

ASX/Media Release

22 January 2018

Presentation to Botanix Advisory Board

- Botanix convened an Advisory Board meeting on 19 January 2018 to review the clinical programs and market opportunities for its product portfolio
- The global acne market is estimated to reach US\$7.3bn in 2025, with the top 2 leading acne products currently generating >US\$1bn of sales in the US
- A topically applied product with a benign safety profile, multiple mechanisms of action and improved efficacy has the potential to generate significant revenues
- BTX 1503 has significant potential to address this market opportunity and first patient data is expected to be available in early Q1 2018

Philadelphia PA and Sydney Australia, 22 January 2018: Medical dermatology company Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or the "Company") is pleased to release a presentation made at its Advisory Board meeting held on 19 January 2018. The presentation focused on the rapidly growing acne market and the positioning of the Company's BTX 1503 product. The meeting was held with the Company's advisers in Philadelphia, Pennsylvania ahead of the upcoming data from the BTX 1503 Phase 1b study.

Botanix Executive Director Matt Callahan said, "The updated global acne market data provides compelling context for the potential of BTX 1503 in the US market. We believe that BTX 1503 is at the forefront of a significant market opportunity. Botanix remains on track to release results from the Phase 1b BTX 1503 study in early 1Q CY2018."

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

Acne Market Assessment

Advisory Board Meeting

January 2018



Agenda

1. Overview
2. Acne disease overview and unmet medical needs
3. Acne market dynamics
4. Acne competitive landscape and BTX 1503 positioning
5. Conclusions and discussion

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1. Overview

+ Executive summary

This presentation provides an update on the global dermatology and acne markets, and the significant market opportunity that exists for BTX 1503

- § Botanix is a leading dermatology focused company with rapidly advancing products underpinned by a deep product portfolio – its flagship product development is targeting acne
- § The global acne market is projected to reach US\$7.3bn in 2025, growing at a CAGR of 4.6% between 2016-2025
- § In 2016, the top 2 leading acne products generated >US1bn of sales in the US¹
 - Epiduo® / Epiduo® Forte (Galderma): topical acne product with sales of ~US\$494m
 - Solodyn® (Valeant): oral acne product with sales of ~US\$596m
- § Current products in mid-to-late stage development lack innovation and predominantly address only one of the four key acne pathologies – primarily bacterial infection
- § A topically applied product with a benign safety profile and multiple mechanisms of action, which improves efficacy as compared to current standard of care, has the potential to generate significantly higher revenues than currently marketed products
- § BTX 1503 has significant potential to address this market opportunity and first patient data is expected to be available in early Q1 2018



Overview

Botanix is an emerging global dermatology company with rapidly advancing products and one of the deepest pipeline of opportunities in the industry

Dermatology Focused

- § Targeting a multi-billion dollar market for acne therapeutics (with no new products approved in the last 20 years) and atopic dermatitis
- § Patient study data for acne planned for early 1Q CY2018 and atopic dermatitis data in 2Q CY2018

Novel Approach

- § Lead products based on synthetic form of a widely studied natural product which 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 and extensive dermatology industry experience
- § Advanced lead product from formulation to successful clinical trial within 12 months and advanced 2nd product into clinic within 18 months

+ Rapidly advancing clinical programs

Two advanced clinical programs in acne and atopic dermatitis, with follow on program in psoriasis all leveraging a synthetic form of the natural product cannabidiol

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	██████████	██████████	██████████	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

§ Cannabidiol is a molecule found in nature which is being studied in more than 100 clinical studies in other therapeutic areas

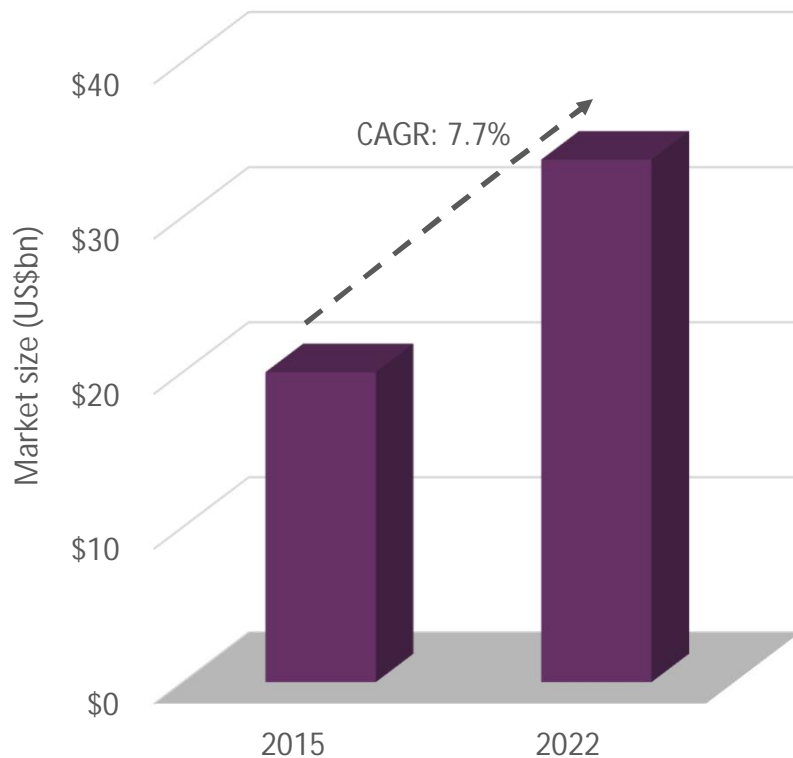
§ No adverse side effects have been identified for cannabidiol and Botanix’s own studies have confirmed that no irritation or safety issues are present with the BTX topical products



Dermatology market overview

The global dermatology market is estimated to grow to US\$33.7bn in 2022

Global dermatology market



- § More than 3,000 types of dermatological conditions exist, ranging in severity and clinical presentation
- § Approximately one third of the US population suffers from an active skin condition
- § The global dermatology market is estimated to be worth US\$33.7bn by 2022, representing an increase of >65% from 2015 (US\$20.0bn)
 - Market growth expected to be driven by strong late-stage products in development
- § Significant unmet medical need for treatment options that:
 - Improve patient compliance
 - Have improved safety/tolerability profiles
 - Allow for long-term use

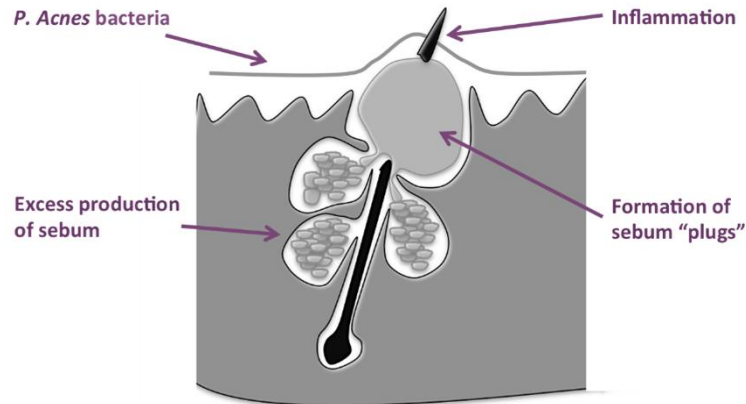
+ 2. Acne disease overview and unmet medical needs



Acne overview

Acne forms as the result of obstruction and inflammation of hair follicles and their sebaceous glands

Formation of acne is caused by four factors



- Goals of acne treatment are to:
- § Inhibit sebaceous gland function
 - § Control the growth of bacteria and bacterial infections
 - § Reduce inflammation
 - § Normalize the pattern of follicular keratinization

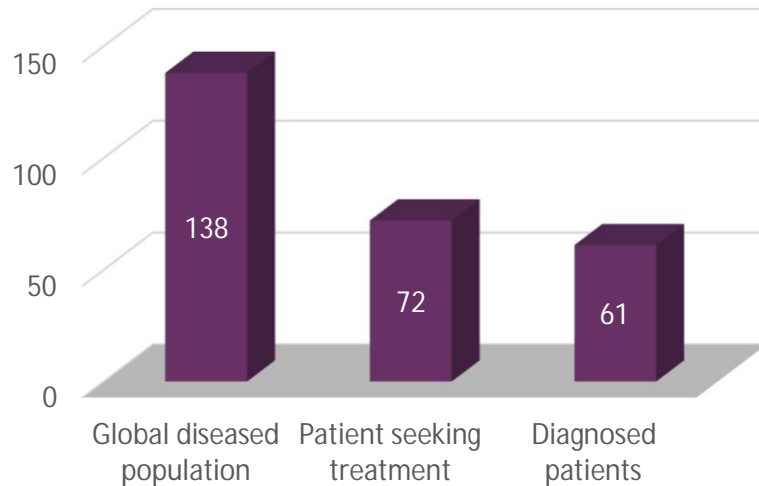
Acne can present as non-inflammatory or inflammatory lesions and / or nodules and is diagnosed by classification of severity:

- § Mild: some noninflammatory lesions; no more than a few papules / pustules; but no nodules
- § Moderate: many non-inflammatory lesions; some inflammatory lesions; but no more than one small nodule
- § Severe: up to many non-inflammatory and inflammatory lesions; but no more than a few nodules

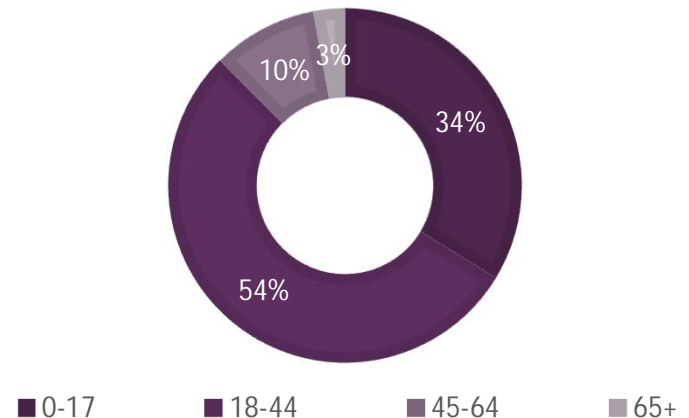
+ Acne epidemiology

Acne is the most common skin disease in the US and more than half of the target population are teenagers

Global acne epidemiology: 2018 estimates (m)



Acne diagnosis by age



- § Acne affects approximately 50m people in the US
- § ~85% of people between 12 – 24 will experience at least minor acne at some point
- § ~54% of acne patients are diagnosed between 18-44 years of age
- § Though acne affects both men and women, 80% of adult acne cases are in women

+ Current acne treatment options

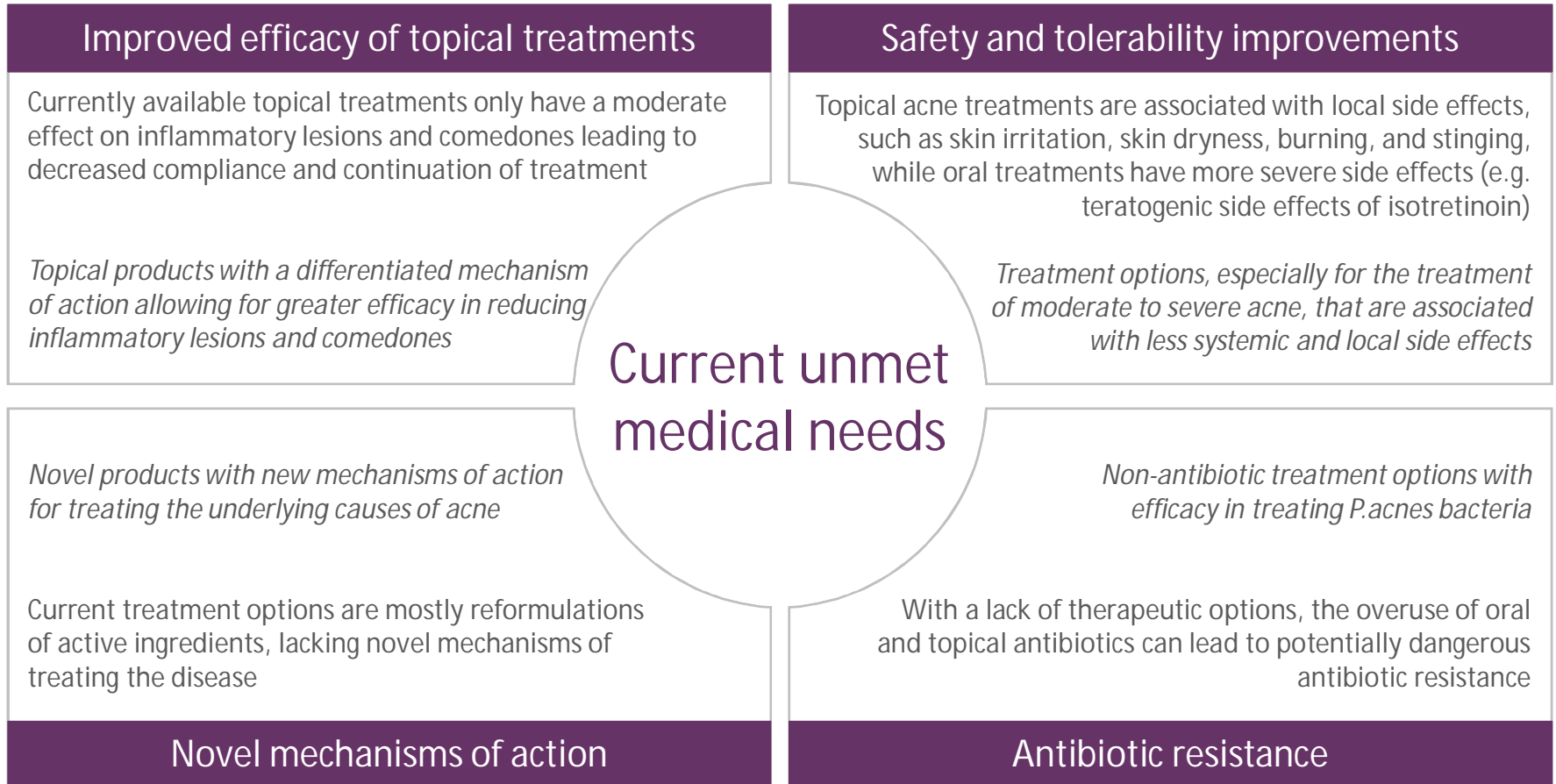
Current acne treatments do not treat all key acne pathogenic factors and have varying levels of side effects and disadvantages

Agents	Pathogenic factors				Key considerations / disadvantages
	Sebum Excretion	Hyper Keratinisation	P.Acnes proliferation	Inflammation	
Benzoyl Peroxide	-	P	P	Possibly	Local irritation; mild acne only
Topical Antibiotics	-	-	P	Possibly	Local irritation; inflammatory acne only; antibiotic resistance
Azelaic Acid	-	P	P	Possibly	Local irritation; mild acne only
Topical Retinoids	-	P	-	Possibly	Local irritation; phototoxic
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



Unmet medical needs in acne

There are four key areas of unmet medical needs in acne



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3. Acne market dynamics

+ Leading branded acne treatments

While a number of branded acne treatments exist, there have been no new drugs approved to treat acne for more than 20 years

Overview

- § Oral acne medications for moderate to severe acne are associated with good efficacy in reducing symptoms, but have significant safety side effects – e.g. oral isotretinoin (Absorica®/Accutane®) birth defects
- § Topical medications tend to have less severe safety side effects, but are not as efficacious as oral therapies

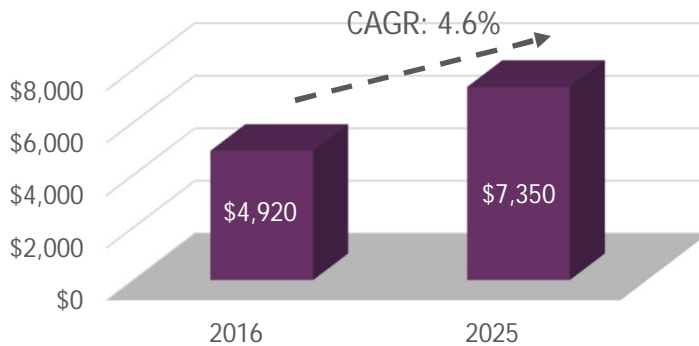
Drug	Company	Severity	Class	Active ingredient	Formulation
Epiduo®/ Epiduo® Forte	Galderma	Mild, Moderate, Severe	Topical retinoid / BPO	Adapalene / Benzoyl Peroxide	Gel
Aczone®	Allergan	Mild, Moderate, Severe	Topical antibiotic	Dapsone	Gel
Fabior®	Mayne Pharma (acquired from GSK)	Mild, Moderate, Severe	Topical retinoid	Tazarotene	Foam
Onexton®/ Acanya®	Valeant	Moderate to Severe	Topical antibiotic / BPO	Clindamycin / Benzoyl Peroxide	Gel
Solodyn®	Medicis / Valeant	Moderate to Severe	Oral antibiotic	Minocycline HCl	Oral
Absorica® (formerly Accutane®)	Sun Pharma	Severe	Oral retinoid	Isotretinoin	Oral



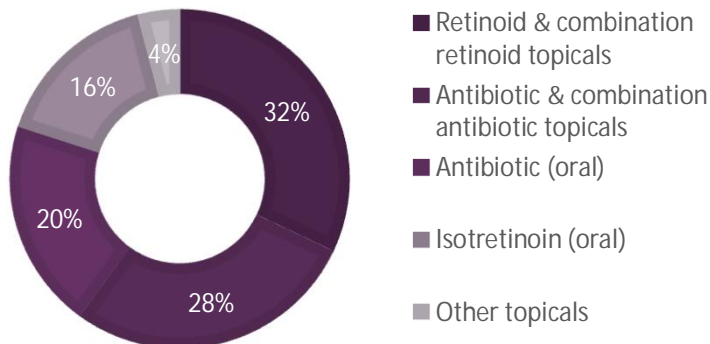
Global acne market

Despite being a significant market, the global acne market is highly genericised and warrants products with novel mechanisms of action

Global acne market size (US\$m)



US acne market by therapeutic class (%)



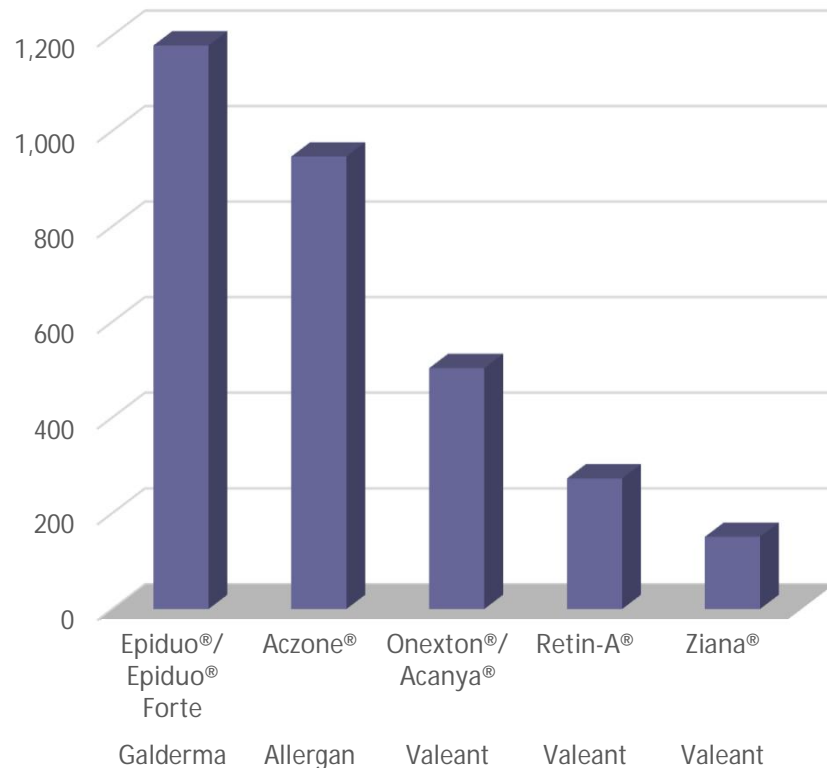
- § The global acne market is projected to reach ~US\$7.3bn in 2025
 - Key drivers: disease population growth and increasing prescription population
 - Market size is largely attributable to the Americas (~90% market share in 2015)
- § For moderate to severe acne, topical retinoids are the most commonly prescribed therapeutic class
 - Accounts for ~32% of the US market
 - Single active topical retinoid market ~US\$850m with 5m prescriptions p.a.
- § Innovation in the acne market has been limited with no new drugs approved in the US since Tazorac® (Allergan) in 1997



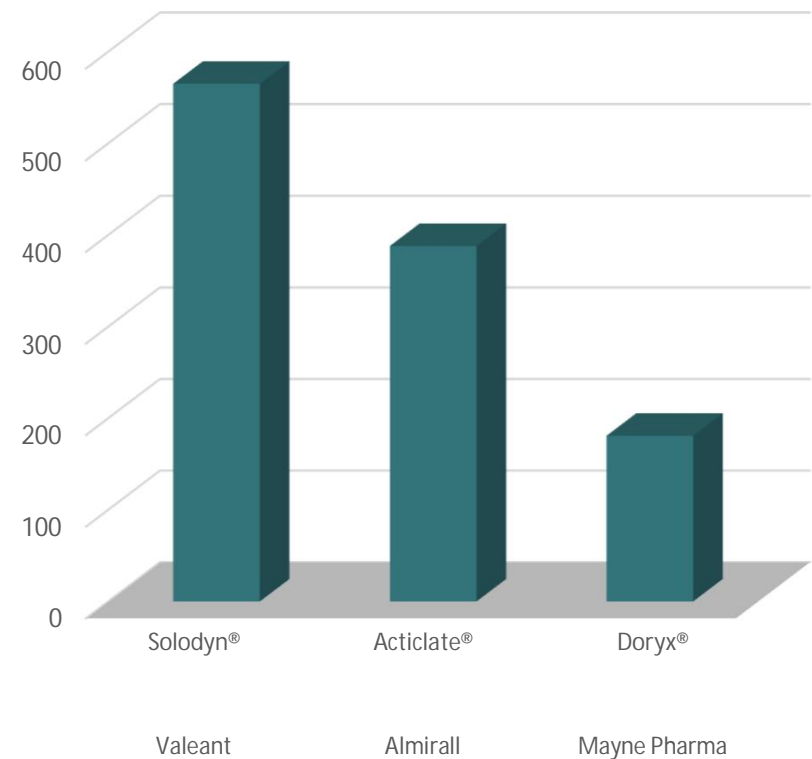
Leading US branded products by prescriptions

Leading topical and oral branded acne products generated >4m prescriptions in 2016

Topical branded acne products in 2016 ('000s)



Oral branded acne products in 2016 ('000s)

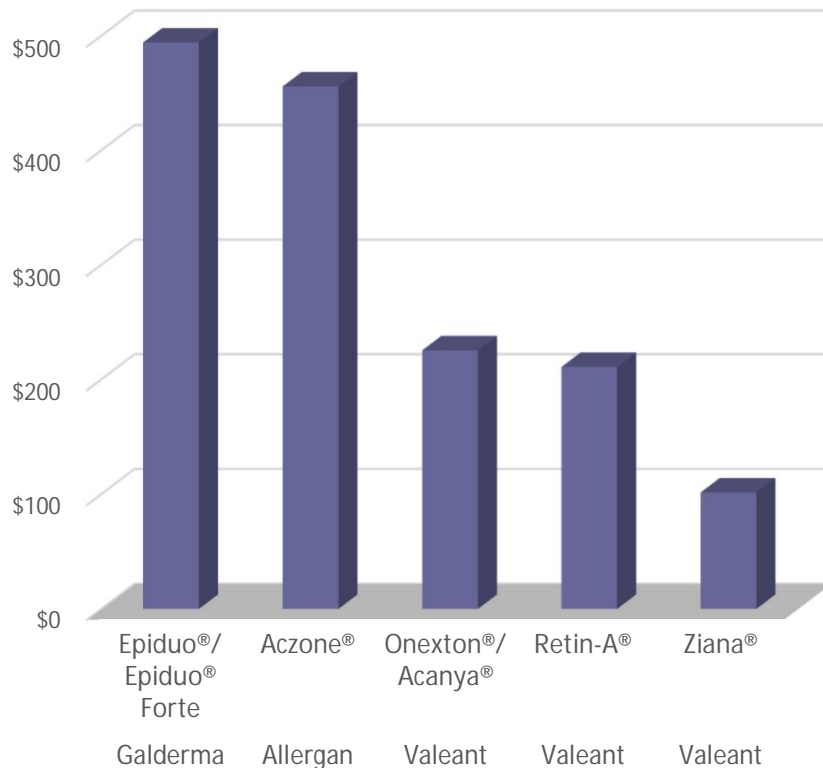




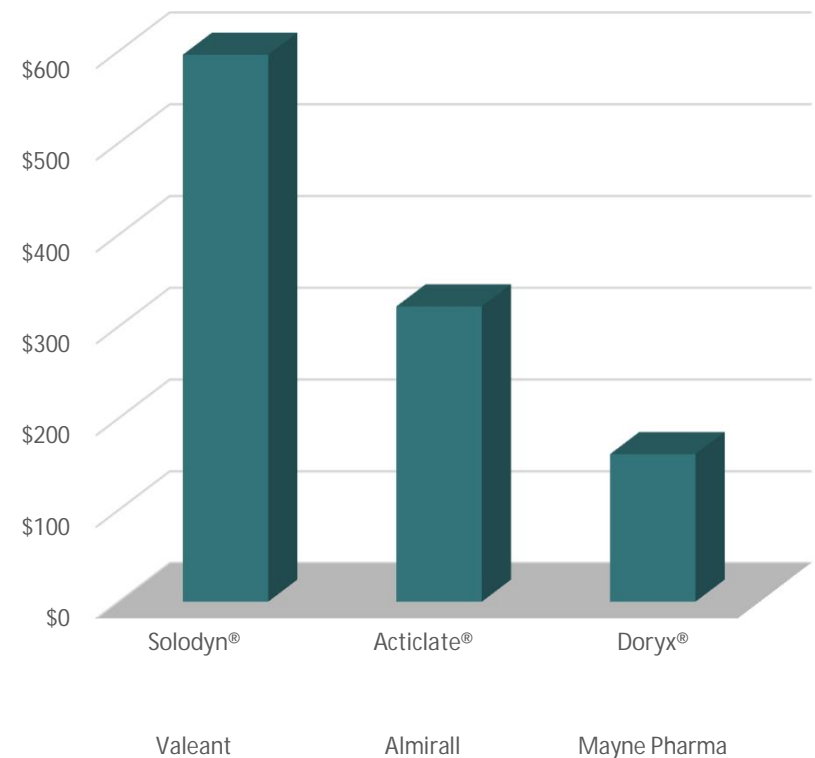
Leading US branded products by revenue

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)





List price of US acne products

Topical products	Drug	2016 unit list cost (US\$)	Estimated annual cost (US\$) ¹
Brand/ Branded Generic	Azelex®	\$344.70	\$4,136
	Acanya®	\$444.00	\$3,197
	Onexton®	\$444.00	\$3,197
	Aczone®	\$258.90	\$3,107
	Retin-A®	\$249.20	\$1,994
	Epiduo® / Epiduo® Forte	\$398.10	\$3,185
Generic	Topical Clindamycin	\$69.10	\$553
	Topical Clindamycin / Benzoyl Peroxide	\$162.80 (low strength) \$340.30 (high strength)	\$1,302 (low strength) \$4,900 (high strength)
	Tretinoin	\$128.00 (low strength) 158.50 (high strength)	\$1,024 (low strength) \$1,268 (high strength)

Oral Drugs	Drug	2016 unit list cost (US\$)	Estimated annual cost (US\$) ¹
Brand/ Branded Generic	Doryx®	\$629.70	\$7,556
	Solodyn®	\$1,040.40	\$12,480
	Absorica®	\$1,802.10	\$21,624
Generic	Doxycycline	\$422.40	\$5,069
	Minocycline	\$338.70	\$4,064

Source: The Medical Letter Vol. 58 (1487)

1. Assuming 1 unit per month for 12 months

+ 4. Acne competitive landscape and
BTX 1503 positioning



Competitive late stage programs in development

Prevalence of antibiotic programs that raise serious concerns about drug resistance and multiple failed programs (with some currently being repeated)

Program	Company	Active Ingredient / Target	Phase	Comment
Olumacostat glasaretil	Dermira	Acetyl coenzyme-A carboxylase inhibitor	Phase 3	§ Only targets single mechanism of action § Questionable side effect profile (i.e. dry skin etc)
ALTRENO™ (IDP-121)	Valeant	Tretionion 0.05%	NDA submission	§ Restricted to non-inflammatory lesions § Challenging IP protection
Seysara™	Allergan / Paratek	Sarecycline	NDA submission	§ Antibiotic – resistance challenges § Systemic side effects
SB204	Novan	Nitric oxide	Phase 3	§ Failed Phase 3 studies (currently repeating)
FMX-101	Foamix	Minocycline	Phase 3	§ Topical antibiotic § Failed Phase 3 studies
B244	AOBiome	Ammonia oxidizing bacteria (AOB)	Phase 2b / 3	§ Topical antibiotic equivalent § Only targets single mechanism of action

+ Acne treatment algorithm

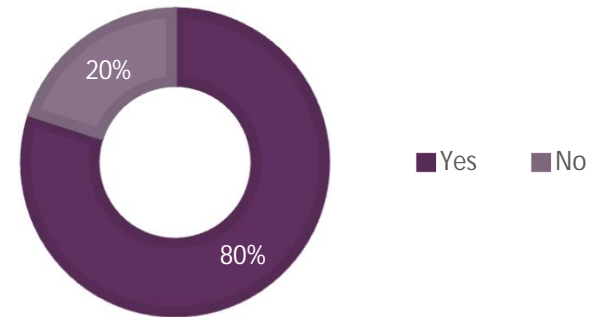
Most dermatologists prescribe more than one product and the majority are unsatisfied with available topical acne treatments

Treatment algorithm background

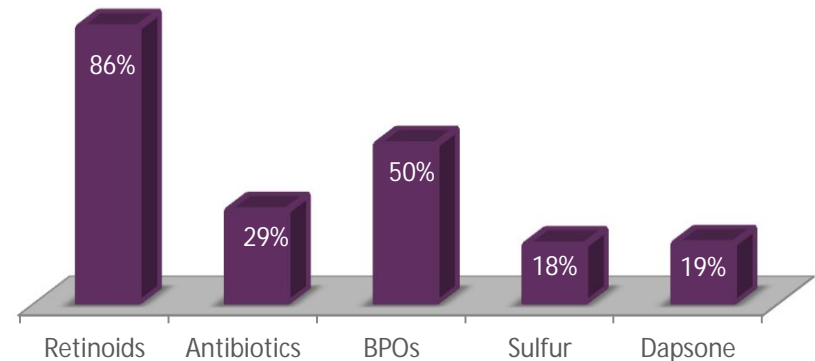
- § For reasons such as patient severity or treatment response, 100% of patients are prescribed more than one acne product
 - ~50% of patients use products at the same time; 50% use products sequentially
 - ~80% of dermatologists stated that they use single agent topical products; ~55% of dermatologists are unsatisfied with existing available topical acne treatments

- § Retinoids are the most commonly prescribed acne product, followed by benzoyl peroxides (BPOs) and oral antibiotics

Patients receiving single agent topical products (%)



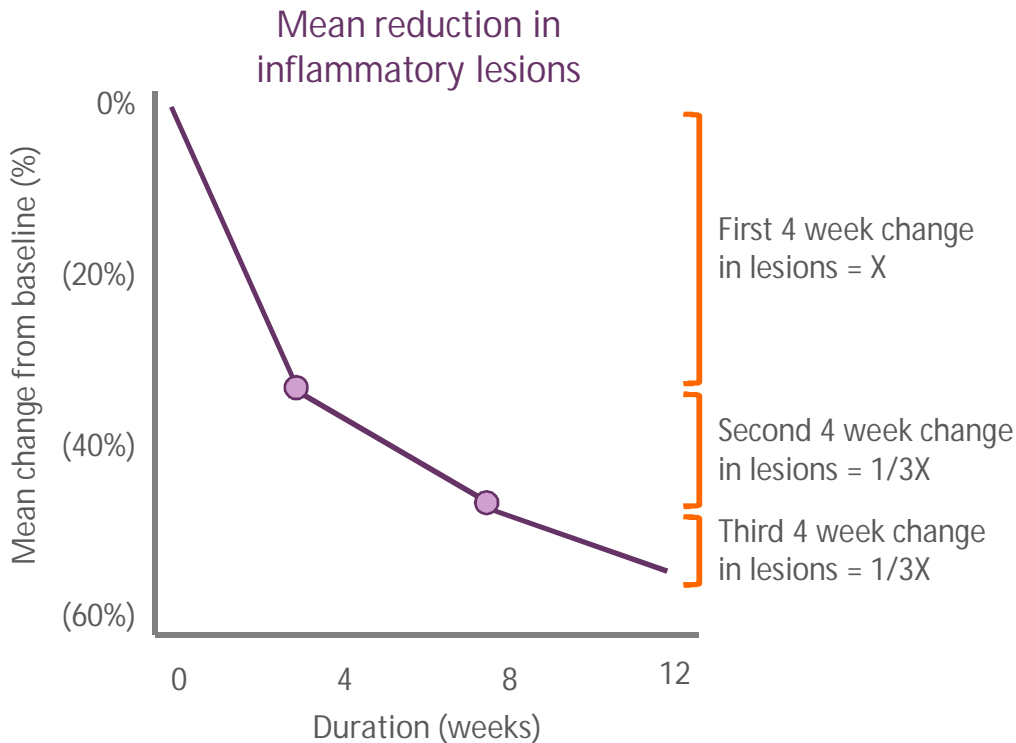
Patients receiving selected acne products (%)



+ 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



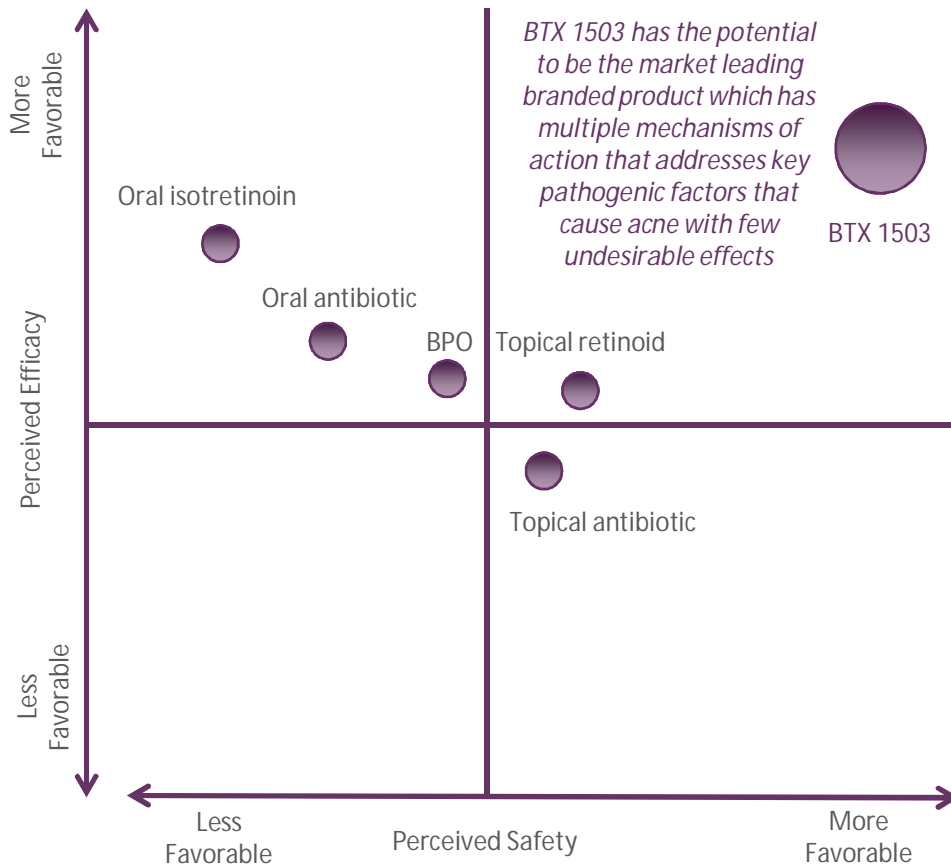
Data that can be drawn from early clinical studies

- § Safety and irritation of topical product in real life repeat dose use
- § Evidence of efficacy to reduce acne lesions (particularly inflammatory lesions)
- § Increases in patient satisfaction with outcomes



BTX 1503 positioning and opportunity

Significant market opportunity exists for a topical acne treatment to meet key unmet medical needs



Unmet medical needs	BTX 1503
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Reduce bacterial infection without promoting antibiotic resistance	ü
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Efficacy in reducing inflammatory lesions and comedones	ü
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Improved safety profile and elimination of severe adverse events	ü
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Novel mechanism of action	ü
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Address underlying inflammation	ü
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Topical option for severe acne patients	ü
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Normalise excessive lipid synthesis of human sebocytes	ü
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5. Conclusions and discussion

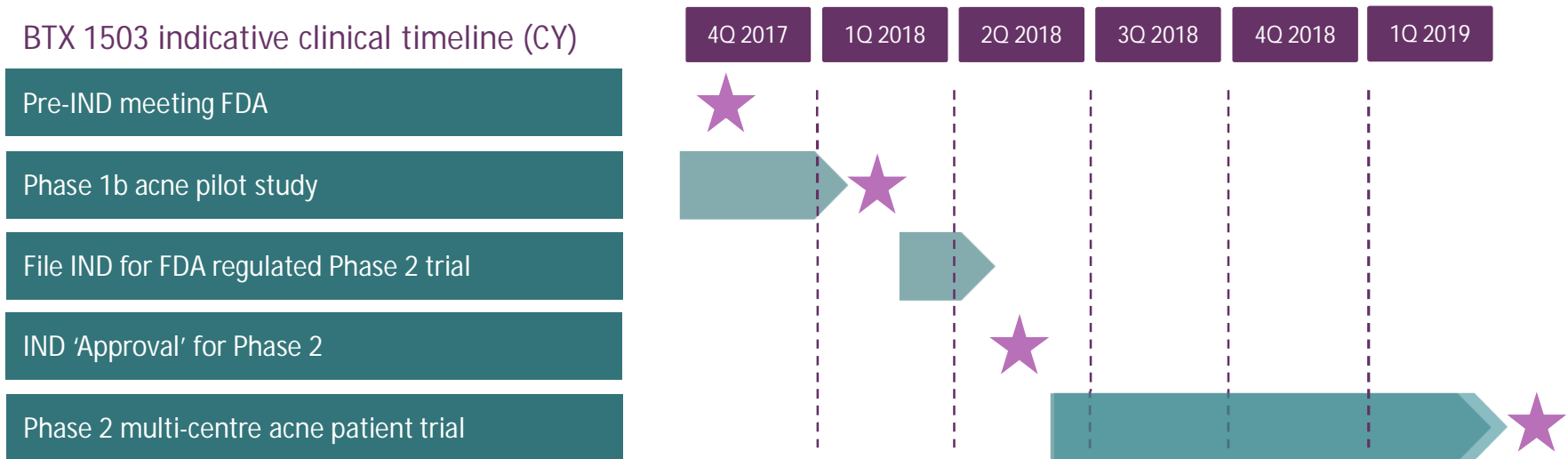


BTX 1503 timeline overview

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 – 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)

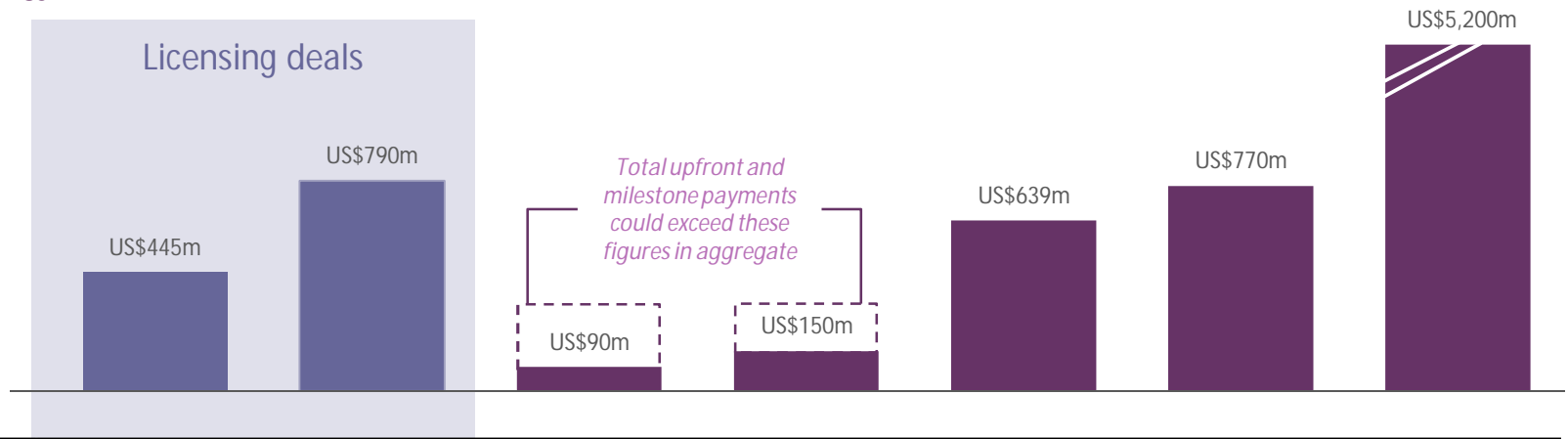


Milestones

+ 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



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



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