- Developed 3 products to date that have received FDA approval, 1 pending approval
- Previous investment director of 2 venture capital firms investing in life sciences



Corporate + IP



Dr Michael Thurn
Chief Operating Officer

- Extensive start up life sciences experience across a range of technology platforms
- Previous MD of Spinifex
   Pharmaceutical, which sold to
   Novartis for A\$700m



**Operations + Regulatory** 



Mr Mark Davis
VP Clinical and Regulatory

- 30 years clinical experience with 19 FDA approved products across dermatology
- Former clinical lead with Medicis and Connetics and FDA experience with cannabidiol



Regulatory + Clinical



Dr Bill Bosch
Executive Director

- 6 FDA approved products and inventor of the iCeutica SoluMatrix Technology
- Founder of NanoSystems and co-inventor of drug delivery technology NanoCrystal



Manufacturing + IP

### 20+ FDA approved products































# BTX 1503 Phase 1b acne patient study

The 4-week open-label acne study, which concluded in December 2017, indicated that BTX 1503 was safe and well tolerated in subjects with moderate to severe acne



### **Baseline**

- 21 subjects enrolled
  - Female: 18; Male: 3
  - Mean age: 23.3 years (range: 18 to 35 years)
  - 76% White; 19% Asian, 5% Other
- Baseline lesion counts (average and range)
  - Inflammatory: 34.6 (range: 20 to 46)
  - Non-Inflammatory: 36.9 (range: 20 to 80)
- Baseline IGA Scores
  - Moderate (3): 81%
  - Severe (4): 19%

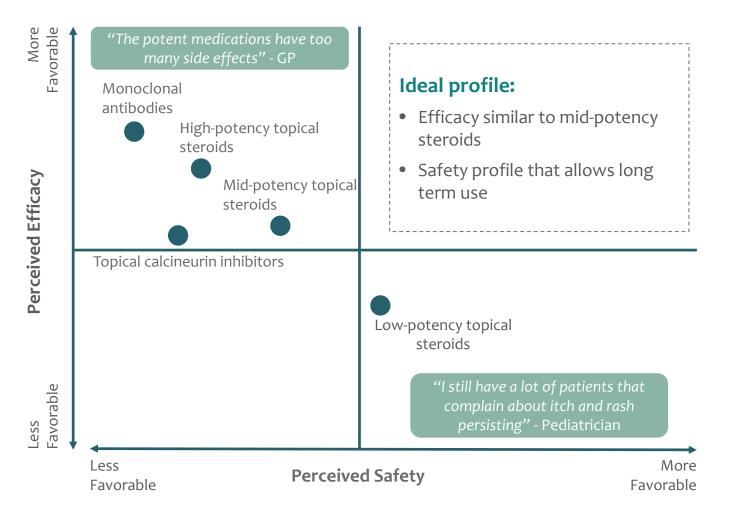
### Safety

- 18 subjects completed the study
  - Lost to follow-up: 2; Withdrawal: 1
- No serious adverse events (AEs)
- No subjects discontinued due to an AE
  - Total of 7 AEs reported (not related)
  - Of the 7 AEs only 1 AE was deemed to be possibly related (mild sore eyes)
- Tolerability
  - Slight burning / stinging in 4 subjects
  - Slight dryness in 2 subjects



# BTX 1204 positioning and opportunity

Botanix is targeting efficacy improvements with much better safety profile than monoclonal antibodies and high potency steroids



# BTX 1204 has potential to meet a number of unmet needs....

- Non-steroidal treatment option
- Increased impact of pruritus
- Improved safety profile and elimination of severe adverse side effects
- Ability to use long term (>12 weeks)
- Address underlying inflammation
- Correct skin barrier dysfunction
- Greater cost effectiveness



## Disclaimer

This presentation prepared by Botanix Pharmaceuticals Limited ("Company") does not constitute, or form part of, an offer to sell or the solicitation of an offer to subscribe for or buy any securities, nor the solicitation of any vote or approval in any jurisdiction, nor shall there be any sale, issue or transfer of the securities referred to in this presentation in any jurisdiction in contravention of applicable law. Persons needing advice should consult their stockbroker, bank manager, solicitor, accountant or other independent financial advisor.

This document is confidential and has been made available in confidence. It may not be reproduced, disclosed to third parties or made public in any way or used for any purpose other than in connection with the proposed investment opportunity without the express written permission of the Company.

This presentation should not be relied upon as a representation of any matter that an advisor or potential investor should consider in evaluating the Company. The Company and its related bodies corporate or any of its directors, agents, officers or employees do not make any representation or warranty, express or implied, as to the accuracy or completeness of any information, statements or representations contained in this presentation, and they do not accept any liability whatsoever (including in negligence) for any information, representation or statement made in or omitted from this presentation.

This document contains certain forward looking statements which involve known and unknown risks, delays and uncertainties not under the Company's control which may cause actual results, performance or achievements of the Company to be materially different from the results, performance or expectations implied by these forward looking statements. The Company makes no representation or warranty, express or implied, as to or endorsement of the accuracy or completeness of any information, statements or representations contained in this presentation with respect to the Company.

It is acknowledged that the Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this presentation except as required by law or by any appropriate regulatory authority.

