

ASX/Media Release

15 February 2018

Botanix to present at the American Academy of Dermatology annual meeting

- Botanix will be presenting at the 76th AAD annual meeting in San Diego, California
- Botanix to showcase recent results of the BTX 1503 study and progression of other clinical development programs to key industry opinion leaders
- Botanix will have the opportunity to engage with several global pharmaceutical companies to explore potential commercial and product opportunities

Philadelphia PA and Sydney Australia, 15 February 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or the "Company") is pleased to release a new company presentation, which Botanix Executive Director, Matt Callahan will be presenting at the 76th American Academy of Dermatology (AAD) annual meeting in San Diego, California.

The presentation at the AAD annual meeting will allow Botanix to provide an update of the Company's leading clinical development programs to key opinion leaders in the industry. Botanix will provide an update on the recent successful BTX 1503 study, and plans for the Company to rapidly advance BTX 1503 into a FDA regulated Phase 2 study which is expected to commence in mid- CY2018.

The Company will update prospective partners on the positioning of BTX 1204 in the broader atopic dermatitis market, as well as the market potential for a safe and effective topically applied product. Botanix remains on track to release Phase 1b results from its current atopic dermatitis patient study (BTX 1204) in 2Q CY2018.

Botanix will also have the opportunity at the AAD meeting to engage with several global pharmaceutical companies that have an interest in treatments for acne, atopic dermatitis and other dermatological conditions. Botanix will continue to explore several commercial and product opportunities in parallel with discussions about its leading clinical programs.

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

American Academy of Dermatology
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 (14-Feb-18)	A\$0.110
52 week low / high	A\$0.040 / A\$0.160
Shares outstanding ¹	681.9
Market capitalisation	A\$75.0m
Cash (Feb-18) ²	A\$17.1m
Debt (Feb-18)	-
Enterprise value	A\$57.9m

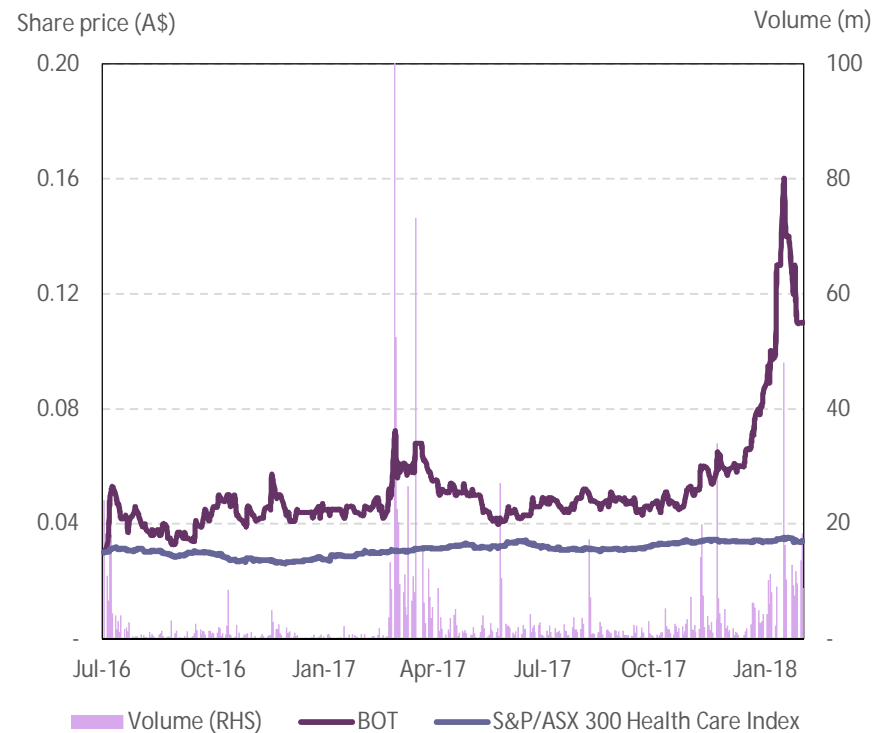
Top shareholders (Feb 2018)

Shareholder	%
Matthew Callahan – <i>Executive Director</i>	10.4
Caperi Pty Ltd – <i>Co-founder</i>	10.4
Board (excl. shareholders above)	3.0

Source: IRESS

- Includes 156.5m fully paid ordinary shares subject to escrow until 15 July 2018 and excludes 47.8m options
- Cash includes A\$14.9m (before costs) received from capital raising announced 5 February 2019

Share price performance



+ 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 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



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

20+ FDA approved products





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	

+ BTX 1503
moderate to severe acne

+ How does BTX 1503 work to treat acne?

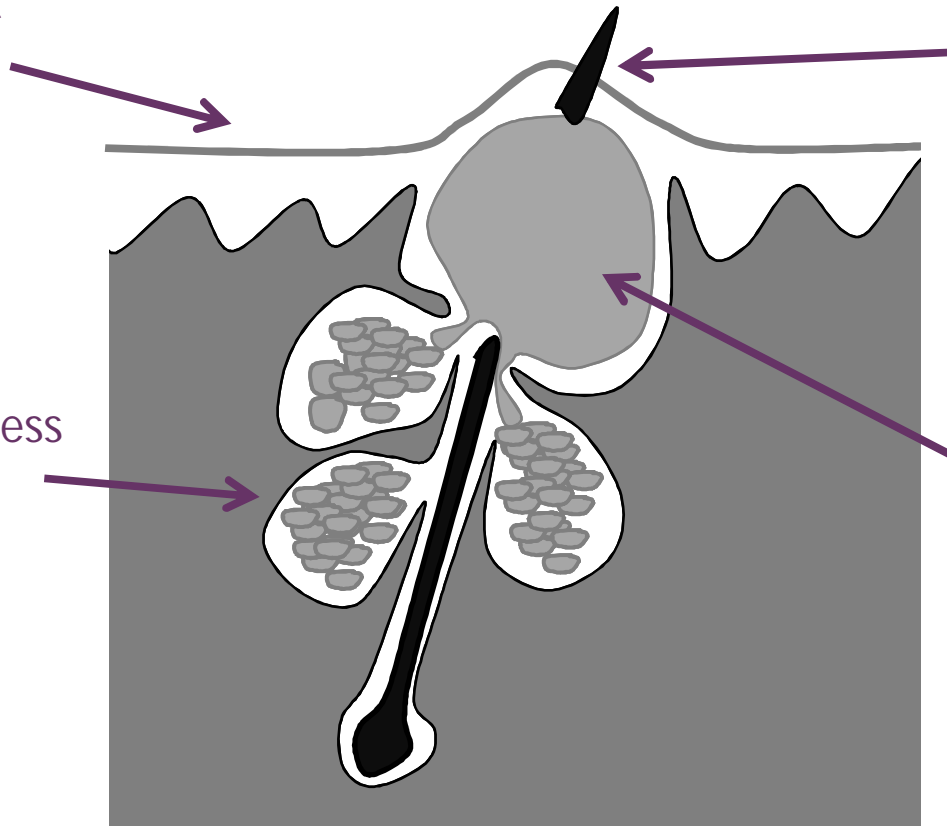
BTX 1503 utilises synthetic form of a natural product known as *cannabidiol*, combined with the novel Permetrex™ skin delivery technology

Attacks *P. Acnes* bacteria

Reduces Inflammation

Switches off excess production of sebum

Retards formation of sebum "plugs"



+ BTX 1503 Phase 1b acne patient study

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

Baseline

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

Safety

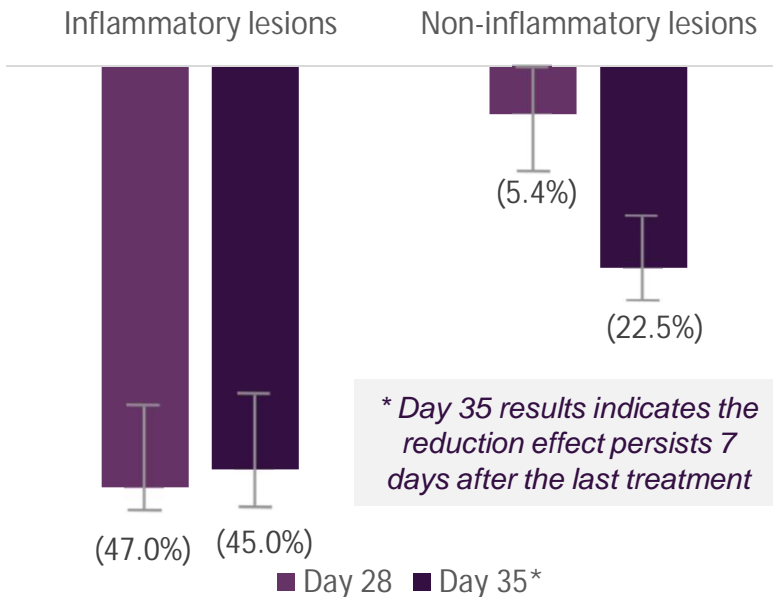
- § 18 subjects completed the study
 - Lost to follow-up: 2; Withdrawal: 1
- § No serious adverse events (AEs)
- § No subjects discontinued due to an AE
 - Total of 7 AEs reported (not related)
 - Of the 7 AEs only 1 AE was deemed to be possibly related (mild sore eyes)
- § Tolerability
 - Slight burning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



BTX 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
 Aczone®	Allergan	~38%	US\$456m
BTX 1503	Botanix	~47%	-

§ Combination of two drugs – benzoyl peroxide and adapalene
 O Common side effects include redness, skin peeling mild burning / stinging and dryness

ü Few side effects
 O Studies showed large placebo / vehicle effect – i.e. at 12 weeks Aczone reduced inflammatory lesions by 54% while vehicle achieved 48% reduction

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

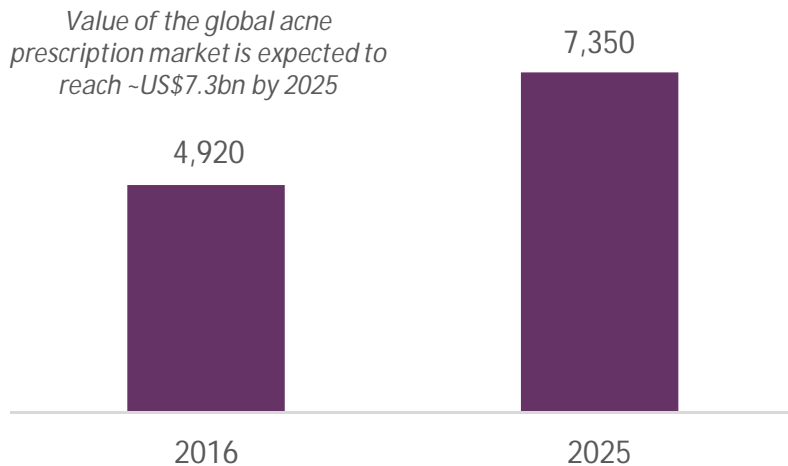
Patient satisfaction report was "Much Better"

1. Patient demographics: 21 year old female

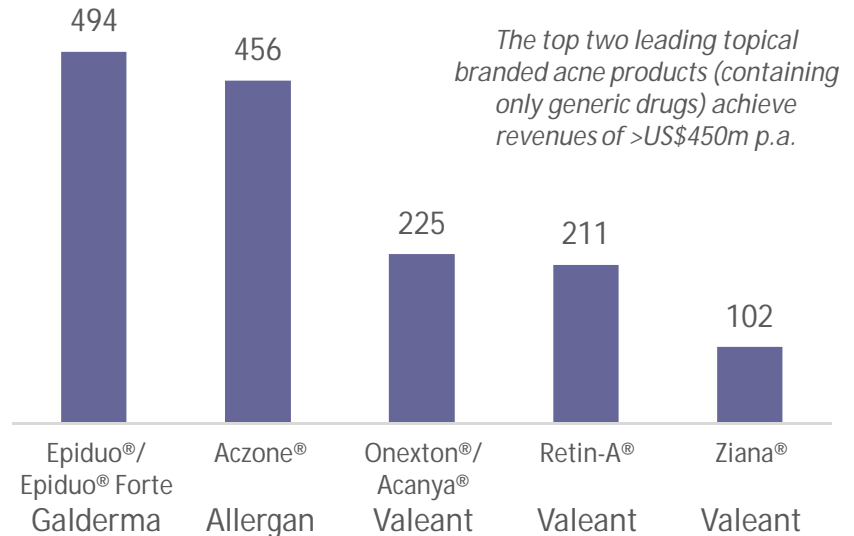
+ Why are we focused first on acne?

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)



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



Large demand with limited recent product development

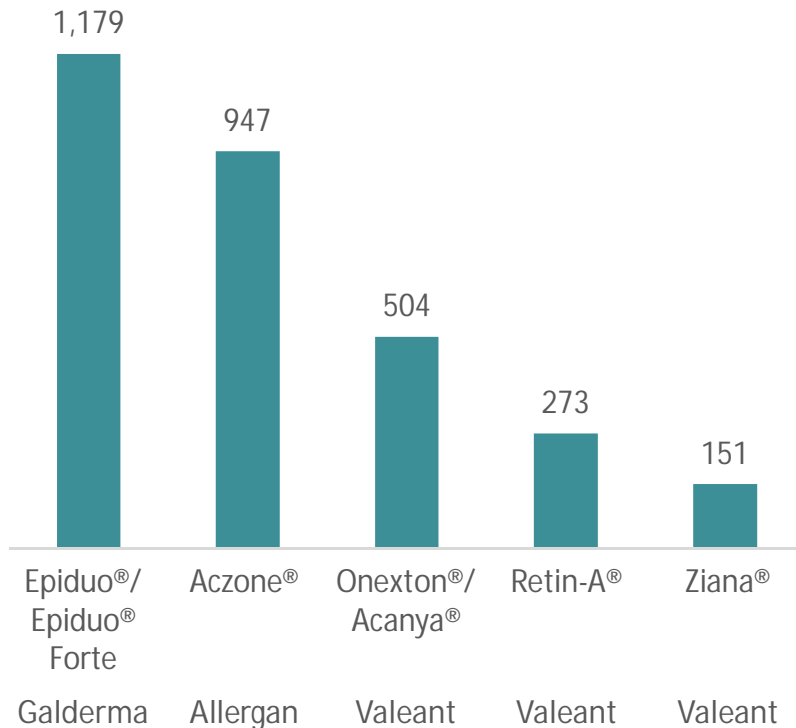
- § No new chemical entities have been approved by the FDA in the last 20 years for the treatment of acne
- § Only “new” products launched were combinations of old drugs in new formulations or packaging



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)

Source: Symphony Health Services (PHAST) 2017; The Medical Letter Vol. 58 (1487)

1. Estimated cost assuming 1 unit per month for 12 months



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	-	P	P	Possibly	Local irritation; mild acne only
	Topical Antibiotics	-	-	P	Possibly	Local irritation; inflammatory acne only; antibiotic resistance
	Topical Retinoids	-	P	-	Possibly	Local irritation; phototoxic
	BTX 1503	P	P	P	P	No known side effects, broad mechanism
Oral	Oral Contraceptives	P (Indirectly)	-	-	-	Gender specific; systemic side effects
	Anti-Androgens	P	-	-	-	Gender specific; systemic side effects
	Oral Antibiotics	-	-	P	P	Systemic side effects; antibiotic resistance; inflammatory acne only
	Oral Isotretinoin	P	P	P (Indirectly)	P	Severe skin and systemic side effects

1. Subject to successful development and approvals

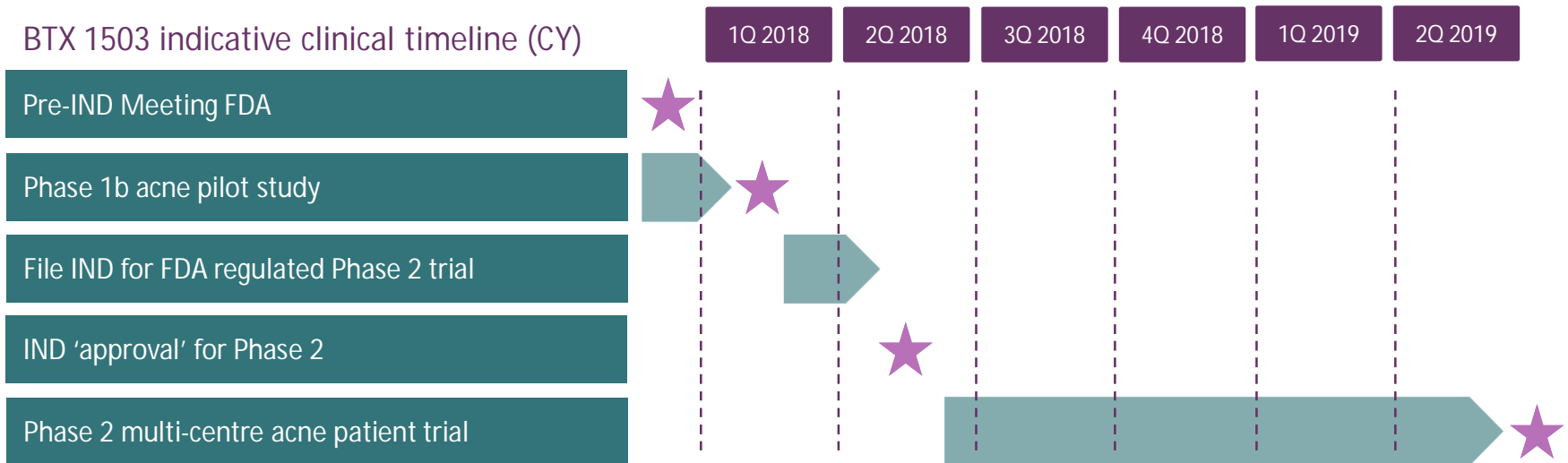


BTX 1503 development timeline overview

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

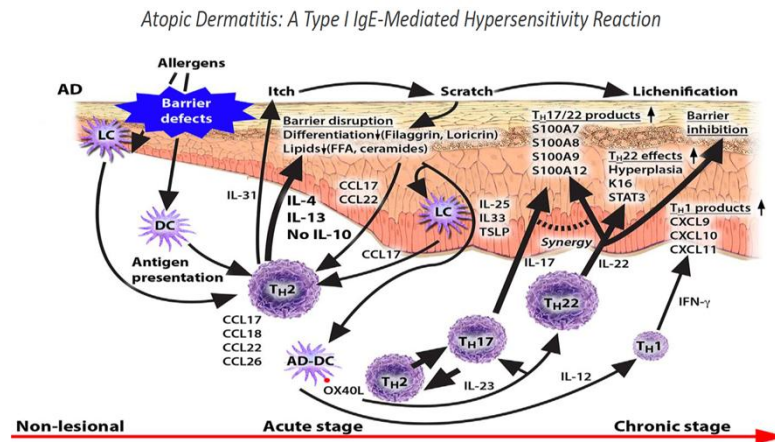


BTX 1204 for atopic dermatitis

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

Potential mechanism of actions

- ü Decrease differentiation, proliferation and activity of t-helper 1, 2, and 17 cells as well as Il-17 levels and downstream effects
- ü Decrease interferon- γ , which may have an inflammatory effect and improve ceramide production in the skin (latter may prevent deterioration of skin barrier function)
- ü Attack most common trigger of AD (i.e. *staphylococcus aureus*) and reduce keratinocyte proliferation
- ü Increase intracellular expression of antioxidants and decrease reactive oxygen species

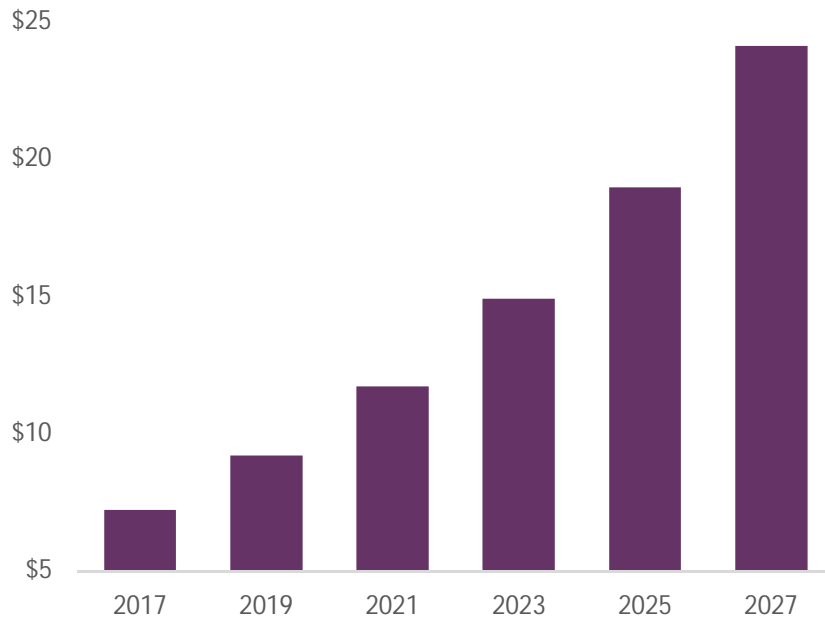




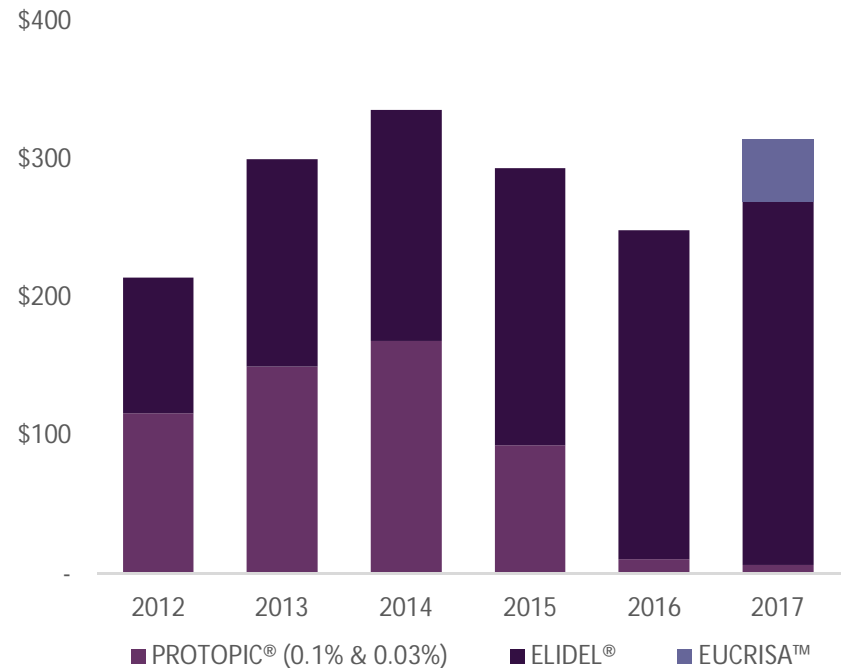
Global atopic dermatitis market

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

Projected AD market by revenue (US\$bn)



Leading topical branded AD products by revenue (US\$m)



Limited innovation and significant remaining unmet needs

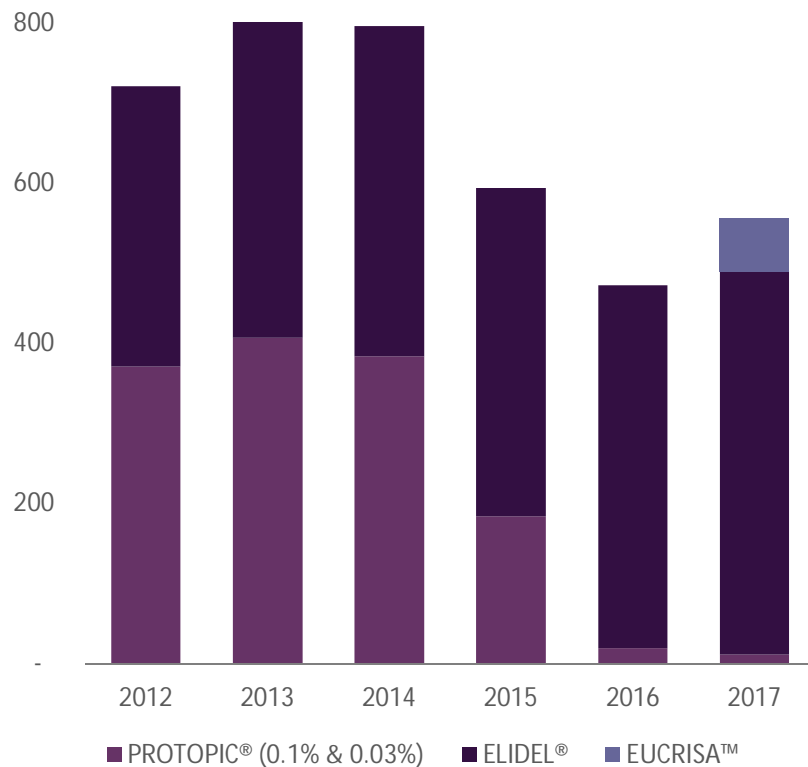
- § Minimal innovation in atopic dermatitis for 15 years before the 2016 approval of Eucrisa®
- § Eucrisa® does not affect itch and has been a launch failure



Leading US branded atopic dermatitis products

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

Leading topical AD products by prescription ('000s)



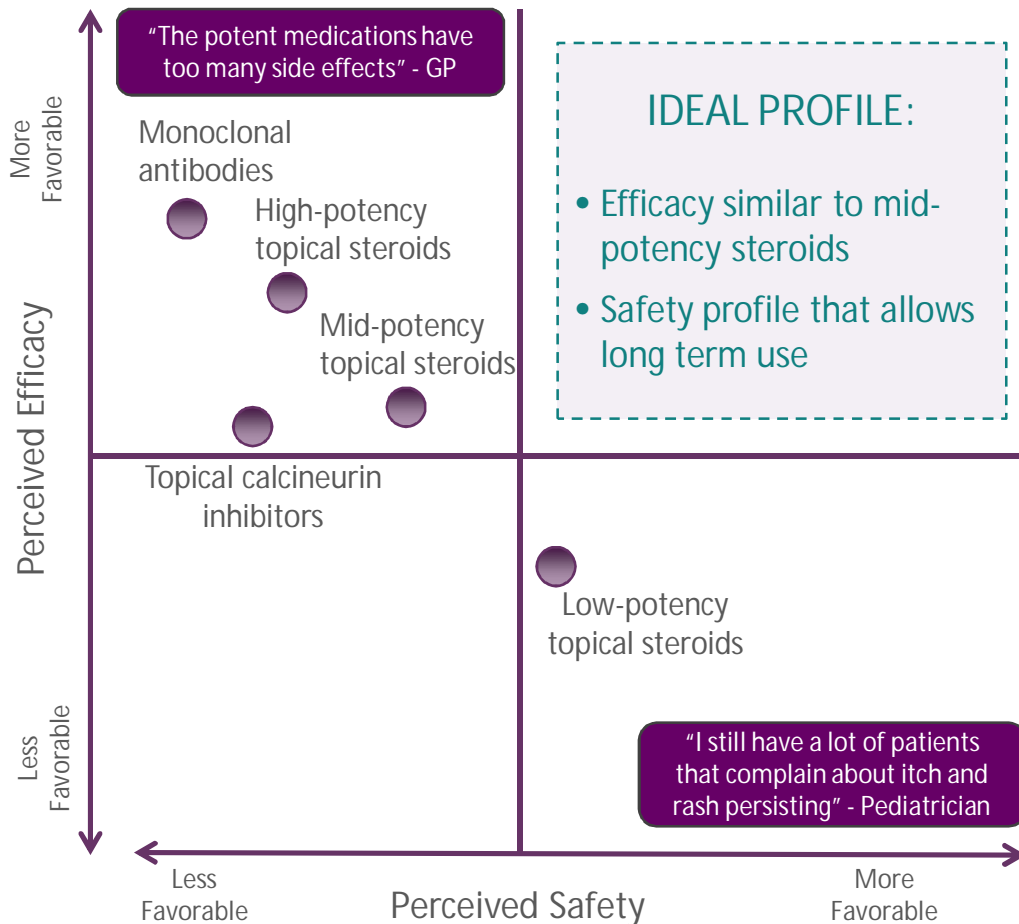
2016 list price and cost of topical AD products

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

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

+ BTX 1204 positioning and opportunity

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



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

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



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



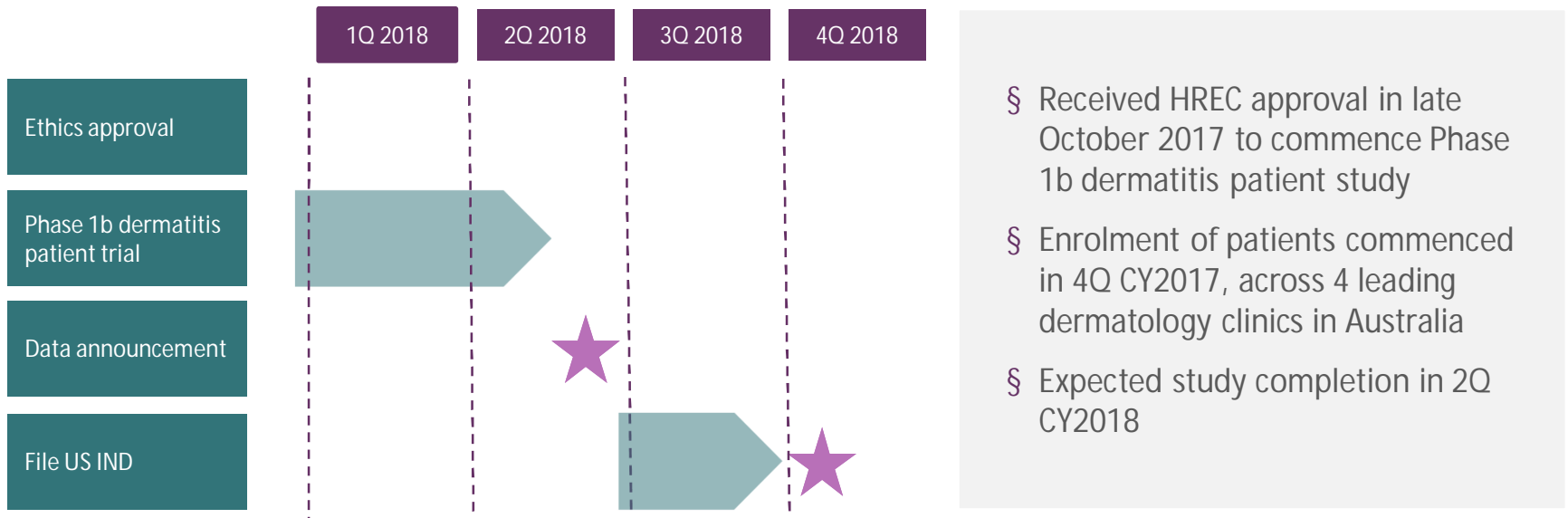
Data available in [2Q CY2018](#)



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)



Study demonstrates Botanix's ability to accelerate the addition of clinical programs by leveraging previous clinical data from acne program

+ 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

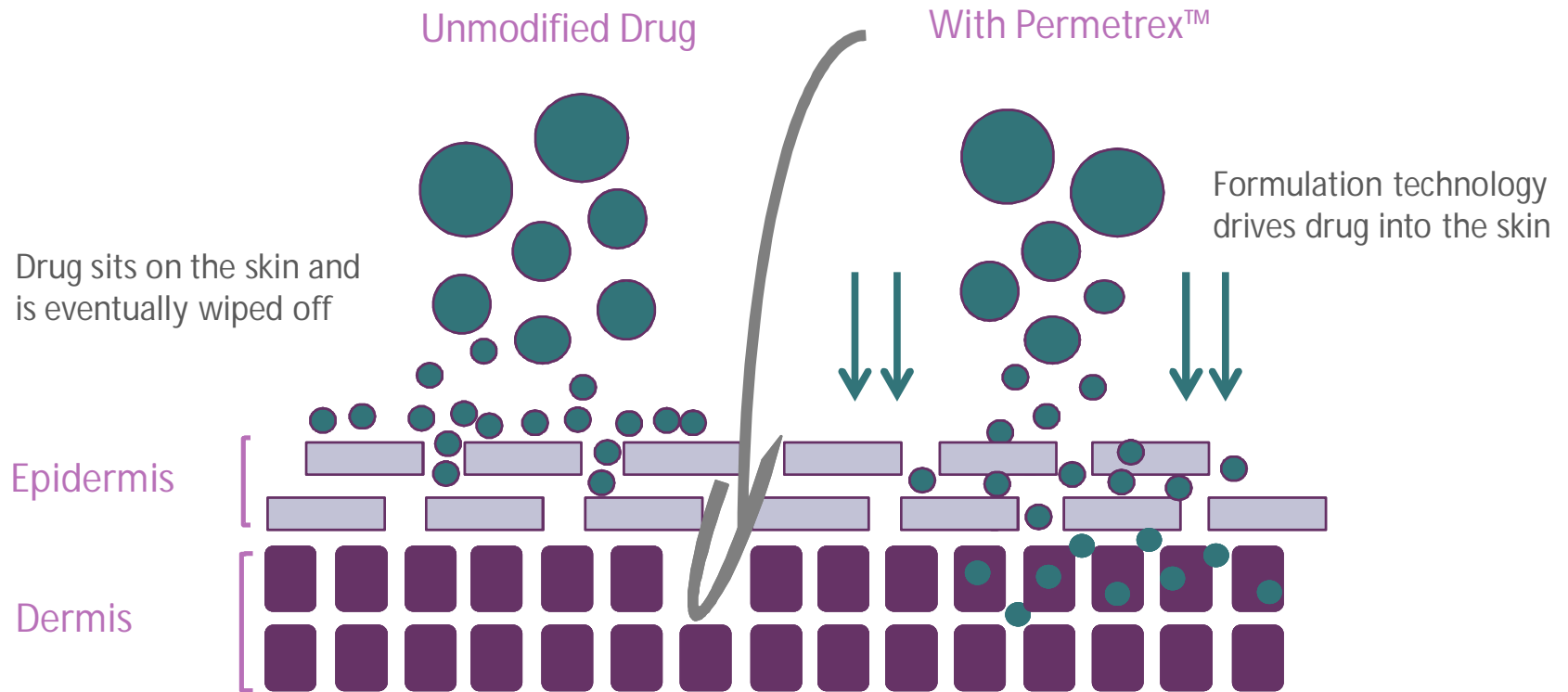
BTX 1308 leverages prior data from:

- ü BTX 1503 acne clinical program
- ü Permetrex™ delivery system studies
- ü 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



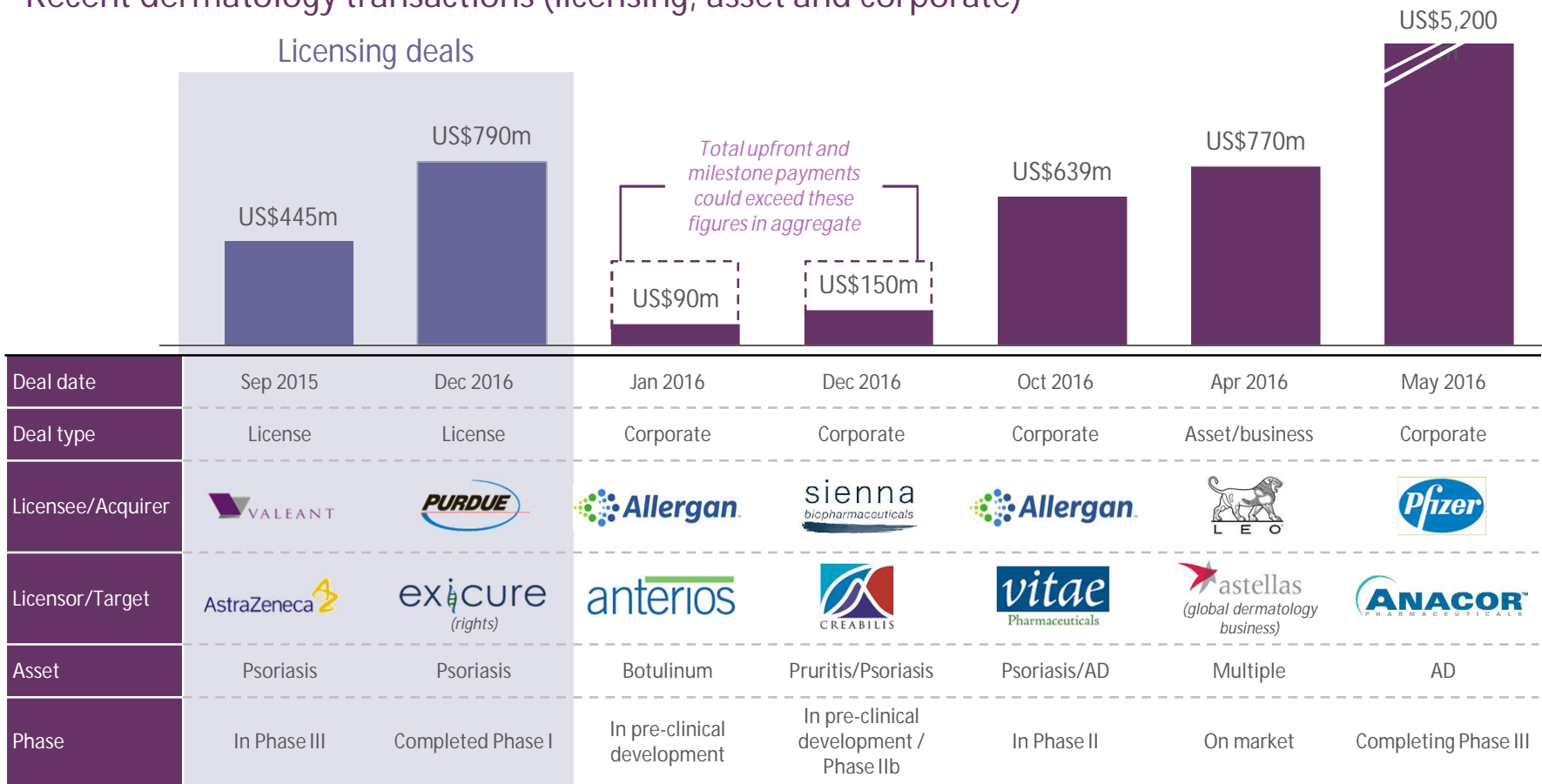
+ Appendix



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)

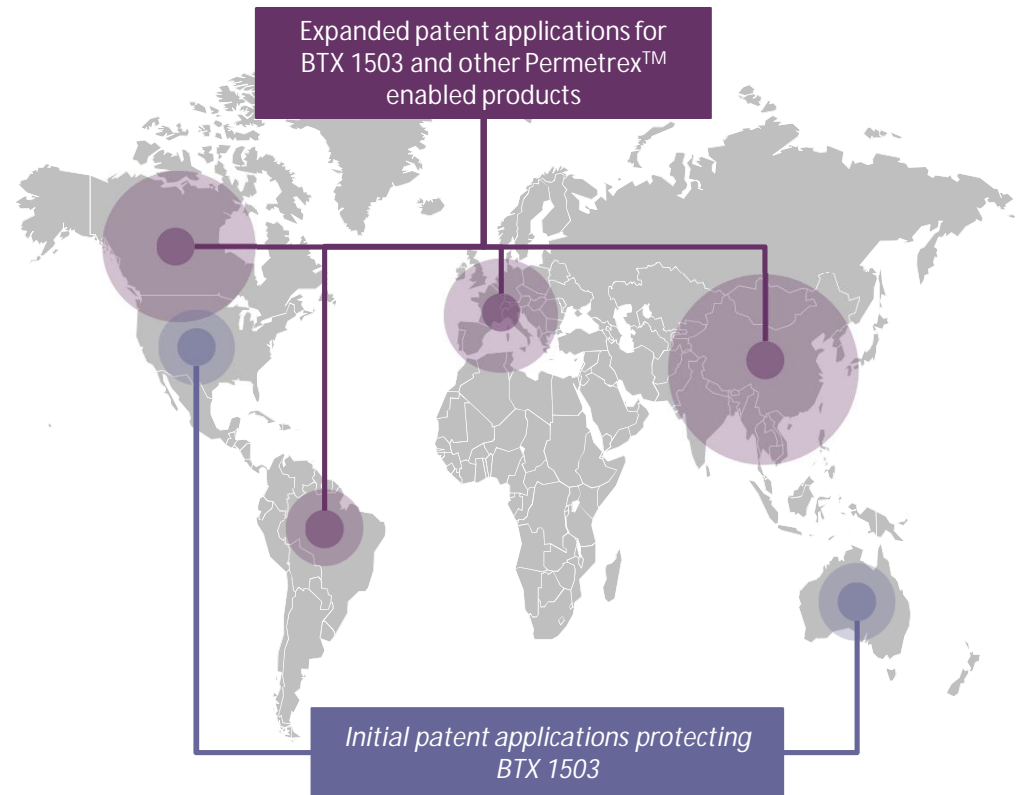




Valuable intellectual property portfolio

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

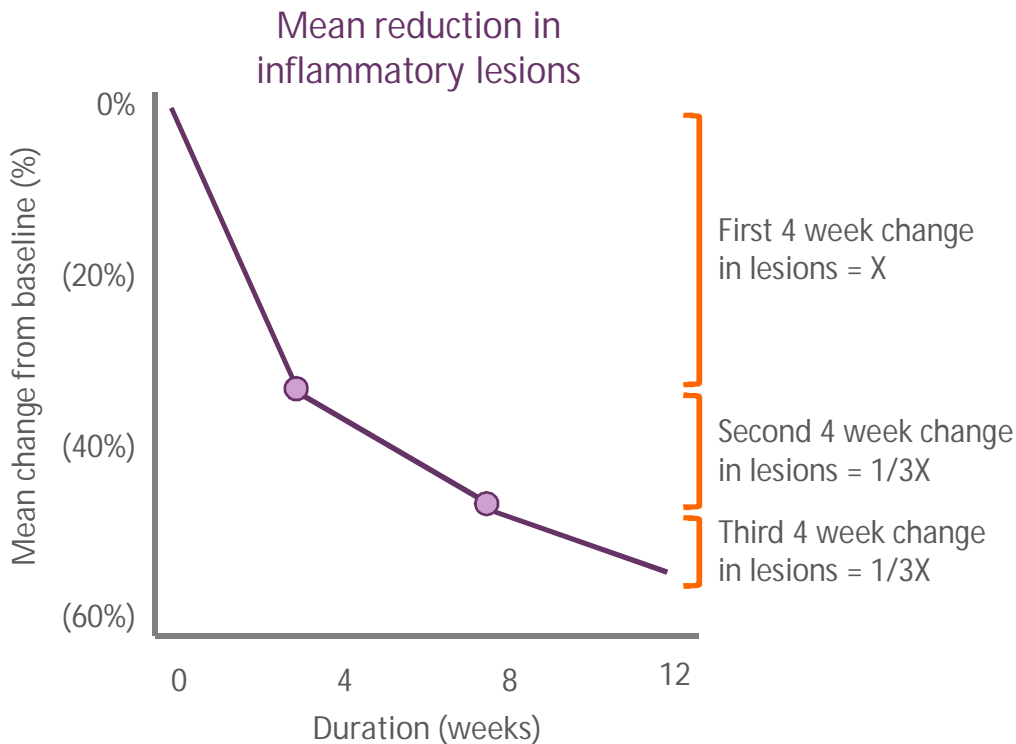
- § Botanix currently has 16 patent applications across 7 different patent families
- § Patents applications cover lead acne product and other Permetrex™ enabled products
- § Patent protection targeted at key geographic regions with large and viable dermatology markets (i.e. initially filed in US and 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



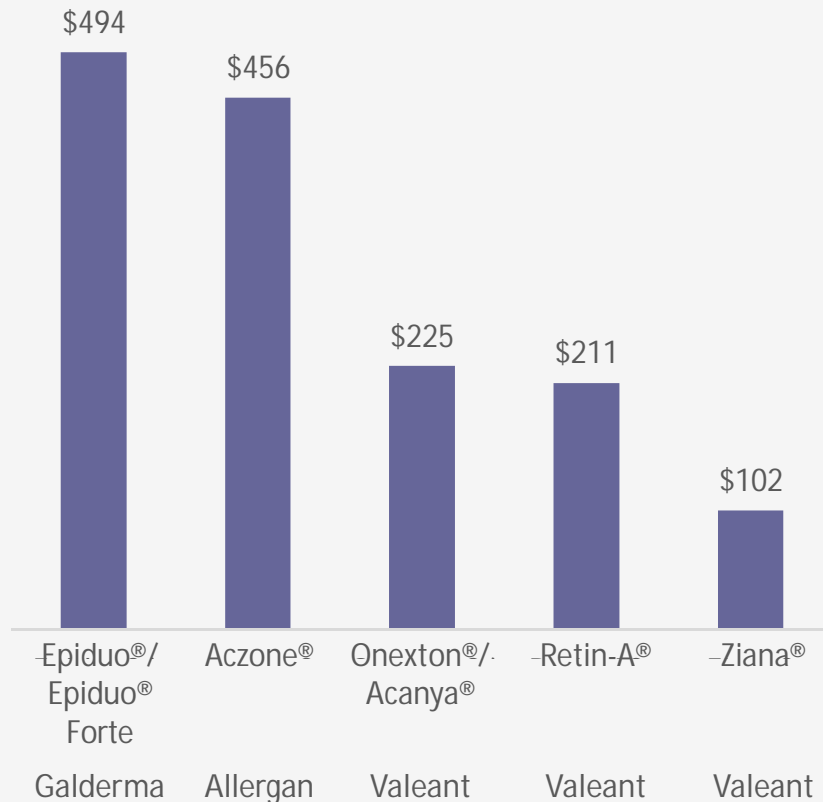
Data that can be drawn from early clinical studies

- § 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

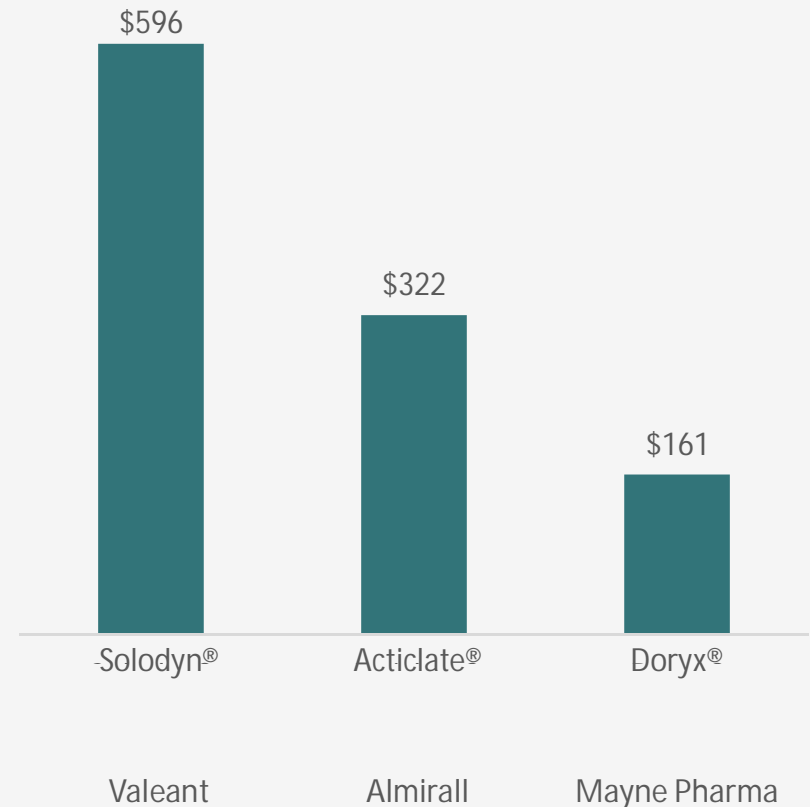
+ Leading US branded products by revenue

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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