

ASX/Media Release

5 February 2018

Company update

Philadelphia PA and Sydney Australia, 5 February 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or the “Company”) is pleased to release a new company investor presentation, which is enclosed with this announcement. The presentation outlines Botanix’s compelling investment case and strategy.

Matthew Callahan, Botanix’s Executive Director, said:

Botanix is now funded to complete the BTX 1503 Phase 2 acne clinical trial and is strongly positioned to advance the development of the broader product portfolio and Permetrex™ opportunities. We are very excited to be entering into a new phase of the company’s growth.”

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 successfully completed its first acne patient studies with BTX 1503 and is currently conducting another patient study in atopic dermatitis subjects for its second clinical program, 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, BTX 1204 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

Investor Presentation
February 2018



Investment highlights

Botanix is an emerging global dermatology company with advanced clinical programs in acne and atopic dermatitis, with a promising development pipeline

Dermatology Focused

- Targeting **multi-billion dollar prescription markets for acne** (with no new products approved in the last 20 years) **and atopic dermatitis**
- Deep pipeline of follow-on dermatology products in development

Clinical Stage

- Successful clinical data from acne patient study shows industry leading reduction in inflammatory lesions after only 4 weeks of treatment
- **Positive safety and anti-inflammatory data de-risks broader portfolio**

Novel Approach

- Lead products use a synthetic form of a widely studied natural product, **greatly enhances the probability of clinical and regulatory success**
- **Exclusive global rights to use Permetrex™** technology for all skin diseases

Experienced Team

- Predominantly US based leadership team with **20+ FDA approvals** between them and extensive dermatology industry experience
- Achieved successful clinical data within 18 months of listing



Corporate overview

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

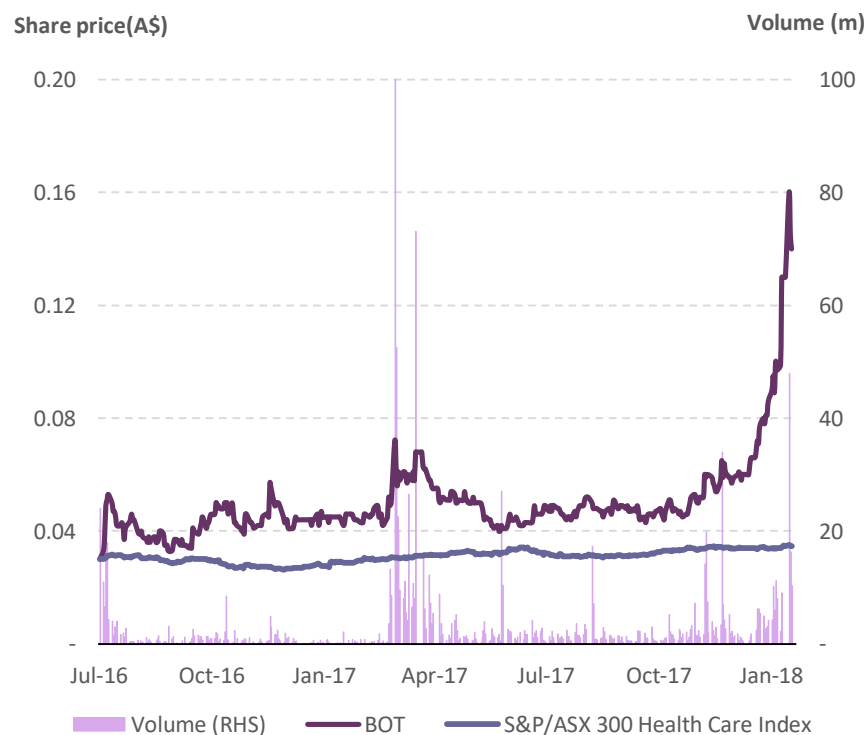
Trading information

Share price (31-Jan-18)	A\$0.140
52 week low / high	A\$0.039 / A\$0.210
Shares outstanding ¹	543.1
Market capitalisation	A\$76.0m
Cash (as at 31-Jan-18) ²	A\$3.2m
Debt (as at 31-Jan-18)	-
Enterprise value	A\$72.8m

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)	4.5

Share price performance



Source: IRESS

1. Includes 156.5m fully paid ordinary shares subject to escrow until 15 July 2018; Excludes 135.8m shares issued in capital raising and 47.8m unlisted options
2. Cash does not include \$14.9m (before costs) received from capital raising announced 5 February 2019



Senior leadership: proven 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



Operations + 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
(ketotifen) Foam, 2%

Vivlodex[™]

Nexavar[™]
(sorafenib) tablets

Tivorbex[™]

Olux-E

MEGACE[®]ES

EMEND
(aprepitant)

Rapamune[®]

Acanya

ZORVOLEX[™]

LUZU

Zyclara[™]

EPOEN
(EPOETIN ALFA)
injection

provant
life. changing.



Clinical programs with near term milestones

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

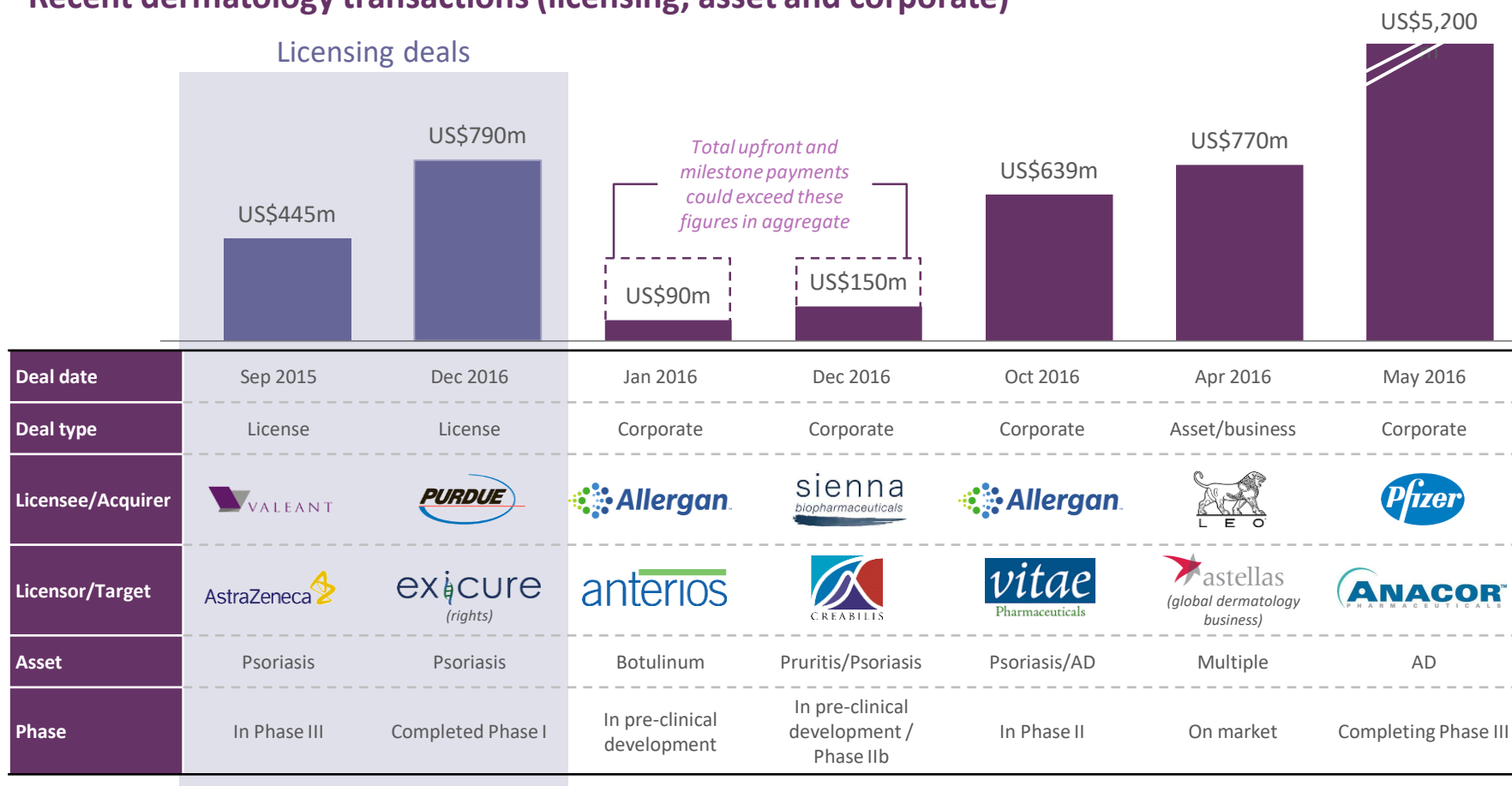
Product candidate	Indication	Pre-Clin	Ph 1	Ph 1b	Ph 2	Next milestones
Synthetic form of natural product cannabidiol	BTX 1503	Moderate to Severe Acne				IND for Phase 2 2Q CY2018
	BTX 1204	Atopic Dermatitis				Phase 1b patient data available 2Q CY2018
	BTX 1308	Psoriasis				Patient study 3Q CY2018
	BTX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



Botanix's product portfolio value considerations

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

Recent dermatology transactions (licensing, asset and corporate)





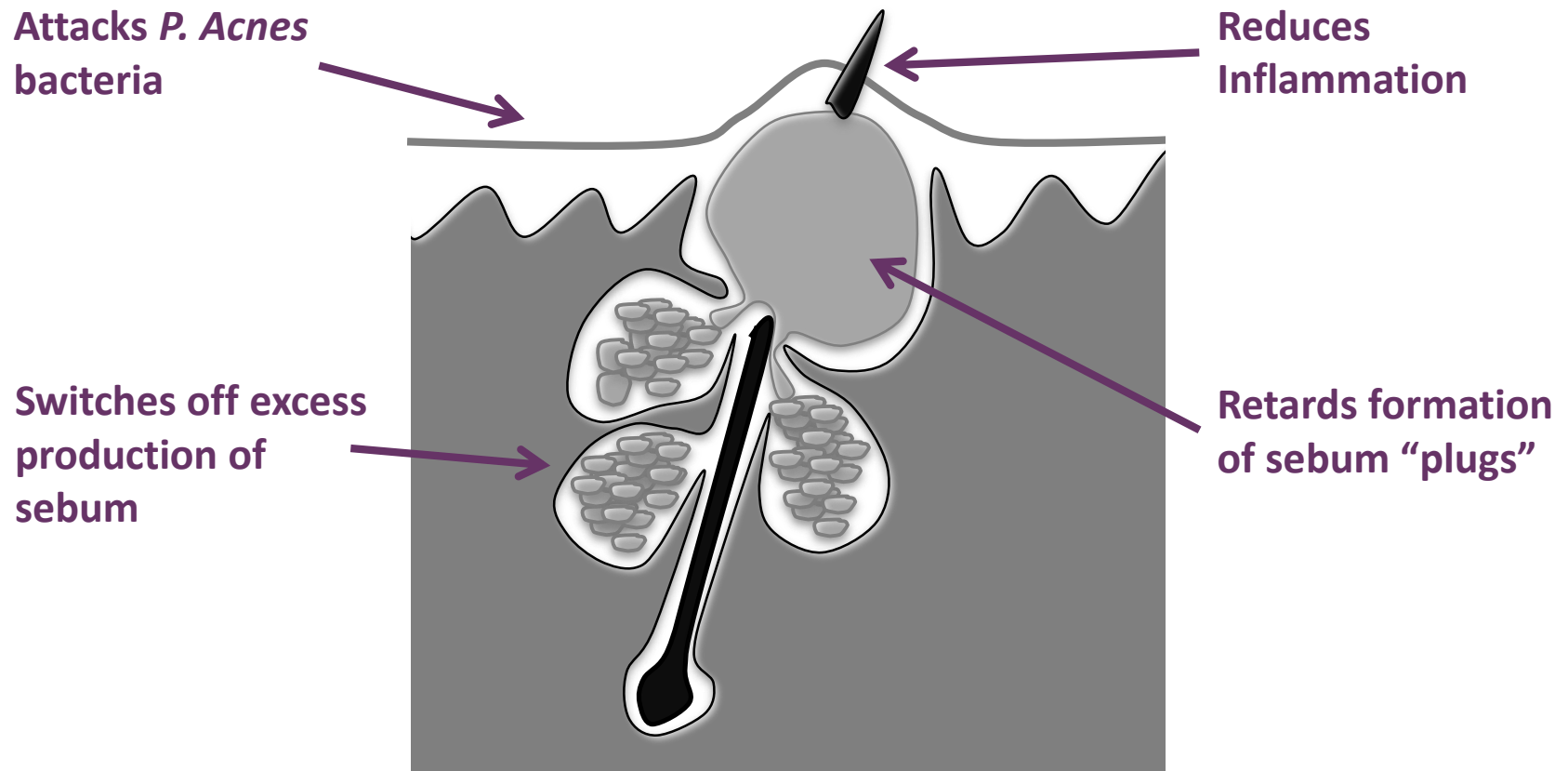
BTX 1503

moderate to severe acne



How does BTX 1503 work to treat acne?

BTX 1503 utilises synthetic form of a natural product known as *cannabidiol*, combined with the novel Permetrex™ skin delivery technology





BTX 1503 Phase 1b acne patient study

The successful 4-week open-label acne study commenced in October 2017 and concluded in December 2017

Design

- ~20 subjects 18 years and older
- 4 Australian dermatology sites
- BTX 1503 solution BID (twice a day) applied topically
- Moderate to severe acne patients (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
 - Self-assessment questionnaire
 - Photography

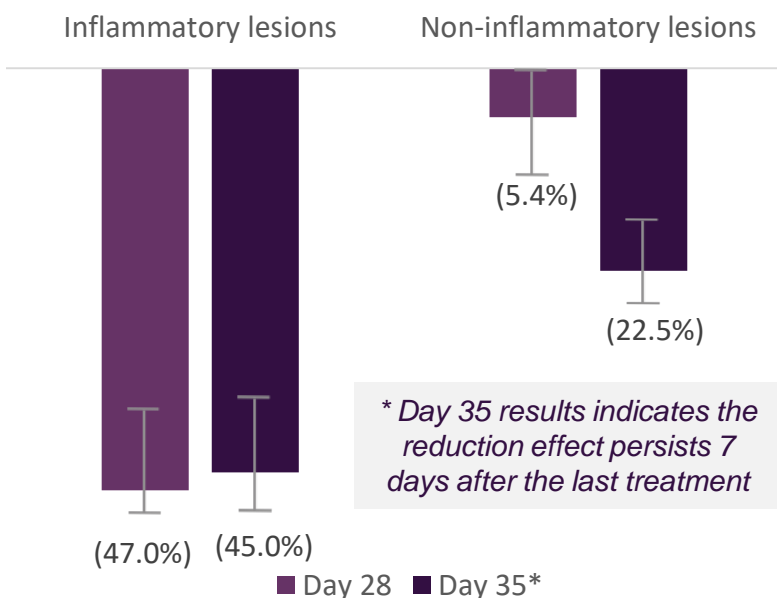




BTX 1503 outperformed leading acne products

Phase 1b acne patient study data resulted in a reduction in inflammatory lesions greater than any other FDA approved topical acne product at 4 weeks



Lesion count reduction (%)



56%

of patients self-reported that their acne was “Slightly Better” or “Much Better” at Day 28

Comparison of other FDA approved products

Product	Owner	Lesion count reduction (%) ¹	2016 annual revenue ²
 Epiduo®	Galderma	~42%	US\$494m
<ul style="list-style-type: none">■ Combination of two drugs – benzoyl peroxide and adapalene✗ Common side effects include redness, skin peeling mild burning / stinging and dryness			
 Aczone®	Allergan	~38%	US\$456m
<ul style="list-style-type: none">✓ Few side effects✗ Studies showed large placebo / vehicle effect – i.e. at 12 weeks Aczone reduced inflammatory lesions by 54% while vehicle achieved 48% reduction			
BTX 1503	Botanix	~47%	-

1. Lesion count reduction based on average inflammatory lesion reduction at 4 weeks
2. 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 treatment¹

Patient result



Baseline



Day 28

57% reduction in inflammatory lesions

15% reduction in non-inflammatory lesions

Patient satisfaction report was
“Much Better”

1. Patient demographics: 21 year old female

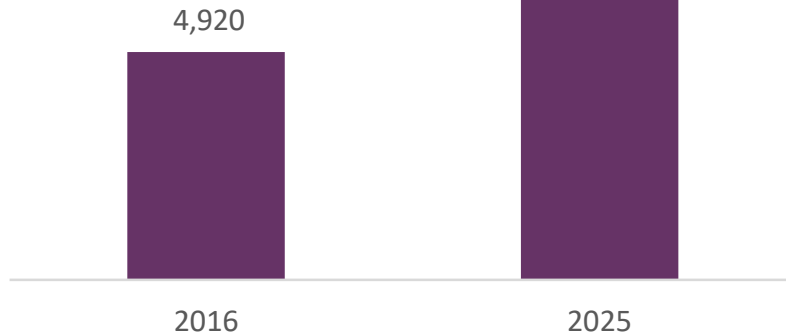


Why are we focused first on acne?

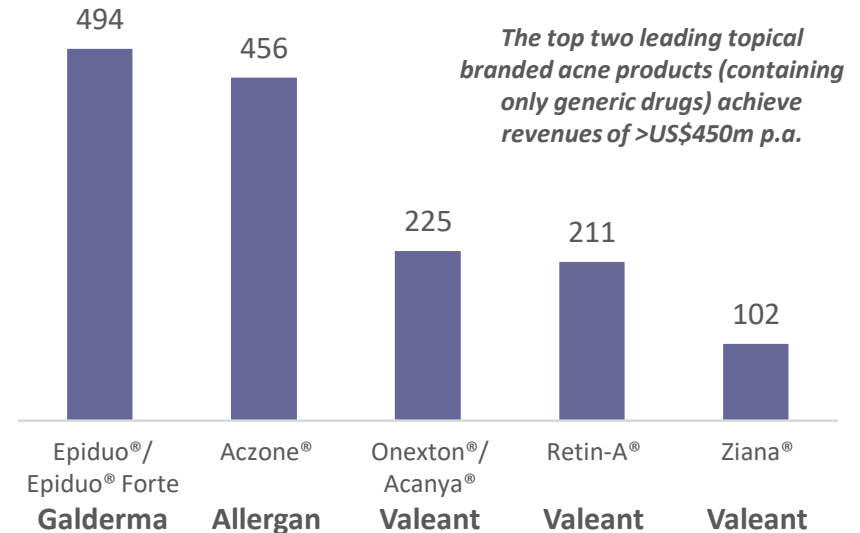
In 2016, the global acne prescription market was worth ~US\$4.9bn, with the potential to grow to ~US\$7.3bn by 2025

Global acne market size (US\$m)

Value of the global acne prescription market is expected to reach ~US\$7.3bn by 2025



Topical acne products revenue in 2016 (US\$m)



Large demand with limited recent product development

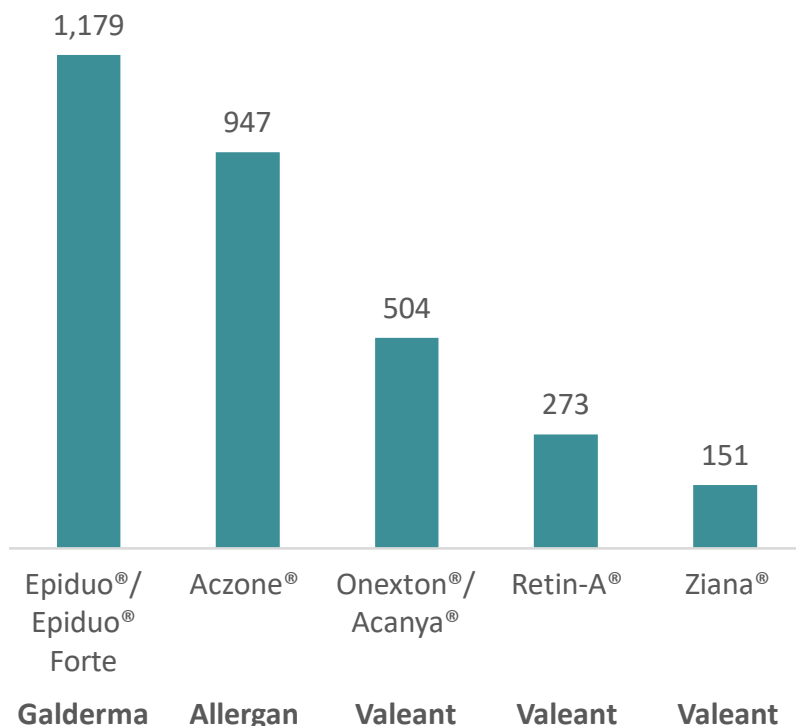
- No new chemical entities have been approved by the FDA in the last 20 years for the treatment of acne
- Only “new” products launched were combinations of old drugs in new formulations or packaging



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®	\$258.90	\$3,107
	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)	\$1,302 (low strength)
		\$340.30 (high strength)	\$4,900 (high strength)
	Tretinoin	\$128.00 (low strength)	\$1,024 (low strength)
		\$158.50 (high strength)	\$1,268 (high strength)



BTX 1503 market positioning

Current acne treatments do not treat all key acne pathogenic factors and have varying levels of side effects and disadvantages

Market landscape for acne treatments¹

Agents		Pathogenic factors				Key considerations / disadvantages
		Sebum Excretion	Hyper Keratinisation	P.Acnes proliferation	Inflammation	
Topical	Benzoyl Peroxide	-	✓	✓	Possibly	Local irritation; mild acne only
	Topical Antibiotics	-	-	✓	Possibly	Local irritation; inflammatory acne only; antibiotic resistance
	Topical Retinoids	-	✓	-	Possibly	Local irritation; phototoxic
	BTX 1503	✓	✓	✓	✓	No known side effects, broad mechanism
Oral	Oral Contraceptives	✓ (Indirectly)	-	-	-	Gender specific; systemic side effects
	Anti-Androgens	✓	-	-	-	Gender specific; systemic side effects
	Oral Antibiotics	-	-	✓	✓	Systemic side effects; antibiotic resistance; inflammatory acne only
	Oral Isotretinoin	✓	✓	✓ (Indirectly)	✓	Severe skin and systemic side effects

1. Subject to successful development and approvals

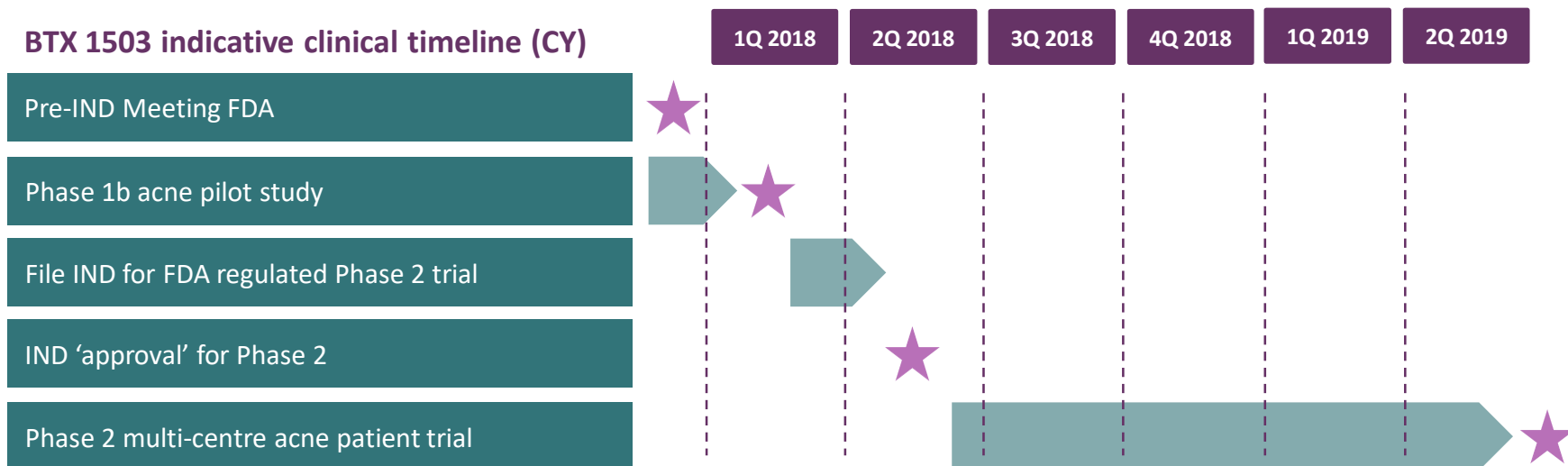


BTX 1503 development timeline overview

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

- Proof of concept established in successful Phase 1b acne patient study
- Pre-IND meeting with the FDA completed – FDA confirmed the proposed development plan and data package to permit Phase 2 clinical development in the US
- Botanix plans to commence a FDA regulated Phase 2 clinical study in 2Q CY2018 involving North American and Australian sites

BTX 1503 indicative clinical timeline (CY)



★ Milestones



BTX 1204

mild to moderate atopic dermatitis



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

Cannabidiol is prospective for atopic dermatitis

Cannabidiol has potential to:

- ✓ reduce inflammation
- ✓ prevent deterioration of skin barrier
- ✓ attack *staphylococcus aureus* bacteria
- ✓ reduce pruritus (itch)
- ✓ reduce skin cell proliferation

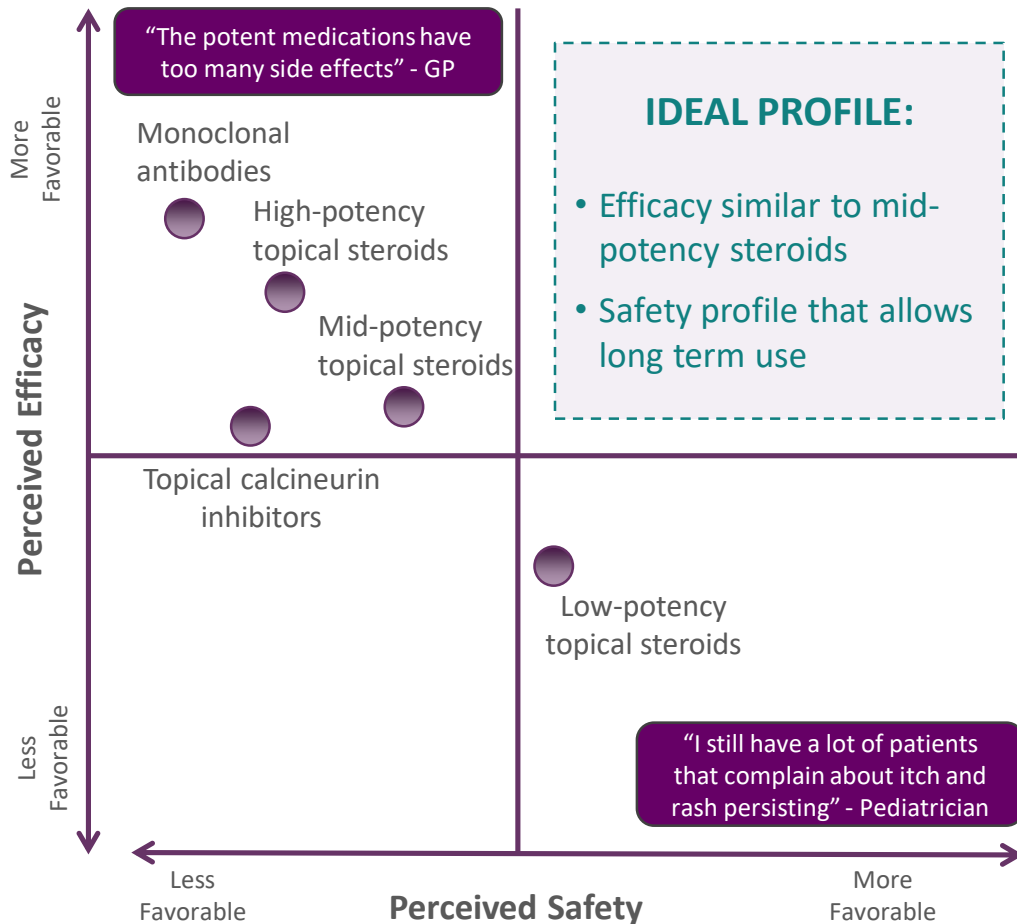


- Little innovation in atopic dermatitis for 15 years, before the 2016 approval of Eucrisa® and Dupixent®
- However, Eucrisa® does not affect itch and has been a launch failure
- Dupixent® is expensive (US\$37k p.a.) and has serious side effects

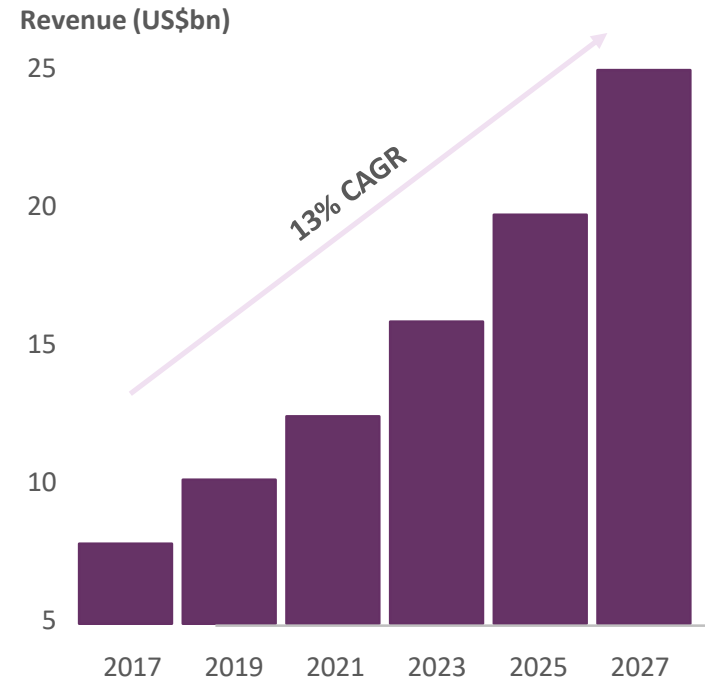


BTX 1204 positioning and opportunity

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



Current and projected atopic dermatitis market by revenue: 2017-2027





BTX 1204 Phase 1b atopic dermatitis study

4-week randomised, double-blind, vehicle controlled patient 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 endpoints: safety – AEs, labs, local tolerability and signs of atopic dermatitis
- Exploratory endpoints:
 - ISGA
 - Target lesion size



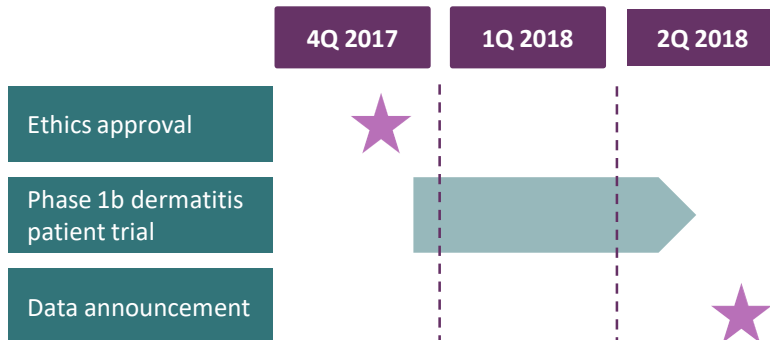
Data available in 2Q CY2018



BTX 1204 for atopic dermatitis

Phase 1b patient study commenced in late October 2017, with expected study completion and data planned for 2Q CY2018

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

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, Permetrex™,
key milestones and next steps**



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

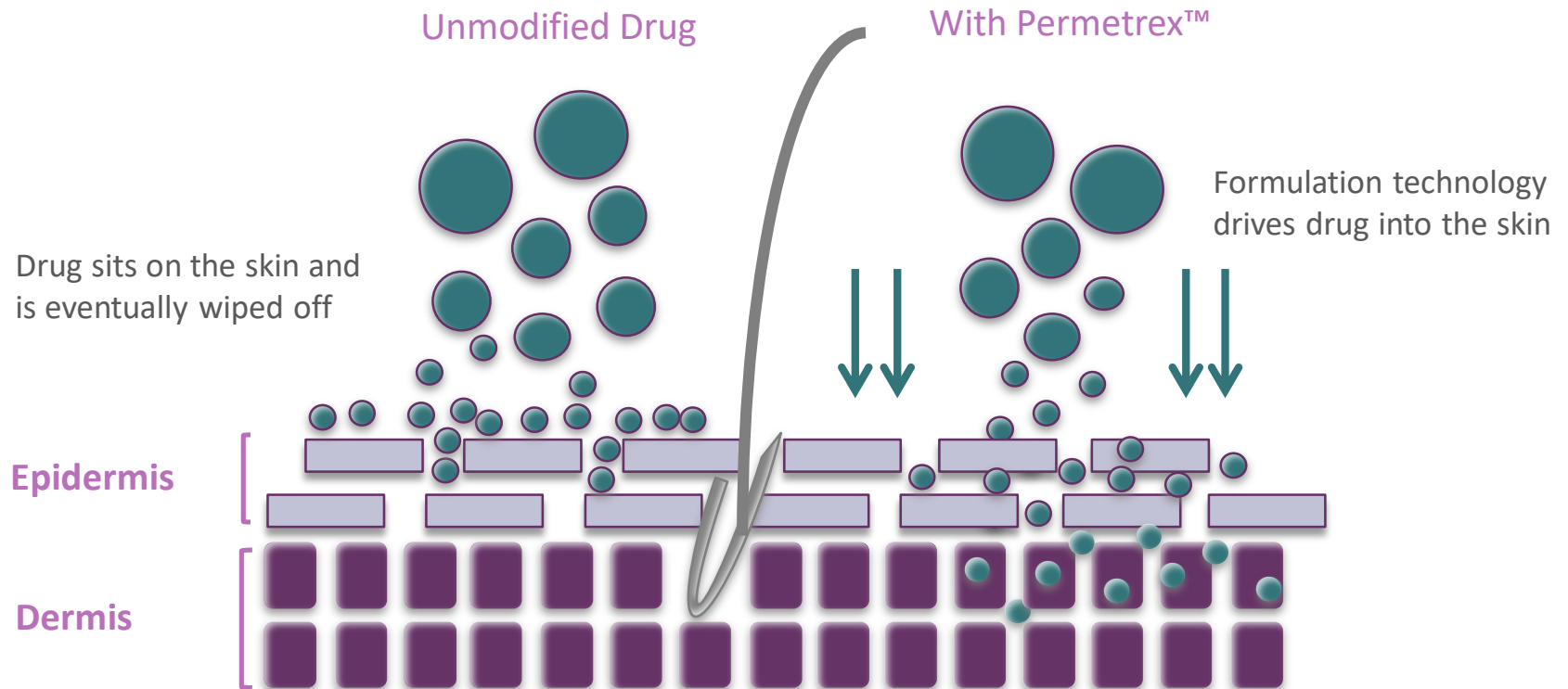
BTX 1308 leverages prior data from:

- ✓ **BTX 1503 acne clinical program**
- ✓ **Permetrex™ delivery system studies**
- ✓ **With no need to repeat early studies**



Permetrex™ skin delivery technology

Permetrex™ 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™ for all drugs that treat skin diseases



Permetrex™ opportunities

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

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™ 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)

Other pipeline products can be developed

- Botanix has developed an acne cleanser (BTX 1701) that has potential as an adjunct to prescription products – currently under review
- Due to the extensive safety and growing efficacy data for Permetrex™, new pipeline products can be added without repeating pre-clinical safety

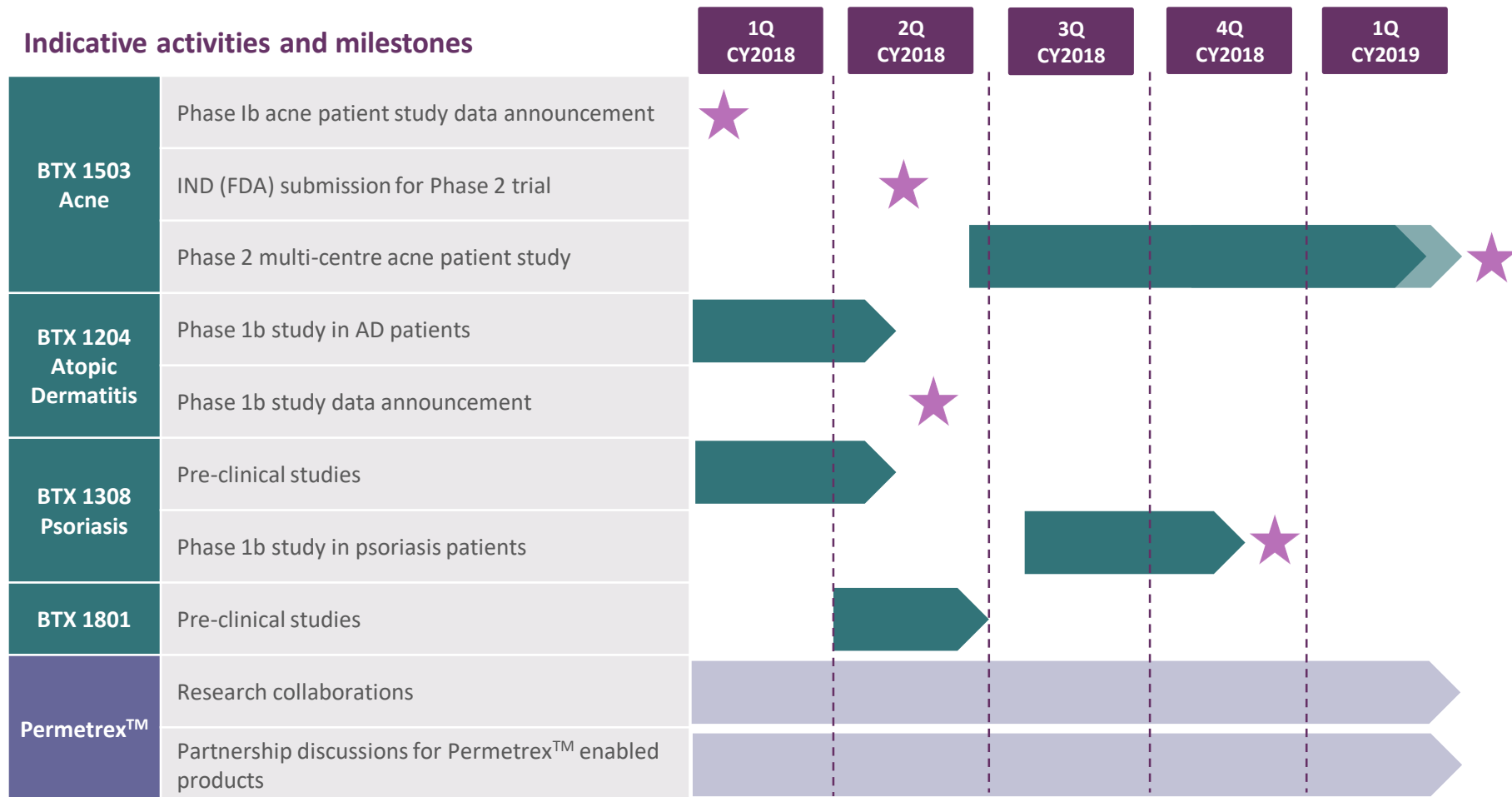




Upcoming milestones

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

Indicative activities and milestones





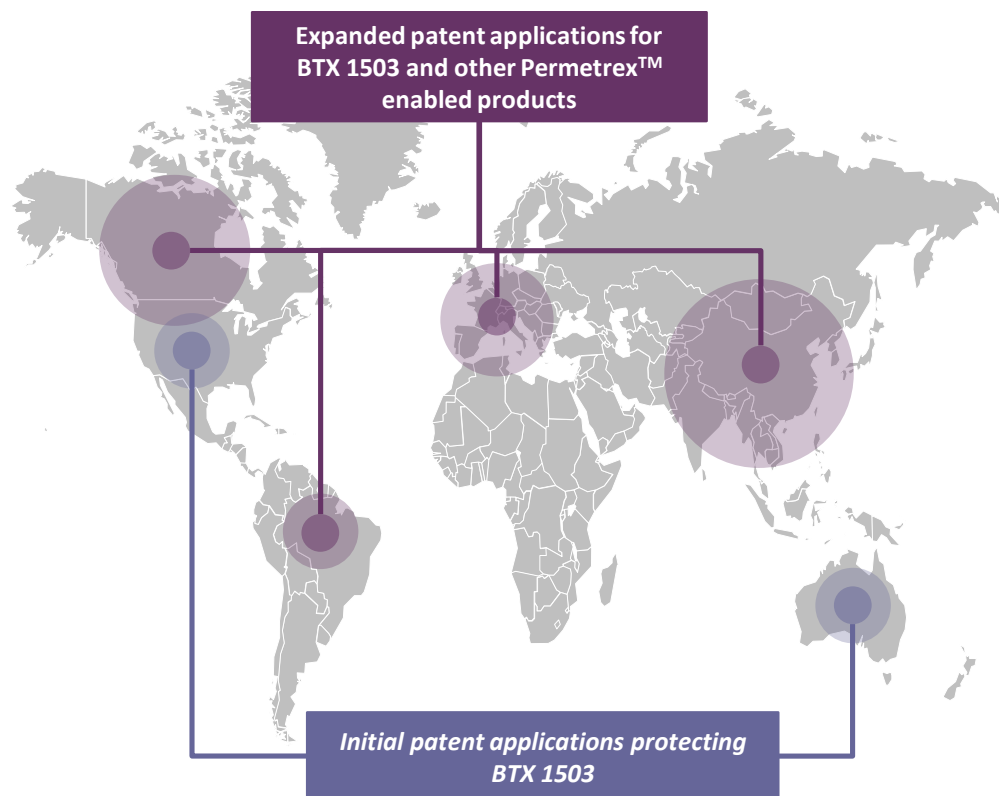
Appendix



Valuable intellectual property portfolio

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

- Botanix currently has 16 patent applications across 7 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

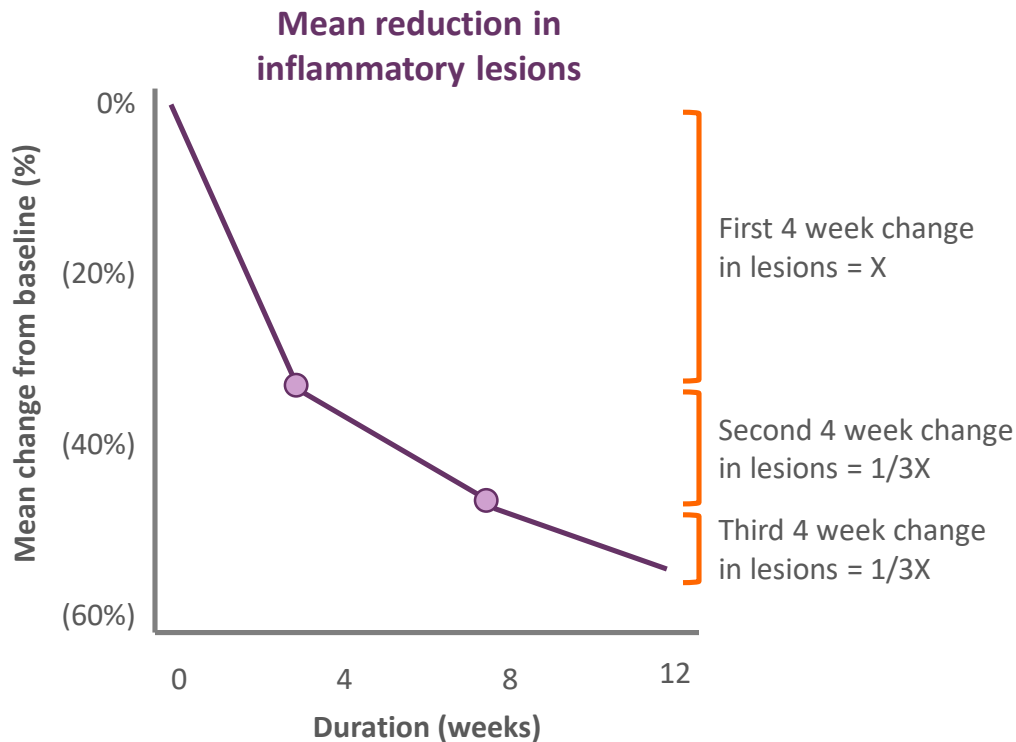




What do early clinical studies tell you?

Short term patient studies are valuable to provide indications of safety and efficacy which can be extrapolated (based on prior clinical data) for potential longer term effect

Prior clinical data to extrapolate potential effect¹



Data that can be drawn from early clinical studies

- Safety and irritation of topical product in real life repeat dose use
- Evidence of efficacy to reduce acne lesions (particularly inflammatory lesions)
- Indications of mechanism (anti-inflammatory) for future clinical development

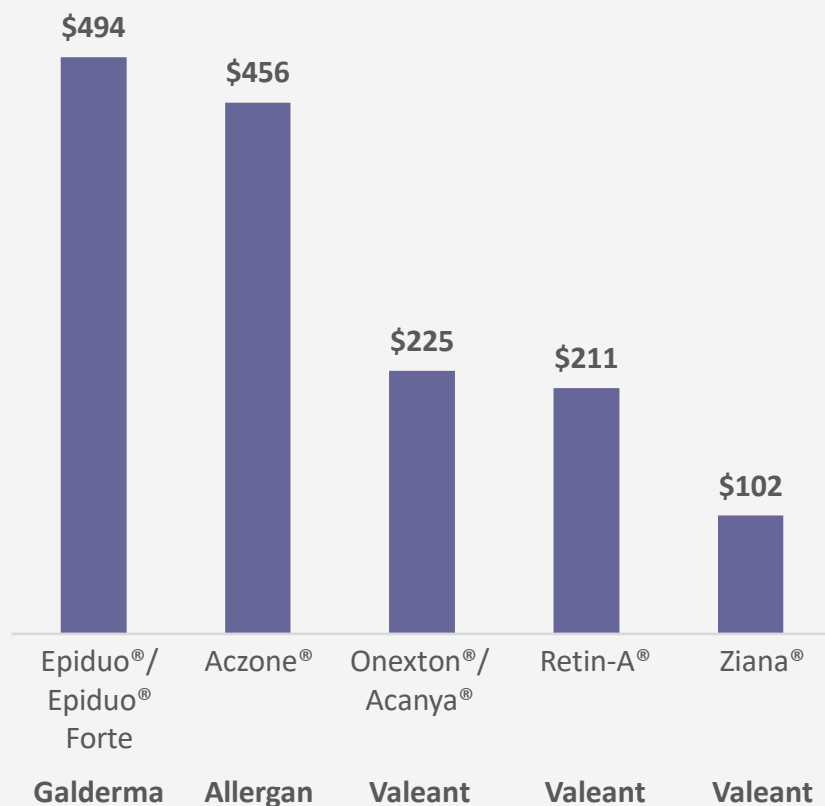
1. Example based on aggregation of 4 recent acne clinical development programs



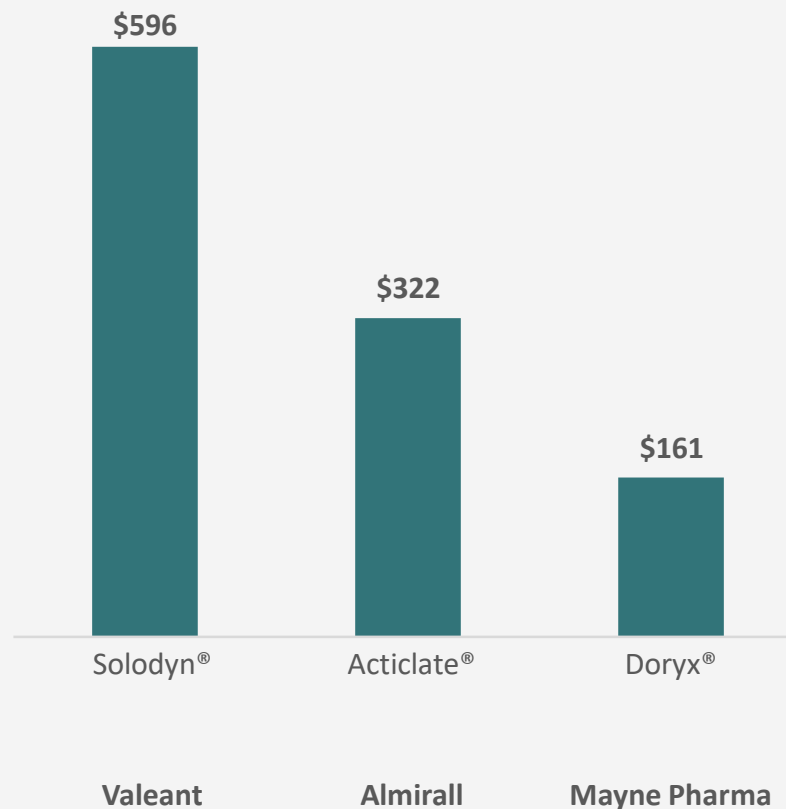
Leading US branded products by revenue

Leading topical and oral branded acne products generated sales of ~US\$4.9bn in 2016

Topical branded acne product sales in 2016 (US\$m)



Oral branded acne product sales in 2016 (US\$m)





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