

ASX/Media Release

7 January 2018

Botanix presents at San Francisco Dermatology Summit

- Botanix presented at the annual Dermatology Summit, as part of the JP Morgan Healthcare Conference in San Francisco, California
- Botanix showcased the BTX1503 acne program and highlighted plans for early Q1 data availability
- Botanix also engaged with several large dermatology companies on potential collaborative commercial opportunities for the Permetrex™ technology

San Francisco, 7 January 2018: Medical dermatology company Botanix Pharmaceuticals Limited (“Botanix” or the “Company”) is pleased to release a new investor presentation, which the Company presented at the 2018 Dermatology Summit meeting in San Francisco, California on 7 January 2018, as part of the JP Morgan Healthcare Conference week.

The presentation at the Dermatology Summit was used as a platform to provide potential partners and key industry opinion leaders with an update on the Company’s lead acne program BTX 1503. Substantial interest was generated in anticipation of the first patient data, which is scheduled for early Q1 CY2018. A successful outcome in this Phase 1b patient study will open up a range of opportunities for Botanix, given the lack of new FDA drug approvals for acne in the last 20 years and will also substantially de-risk the broader Botanix dermatology focused pipeline.

Botanix was also able to highlight the progress of its second clinical program for the treatment of atopic dermatitis (BTX 1204), which is rapidly enrolling across 4 clinical sites in Australia. Data from the BTX 1204 study is planned to be available in Q2 2018.

During the Summit, Botanix engaged with several global pharmaceutical companies that have an interest in utilizing the Permetrex™ drug delivery technology for their own development programs that have experienced challenges in clinical studies. Botanix is currently collaborating with a number of specialist dermatology and general pharmaceutical companies with the Permetrex™ formulation technology and expects to continue to generate revenue from these collaborations in 2018.

Botanix has a number of further presentations and meetings scheduled this week with some of the world’s leading dermatology companies during the course of the JP Morgan Healthcare Conference and related events in San Francisco.

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 and a newly announced clinical trial in atopic dermatitis patients for BTX 1204. 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.

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botanix

PHARMACEUTICALS

RESTORING HEALTHY SKIN

Overview Presentation
San Francisco
January 2018



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**
- **Patient study data for acne planned for 1Q CY2018** and **atopic dermatitis data in 2Q CY2018**

Novel Approach

- Lead products based on synthetic form of widely-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 (5-Jan-18)	A\$0.077
52 week low / high	A\$0.040 / A\$0.077
Shares outstanding ^{1,2}	543.1
Market capitalisation	A\$41.8m
Cash (as at 30-Sep-17)	A\$4.2m
Debt (as at 30-Sep-17)	-
Enterprise value	A\$37.6m

Top shareholders (Jan 2018)

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

1. Includes 156.5m fully paid ordinary shares subject to escrow until 15 July 2018
2. Excludes 47.8m 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**

extina
(tretinoin) Foam, 2%

Vivlodex[™]

Nexavar
(sorafenib) tablets

Tivorbex[™]

Olux-E

MEGACE^{ES}

EMEND
(aprepitant)

Rapamune[®]

Acanya

ZORVOLEX[™]

LUZU

Zyclara[™]

EPOGEN[®]
(EPOETIN ALFA)
INJECTION

provant
life. changing.



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 1	Ph 1b	Ph 2	Next milestones
Synthetic Cannabidiol	BTX 1503 Moderate to Severe Acne					Phase 1b patient data available 1Q CY2018
	BTX 1204 Atopic Dermatitis					Phase 1b patient data available 2Q CY2018
	BTX 1308 Psoriasis					Pre-clinical testing 1Q CY2018
Permetrex™ Enabled	BTX 1701 Mild Acne					Pilot patient study start 1Q CY2018
	BTX 1801 Not disclosed					Formulation complete 4Q CY2017

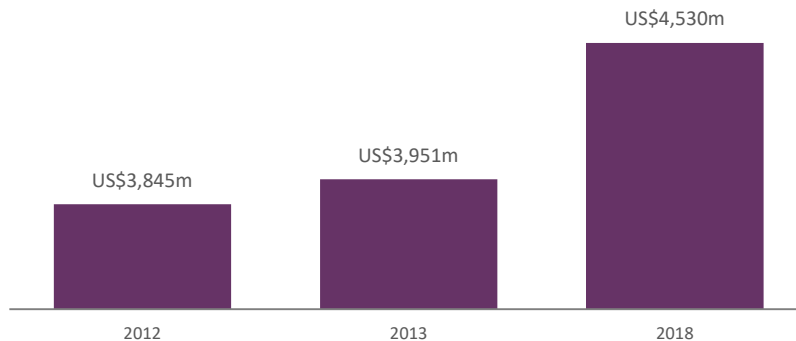


Why are we focused first on acne?

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

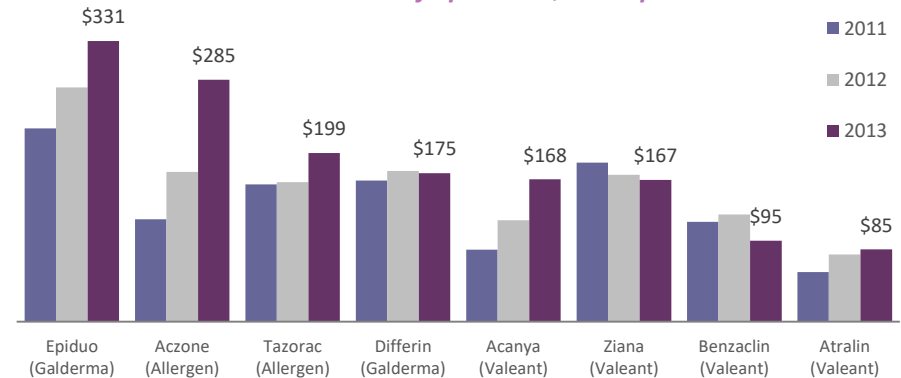
Global prescription acne product revenues (topical and oral treatments)

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

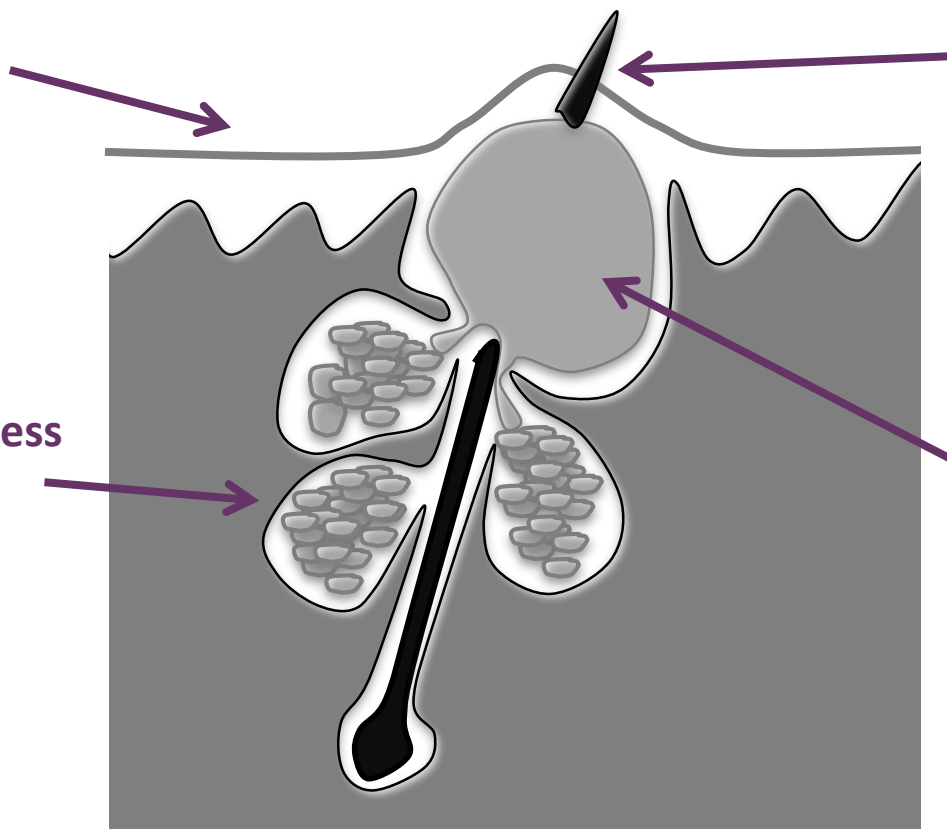
BTX 1503 utilises synthetic cannabidiol combined with a novel skin delivery technology

Attacks *P. Acnes* bacteria

Reduces Inflammation

Switches off excess production of sebum

Retards formation of sebum "plugs"





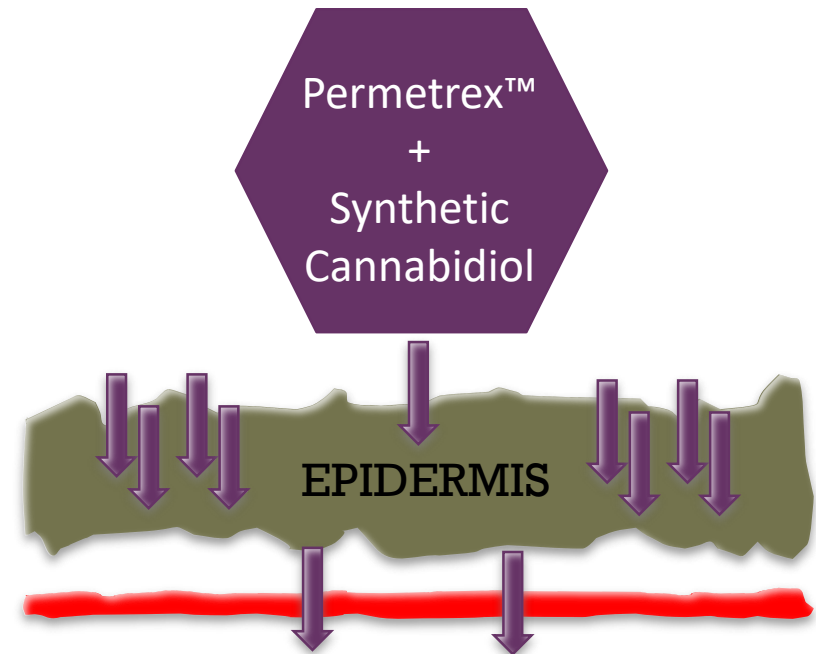
BTX 1503 Phase 1a clinical trial results

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



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



BTX 1503 Phase 1b acne patient study

4-week open-label study to determine the safety and tolerability of BTX 1503 solution in subjects with moderate to severe acne

Design

- ~20 subjects 18 years and older
- 4 Australian dermatology sites
- BTX 1503 solution BID (twice a day) applied topically
- At least 20 inflammatory and 20 non-inflammatory lesions
- Investigator's Global Assessment (IGA) ≥ 3

Endpoints

- Primary endpoints – safety: adverse events (AEs), labs and local tolerability
- Exploratory endpoints:
 - Lesion counts and IGA
 - Acne questionnaire
 - Photography



Data available early in 1Q CY2018










BTX 1503 market positioning

BTX 1503 has the potential to be the market leading branded product for acne treatment, with few undesirable side effects

Market landscape for acne treatments¹

- 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



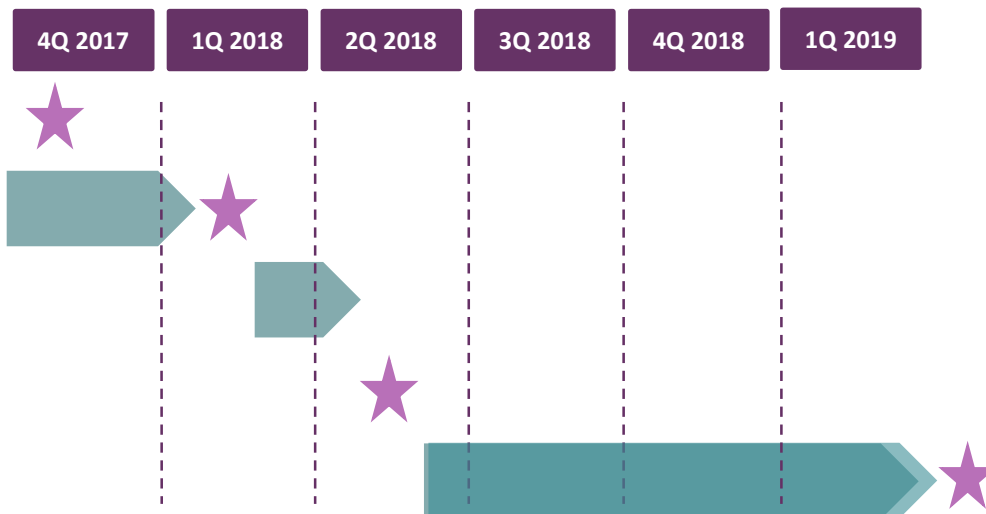
BTX 1503 timeline overview

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

- Phase 1b acne pilot study data expected to be available in early 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 permit Phase 2 clinical development in the US
- BTX 1503 well placed to commence FDA regulated Phase 2 clinical study end 1H CY2018
- Phase 2 clinical study to be conducted in US and Australian sites

BTX 1503 indicative clinical timeline (CY)

Pre-IND Meeting FDA
Phase 1b acne pilot study
File IND for FDA regulated Phase 2 trial
IND 'Approval' for Phase 2
Phase 2 multi-centre acne patient trial

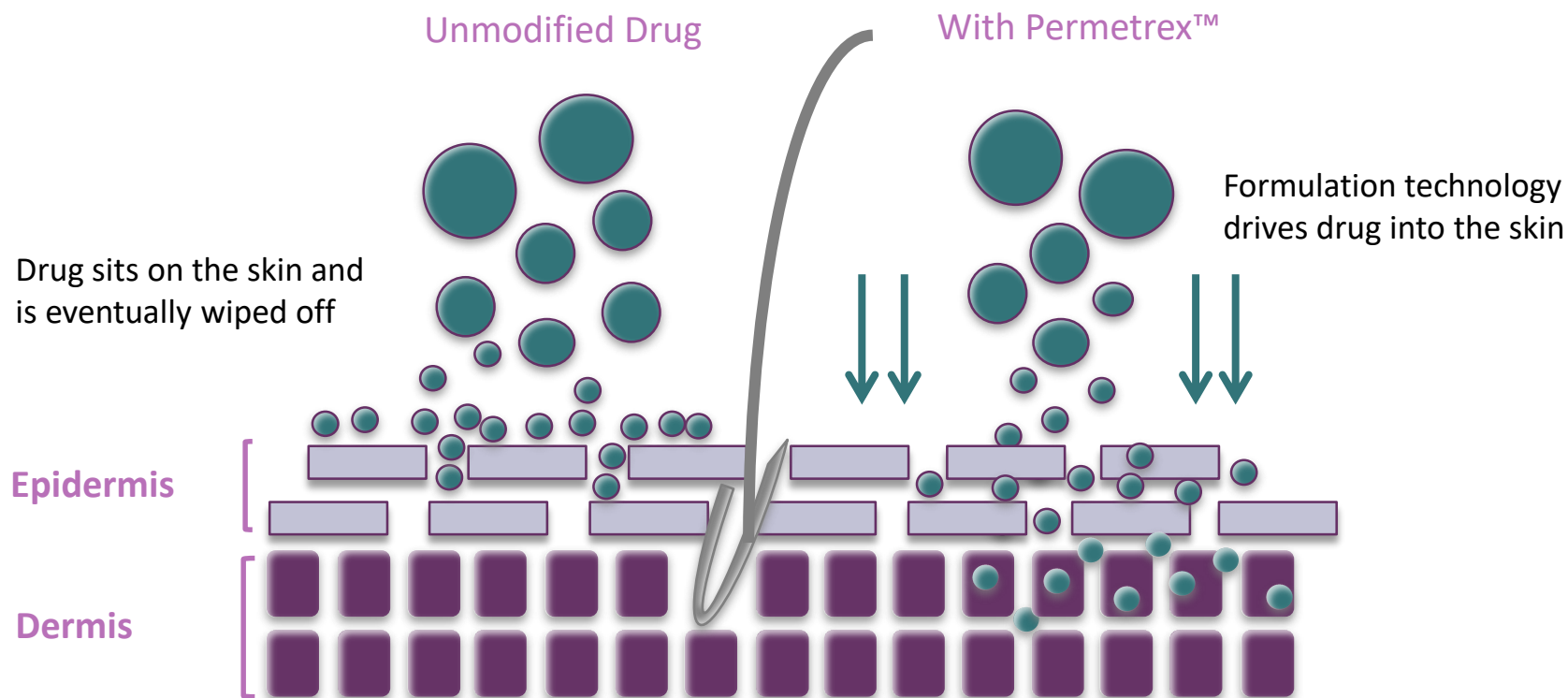


 Milestones



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

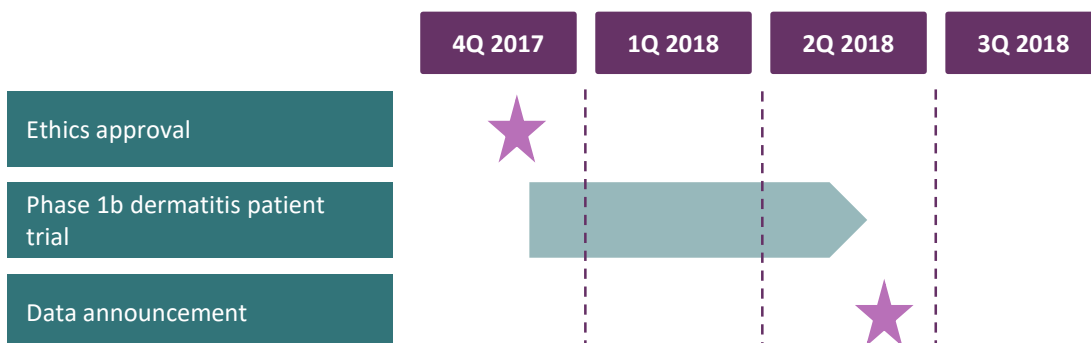
Phase 1b patient study commenced in late October, with data planned for 2Q 2018

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 (AD) 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)

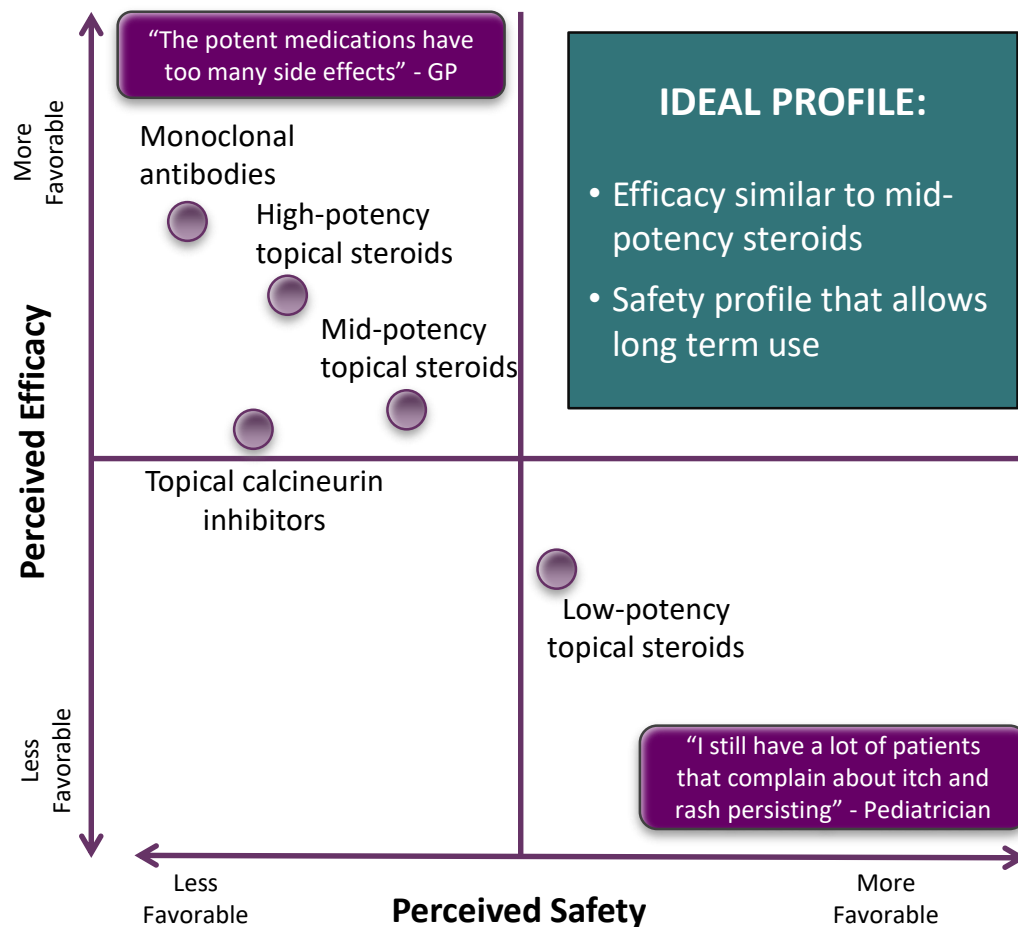


- Received HREC approval in late October 2017 to commence Phase 1b dermatitis patient study
- Enrolment of patients commenced in 4Q CY2017, across 4 leading dermatology clinics in Australia
- Expected study completion in 2Q CY2018
- Study demonstrates Botanix's ability to accelerate the addition of clinical 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



US\$5.2 bn



- **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



BTX 1204 Phase 1b AD patient study

4-week randomized, double-blind, vehicle controlled study to determine the safety and tolerability of BTX 1204 in subjects with mild to moderate atopic dermatitis

Design

- ~36 subjects 18 years and older (24 active / 12 vehicle)
- 4 Australian dermatology sites
- BTX 1204 solution BID applied topically
- 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 safety endpoints - (AEs, labs, local tolerability and signs of AD)
- Exploratory endpoints:
 - ISGA
 - Target lesion size



Data available in 2Q CY2018



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)

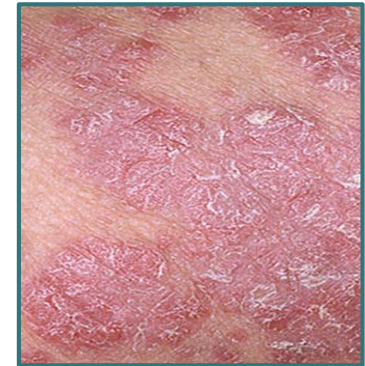
Intend to undertake study in pre-clinical skin models in 1Q CY2018

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

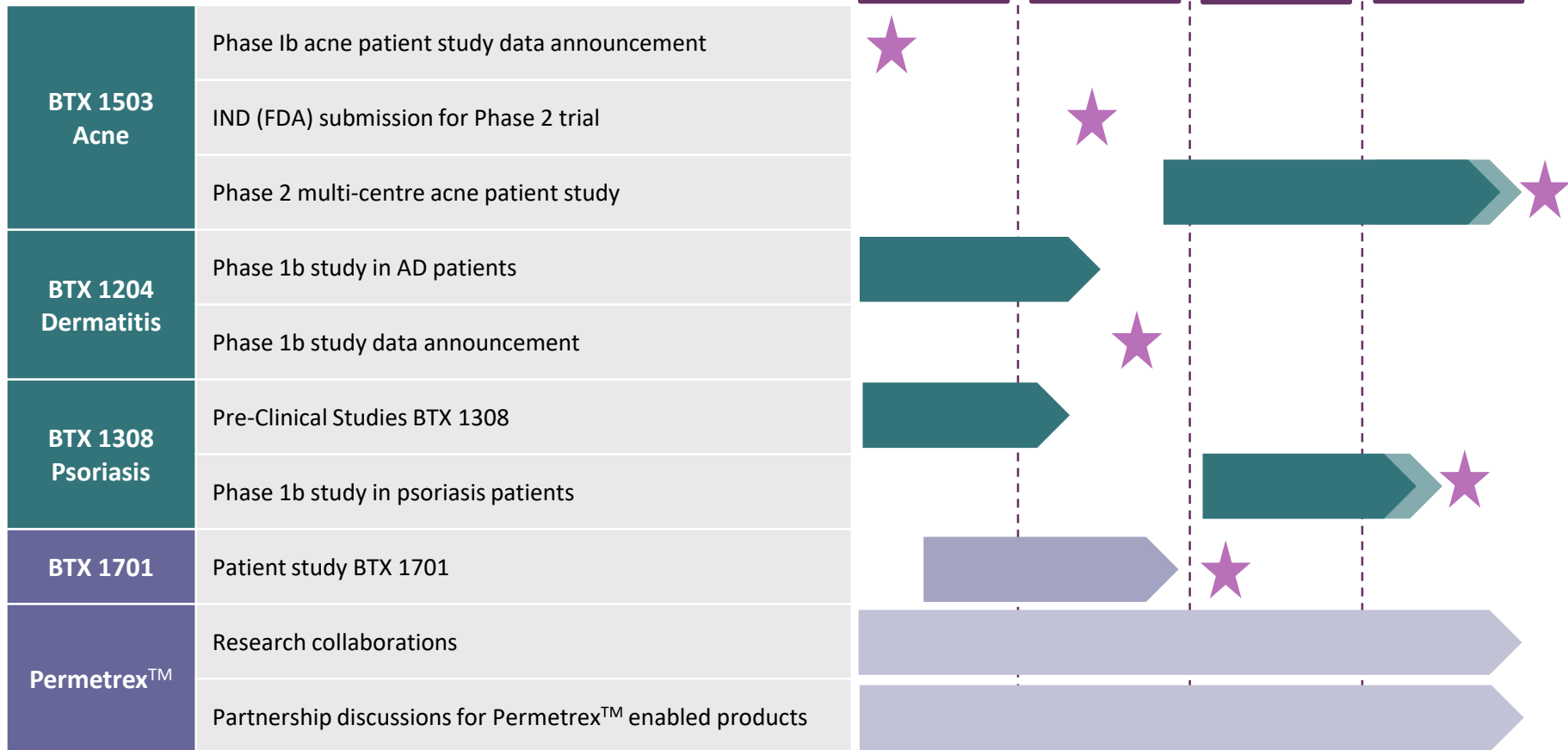
- Many companies have challenges formulating drugs for delivery into the skin
- Botanix is working with multiple parties to test application of Permetrex™ technology to solve problems that have arisen in clinical studies
- Engagement generally starts as fee-for-service by Botanix
- License trigger is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





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

1Q CY2018	2Q CY2018	3Q CY2018	4Q CY2018
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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

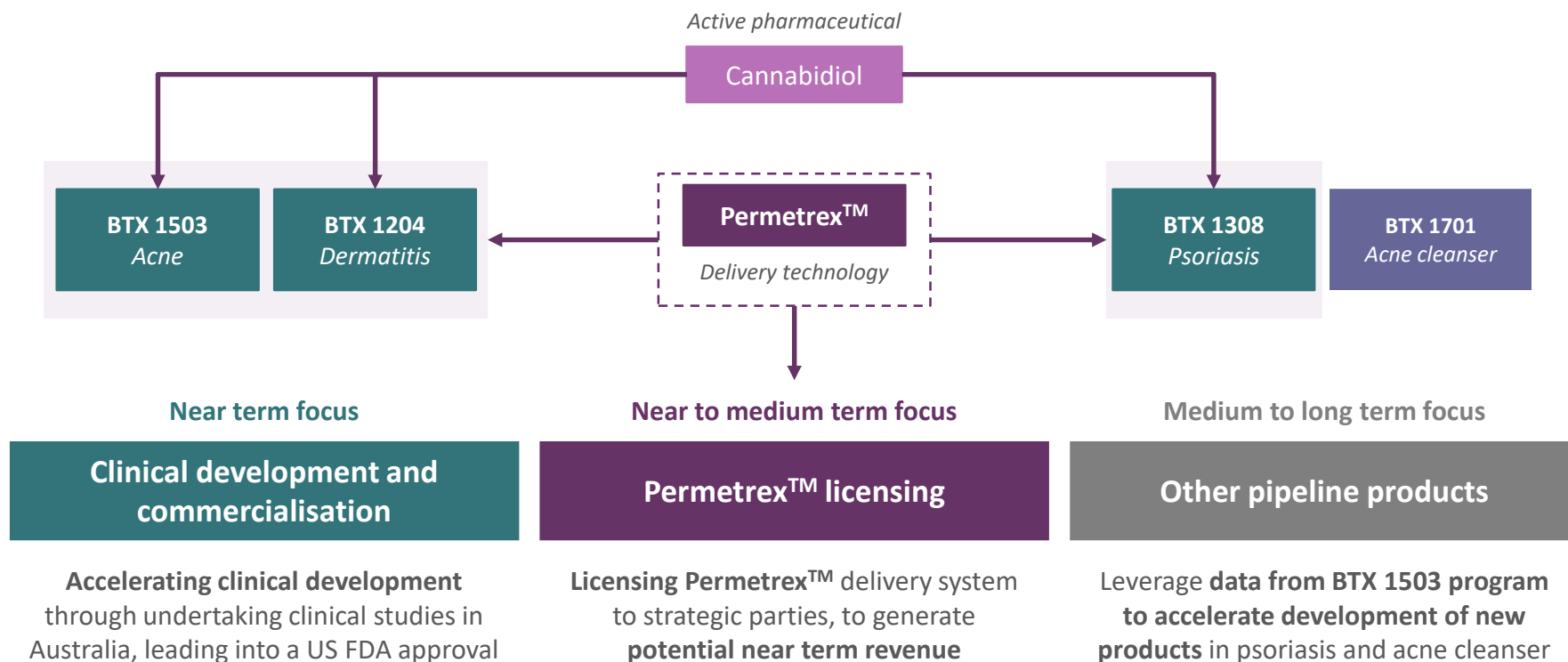
- Professor of Dermatology at Pennsylvania State University
- Researcher in acne and rosacea
- Pre-clinical and clinical trials services provider

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

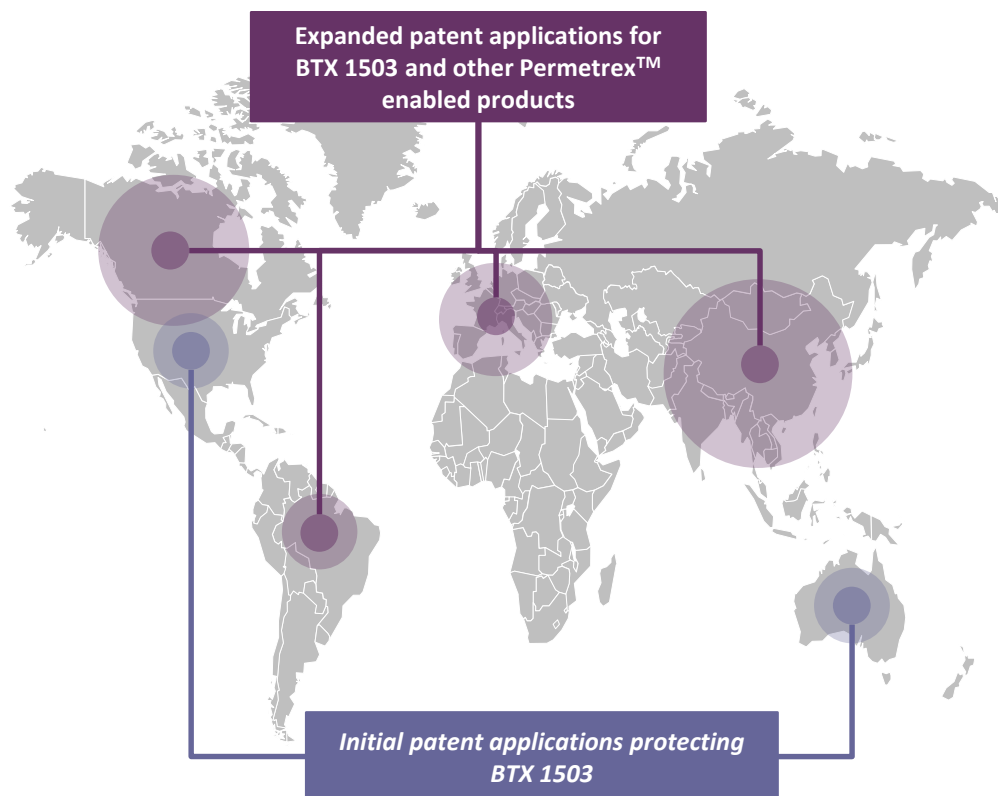




Valuable intellectual property portfolio

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

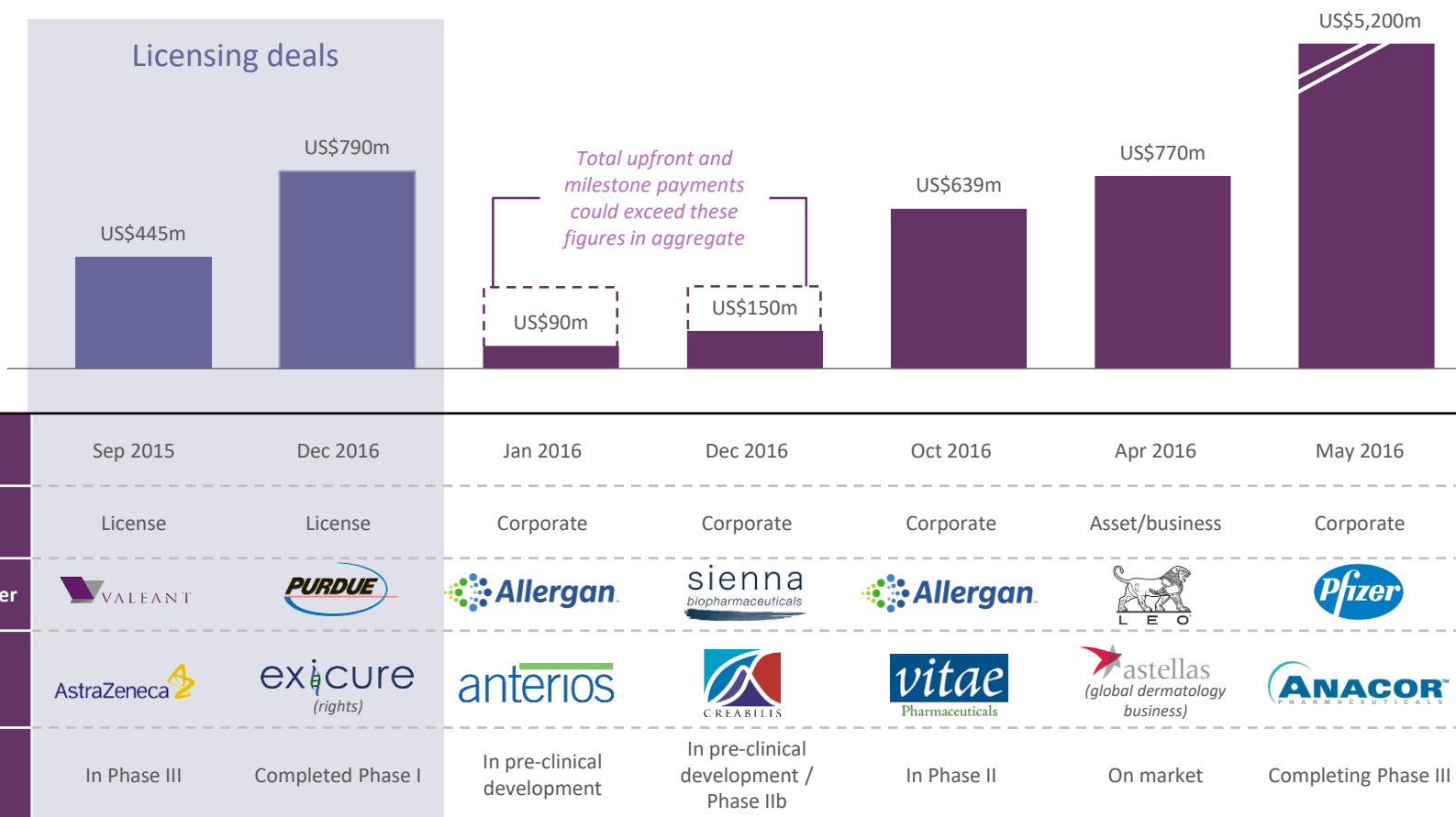




Recent dermatology transactions

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




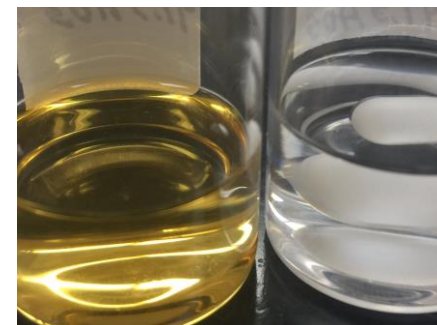
Source: Bloomberg, Company disclosure



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" ¹



1. Botanical Drug development – Guidance for Industry. FDA



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