

**ASX/Media Release**

**13 November 2017**

**Investor Presentation**

**Sydney, 13 November 2017:** Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or the “Company”) is pleased to release an updated investor presentation, to be presented at the Botanix AGM in Perth (Tuesday 14 November) and 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: rapid operational progress over the last 12 months; lead clinical development program (BTX 1503) for acne; dermatitis clinical program (BTX 1204); development of other pipeline products; Permetrex™ collaborations 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, 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 has a well-established safety profile. Botanix has successfully completed its first-in-man studies with BTX 1503 and is currently conducting a follow-on clinical trial with acne patients in 2H 2017. 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 for acne and its pipeline of other Permetrex™ enabled products alone, or in collaboration with partners.

For more information on Botanix, please visit [www.botanixpharma.com](http://www.botanixpharma.com) or follow us on Twitter @Botanixpharma.

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# botanix

PHARMACEUTICALS



RESTORING HEALTHY SKIN

Roadshow and AGM Presentation  
November 2017



# Investment highlights

Botanix is one of the most compelling emerging companies on the ASX

## Dermatology Focused

- Targeting a **multi-billion dollar market for acne therapeutics** with **no new products approved in the last 20 years**
- Not typical biotech – much **faster development pathway** for dermatology products, **drives lower costs** and much **quicker timeline to approval**

## Novel Approach

- Lead products based on synthetic form of well-studied drug “cannabidiol” - **greatly enhances the probability of clinical and regulatory success**
- **Exclusive global rights to use Permetrex™** delivery technology for all skin diseases, with **potential to deliver near term partnerships and revenues**

## Experienced Team

- Predominantly US based leadership team with **20+ FDA approvals** between them
- Advanced lead product from formulation to successful clinical trial **within 12 months** and **advanced second product into clinic within 18 months**



# Corporate overview

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

## Trading information

Share price (9-Nov-17)	A\$0.050
52 week low / high	A\$0.039 / A\$0.072
Shares outstanding <sup>1,2</sup>	543.1
<b>Market capitalisation</b>	<b>A\$27.2m</b>
Cash (as at 30-Sep-17)	A\$4.2m
Debt (as at 30-Sep-17)	-
<b>Enterprise value</b>	<b>A\$22.9m</b>

## Top shareholders (Nov 2017)

Shareholder	%
Matthew Callahan – <i>Executive Director</i>	13.0
Caperi Pty Ltd – <i>Co-founder</i>	13.0
Board and management (excl. shareholders above)	3.7

## Share price performance



Source: IRESS

- Includes 156.5m fully paid ordinary shares subject to escrow until 15 July 2018
- Excludes 47.9m unlisted options with exercise price range of A\$0.03 - A\$0.07 and expiry date range of Jan 2018 to May 2020



# Senior leadership: track record of success

Proven industry professionals with experience in rapid development of pharmaceuticals



**Mr Matthew Callahan**  
Executive Director



*corporate + IP*

- 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



**Dr Bill Bosch**  
Executive Director



*manufacturing + IP*

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



**Dr Michael Thurn**  
Chief Operating Officer



*ops + regulatory*

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



**Mr Mark Davis**  
VP Clinical and regulatory



*regulatory + clinical*

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

**20+ FDA approved products**





# Clinical programs with near term milestones

Two programs in patient studies, with partnerships on the Permetrex™ technology to augment revenue and news flow in the near term

Product Candidate	Indication	Pre-Clin	Ph I	Ph Ib	Ph II	Next milestones
Synthetic Cannabidiol	BTX 1503	Moderate to Severe Acne	Completed	Completed	In Progress	Phase Ib patient data available 1Q CY2018
	BTX 1204	Atopic Dermatitis	Completed	Completed	In Progress	Phase Ib patient data available 1H CY2018
	BTX 1308	Psoriasis	In Progress			Pre-clinical testing 1Q CY2018
Permetrex™ Enabled	BTX 1701	Acne Cleanser	In Progress	In Progress		Pilot patient study start 1Q CY2018
	BTX 1801	Not disclosed	In Progress			Formulation complete 4Q CY2017

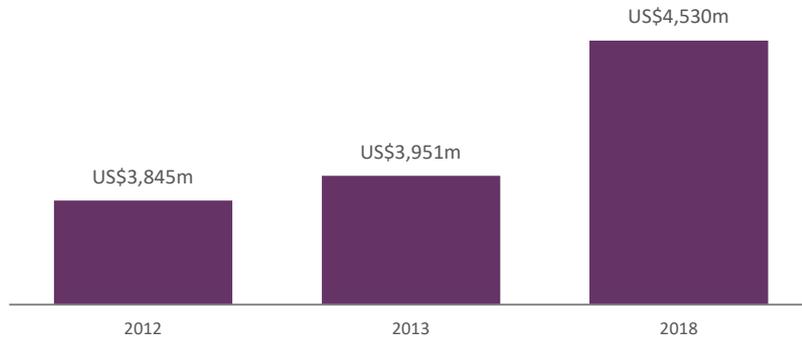


# Why are we focused first on acne?

Global prescription market expected to grow to >US\$4.5bn by 2018

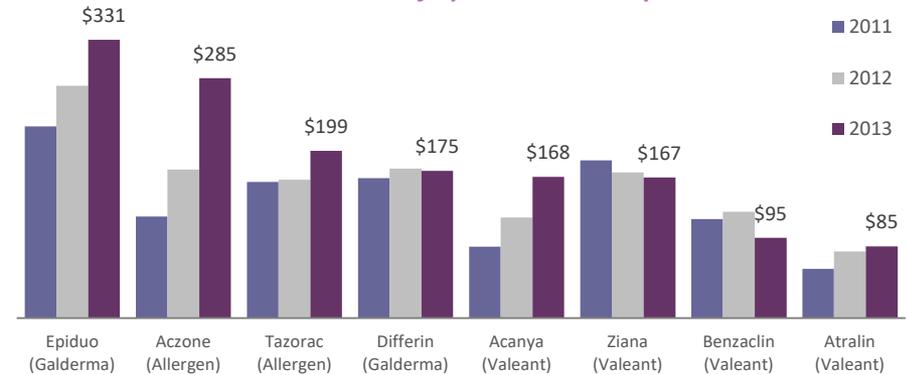
## Global prescription acne product revenues (topical and oral treatments)

*Value of the global acne prescription market is expected to reach US\$4.5bn by 2018<sup>1</sup>*



## Annual topical prescription acne product revenues

*Top branded acne products containing only generic drugs have achieved revenues of up to >US\$300m p.a.<sup>2</sup>*



## Large demand with limited recent product development

- 50 million patients (in the US alone) used an acne product in 2015
- 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

1. BCC Research, May 2013. Skin Disease Treatment and Global Markets  
 2. Symphony Health Solutions, Pharmaceutical Audit Suite for 2012 as reported in Demira S1



# How does BTX 1503 work to treat acne?

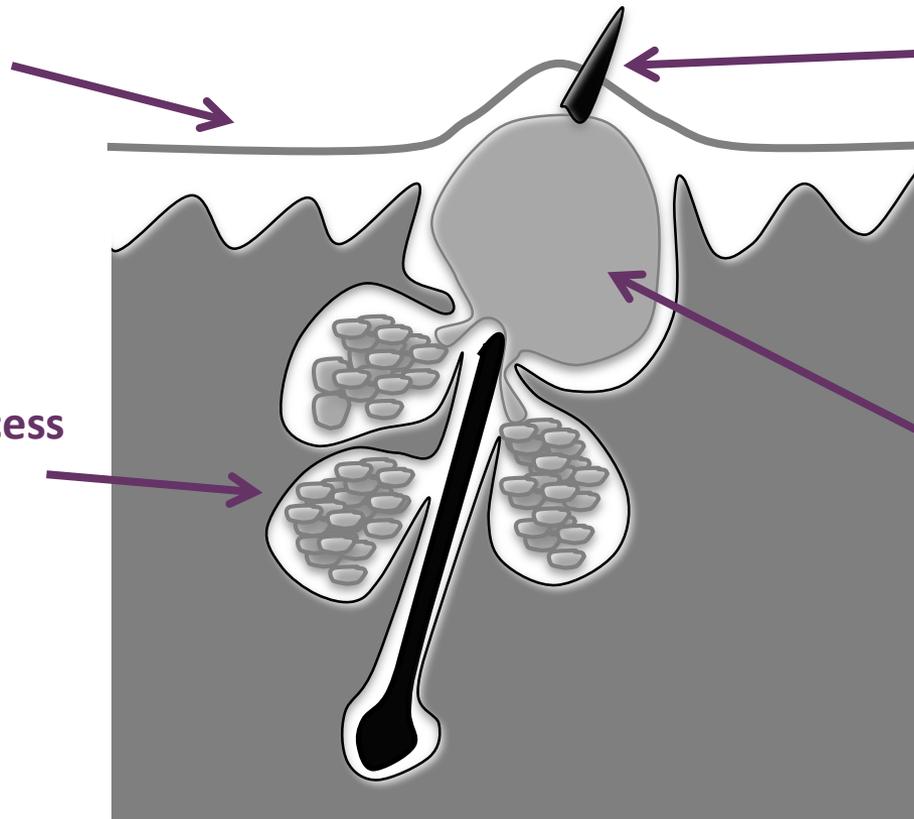
BTX 1503 utilises synthetic cannabidiol combined with a novel skin delivery technology

**Attacks *P. Acnes* bacteria**

**Reduces Inflammation**

**Switches off excess production of sebum**

**Retards formation of sebum "plugs"**





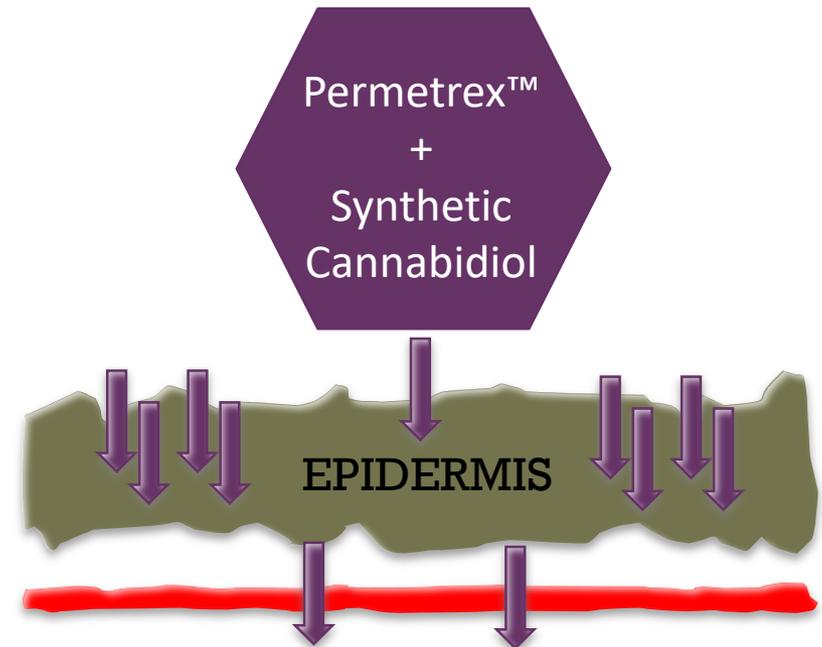
# BTX 1503 Phase Ia clinical trial results

BTX 1503 utilises synthetic cannabidiol combined with a novel skin delivery technology

## Safety, Tolerability and Irritation

- BTX 1503 displayed an **excellent safety profile**
- **Little to no evidence of skin irritation** observed across all dose levels
- **No severe adverse events recorded** and the incidence of **other adverse events was very low**
- Most common adverse event was mild dryness - consistent with the mechanism of action of BTX 1503

## Effective delivery into and deposition in the skin



Significant deposition into the skin –  
very little into the blood stream



# BTX 1503 market positioning

BTX 1503 has the potential to be the market leading branded product for acne treatment, with no undesirable side effects

## Market landscape for acne treatments<sup>1</sup>

- BTX 1503 has multiple mechanisms of action that address the key pathogenic factors that cause acne – not just symptoms
- While systematic therapies (i.e. Accutane) may inhibit sebum (skin-oil) production, its use is limited by very serious side-effects
- Significant unmet need for an effective therapy that targets the causes of acne but does not have the undesirable side effects
- Leading existing treatments fetched annual revenues in the range of US\$700m-US\$800m when they were patented products
- BTX 1503’s patent protection is a significant competitive advantage, as all other treatments below are now generic products

Method of action	 BTX 1503	 Clindamycin	 Tretinoin	 Adapalene	 Minocycline	 Erythromycin	 Accutane
Reduces excessive sebum (skin oil) production	✓						✓
Anti-inflammatory	✓		✓	✓			✓
Anti-bacterial	✓	✓			✓	✓	✓
Topical (applied to a specific area of the body)	✓		✓	✓			
Minimal side effects	✓		✓	✓		✓	
Patent protected (not a generic product)	✓						

1. Subject to successful development and approvals

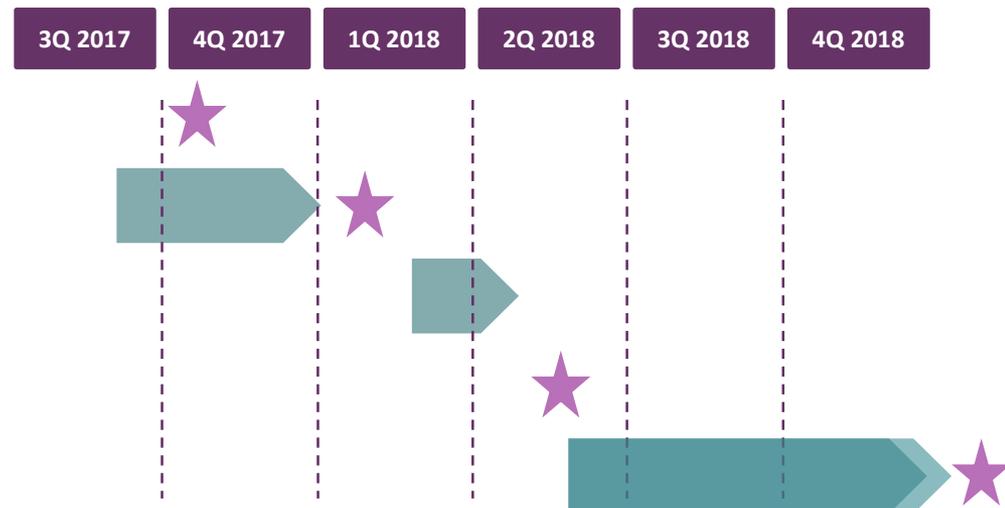
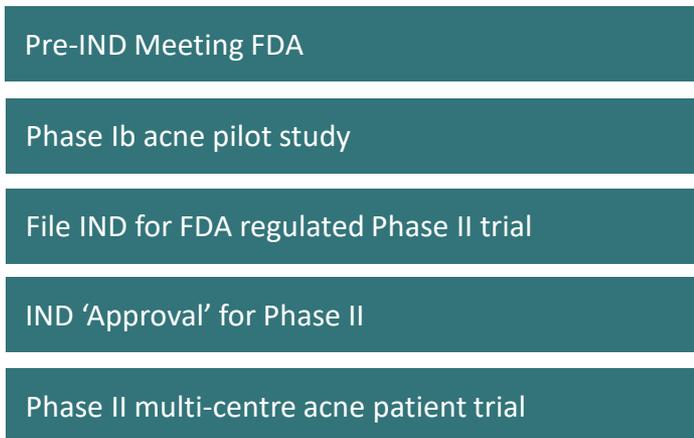


# BTX 1503 acne patient study underway

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

- Phase Ib acne pilot study currently underway, with study enrolment complete in 4Q CY2017 and data expected to be available in 1Q CY2018
- In October 2017, Botanix successfully completed a Pre-IND meeting with the FDA for BTX 1503 acne product – FDA confirmed the proposed development plan and data package to allow Phase 2 clinical development in the US
- BTX 1503 well placed to commence FDA regulated Phase 2 clinical study in 1H CY2018

## BTX 1503 indicative clinical timeline (CY)

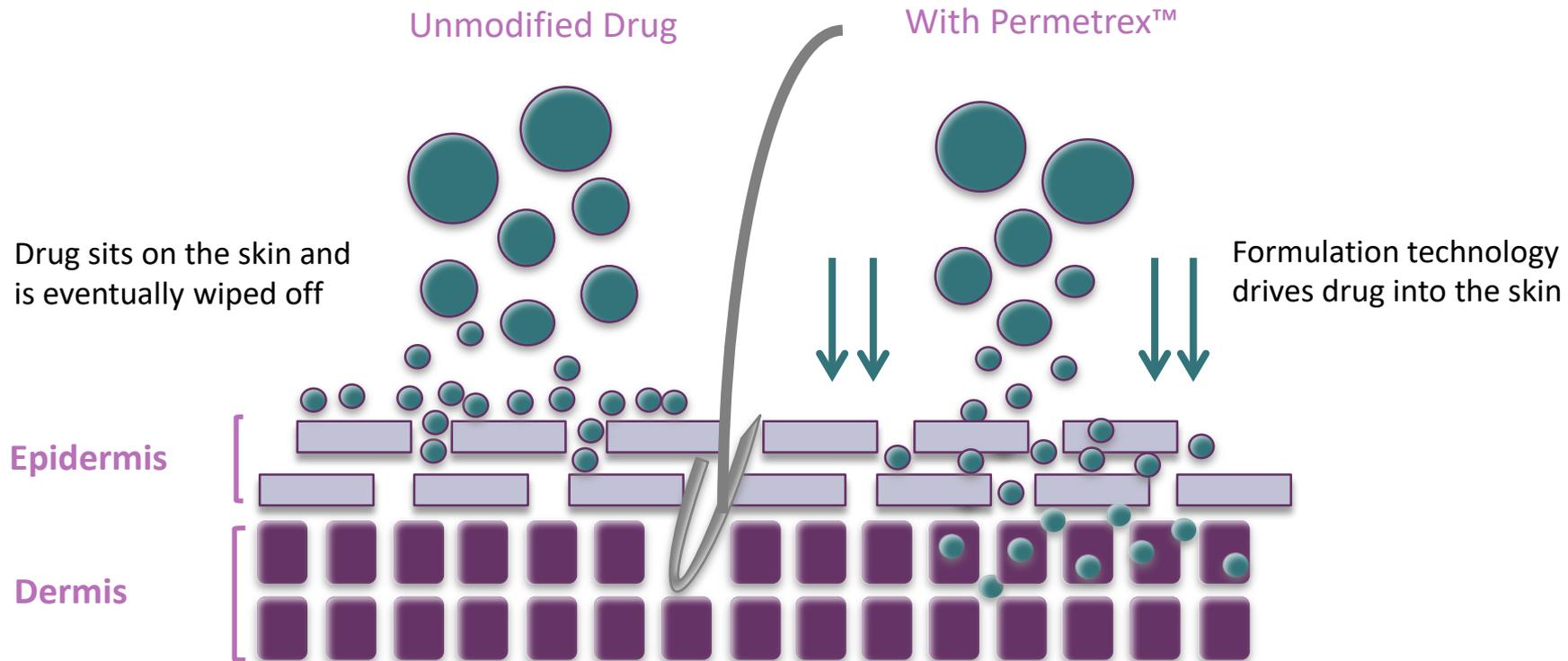


★ Milestones



# Permetrex™ skin delivery technology

Permetrex™ delivers high doses of synthetic cannabidiol directly 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™ for all drugs that treat skin diseases



# BTX 1204 for atopic dermatitis

Phase Ib patient study commenced in late October, with data planned for 2Q 2018

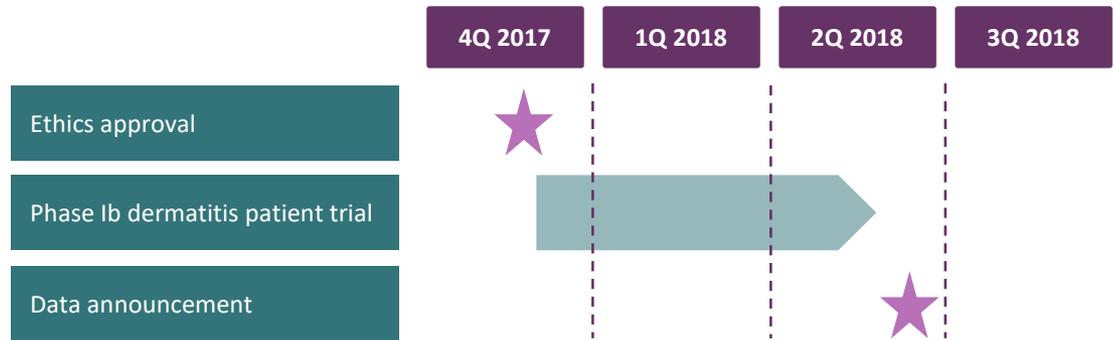
## Market overview

### BTX 1204: dermatitis

- **Target market:** US patient incidence estimated to be 25 million people (10% to 18% of children)
- **Market size:** estimated annual cost of treating atopic dermatitis in the US is ~US\$4bn
- **Current issues:** most treatments on the market (i.e. steroids) only address the symptoms



## BTX 1204 indicative clinical timeline (CY)

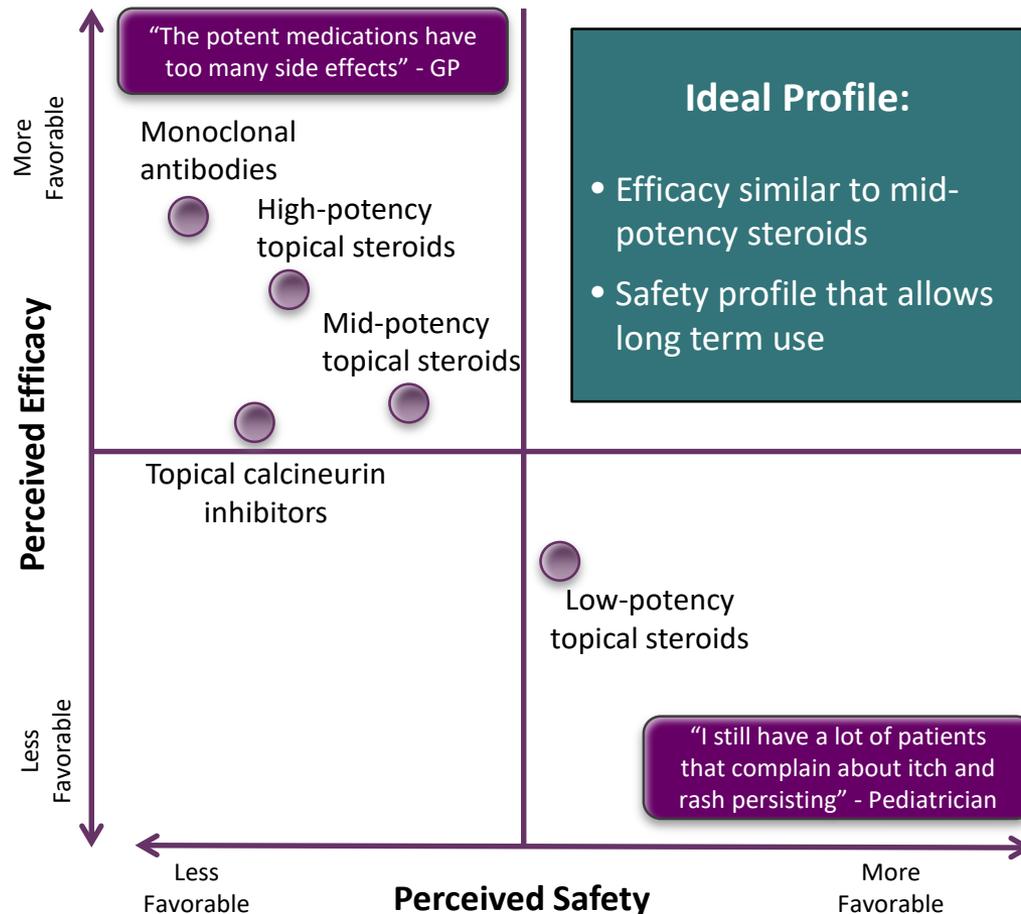


- Received Human Research Ethics Committee approval recently (late October 2017) to commence Phase Ib dermatitis patient study
- Enrolment of patients to commence in 4Q CY2017, across 4 leading dermatology clinics in Australia
- Expected study completion in 1H CY2018 – Phase Ib study focused on assessing safety and indications of efficacy of BTX 1204
- Study demonstrates Botanix’s ability to accelerate the addition of clinical programs by leveraging previous clinical data from acne program



# BTX 1204 positioning and opportunity

Targeting efficacy improvements with much better safety profile than monoclonal antibodies and high potency steroids



## Market comparable



- **Product:** Crisaborole® - a non-steroidal anti-inflammatory PDE-4 inhibitor
- **Data:** Phase 3 studies showing a pooled improvement of ~ 10% over placebo
- **Opportunity:** Forecast to generate sales of ~US\$750m p.a.
- **Deal:** Pfizer acquired Anacor for US\$5.2bn in late 2016



# 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 (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 have serious side effect issues (including lymphoma)

*Intend to undertake study in pre-clinical skin models in 1Q CY2018*

## BTX 1701: mild acne

- **Target market:** ~50m Americans have acne – symptoms vary in seriousness
- **Market size:** ~US\$1.5bn p.a. – pilot study validated prospective activity vs. leading competitor
- **Current issues:** existing products use high levels of preservatives or alcohol which dry and irritate skin

*Intend to undertake small patient study in 1Q CY2018*

These products leverage data from the BTX 1503 synthetic cannabidiol clinical program and/or the Permetrex™ delivery system studies



*Psoriasis*



*Mild Acne*



# Permetrex™ collaborations advancing

Third party dermatology companies working with Botanix to solve drug delivery problems for their molecules

## Early collaborations leading to license discussions

- Many companies have challenges formulating drugs for delivery into the skin
- Botanix is working with multiple parties to test application of Permetrex™ technology to solve problems that have arisen in clinical studies
- Engagement generally starts as fee-for-service by Botanix
- License trigger is generally proof of concept human study
- Traditional license structure likely (upfront payments, milestones, royalties)





# Achievements since listing in July 2016

Botanix has advanced 2 products into the clinic within 18 months, progressed 3 pipeline products and leveraged Permetrex™ technology into a number of collaborations

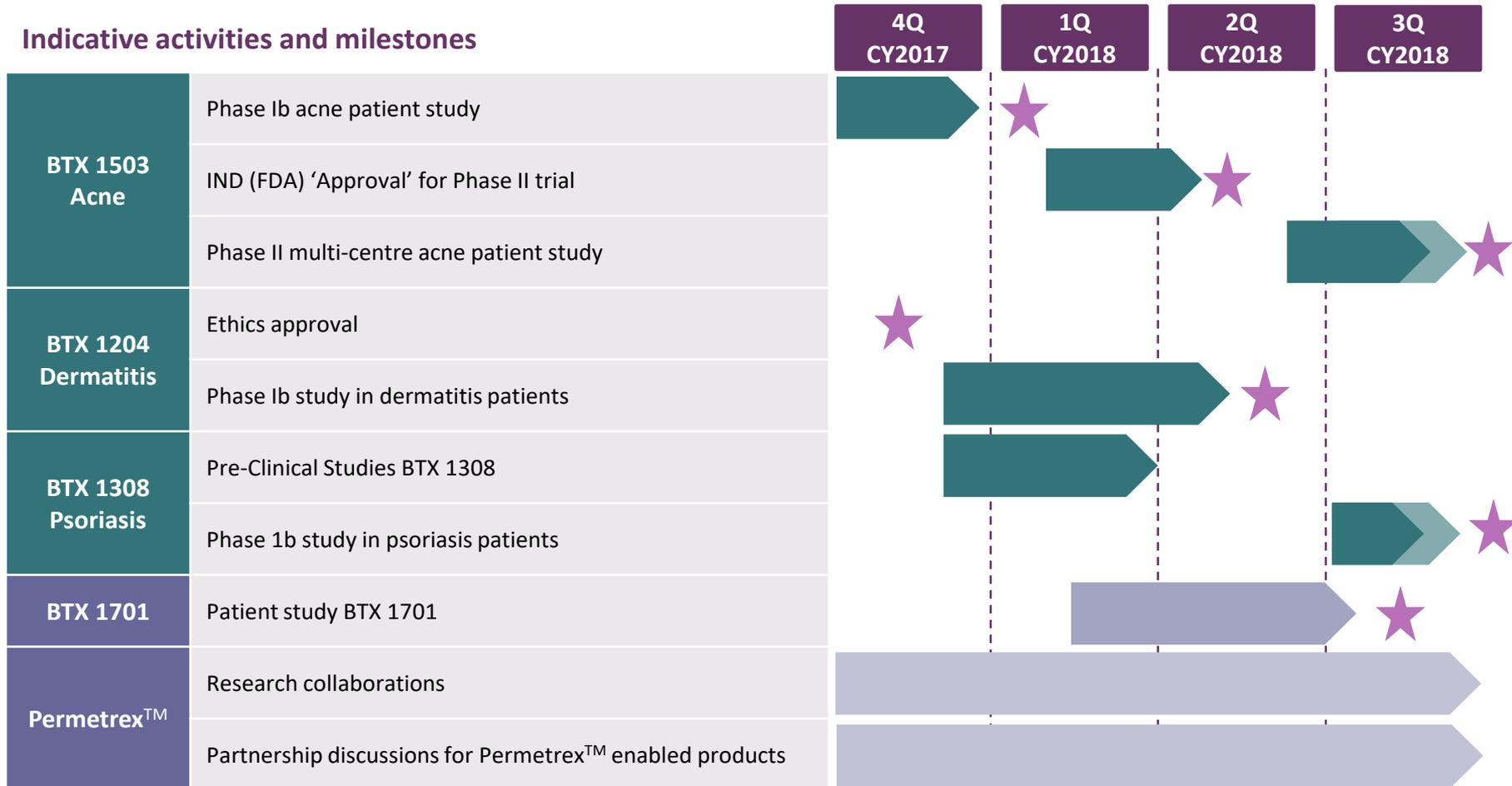
Clinical Programs	BTX 1503 Acne		<ul style="list-style-type: none"><li>• Successful Phase 1a clinical study</li><li>• First acne patient studies underway</li><li>• Successful Pre-IND meeting with FDA</li></ul>
	BTX 1204 Dermatitis		<ul style="list-style-type: none"><li>• Pre-clinical and formulation completed</li><li>• Leveraged BTX 1503 data to skip Phase 1a</li><li>• First dermatitis patient studies underway</li></ul>
	BTX 1308 Psoriasis		<ul style="list-style-type: none"><li>• Formulation and pre-clinical studies</li><li>• Leveraged BTX1503 data to skip Phase 1a</li><li>• Psoriasis model studies underway</li></ul>
Permetrex™ Pipeline	BTX 1701 Acne Cleanser		<ul style="list-style-type: none"><li>• Pilot patient study completed</li><li>• Commercial review undertaken</li><li>• Prep for patient study underway</li></ul>
	BTX 1801 + Permetrex™		<ul style="list-style-type: none"><li>• New product leveraging Permetrex</li><li>• Collaborations with derm companies</li><li>• More pipeline products in development</li></ul>
General	Corporate and Operations		<ul style="list-style-type: none"><li>• Established US and Aus operations</li><li>• Built experienced team in dermatology</li><li>• Rapid advancement – solid planning</li></ul>



# Near term key catalysts

Significant operational milestones expected over the next 12 months, as Botanix advances key products, broadens pipeline and undertakes corporate development

## Indicative activities and milestones





Appendix



# Botanix Board of Directors

Highly credentialed Board of Directors with a proven record of building and leading successful pharmaceuticals businesses



**Graham Griffiths**  
**Chairman**  
*Appointed July 2016*

- 40 years executive experience in technology based companies, across sales, marketing and product development
- Former Managing Director of ipernica, responsible for acquisition and commercialisation of nearmap.com (ASX:NEA)
- Non-Executive Director of Pointerra (ASX:3DP), iperative and NGIS Australia



**Commercialisation**



**Matthew Callahan**  
**Executive Director**  
*Appointed July 2016*

- Founding CEO of iCeutica and Churchill Pharmaceuticals
- Co-inventor of iCeutica's SoluMatrix Technology
- Developed 3 FDA approved products
- Investment director at 2 venture capital firms
- 20 years experience in legal, IP and investment management
- Director of Orthocell (ASX:OCC) and Glycan Bioscience LLC



**Corporate and IP**



**Dr Bill Bosch**  
**Executive Director**  
*Appointed July 2016*

- 20 years experience in the pharmaceutical industry
- Co-inventor of iCeutica's SoluMatrix Technology
- Developed 6 FDA approved products
- Developed 4 commercial nanotechnology products at Elan Corporation
- Co-founder of NanoSystems LLC and co-inventor of NanoCrystal Technology



**Manufacturing and IP**



**Rob Towner**  
**Director**  
*Appointed July 2016*

- 20 years corporate advisory experience
- Founder and sole director of Cornerstone Corporate
- Founding Executive Director of bioMD
- bioMD merged with Allied Health Care in 2011 to form Admedus (ASX:AHZ, \$200m market capitalisation)
- Executive Director of Triangle Energy (ASX:TEG)



**Financing and capital markets**



# Botanix executive management

Highly credentialed clinical development team with extensive expertise in leading novel products through clinical and regulatory development



**Mr Mark Davis**  
VP Clinical and Regulatory

- 30 years of clinical experience with 19 FDA approved products
- Unique experience with cannabidiol through Insys
- Former clinical lead with Medicis and Connetics

Clinical and regulatory



**Dr Michael Thurn**  
Chief Operating Officer

- Extensive start up life sciences experience across a range of technology platforms
- +20 years experience in drug regulation, drug discovery, pre-clinical and clinical
- Previous Managing Director of Spinifex Pharmaceuticals

Regulatory and operations



**Dr Gene Cooper**  
Consultant

- 40 years pharmaceutical experience
- 10 FDA approved products
- Expert in skin delivery
- Inventor of Permetrex™

Technology and innovation



**Dr Joel Gelfand**  
Medical Director  
of Clinical Studies

- Professor of Dermatology at the University of Pennsylvania
- Expert in skin disease and clinical trial management

Clinical Studies



**Professor James Leyden**  
Scientific Adviser

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

Key Opinion Leader



**Professor Diane Thiboutot**  
Scientific Adviser

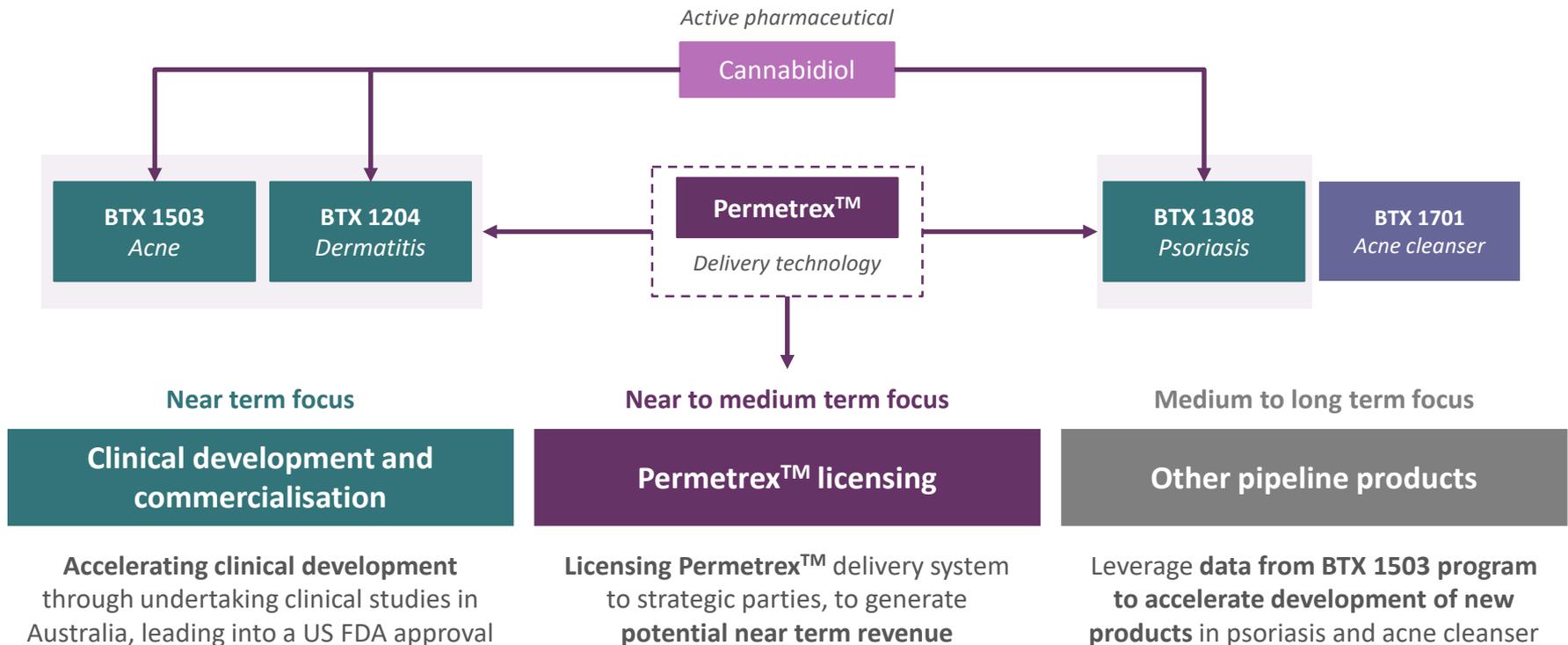
- Professor of Dermatology at Pennsylvania State University
- Researcher in acne and rosacea
- Pre-clinical and clinical trials services provider

Key Opinion Leader



# Strategic and commercialisation focus

Primary strategy is commercialising BTX 1503, advancing BTX 1204, explore licensing opportunities for Permetrex™ and development of a supportive product pipeline





# Recent corporate and product development

Recent developments have provided a strong platform for Botanix to accelerate its clinical development program

## Key milestones over the last 12 months

**Jul 2016 to Feb 2017**  
Key staff hires across key business divisions

**Feb 2017**  
Completed expansion of Permetrex™ license to cover the delivery of drug actives used in treating skin diseases

**Mar 2017**  
Received DEA approval for export and import of synthetic cannabidiol for clinical studies

**Apr 2017**  
Completed A\$7.4m oversubscribed placement

**Aug 2017**  
Commence BTX 1503 Phase Ib Acne patient study

**Oct 2017**  
Received ethics approval for BTX 1204 and commence dermatitis study



4Q CY2016



1Q CY2017



2Q CY2017



3Q CY2017



4Q CY2017

**Nov 2016**  
Manufactured BTX 1503 trial formulation using FDA quality components

**Dec 2016**  
Completed first human safety and irritation study with Permetrex™

**Mar 2017**  
Received ethics approval for BTX 1503, and commenced first clinical study

**June 2017**  
Completion of successful pilot study for BTX 1701 facial cleanser

**July 2017**  
Successful completion of Phase I clinical study for BTX 1503

**Oct 2017**  
FDA clears development path for BTX 1503

Formulation



Safety and Efficacy



Proof of Concept

Key milestones achieved



# Accelerated development timeline

Botanix is executing on an efficient, more economical and less risky clinical development strategy compared to traditional pharmaceutical development pathways

## Botanix’s accelerated clinical timeline

*Proven ability to execute: Achieved since listing*

Phases	Traditional process		Botanix approach	
	Costs (est.)	Timing (est.)	Costs (est.)	Timing (est.)
Discovery and pre-clinical	~\$430m	~5 years	~\$1m	~6 months
Investigational New Drug filing	~\$1m			
Phase I clinical	~\$25m	~7 years	~\$2m	~6 months
Phase II clinical	~\$35m		~\$7m	~28 months
Phase III clinical	~\$54m		~\$23m	
New Drug Application	~\$5m	~2 years	~\$2m	~12 months
Total	~\$460m	~14 years	~\$35m	~4 years

- Accelerated development timeline, due to:
  - Minimal pre-clinical development due to **known safety profile** of cannabidiol
  - Dermatology studies tend to be shorter in duration and require smaller study populations
  - Objective measurements of efficacy** (end points are typically visual assessments)
- Opportunity to generate **near term revenue** from potential licensing agreements for Permetrex™
- In house expertise ensures clinical trials are appropriately designed and efficiently implemented
- Known safety profile **increases probability of successful clinical development**



# Commercialisation strategy

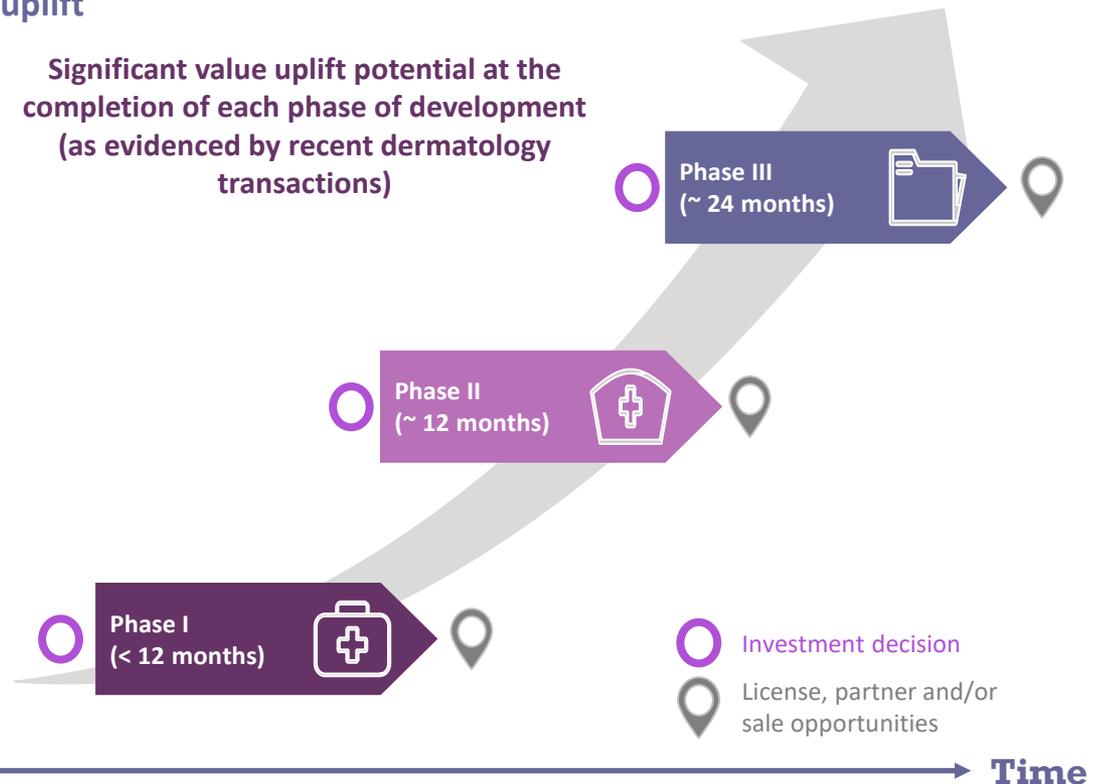
Botanix's focused and accelerated timeline to product commercialisation results in significant potential value uplift

## Efficient commercialisation path with multiple options

- Continued clinical development success is reflected in significant value uplift after each successive phase
  - Typically monetised via licensing, partnering and/or sale/merger opportunities
  - Additional indications can be partnered while pursuing acne focus
- Potential future revenue streams:
  - Product licensing agreements
  - Partnership with strategic parties
  - Product sales revenue

Value uplift

Significant value uplift potential at the completion of each phase of development (as evidenced by recent dermatology transactions)

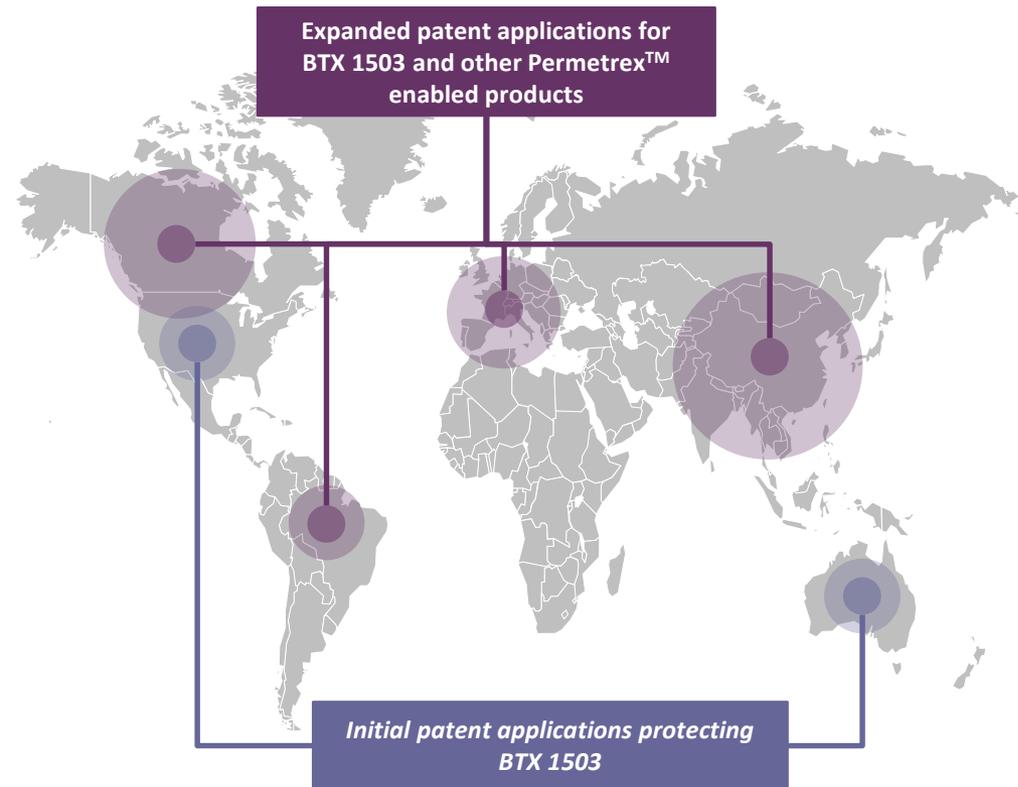




# Valuable intellectual property portfolio

Botanix has protected its suit of development products through various patent applications across key global markets

- Botanix currently has 12 patent applications across 6 different patent families
- Patents applications cover lead acne product and other Permetrex™ enabled products
- Patent protection targeted at key geographic regions with large and viable dermatology markets (i.e. initially filed in US and Australia, but following into the EU, UK, Japan, India, China, South America and other jurisdictions in National phase)
- Botanix positioned as the leading player in the sector – underpinned by substantial volumes of proprietary knowledge, manufacturing know-how and trade secrets
- Additional IP opportunities will be pursued on each Permetrex™ product developed internally or with partners

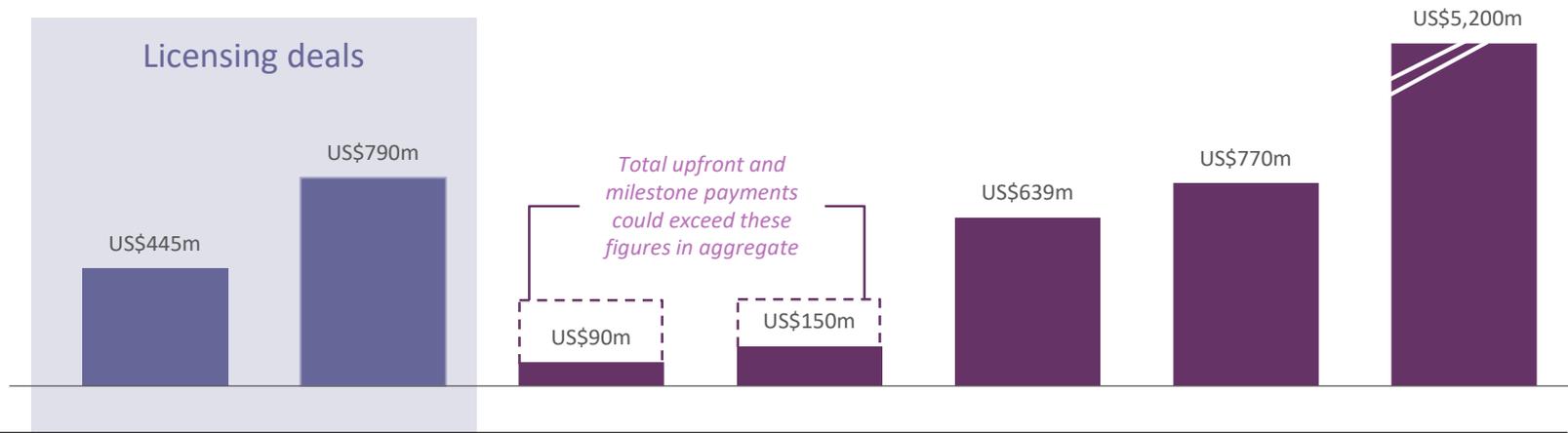




# Recent dermatology transactions

Licensing and partnering transactions are potential monetisation options before product sales, with value increasing significantly as a product progress through the FDA process

## Dermatology transactions



<b>Deal date</b>	Sep 2015	Dec 2016	Jan 2016	Dec 2016	Oct 2016	Apr 2016	May 2016
<b>Deal type</b>	License	License	Corporate	Corporate	Corporate	Asset/business	Corporate
<b>Licensee/Acquirer</b>							
<b>Licensor/Target</b>							
<b>Phase</b>	In Phase III	Completed Phase I	In pre-clinical development	In pre-clinical development / Phase IIb	In Phase II	On market	Completing Phase III

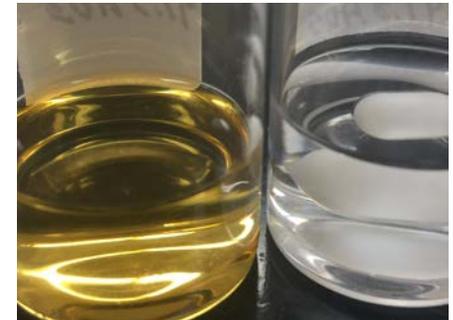
Source: Bloomberg, Company disclosure



# BTX 1503 key advantage: synthetic material

Use of synthetic cannabidiol greatly increases the chance of clinical success and regulatory approval - at a much lower COGS than naturally extracted material

	
Synthetic cannabidiol	Naturally extracted cannabidiol
1 chemical	100+ chemicals
100% pure	Multiple impurities (anything above 0.05% needs to be identified and tested)
Scaled up to 50kg	Scaled up to <1kg
No additional compliance required	Must comply with FDA's "Botanical Drug Development Guidance for Industry" <sup>1</sup>



1. Botanical Drug development – Guidance for Industry. FDA



# Disclaimer

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