



AGM Presentation – 30 November 2016

ASX:BOT

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+ Agenda

1. Recap on Botanix
2. Achievements since listing/program update
3. Acne market opportunities and developments
4. Permetrex™ and other opportunities
5. Upcoming news flow and milestones





Recap on Botanix

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- Focused on new treatments for serious skin diseases – initial target is acne
- First product (BTX1503) utilizes a *synthetic* form of cannabidiol as the drug active - pharmaceutical grade and commercially manufactured
- Permetrex™ is the drug delivery system that provides the technological advantage
- First products will be in safety and efficacy studies within 12 months of listing
- Experienced team with more than 10 FDA approvals between them
- Raised \$3.5M to fund Phase 1 studies for (BTX1503)

Business focus:

- medical dermatology

Initial Product:

- BTX 1503 for acne

Drug active:

- synthetic cannabidiol

Drug delivery system:

- Permetrex™

Corporate

ASX	BOT
Offer Price	\$0.020
Cash raised under the Offer	\$3,500,000
Share Price (@ close 30/11/16)	\$0.046
Market Capitalisation (@close 30/11/16)	\$18.6 million

Team

Chairman	Graham Griffiths	<ul style="list-style-type: none"> • Nearmap • Pointerra • NGIS
Exec Director	Matt Callahan	<ul style="list-style-type: none"> • iCeutica • Churchill Pharma • Orthocell
Exec Director	Dr Bill Bosch	<ul style="list-style-type: none"> • iCeutica • Elan Drug Technologies • Nanosystems
Director	Rob Towner	<ul style="list-style-type: none"> • bioMD • Triangle Energy • Cornerstone Corporate

Shareholding Structure*



+ Cannabidiol drug showing promising results...

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
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Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

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Rank	Status	Study
41	Completed	A Study to Investigate the Efficacy and Safety of Cannabidiol Seizures Associated With Lennox-Gastaut Syndrome in Children Conditions: Epilepsy; Lennox-Gastaut Syndrome Interventions: Drug: GWP42003-P; Drug: Placebo
42	Active, not recruiting	A Randomized Controlled Trial to Investigate Possible Drug-Drug Interactions Between Cannabidiol and Antiepileptic Drugs Condition: Epilepsy Interventions: Drug: Placebo; Drug: GWP42003-P
43	Recruiting	A Randomized Controlled Trial of Cannabidiol (GWP42003-P) in Patients With Tuberous Sclerosis Complex (GWPCARE6) Conditions: Tuberous Sclerosis Complex; Epilepsy

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
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Found no studies with search of: acne | cannabidiol

Query Suggestions:

No documents are found by all search clauses

Drop Conditions clause leaving [cannabidiol](#)

Drop Interventions clause leaving [acne](#)

+ BTX1503 – novel mechanism of action in acne

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Switches off excessive oil
or 'sebum' production



Reduces
inflammation



Blocks cell
proliferation



Reduces infection



BTX1503 also targeting a benign side effect profile

+ Source and purity of drug material is important

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botanix
PHARMACEUTICALS

Extracted and purified

100+ chemicals

Multiple impurities

Scaled up to \approx 1kg

Not registered with FDA

Must comply with FDA's
"Guidance on Botanicals"

Synthetically manufactured

1 chemical

100% pure

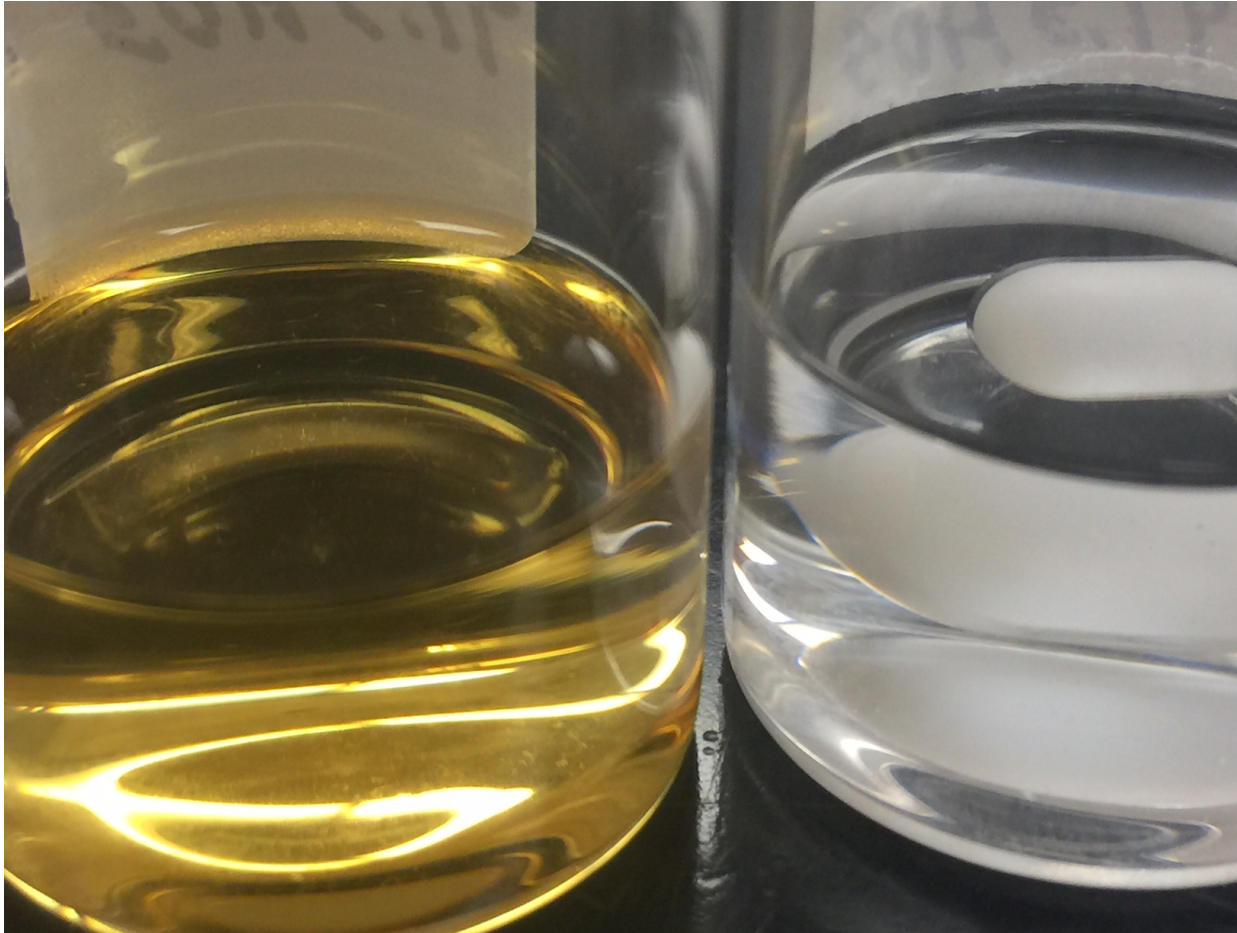
Scaled up to 50kg

Registered with FDA

No additional compliance required

botanix
PHARMACEUTICALS

+ The difference is clear



Naturally extracted Cannabidiol

Synthetic Cannabidiol

+ BTX1503 - planned positioning versus existing acne products

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	BTX1503	Clindamycin	Topical retinoid	Adapalene	Minocycline	Erythromycin	Accutane
Reduces Sebum	✓	✗	✗	✗	✗	✗	✓
Anti-inflammatory	✓	✗	✓	✓	✗	✗	✓
Anti-microbial	✓	✓	✗	✗	✓	✓	✓
Topical	✓	✗	✓	✓	✗	✗	✗
Minimal side effects	✓	✗	✓	✓	✗	✓	✗

“...the ‘Holy Grail’ of acne treatments would be a topical that can influence sebum production or the physiochemical properties of sebum.”

Prof Emeritus James Leyden

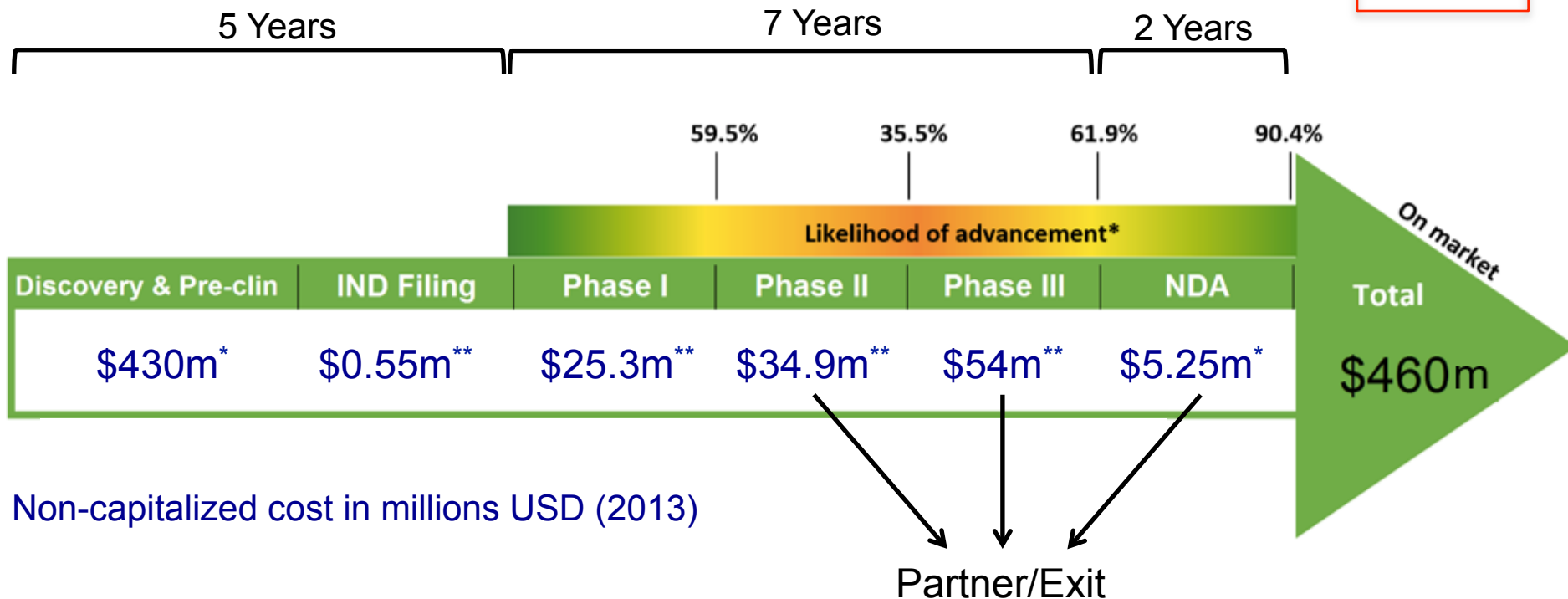
+ Agenda

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+ Objective – avoid the usual drug development process

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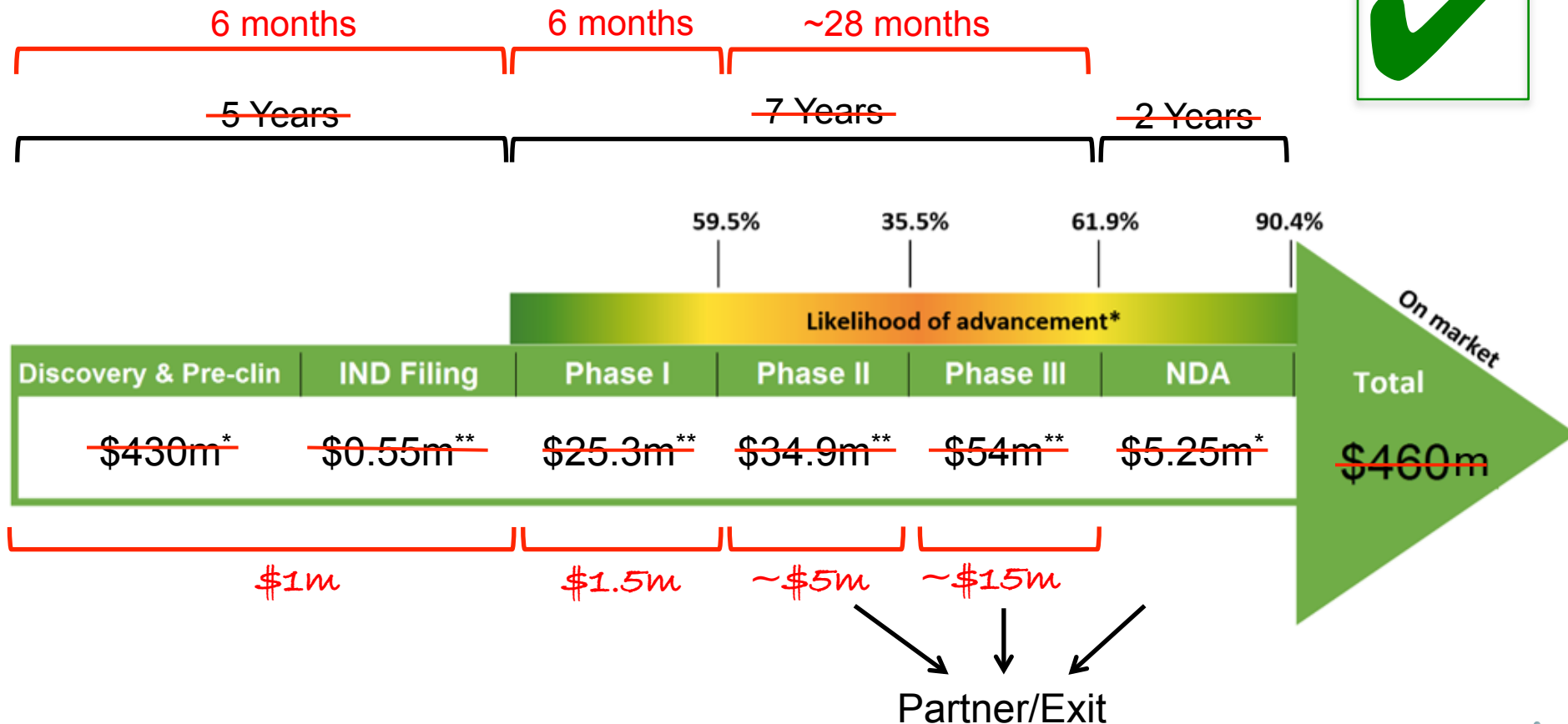


Sources: * J. A DiMasi et al / *Health Econ.* 2016

** <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093484.htm>

+ Botanix is pursuing a more investable approach

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Sources: * J. A DiMasi et al / Health Econ. 2016

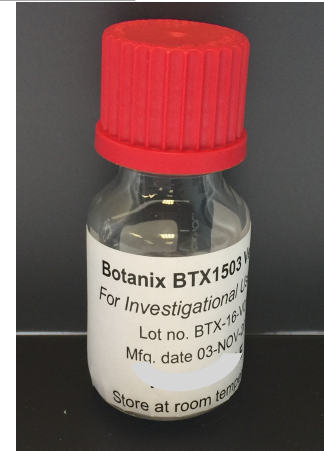
** <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093484.htm>

+ Achievements since listing

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BTX-1503:

- Source of commercial scale synthetic cannabidiol secured
- DEA Schedule-1 manufacturer engaged
- Phase 1 trial formulation manufactured using FDA quality components
- Genotox, bioassay, animal tox and other testing advanced
- Phase 1a and 1b product packaging options refined
- Clinical trial site identified and contracted
- Phase 1a and 1b clinical trial protocols written
- FDA standard Permetrex™ formulation manufactured
- First Permetrex™ safety/irritation study completed and data pending



+ Achievements since listing (cont'd)

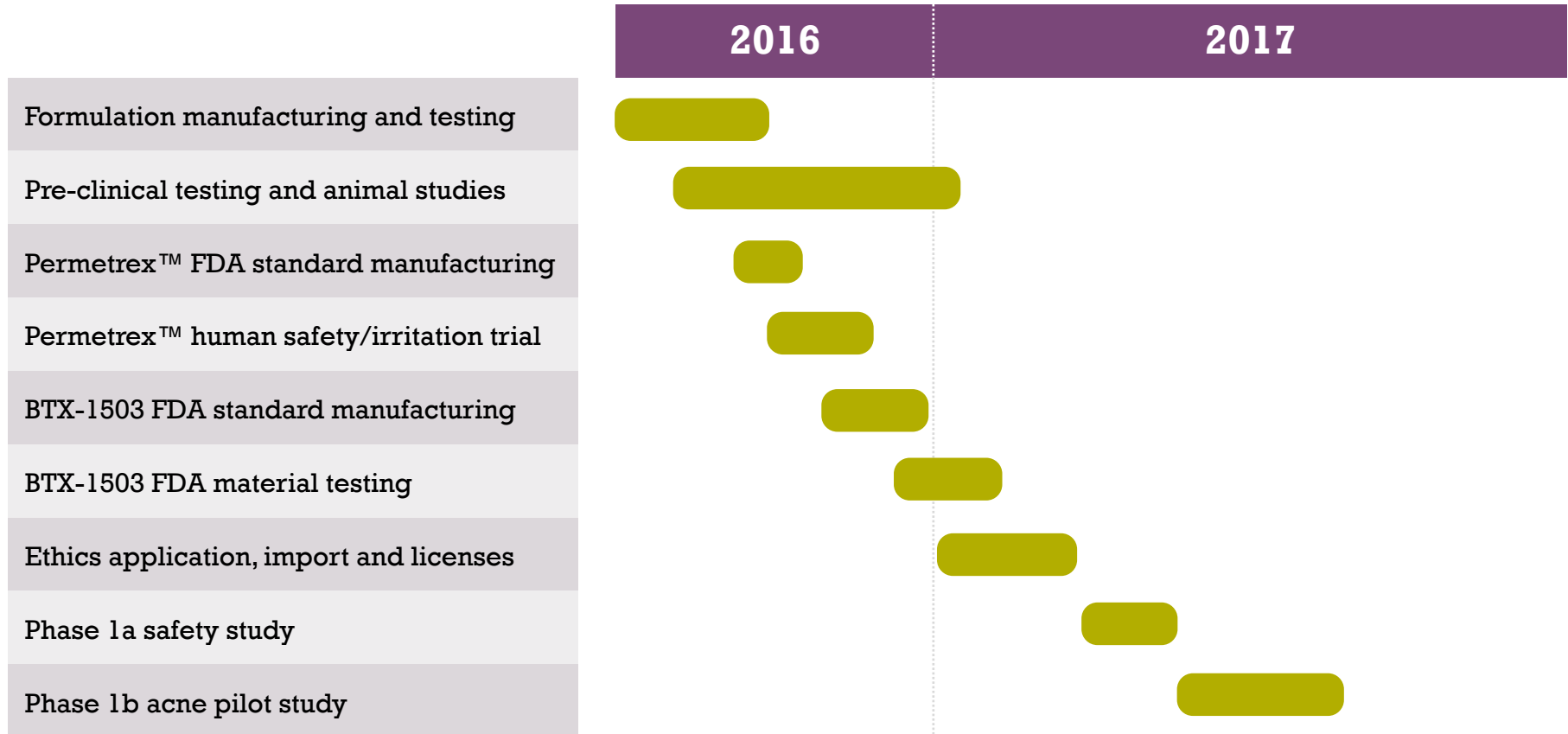
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General:

- Experienced staff engaged including:
 - Mark Davis – clinical and regulatory – 35 years experience
 - Steve Newhard – manufacturing and packaging – 30 years experience
 - Doug Bakan - manufacturing and packaging – 28 years experience
 - Phil Johns – toxicology – 35 years experience
- Initial market positioning and competitive assessment completed
- Business development engagement with potential licensors and partners advancing
- Pipeline of new products leveraging Permetrex™ platform identified



BTX 1503 – updated timeline



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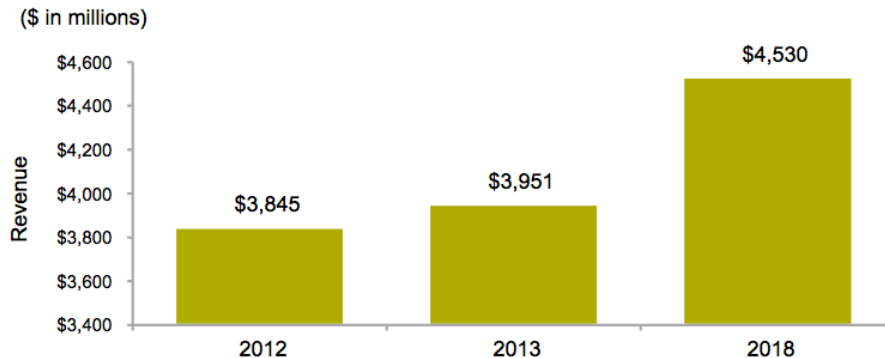
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+ Market for prescription acne products is very large

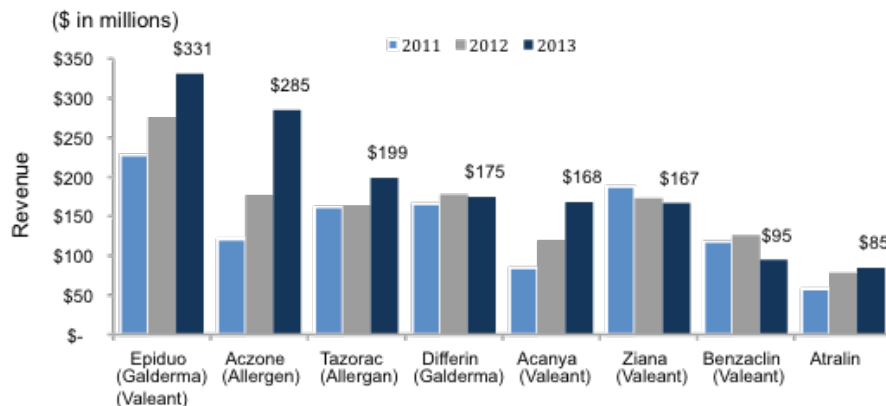
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Prescription Acne Product Revenue 2012-2018



Value of the Global Acne Prescription Market is expected to reach \$4.5 billion by 2018 ⁽¹⁾

Sales of Topical Prescription Acne Products



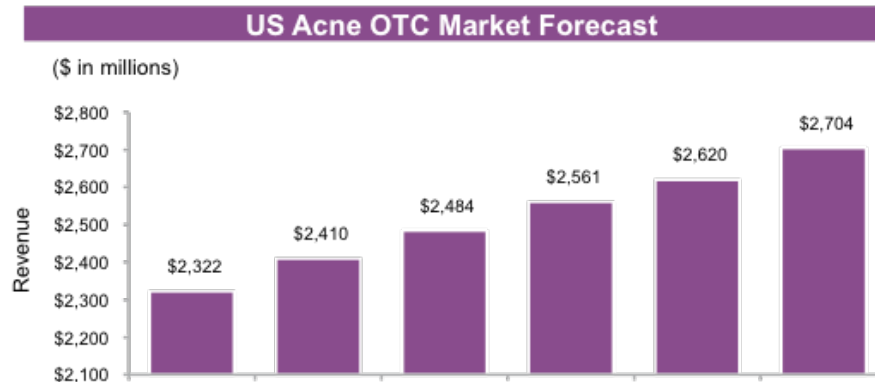
The top branded topical prescription acne products have achieved peak revenues in the range of \$85 - \$331 million ⁽²⁾

1) BCC Research, May 2013. Skin Disease Treatment and Global Markets.

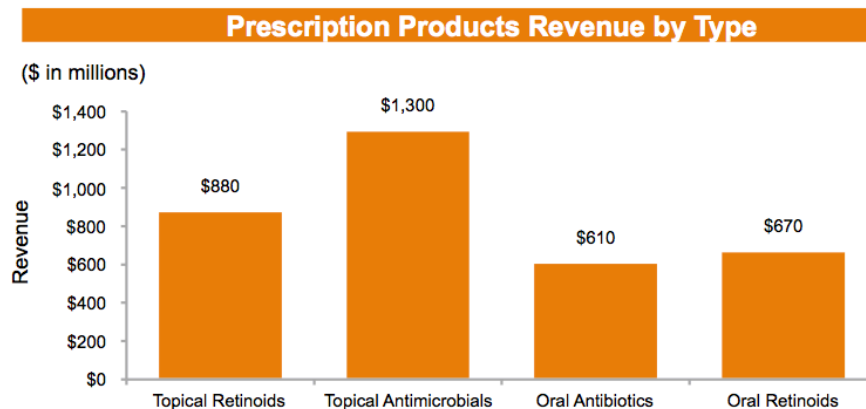
2) Symphony Health Solutions, Pharmaceutical Audit Suite for 2012 as reported in Dermira S1

+ Market for OTC and generic acne products is also very large

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Revenue from OTC acne treatments expected to increase to \$2.7 billion by 2018 ⁽¹⁾



Market is dominated by “me too” reformulations of old drugs and generics that carry significant side effect and patient usage issues ⁽²⁾

1) BCC Research, May 2013. Skin Disease Treatment and Global Markets

2) IBIS Research Acne Treatment Manufacturing OTC Market Research Report Jul 2014

+ Nothing new for the last 10 years and little expected

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- No products have approved by FDA in the last 10 years containing a new active ingredient
- All “new products” launched in this period contain combinations of old drugs in new formulations or packaging
- 50 million patients in the US alone consumed an acne product in 2015



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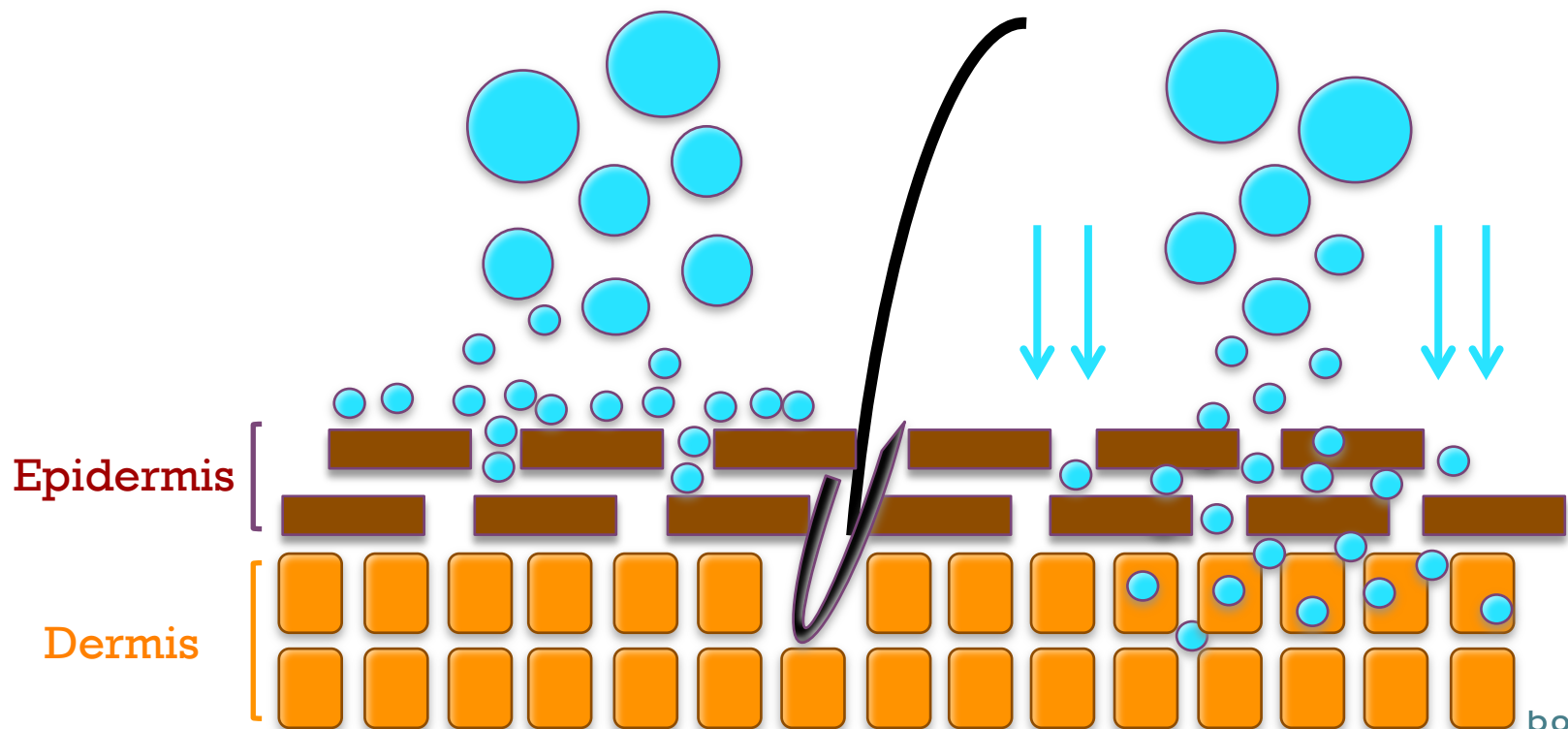
+ Permetrex™ - superior skin delivery

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Oral delivery of cannabidiol is only 6% bioavailable

Unmodified Drug

With Permetrex™



+ Pipeline – cannabidiol products

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BTX 1308 (psoriasis)

- 7.5 million Americans have psoriasis (most have *plaque* psoriasis)
- Cost of injectable biologic treatments in 2014 was \$20 billion
- Biologic drugs have serious side effect issues (including lymphoma)



BTX 1204 (dermatitis)

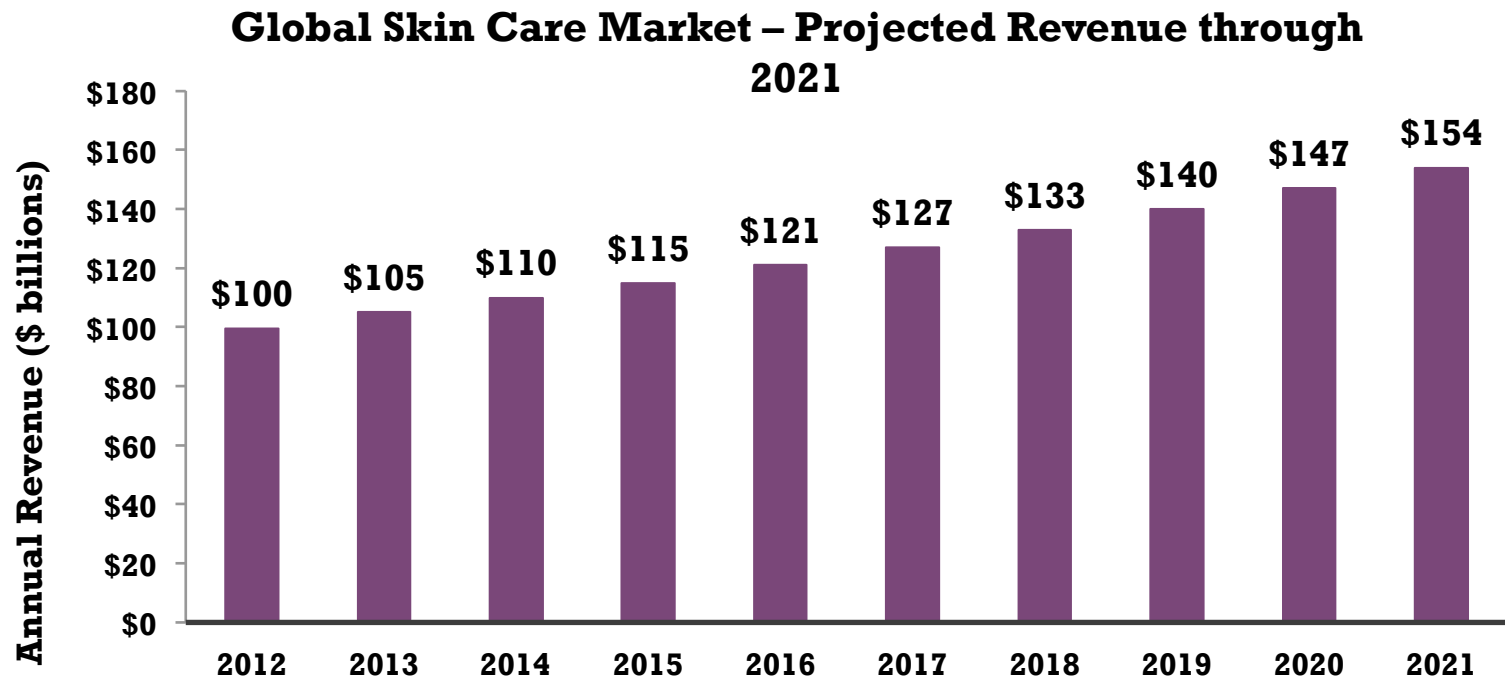
- US patient incidence estimated to be 31 million people – 10 -18% of children
- Estimated annual cost of treating Atopic Dermatitis in the US is \$3.8 billion
- Most treatments (such as steroids) only address the symptoms



+ Market for skin care products (particularly facial) is significant

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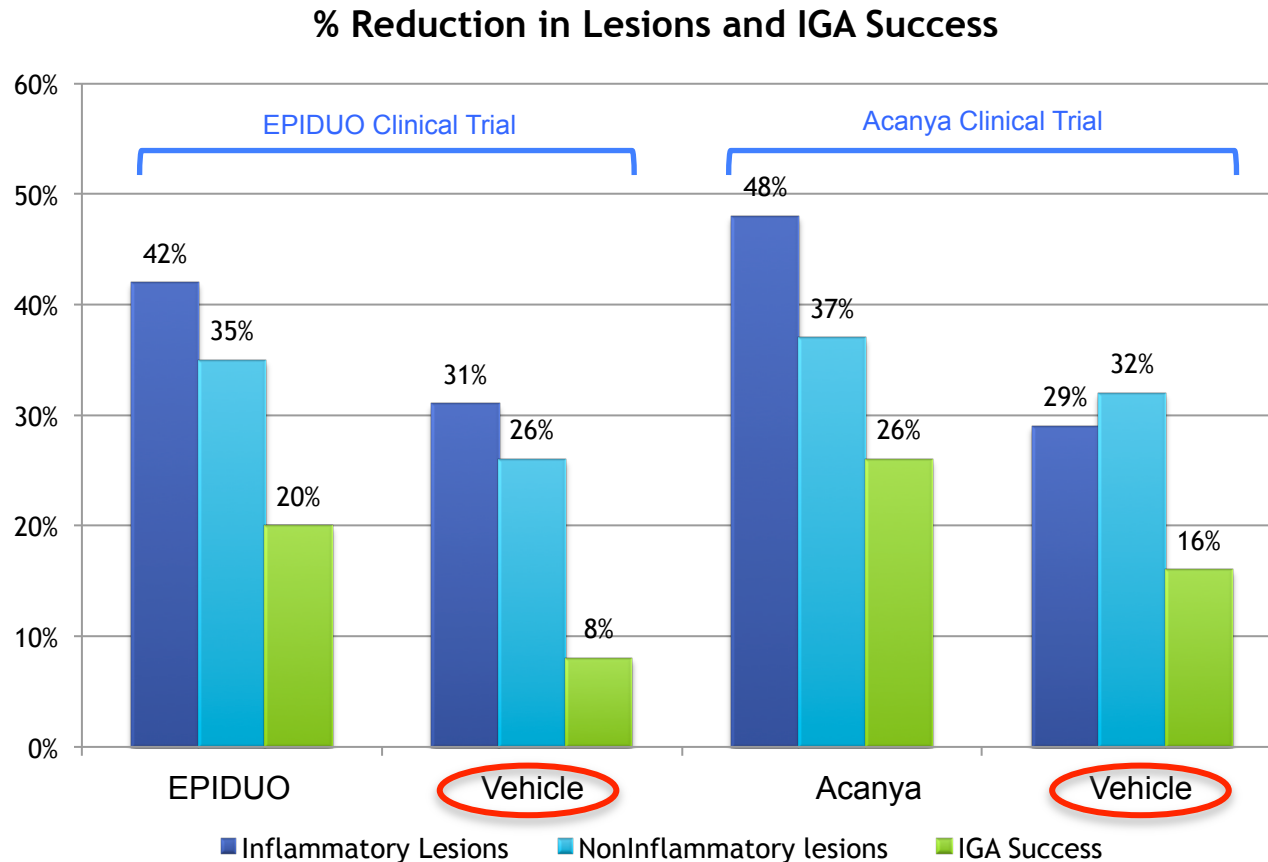
The global skin care market is estimated to be worth \$154 billion by 2021



Source: Trefis.com, March 2014. Total sales of skin care products at retail selling price

+ Many existing acne products can be improved

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EPIDUO (Adapalene 0.1% / BPO 2.5%) NDA 022320 – Phase 3 Trials (n=564)
ACANYA (Clindamycin 1% / BPO 2.5%) NDA 050819 – Phase 3 Trials (n=809)

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+ Upcoming news flow and milestones in next 9 months

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- Permetrex™ safety and irritation clinical study results
- Ethics application for Phase 1 studies
- Import licenses for BTX-1503 clinical trial material
- Collaborative research arrangements
- New product addition to pipeline (based on Permetrex™)
- Ethics approval for Phase 1 studies
- Commencement of Phase 1a study
- Completion of Phase 1a study and results
- Commencement of Phase 1b study
- Completion of Phase 1b study and results
- New pipeline products data



Botanix ...a compelling investment case

- ✓ Significant unmet patient needs in serious skin diseases
- ✓ Novel treatment for acne with a growing evidence base
- ✓ Proprietary drug delivery system
- ✓ Fast and efficient development pathway, relative to usual pharmaceutical development
- ✓ Very large markets with few competing products in development
- ✓ Experienced team with track record of FDA approvals