

ASX/Media Release

11 July 2017

Non-Deal Roadshow Presentation

Sydney, 11 July 2017: Medical dermatology company Botanix Pharmaceuticals Limited (“Botanix” or the “Company”) is pleased to release a new corporate overview, to be presented to investors 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 first 12 months since listing on ASX, its lead clinical development program (BTX 1503) for acne and recently generated Phase 1a results, plans for progressing BTX1503 rapidly into patient studies in the coming months, development of other pipeline products, as well as key milestones planned for 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 preparing to conduct 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 or follow us on Twitter @Botanixpharma.

For more information, please contact:

General enquiries

Matt Callahan
Botanix Pharmaceuticals Ltd
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 enquiries

Harrison Polites
MC Partners
P: +61 409 623 618
E: Harrison.polites@mcpartners.com.au

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botanix 
PHARMACEUTICALS

RESTORING HEALTHY SKIN

Non-Deal Roadshow
Investor Presentation
July 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 treatments** 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 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 deals and revenues**

Experienced Team

- Predominantly US based leadership team with **20+ FDA approvals** between them
- Advanced lead product from formulation to successful clinical trials **within 12 months** and **created 5 new products using Permetrex™ technology**



Trading information

Top shareholders (as at July 2017)

Share price performance





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**



Vivlodex™



Tivorbex™



MEGACEES



Rapamune®



ZORVOLEX™



Zyclara™



provant
life. changing.



Multiple near term milestones from pipeline

De-risked pipeline of dermatology products, with deals on the Permetrex™ technology to augment revenue and news flow in the near term

Product Candidate	Indication	Pre-Clin	Phase 1	Phase 2	Next Milestones
Synthetic Cannabidiol	BTX 1503	Moderate to Severe Acne			Phase 1b Acne Patient Study Start Q3 CY2017
	BTX 1204	Atopic Dermatitis			Phase 1b AD Patient Study Start Q4 CY2017
	BTX 1308	Psoriasis			Pre-clinical formulation Q4 CY2017
Permetrex™ Enabled	BTX 1701	Acne Cleanser			Patient study start Q4 CY2017
	BTX 1801	Not disclosed			Formulation complete Q3 CY2017

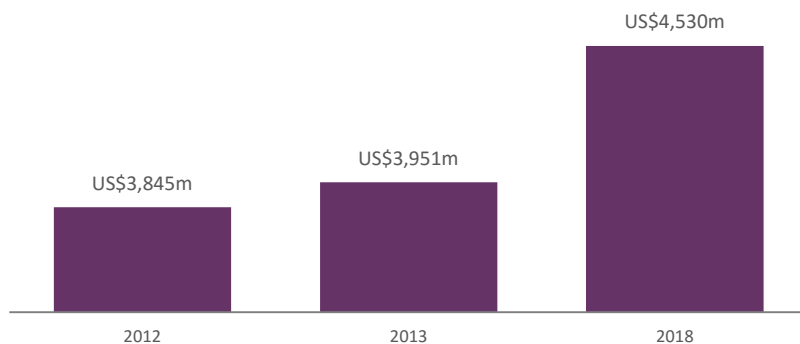


Why are we focused first on acne?

Global prescription market expected to grow to >US\$4.5bn by 2018 and is only a subset of the global dermatology opportunity

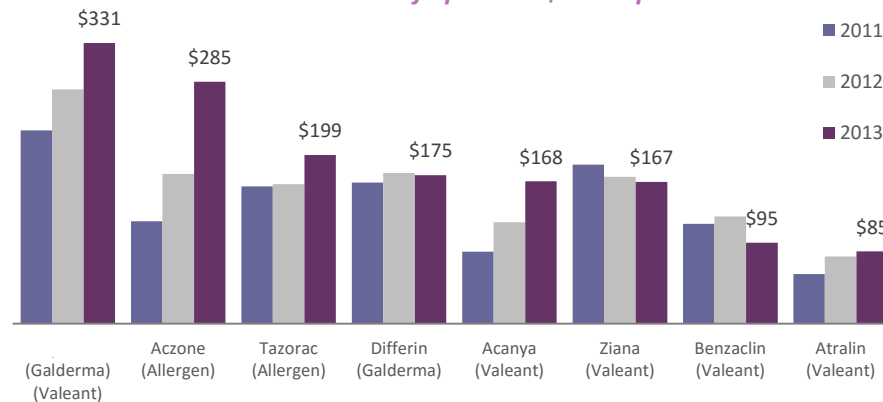
Global prescription acne product revenues (topical and oral treatments)

Value of the global acne prescription market is expected to reach US\$4.5bn by 2018¹



Annual topical prescription acne product revenues

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



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?

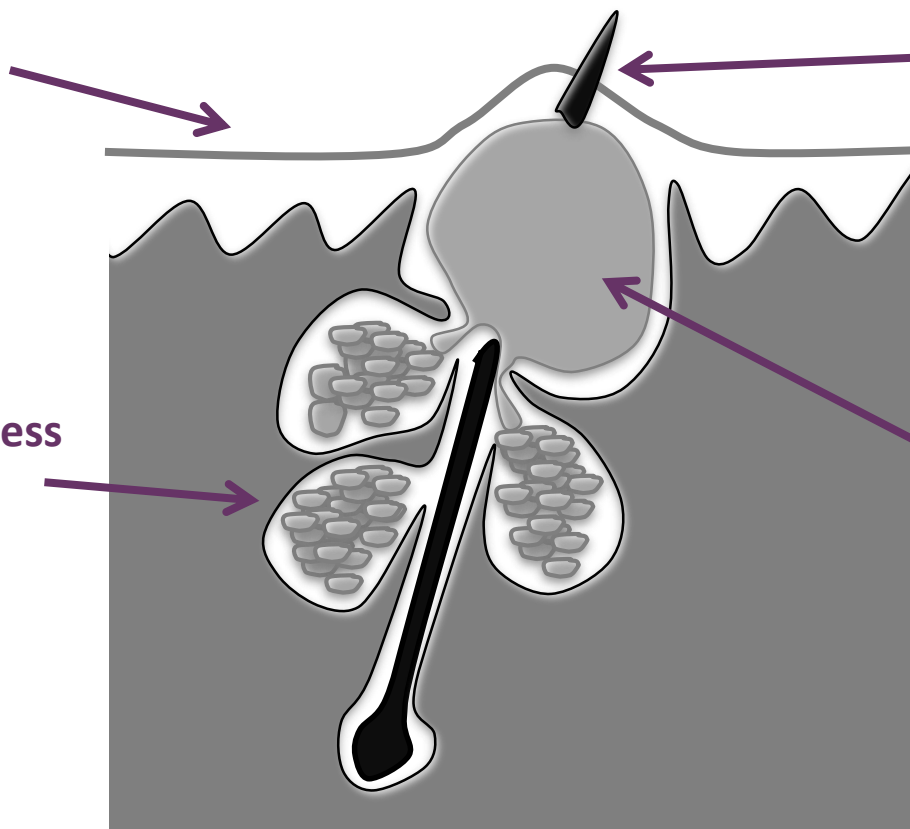
BTX 1503 utilises synthetic cannabidiol combined with a novel skin delivery technology

Attacks *P. Acnes* bacteria

Reduces Inflammation

Switches off excess production of sebum

Retards formation of sebum "plugs"





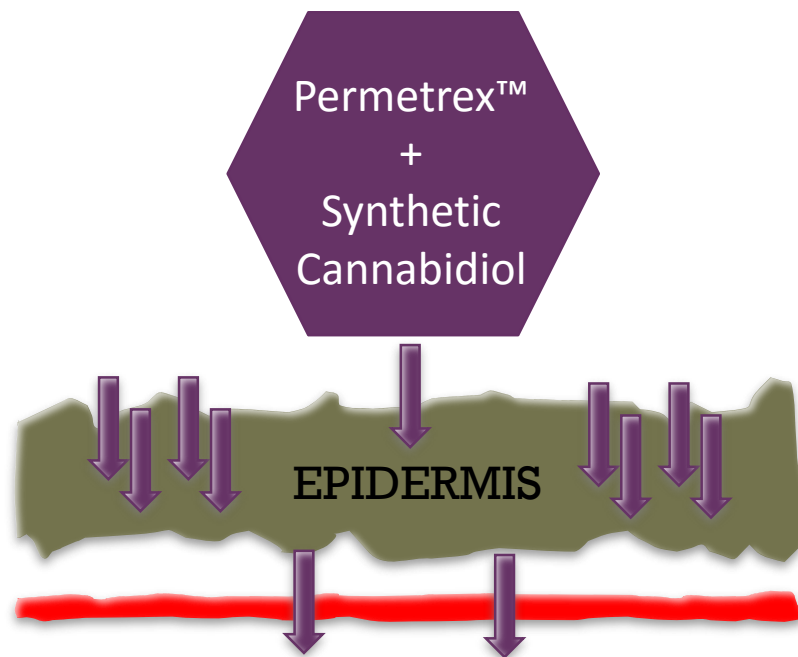
BTX 1503 Phase 1a clinical trial results

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

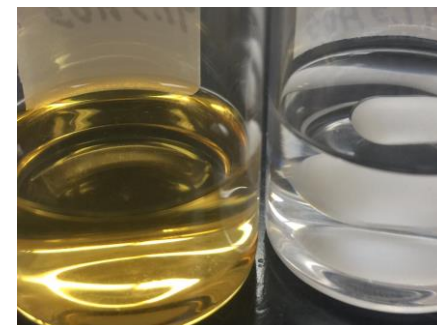




BTX 1503 key advantage 1: synthetic material

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

botanix PHARMACEUTICALS	
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" ¹

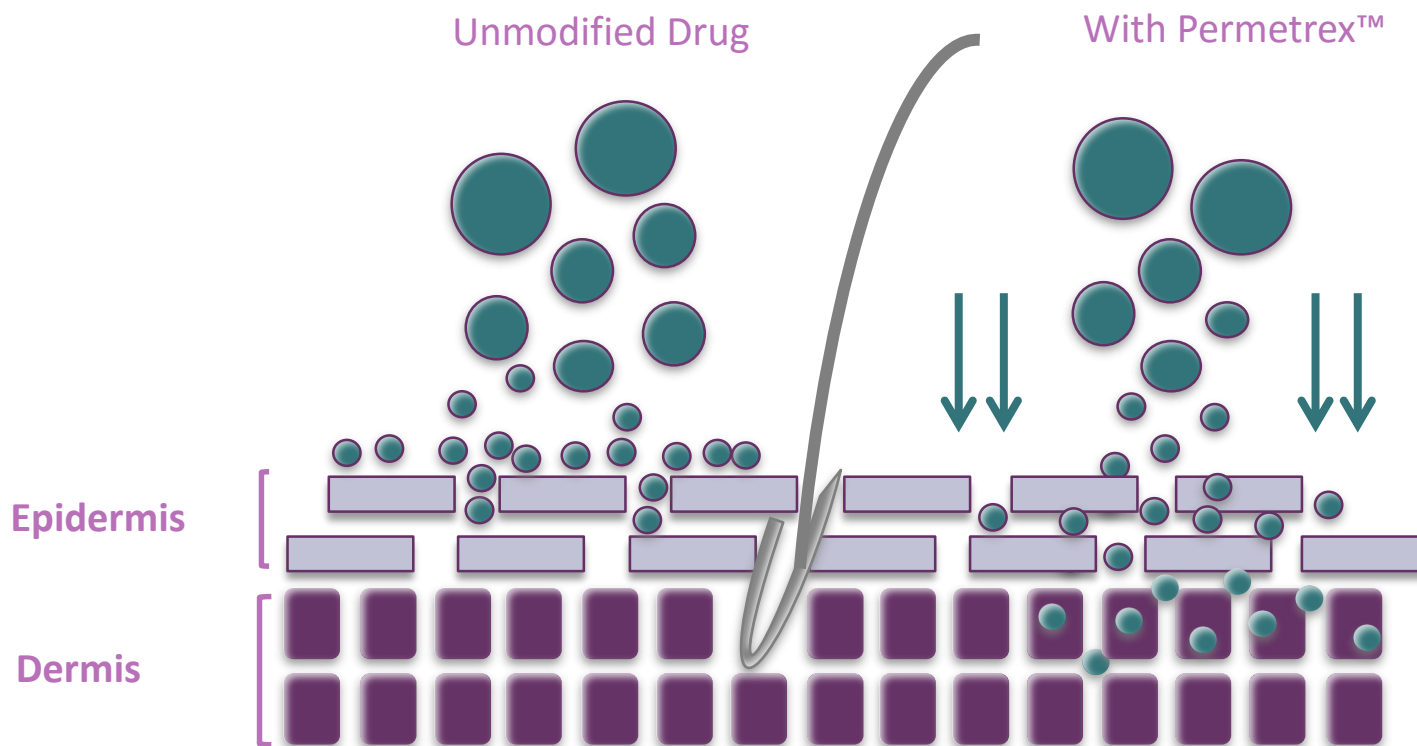


1. Botanical Drug development – Guidance for Industry. FDA



BTX 1503 key advantage 2: drug delivery

Permetrex™ technology drives synthetic cannabidiol directly into the skin – oral administration only delivers ~6% to the blood



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










BTX 1503 market positioning

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

Market landscape for acne treatments¹

- BTX 1503 has multiple mechanisms of action that directly treat the key pathogenic factors causing acne, making it a potentially superior treatment to existing therapies
- While systematic therapies (i.e. oral isotretinoin) 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 cause of acne (i.e. sebum production) and does not have the undesirable side effects associated with traditional acne treatments
- Significant market opportunity; major 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 relevant successful development and approvals

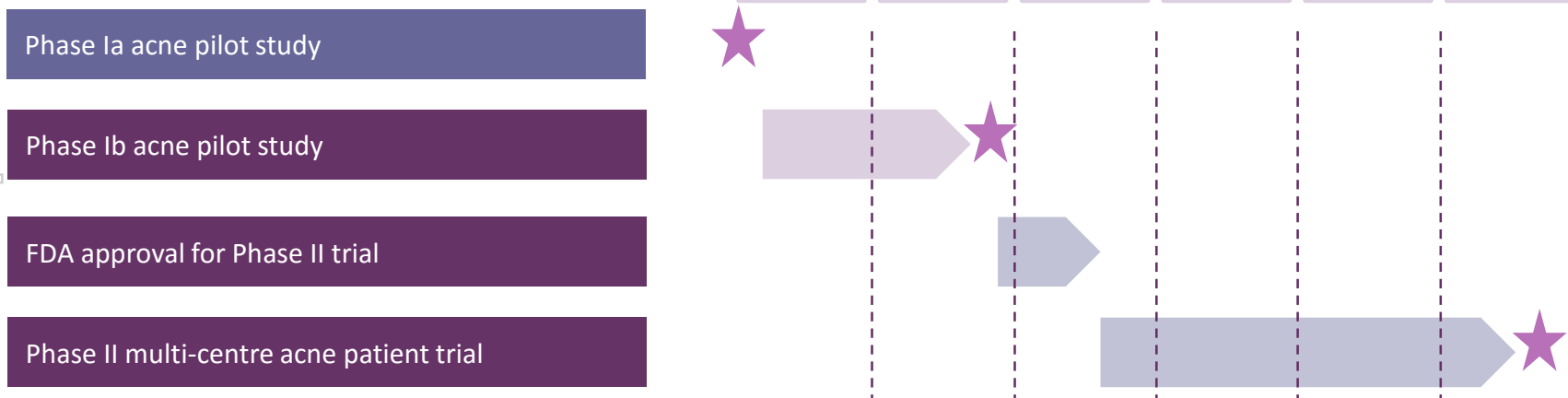


BTX 1503 accelerated clinical development

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

- First enrolment of Phase Ib acne pilot study expected to commenced in August 2017, with study data expected to be available in 4Q CY2017
- Botanix is fully funded for the Phase Ib clinical trial of BTX 1503, with potential further funding from Permetrex™ licensing revenues

BTX 1503 indicative clinical timeline



Clinical milestones where potential development partnerships and/or licensing agreements may be considered



Clinical development pipeline

Development pipeline also includes other synthetic cannabidiol clinical products targeting key dermatology markets

BTX 1204: dermatitis

- **Target market:** US patient incidence estimated to be 31 million (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

These products will leverage both the BTX 1503 synthetic cannabidiol clinical program as well as the Permetrex™ delivery system

BTX 1308: psoriasis

- **Target market:** 7.5 million Americans have psoriasis (most have plaque psoriasis)
- **Market size:** estimated annual costs of injectable biologic treatments in the US is ~US\$20bn
- **Current issues:** biologic drugs are very expensive have serious side effect issues (including lymphoma)



Psoriasis



Dermatitis



Non-cannabidiol pipeline advancing quickly

Development pipeline includes a Permetrex™ enabled product with near term revenue potential - could be developed and marketed without FDA approval

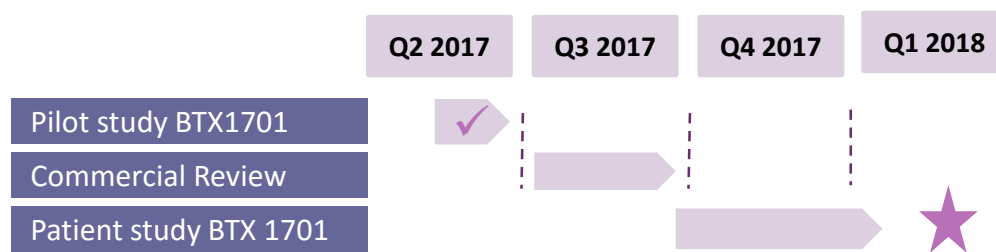
Product overview

BTX 1701: acne cleanser

- **Safety:** Successful pilot human study completed, demonstrating a positive safety profile
- **Efficacy:** Pilot study validated prospective activity in removing skin oiliness and reducing bacteria
- **Market size:** for acne cleansers > US\$1.5bn+ p.a.



Indicative development timeline for BTX 1701



- Botanix is reviewing multiple commercialisation strategies and will elect the option that delivers the highest shareholder value for the investment
- Potential for accelerated advancement as this product could be developed and marketed without FDA approval
- Permetrex™ enabled formulation has competitive advantages over incumbent brands, many of which contain alcohol and preservatives that can actively dry out the skin and/or cause allergic reactions



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)

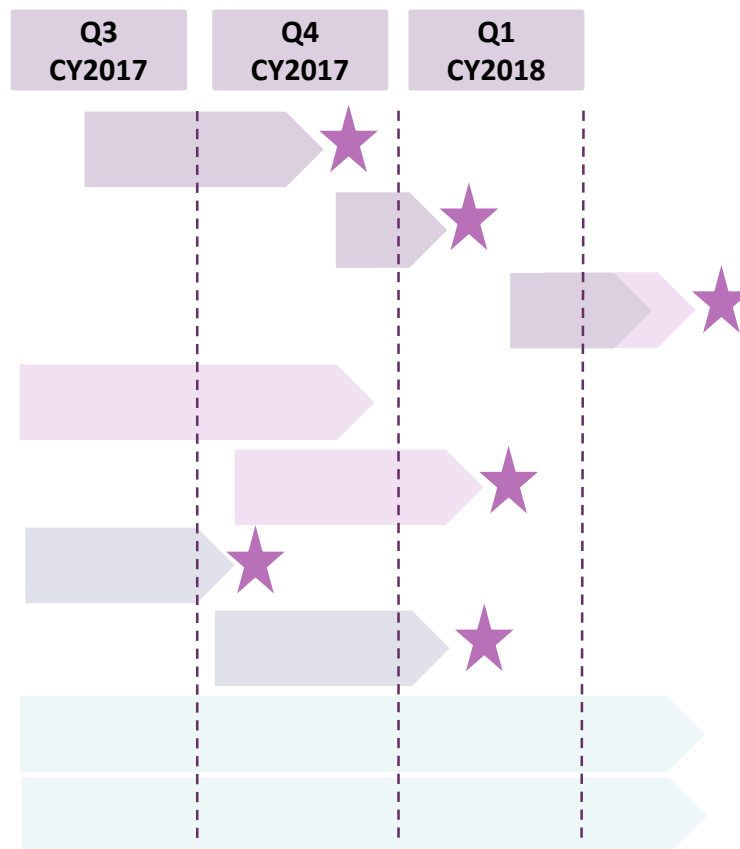




Botanix key catalysts

Significant operational milestones expected over the next 9 months, as Botanix advances BTX 1503, broader pipeline and corporate development

Indicative activities and milestones



Milestones where potential licensing deals may be considered



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

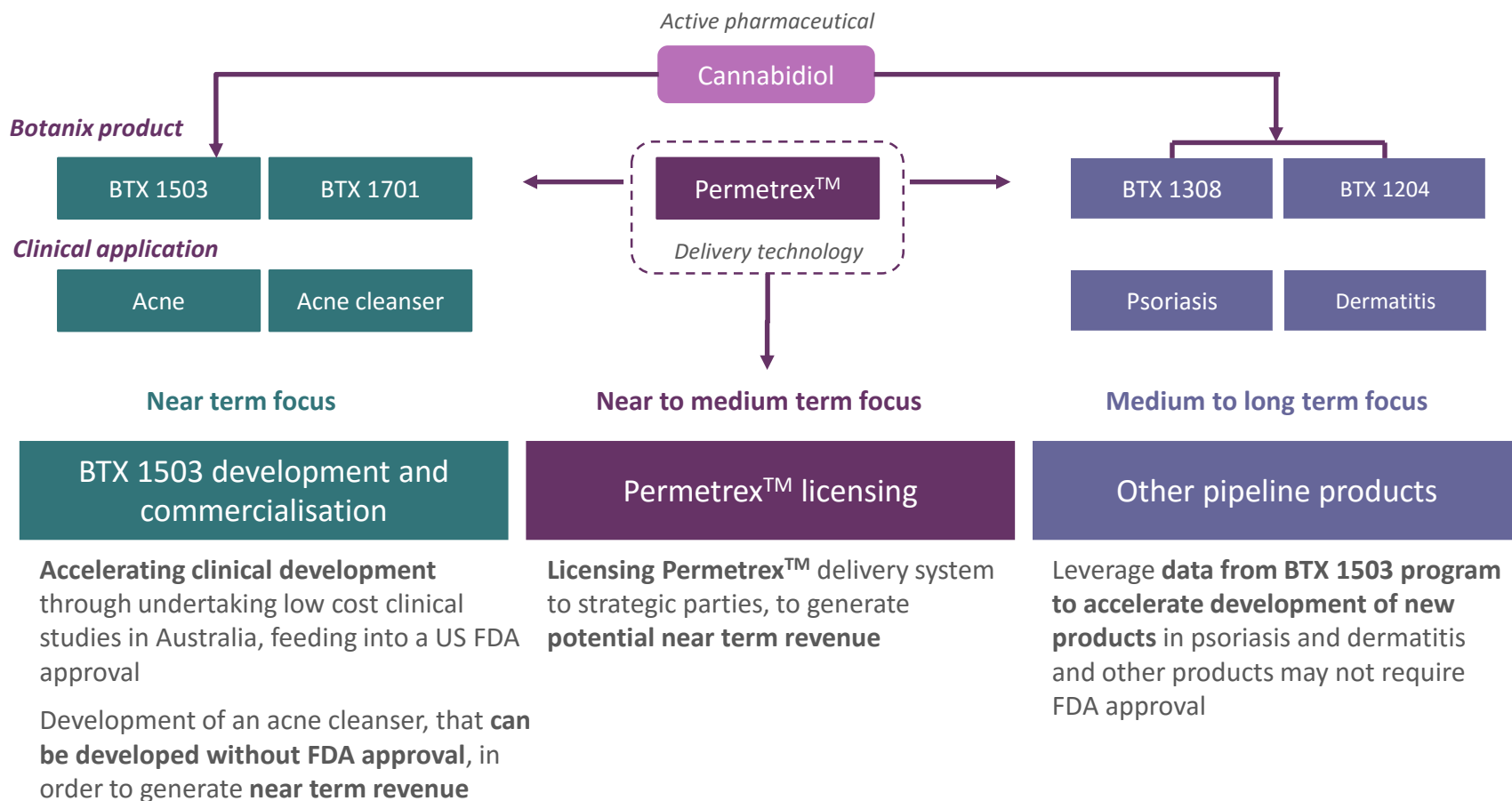
Key Opinion Leader

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Strategic and commercialisation focus

Primary strategy is commercialising BTX 1503, with a supportive pipeline of other medical dermatology products and opportunities for near term revenue generation





Recent corporate and product development

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

Corporate milestones

Mar 2016

Pre-RTO: Bone Medical announce reverse take over (RTO) by Botanix Pharmaceuticals

Jul 2016

Completed RTO and commencement of trading as Botanix Pharmaceuticals (ASX:BOT)

Jul 2016 to Feb 2017

Key staff hires across the business divisions of clinical and regulatory, manufacturing, toxicology and operations

Feb 2017

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

Mar 2017

Received DEA approval for export and import of synthetic cannabidiol for planned clinical studies

Apr 2017

Completed A\$7.4million oversubscribed placement

Development milestones

Jul 2016

Secured access to commercial scale synthetic cannabidiol

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 HREC approval for BTX 1503 clinical studies, and commenced first clinical study

June 2017

Completion of successful pilot study for BTX 1701 facial cleanser

July 2017

Successful completion of Phase 1 clinical study for BTX 1503

Formulation → **Confirm Permetrex™ Safety** → **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		~\$5m	
Phase III clinical	~\$54m		~\$20m	
New Drug Application	~\$5m	~2 years	~\$2m	~12 months
Total	~\$460m	~14 years	~\$30m	~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**

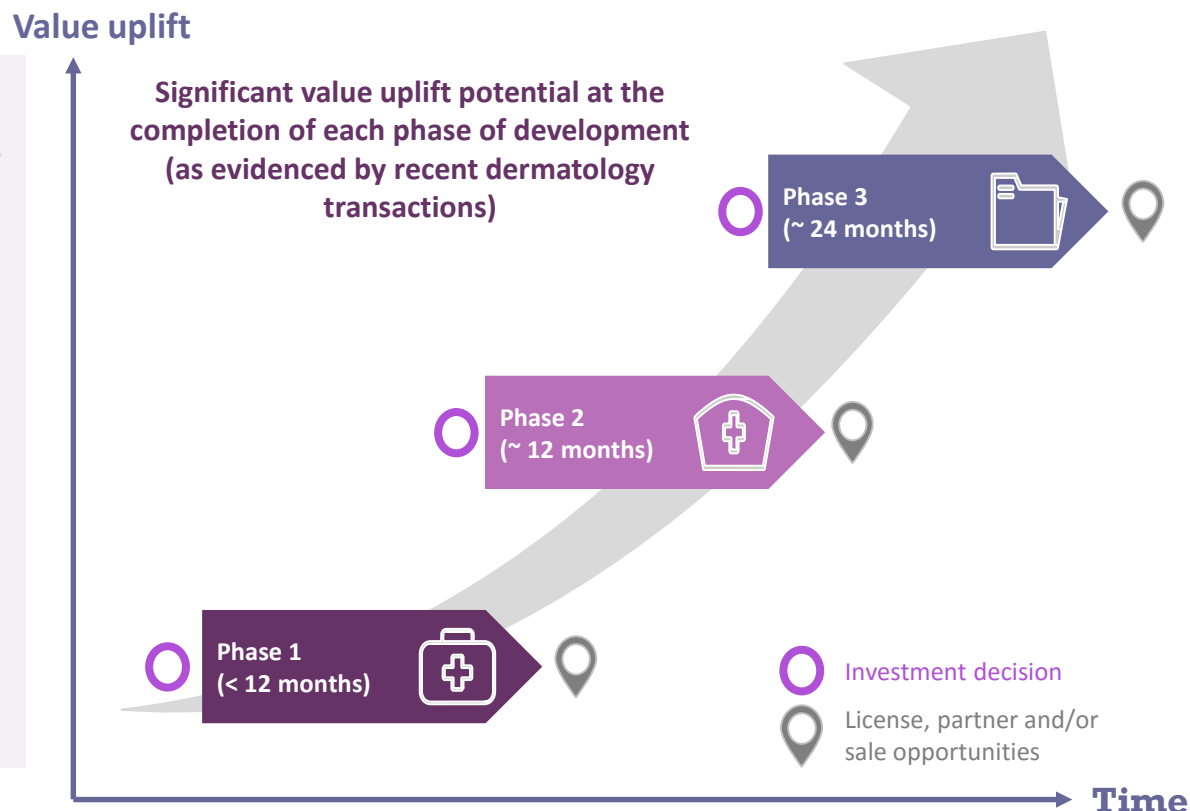


Commercialisation strategy

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

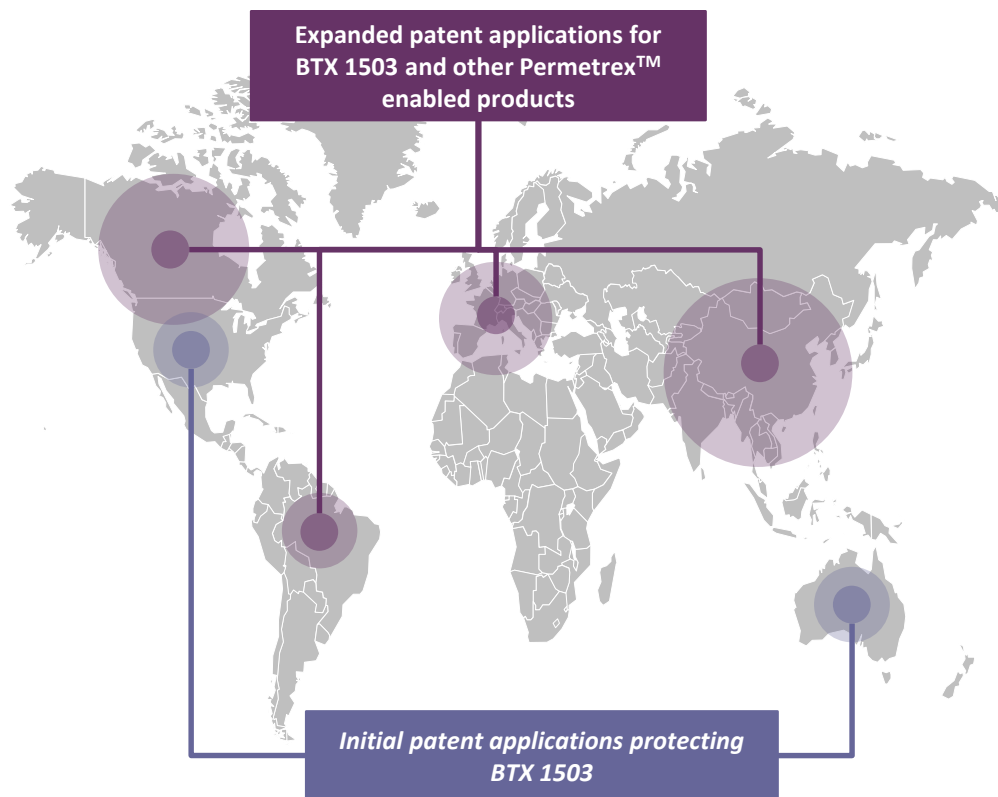




Valuable intellectual property portfolio

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

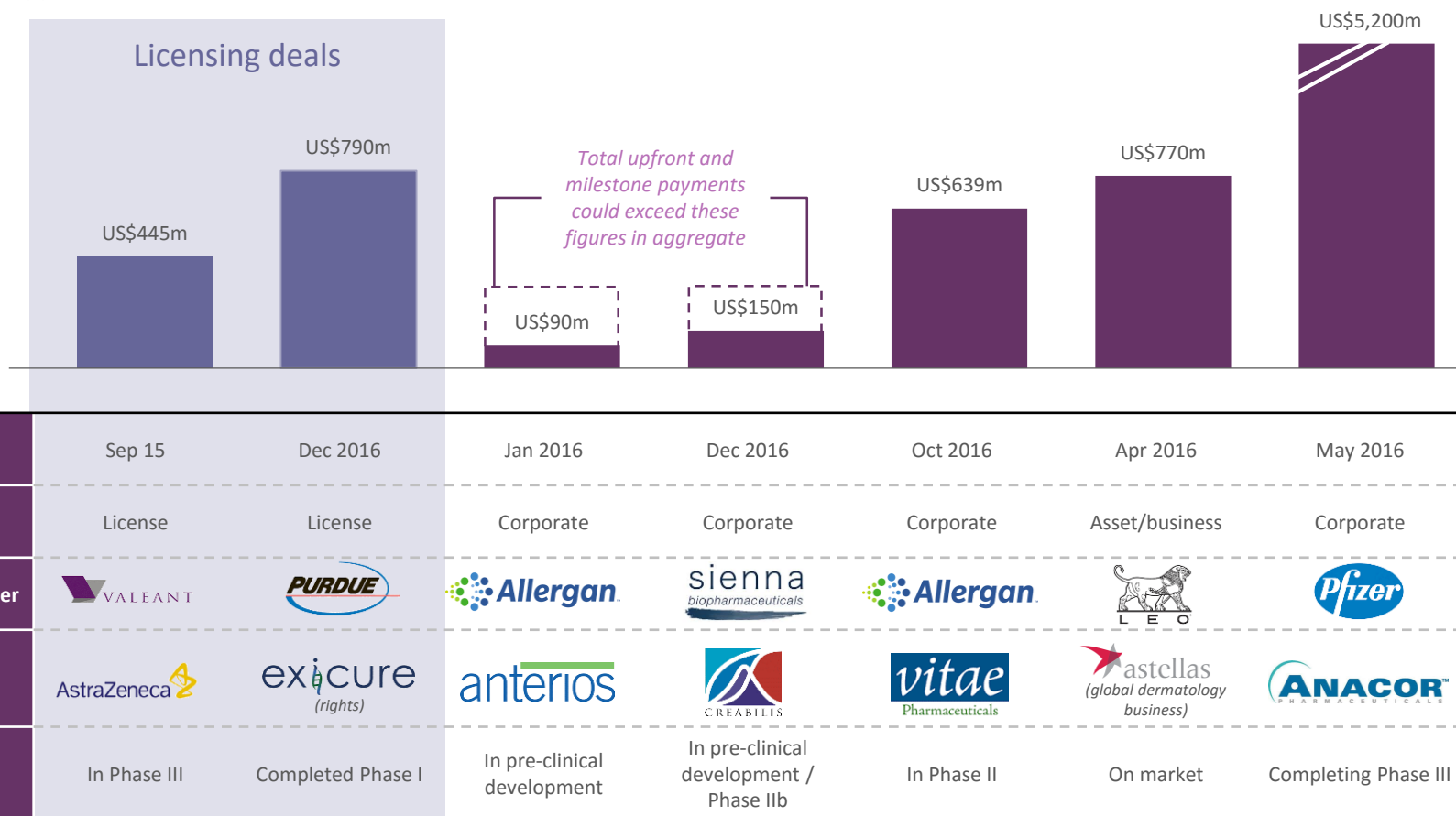




Recent dermatology transactions

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



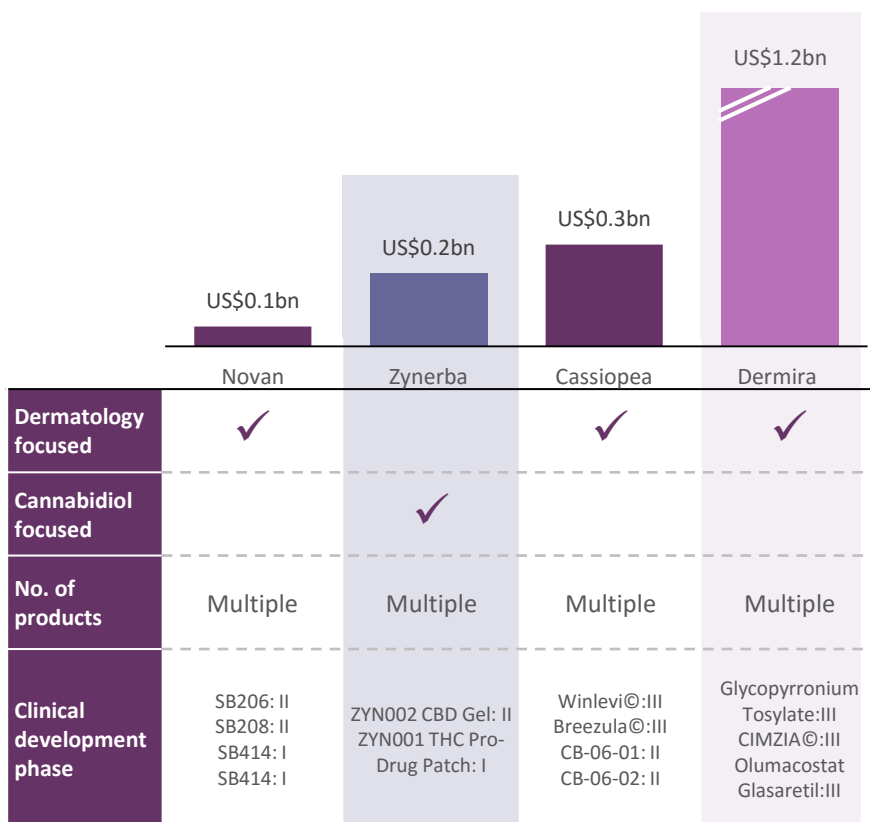
Source: Bloomberg, Company disclosure



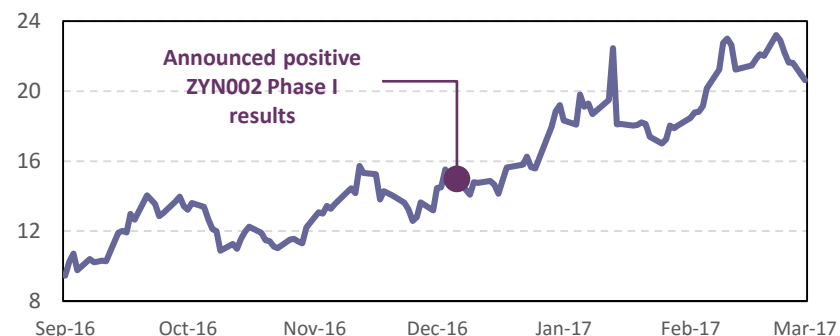
International landscape

Botanix represents a significant value accretive opportunity when compared to key global peers with positive Phase I and Phase II data

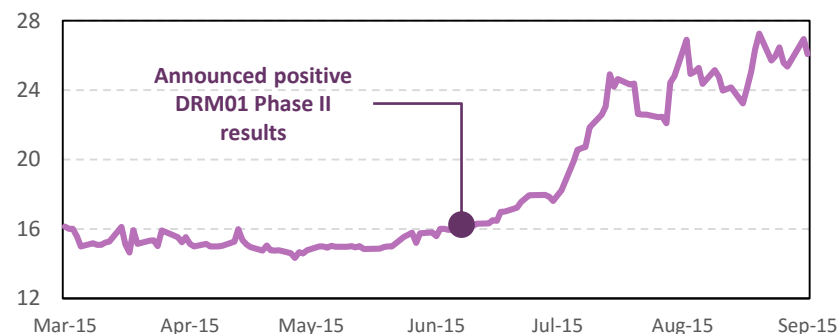
Market capitalisation of key international peers¹



Zynerva share price performance (US\$)



Dermira share price performance (US\$)



Source: Bloomberg, Company disclosure

1. Market capitalisation figures as at close 6 July 2017



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