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SPEC BUY

Current Price	$0.06
Market Cap.	$24.5m

Ticker:	BOT.ASX
Sector:	Biotechnology
Shares on Issue (m):	408.8
Market Cap ($m):	24.5
Net Debt / (Cash) ($m):	-2.4
Enterprise Value ($m):	22.2
52 wk High/Low:	0.07 0.02
12m Av Daily Vol (m):	1.21

Financials:

	4Q16A	1Q17A	2Q17A
Op CF ($m)	-0.1	-0.4	-0.8
Inv CF ($m)	0.0	0.0	0.0
Fin CF ($m)	3.2	-0.1	0.0
Net CF ($m)	3.2	-0.5	-0.8
Cash ($m)	3.7	3.1	2.4

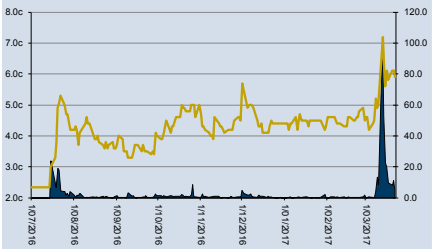
Top Five Shareholders:

Matthew Callahan	17.3%
Henry Bosch	3.7%
Nutsville Pty Ltd	3.1%
Osagie Imasogie	1.3%
Cabletime Pty Ltd	1.2%

Shareholder Structure:

Board	23%
Escrowed (incl. board shares)	41%
Free Float	39%

Share Price Graph



Company Summary: Botanix (BOT) is a small biotech company focused on developing new topical drugs for the treatment of serious skin disease. The Company's development products focus on the use of a synthetic cannabidiol active with a novel drug delivery system (called Permetrex). Initially BOT will focus on its flagship product, BTX-1503, for the treatment of acne.

Wednesday, 22 March 2017

Botanix (BOT)

Initiation

Analysts | Daniel Williamson | Ian Christie, CFA

Quick Read

We initiate coverage of BOT with a speculative buy call. BOT's flagship product, using a synthetic cannabidiol based active, has the potential to be a 'game-changing' treatment for moderate to severe acne, a global market currently valued at over US$4bn. Significantly, the Company is investigating potential pipeline products that pair its Permetrex drug delivery technology with on-the-market active ingredients to generate early revenues (these reformulations will not require FDA approval).

View | Positive

Sizeable global markets: The global prescription acne market is estimated to generate revenues of over US$4bn per year. Epiduo, currently the top-billed prescription acne treatment, had estimated sales of over US$350m in 2016. It is these large potential revenues that BOT is chasing with the Company's flagship product, BTX-1503.

First in class: No currently marketed topical treatment for acne reduces or influences the production of sebum (the cause of oily skin and acne). Evidence suggests that cannabidiol has the potential to influence sebum production, and as such BTX-1503 may possibly become a 'first-in-class' topical treatment for moderate to severe acne.

FDA approvals process: As with all small biotech companies, substantial resources of time and money are required to meet FDA approval requirements to bring a drug to market. Maintaining sufficient funding through the clinical trials process is critical to BOT's success and will ultimately provide the basis for potential returns to investors in the future.

Unlocking value: BOT is exploring ways to unlock value by leveraging its worldwide exclusive license to the Permetrex drug delivery technology. By pairing Permetrex with already approved active ingredients, BOT sidesteps the FDA approvals process and is able to market these drugs in a much shorter time period (compared to new drugs with new active ingredients requiring Phase 1 to 3 clinical trials).

Restricted substance: BOT also faces regulatory constraints on the import, export and use of synthetic cannabidiol as it's a controlled substance according to US and Australian drug enforcement laws. Whilst the use of cannabidiol for medical purposes is permitted, BOT must tick all the boxes with regulatory agencies to guarantee that the Company's progress is not halted by drug enforcement authorities.

Recommendation

Although it is premature to forecast revenues or cash flows, we believe the potential prize is sufficiently large to warrant a speculative buy call.

Executive Summary

BOT has a strong product pipeline, enabled by Permetrex, that has the potential for early revenue

Product pipeline: BOT's pipeline of products focus on the topical treatment of serious skin diseases using cannabidiol as the active ingredient. The cannabidiol active is driven deep into the skin using a novel drug delivery technology called Permetrex. Initially BOT is concentrating on trialling a formulation of cannabidiol and Permetrex, called BTX-1503, for the treatment of acne. Additionally, BOT is investigating pairing Permetrex with already approved active ingredients in new formulations that will not need to undergo the lengthy FDA approvals process.

The global acne drug market is valued at over US$4bn

Large global markets: BOT's target markets are large, and are expected to continue to grow with sustained global population growth. The global prescription acne market is expected to grow to over US$4.5 billion by 2018. Competing products in the prescription acne treatment market have generated substantial revenues in recent years; with revenues for the top-billed product, Epiduo, expected to exceed US$350 million for 2016.

There were 493 acquisitions in the biotech space in 2015, at an average value of over US$500m

Value for investors: Large pharmaceutical companies are constantly seeking to shore up their pipeline of new products by acquiring small biotech companies. 493 deals were completed in 2015 at an average value of over US$500 million per transaction. Recent deals in the dermatology space have ranged from US$90 million for Allergan's acquisition of Anterios to upwards of US$5 billion for Pfizer's acquisition of Anacor.

BOT expects to commence Phase I trials of BTX-1503 in CY2017

Stage of development: BOT has progressed its flagship product (BTX-1503) through discovery and pre-clinical development, with Phase 1 trials expected to commence in CY2017. Pipeline products for the treatment of psoriasis (BTX-1308) and atopic dermatitis (BTX-1204) are yet to progress past the initial discovery phase.

Timing and cashflows as BOT navigates the FDA approvals process pose key risks

Key risk areas: Aside from completing successful clinical trials, the key risks facing BOT is cashflow and timing. The Company needs to maintain sufficient cash reserves to fund the clinical trial program for BTX-1503. Timing is also critical for being first-to-market with a new acne formulation. As BOT has stated, no new formulations have hit the acne market in over a decade; the first company to bring a new formulation to the market has potential advantages in marketing and distributing its product.

The FDA approvals process can take anywhere from 2-7 years, with only 6-7% of trials progressing past Phase III

Regulatory hurdles: Obtaining FDA approval, through Phase 1,2 and 3 clinical trials, can be a long and arduous task with many hurdles to overcome along the way. The FDA themselves state that the approvals process can take anywhere from 2 to 7 years and there is only a 6-7% chance of successfully getting a drug to market. BOT has to navigate the approvals process whilst also meeting the demands of drug agencies in Australia and the US due to cannabidiol being registered as a restricted substance (as it is derived from the cannabis sativa plant).

BOT's board has strong prior experience in bringing new drugs to market

Key personnel: BOT has assembled a strong board with impressive experience in developing new drugs for the skin care market. The Company's strong relationship with Dr Eugene Cooper, the inventor of Permetrex and holder of its patent, sets a solid foundation for developing potential future pipeline products leveraging the Permetrex drug delivery vehicle.

Development Products

BOT is focused on developing cannabidiol-based topical drugs for the treatment of serious skin disease

BOT's core business is generating new topical drugs for the treatment of common serious skin diseases (e.g. acne, psoriasis, eczema). The Company's development products focus on the use of a synthetic cannabidiol active with a novel drug delivery system (called Permetrex).

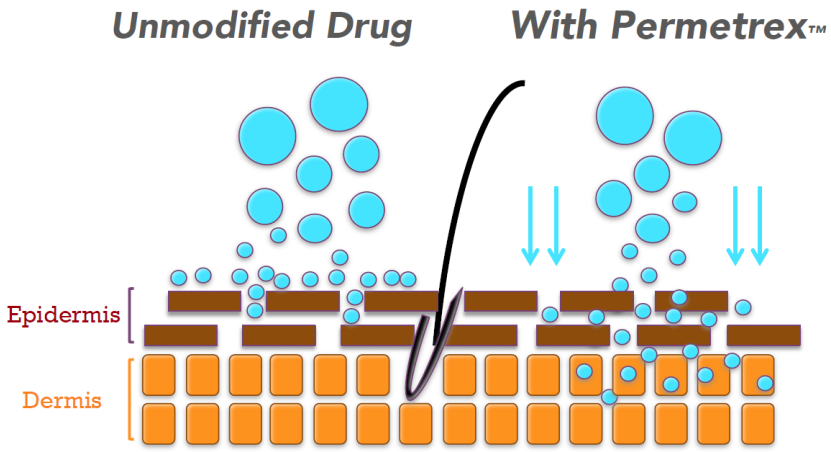
The 'endocannabinoid system', which regulates skin function, growth and renewal, consists of receptors that are configured only to accept cannabinoids, especially tetrahydrocannabinol (THC) and cannabidiol (CBD). It is believed that cannabidiol may play a significant role in modulating the endocannabinoid system of receptors; potentially normalising unwanted skin growth, reducing excessive production of oils and reducing inflammation and infection, among other functions.

Permetrex™

The Permetrex drug delivery technology is critical to the success of BOT's pipeline products

Although there is published scientific support for the potential benefits of cannabidiol as a treatment for serious skin diseases, the active's development into marketable products has been inhibited by its ineffectiveness at distributing across the skin and penetrating the epidermis. Permetrex addresses this limitation of cannabidiol by super-concentrating the drug on the skin, driving it deeper into the dermis.

Figure 1: Permetrex action in driving actives deeper into the skin



Source: BOT releases

BOT has a worldwide exclusive license for the use of Permetrex to treat skin disease

Whilst BOT does not own the patent for Permetrex, it does have worldwide exclusive rights to its use with any drug actives that can be used to treat skin diseases. The Permetrex license provides opportunities for BOT to expand its pipeline of novel skin disease treatments.

There exist opportunities for reformulated drugs that avoid the FDA approvals process, using Permetrex

The chemicals that make up Permetrex are on the FDA approved inactive ingredients list, meaning that Permetrex may be combined with already approved active ingredients without undergoing lengthy FDA approved clinical trials. This presents the opportunity for BOT to generate revenues and cash flows in a much shorter time-frame than other biotech companies developing new products. The only conditions being that the active must be dosed in similar amounts as previous formulations and the drug shall be purposed for

similar indications as was approved historically. The time to market for these reformulated drugs is estimated to be approximately 12 months. This provides potential early revenue for BOT as the Company proceed its cannabidiol based products through Phase 1 clinical trials.

Permetrex has been proven to show minimal or weak irritancy potential

A study testing the safety and irritability of Permetrex found that the delivery technology has "minimal or weak irritancy potential" and no safety issues. These results de-risk BOT's pipeline of skin disease treatments and pave the way for the Company to begin reformulating existing drugs using the Permetrex vehicle. BOT recently announced that it has filed 5 new patent applications covering Permetrex enabled products; some of which are aimed at protecting new formulations of currently approved actives.

The Permetrex patent is held by its inventor Dr Eugene Cooper, who in turn licenses it to BOT

Permetrex is patented by Dr. Eugene Cooper, who in turn has licensed it to BOT for worldwide exclusive use with any active that can be used to treat skin diseases. Under the terms of the licensing agreement BOT must pay Dr Cooper a royalty of 5% of net sales of each licensed product utilising the Permetrex drug delivery system. BOT must also pay Dr Cooper the following fixed milestone lump sums:

1. US$50,000 upon commencement of the first human trial of a licensed product;
2. US$50,000 upon acceptance of filing for regulatory approval for the manufacture, distribution, use and sale of the first licensed product; and,
3. US$100,000 upon the receipt of regulatory approval for the manufacture, distribution, use and sale of the first licensed product.

Acne Treatment (BTX-1503)

Whilst the global acne drug market is worth over US$4bn, there has been little innovation in treatments over the past decade

There has been little innovation in the field of acne treatment in recent times, with all "new" products entailing reformulations and rebranding of existing acne treatments. BOT's lead product, BTX-1503, seeks to address significant unmet demand in the sizeable global prescription acne market. The global acne prescription market is expected to reach ~US$4.5 billion by 2018. The top branded topical prescription product, Epiduo, generated revenues of ~US$330 million in 2013.

Figure 2: BTX-1503 planned positioning versus existing acne products

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

Source: BOT investor presentation

BTX-1503 aims to be the first topical acne drug capable of influencing sebum production

Currently, no topical acne treatment influences sebum (skin oils) production or the physiochemical properties of sebum; BTX-1503 aims to be the first topical acne treatment to do so. Reducing sebum production is the most effective method of treating acne and is currently the domain of the leading oral product (isotretinoin or 'Accutane'); which has

considerable side effects, including potential birth defects, depression or liver damage, among others. It is the aim of BOT for BTX-1503 to have the efficacy of Accutane, without the potentially serious side effects.

BTX-1503 uses synthetic cannabidiol as its active ingredient, with Permetrex as the drug delivery vehicle

The drug active for BTX-1503 will be a synthetic form of the naturally occurring cannabidiol. By synthetically manufacturing cannabidiol, BOT can produce a 100% pure product that can be scaled up more readily than extracting naturally from the Cannabis Sativa plant. Synthetic cannabidiol is a "Schedule I" drug substance under the Controlled Substances Act (US) and is subject to strict control and regulation by the DEA. Accordingly, BOT has secured the use of Sharp Clinical Services facilities, in Pennsylvania, to develop BTX-1503. Sharp's facility is licensed with the DEA and FDA to handle "Schedule I" substances. Additionally, BOT has received an import permit from the DEA to import cannabidiol into the US for its drug development activities.

Initial testing of Permetrex de-risks BOT's suite of pipeline products

The majority of the BTX-1503 formulation will consist of the Permetrex drug delivery system, which has already been shown to have "minimal or weak irritancy potential" and no safety issues in trials completed in December 2016. BOT expect to complete the Phase 1a safety study and Phase 1b acne pilot study for BTX-1503 in the next 6-7 months.

Pipeline Products

BOT's pipeline products similarly use a cannabidiol drug active, leveraging the Permetrex drug delivery technology to penetrate the active deep into the skin. BOT has flagged two additional pipeline products to treat plaque psoriasis (BTX-1308) and atopic dermatitis (BTX-1204).

BOT has flagged two additional pipeline products for the treatment of plaque psoriasis and atopic dermatitis

Plaque Psoriasis (BTX-1308): According to the World Health Organisation the prevalence of psoriasis in the United States is approximately 3.3%, meaning that over 10 million people in the United States are living with psoriasis. Many of those have *plaque* psoriasis. The current treatment for the disease is injectable biologics, with BOT stating that the cost of these treatments in 2014 was $20 billion. These biologics have potentially serious side effects such as serious nervous system disorders (e.g. multiple sclerosis), blood disorders or certain types of cancers (e.g. lymphoma). BOT believes that BTX-1308 may be able to treat the signs and symptoms of psoriasis without incurring the serious side effects of existing on-market drugs.

Atopic Dermatitis (BTX-1204): It is estimated that approximately 31 million people have atopic dermatitis in the United States. This comes at an estimated annual cost for treatment of $3.8 billion. Current treatments have been shown to potentially cause serious side effects, including thinning of the skin and loss of barrier function as well as the potential to induce cancer. BTX-1204 may be able to control inflammation and improve skin barrier function in atopic dermatitis sufferers whilst avoiding the aforementioned side effects.

Global Skin Disease Markets

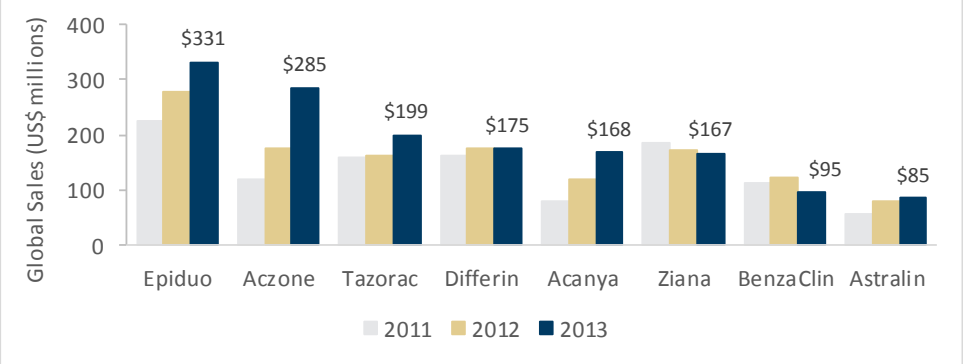
The majority of the global population will seek treatment for skin disease at some point in their life

The majority of the global population will be affected by some form of skin disease in their lifetime. At any one time, acne is estimated to affect up to 9% of the global population, making it the eighth most prevalent disease worldwide. The American Academy of Dermatology believes that it affects more than 50 million Americans annually. The prevalence of psoriasis is estimated to be between 1% and 5% globally, with at least 100 million individuals affected worldwide (according to the World Health Organisation). And atopic dermatitis (or Eczema) affects up to 20% of children and up to 3% of adults; with recent data showing prevalence is increasing, especially in low-income countries.

Sales of Epiduo are expected to reach US$350m in 2016

BOT's flagship product (BTX-1503) aims to be a first-in-class topical acne treatment, addressing one of the largest skin disease markets. The global prescription acne market is expected to reach US$4.5 billion by 2018, up from estimated revenue of ~US$4 billion in 2013. BOT's top branded potential competitors generated revenues of between US$85-US$331 million in 2013. In 2016 sales of Epiduo are expected to exceed US$350 million.

Figure 3: Annual revenues for top branded prescription topical acne treatments

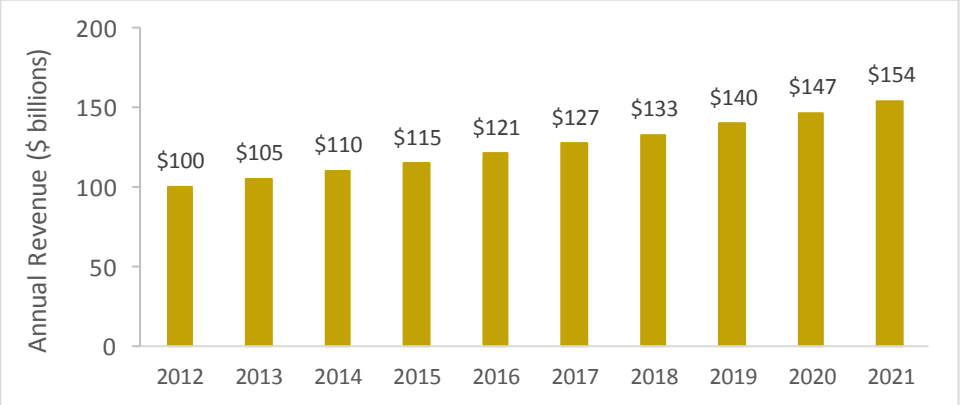


Source: BOT releases

The global skincare industry is expected to grow to over US$150bn by 2021

BOT's pipeline products (BTX-1308 and BTX-1204) also address sizeable markets. The leading treatment for psoriasis came at a cost of US$20 billion in 2014, whilst the annual cost of treating atopic dermatitis in the US is US$3.8 billion. More broadly revenues in the global skincare market are projected to rise to over US$150 billion by 2021 at a compound annual growth rate of approximately 5%.

Figure 4: Global skincare revenue projections through 2021



Source: BOT releases

Revenue Model and Earnings Potential

Generating income

BOT can generate income through licensing/partnering its products or commercialising the products themselves

BOT has two potential sources of revenue for its dermatological products:

1. License milestones and royalties from agreements to license or partner its portfolio of pipeline products; and,
2. Sales revenue from the commercialisation of approved dermatological products.

There is a significant time lag between product development and potential income due to the onerous FDA approvals process. BOT is aiming to significantly reduce the time required for drug approval, providing earlier opportunities for income from partnering or licensing agreements. However, commencement of Phase II clinical trials is still up to 12 months away for BOT's flagship product (BTX-1503). This suggests that potential partnering opportunities and associated income will not occur in the near term.

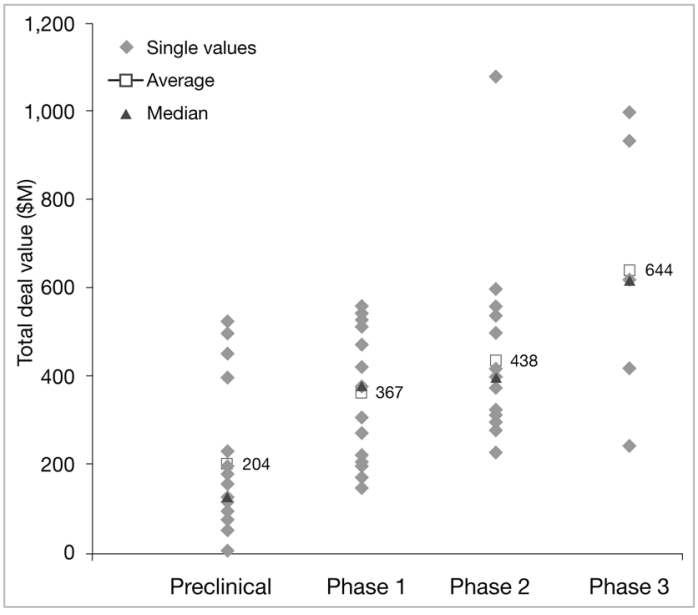
Take-over Target

A more likely outcome is being acquired by a large pharma company

The other option is for BOT to strike a deal with a larger biotech or pharmaceuticals company to acquire BOT's pipeline products. Such deals can be substantial in size and provide potential early returns for investors in biotech companies. A study of M&A deal value between 2005 and 2012 shows that deal value increases significantly as a product is progressed through the stages of clinical development.

Figure 5: Price distribution of biopharma M&A deals

The value of M&A deals increases as a drug progresses through the FDA approvals process



Source: bioentrepeneur

In 2015, the average transaction was valued at over US$500m

According to HBM Partners, 2015 saw approximately US$250 billion worth of M&A deals in the biopharma space, up 8% on 2014. The number of deals completed increased from 371 in 2013 and 438 in 2014, to 493 deals in 2015; meaning the average value of deals in 2015 was over US$500 million. Such M&A activity highlights the efforts of big pharma to shore up their future revenue as they face generic drug competition in a period where their products are coming off patent.

Recent deals in the dermatology space have ranged from US$90m to US$5bn

Recent deals in the dermatology space have ranged from US$90 million for Allergan's acquisition of Anterios, with products in pre-clinical development, to upwards of US$5 billion for Pfizer's acquisition of Anacor, with products about to go to market after completing Phase III clinical trials.

Figure 6: Recent biotech deals in the dermatology space

Deal	Treatments	Deal Value
Allergan acquired Vitae Pharmaceuticals in October 2016	Oral psoriasis treatment (VTP-43742), in Phase II clinical trials Topical atopic dermatitis treatment (VTP-38543), in Phase II clinical trials	**US$639m**
Sienna Biopharmaceuticals acquired Creabilis in December 2016	Topical psoriasis treatment (CT327), in Phase IIb clinical trials Topical atopic dermatitis treatment (CT340), in pre-clinical development	**US$150m**
Allergan acquired Anterios in January 2016	Topical drug delivery technology (NDS™) Topical acne treatment (ANT-1207), in pre-clinical development	**US$90m**
Leo Pharma acquired Astells global dermatology business in April 2016	Topical atopic dermatitis treatment (Protopic®), currrently on the market …among other products for the treatment of acne and skin infections	**~US$770m**
Pfizer acquired Anacor in May 2016	Topical atopic dermatitis treatment (Crisabarole), completing Phase III clinical trials	**US$5.2b**
Purdue acquired drug rights from Exicure in December 2016	Topical psoriasis treatment (AST-005), completed Phase I clinical trials	**US$790m**

Source: pharmamedtechbi.com

Several large deals were completed in 2016 in the dermatology space

Stage of Development

BOT is progressing BTX-1503 through pre-clinical development towards FDA approved clinical trials

BOT has progressed its flagship product (BTX-1503) through discovery and pre-clinical development, with Phase 1 trials expected to commence in CY2017. Pipeline products for the treatment of psoriasis (BTX-1308) and atopic dermatitis (BTX-1204) are yet to progress past the initial discovery phase.

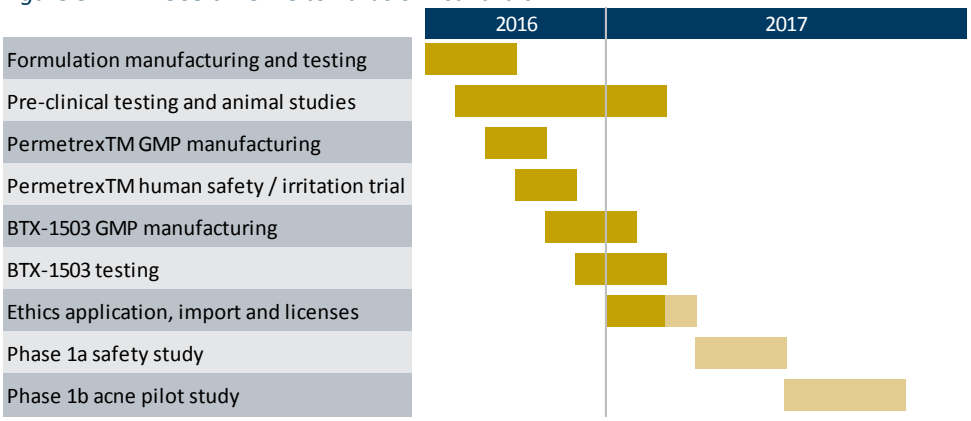
Figure 7: Product development stages

Product	Current Applications / Study	Stage of Development			Regulatory targets[1]	
		Discovery	Pre-clinical	Clinical	Within 6 mths	Thereafter
BTX-1503	Acne treatment	→	→		Commence Phase 1a studies	FDA Phase I, II and III Processes; FDA Approval
BTX-1308	Plaque psoriasis treatment	→				
BTX-1204	Atopic dermatitis treatment	→				

1. *Argonaut expectations based on Company commentary*

Source: BOT releases

Figure 8: BTX-1503 timeline towards clinical trials



Source: BOT releases

Phase I trials for BTX-1503 are expected to commence in the coming months

BOT has patent applications covering BTX-1503 and its suite of pipeline products

BOT has the following patent applications in progress, protecting its suite of pipeline products:

- "Topical composition and the use thereof for the treatment of acne", protecting BTX-1503 in Australia and the US
- 5 new patent applications "covering Permetrex enabled products"; some of which are aimed at protecting new formulations of currently approved actives, and the others which protect additional uses for the Company's drug active, synthetic cannabidiol.

BOT has licenses with Dr Eugene Cooper for the use of Permetrex and with Sharp Clinical Services for the production of cannabidiol

BOT has secured a worldwide exclusive license for the use of Permetrex for the topical treatment of skin diseases; protecting the Company's pipeline products and adding potential new income streams from pairing Permetrex with already approved actives. The Company has also signed a services agreement with Sharp Clinical Services, Inc (licensed by the FDA and DEA to handle "Schedule I" substances) for the supply of cannabidiol and access to Sharp's facilities for clinical development purposes.

Risks

Cash Flows and Funding

Cash flows and funding are critical to BOT's ability to progress through FDA clinical trials

BOT's cash expenditure has been slowly ramping up to accommodate BOT's progress of its flagship BTX-1503 product. We estimate that as BOT proceeds through the FDA approvals process, spending will increase accordingly. At current and forecast cash burn rates BOT will require additional funding at some point in CY2017.

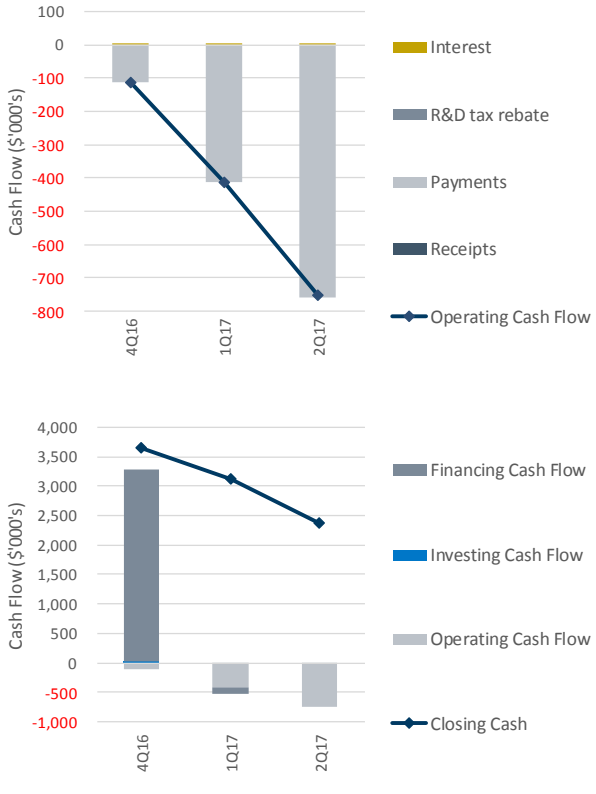
Figure 9: BOT's quarterly cashflows since backdoor listing

Cash Flow ($'000's)	*4Q16*	*1Q17*	*2Q17*
Receipts			
Payments	-113	-414	-761
R&D tax rebate			
Interest	2	1	5
Other	-4	-2	1
Operating Cash Flow	*-115*	*-415*	*-755*
Investing Cash Flow	*33*		
Financing Cash Flow	*3,241*	*-116*	
Net Cash Flows	*3,159*	*-531*	*-755*
Opening Cash	493	3,652	3,121
Closing Cash	**3,652**	**3,121**	**2,366**

Source: BOT releases

At current cash burn rates, BOT will need to raise additional funds at some point in CY2017

Figure 10: BOT operating cashflow and closing cash position (forecast for 3Q17)



Source: BOT releases

BOT's operational cash burn has steadily increased as it moves towards commencing Phase I clinical trials for BTX-1503

Timing

Maintaining a strict schedule for clinical trials is imperative to sustaining funding

The key risk to investors in small biotech companies is the lengthy timelines required to gain FDA approval for new drugs. For dermatological indications, progressing through the FDA approvals process costs on average about US$24m and takes anywhere from 2-8 years. Maintaining sufficient funding through initial stages of the FDA approvals process is critical to BOT advancing its products to a stage where it attracts the interest of potential partners. BOT is targeting the start of FY18 for initiating Phase 1 testing of BTX-1503.

BOT also aims to be a first-in-class topical acne treatment, meaning time to market is crucial

Through Permetrex, BOT is targeting early revenue by pairing it with existing active agents; avoiding the FDA clinical trial process. However, the reformulation process will still take up to 12 months to develop a marketable product. BOT then need to market the new formulation and seek potential partners to distribute the product adding further time between product reformulation and first revenues.

The arduous process for demonstrating safety and efficacy of a product, through the FDA approvals process, takes significant amounts of time and money. As with all biotech companies, it is imperative that BOT maintain a strict schedule through this process to avoid potential budget blowouts which could eat away at the Company's cash balance and delay or potentially derail the advancement of BOT's pipeline products.

Technical

The efficacy of cannabidiol as an acne treatment will be demonstrated in Phase II clinical trials

BOT's success, and investors' returns, hinge on the efficacy of its development products in treating serious skin disease. In particular, the ability of cannabidiol to influence sebum production and reduce inflammation in the skin is paramount to BOT's future appeal to large pharmaceutical companies as a potential take-over target.

A lack of new drugs for the treatment of acne over the past decade has opened a gap for BTX-1503 to be a 'first-in-class' acne treatment. Progressing through the clinical trials as quickly as possible and proving efficacy of BTX-1503 is therefore critical to maintain the Company's competitive advantage over other new acne treatments undergoing clinical trials.

Regulatory

Clinical trials

BOT has completed safety and irritancy testing on Permetrex

BOT has completed a safety and irritation clinical trial for Permetrex with results showing "minimal or weak irritancy potential" and no safety issues when the drug is applied to the skin. The Permetrex results de-risk the impending BTX-1503 clinical trials as Permetrex makes up the majority of the BTX-1503 formula. BTX-1503 is on schedule to commence Phase I testing in the first half of CY2017.

Figure 11: FDA clinical trial process explained

Phase I	20 - 100 Participants *Period: Several months* Safety and dosage - how a drug interacts with the human body	~70% Success Rate	Phase Ia	*Assesses safety and tolerability to single doses of the drug*
			Phase Ib	*Assesses safety and tolerability to multiple doses of the drug*
Phase II	100 - 300 Participants *Period: Several months to 2 years* Efficacy and side effects - asess how well the drug works	~33% Success Rate	Phase IIa	*Dosing - how much of the drug should be given?*
			Phase IIb	*Efficacy - how well does the drug work at the prescribed doses*
Phase III	300 - 3,000 Participants *Period: 1 to 4 years* Efficacy & monitoring of adverse reactions - demonstrates whether or not a product offers a treatment benefit	~25-30% Success Rate		

The FDA approval process is long and arduous, with a low success rate

Source: FDA website

Patent protection

BOT has protected its suite of products through various patent applications in Australia and the US

BOT has two separate provisional patent applications for its "topical composition and use thereof for the treatment of acne" protecting BTX-1503 in Australia and the USA. The provisional patent applications provide the filing date for all subsequent patent applications worldwide, protecting BOT's IP internationally.

BOT has also filed 5 new patent applications "covering Permetrex enabled products"; some of which are aimed at protecting new formulations of currently approved actives, and the others which protect additional uses for the Company's drug active, synthetic cannabidiol.

The patent for Permetrex is held by its inventor, Dr Eugene Cooper, who in turn licenses the product to BOT

The patent for Permetrex is held by Dr Eugene Cooper, who in turn has granted BOT a license for exclusive worldwide use of the drug delivery technology when used with any drug active purposed for the topical treatment of any skin disease. It is the responsibility of Dr Cooper to enforce and defend his intellectual property rights with respect to Permetrex. Any failure to do so, on Dr Cooper's behalf, may present a significant risk to BOT and its wider portfolio of pipeline products.

Restricted substances

Synthetic cannabidiol is a controlled substance in both Australia and the US

Synthetic cannabidiol, the drug active in BOT's current pipeline of products, is a restricted substance in both the US (cannabidiol is a Schedule I substance under the CSA) and Australia (cannabidiol is a Schedule 4 substance under CPI regulations).

BOT has already received an import license from the DEA to import cannabidiol into the US. Additionally, BOT has contracted with a specialised Good Manufacturing Practice (GMP) facility, which is licensed by the FDA and DEA to handle Schedule I substances, to provide clinical development services for the production of BTX-1503.

BOT is required to fulfil several regulatory obligations to conduct clinical trials with the controlled cannabidiol active

In Australia: Cannabidiol is a Schedule 4 restricted substance under CPI regulations. Therefore, BOT require licenses and the necessary permits to import BTX-1503 for clinical trial purposes. It is unlawful in Australia to import, export, manufacture or supply any medicine that is not registered with the Australian Register of Therapeutic Goods (ARTG). To register a drug with the ARTG, BOT must obtain a Clinical Trial Notification (CTN), which essentially grants approval for the clinical trial in Australia. After obtaining a CTN, BOT should have sufficient leverage to be granted the necessary import licenses and permits for its cannabidiol based medicines.

In the US: Cannabidiol is a Schedule I substance under the Controlled Substances Act (CSA), enforced by the DEA. In order to conduct clinical trials with a Schedule I substance, BOT must first obtain a registration under the CSA from the DEA. To receive such a registration, BOT must demonstrate that it is a qualified researcher and competent to conduct the proposed trials, as determined by the Department of Health and Human Services.

Legal experts see no inherent issues in BOT's plan to conduct trials with cannabidiol in Australia and the US

According to legal experts in both Australia and the US, there are no inherent issues with BOT's proposed conduct of a clinical trial of a topical formulation of cannabidiol if the Company fulfils all of its regulatory requirements with respect to the restricted nature of the cannabidiol active.

Key Personnel

Board of Directors

The board has a track record of taking medical products and technologies from the R&D phase through regulatory approvals to commercialisation

Graham Griffiths, Non-Executive Director & Chairman: Mr Griffiths has an executive career in technology based companies that spans over 39 years. In 2000, Mr Griffiths became Managing Director of ASX listed company ipernica Ltd, a diversified technology and intellectual property commercialisation group. During this time, he oversaw the successful acquisition of Nearmap Ltd (ASX: NEA).

Matthew Callahan, Executive Director: Mr Callahan is the founding CEO of iCeutica Inc and a co-inventor of some of the technologies that comprise the Submatrix Fine Particle Technology™ for improving the bioavailability of pharmaceuticals. iCeutica has developed 3 products to date that have received FDA approval. He has more than 20 years legal, licensing and investment management experience and is also a Director of Glycan Bioscience LLC and a founding director of ASX listed Orthocell Ltd (ASX: OCC).

Dr Bill Bosch, Executive Director & Chief Scientific Adviser: Dr Bosch has more than 20 years' experience in the pharmaceutical industry, focusing on applications of nanotechnology to drug product development. Dr Bosch also works with iCeutica Inc and is a co-inventor of the SoluMatrix™ technology and has been instrumental in the development and scale up of the platform and the development of the 3 FDA approved products that use the SoluMatrix™ drug delivery technology.

Robert Towner, Non-Executive Director: Mr Towner has over 20 years' corporate advisory and executive experience in the financial markets. Mr Towner is the founder and sole director of Cornerstone Corporate Pty Ltd, a corporate advisory company. Mr Towner's prior board experience includes serving as; a founding Executive Director of bioMD Limited, playing a major role in the merger of bioMD Limited with then-private Allied Health Care Limited to create Admedus Limited (ASX: AHZ); and, an Executive Director of Triangle Energy (Global) Limited (ASX: TEG).

Consultants

Key consultants provide significant IP and guidance for skin disease treatment

Dr Eugene Cooper: Dr Cooper is the inventor and patent-holder of the Permetrex topical drug delivery system used by BOT in its product formulations. Dr Cooper also co-invented the NanoCrystal® drug delivery technology, which has been used in six products approved by the FDA.

Professor Diane Thiboutot and Emeritus Professor James Leyden: Prof Thiboutot and Prof Leyden have been engaged by BOT to help guide the development of BOT's product candidates. They are two of the leading acne researchers and clinicians in the US and have been involved in the development of numerous skin disease products.

Dr Michael Thurn, Chief Operating Officer: Dr Thurn has unique experience in drug development, having recently led development of a topical treatment for acne being developed by venture capital backed company Mimetica. The relationships forged in his role at Mimetica will be invaluable to BOT as it progresses the FDA clinical trials for BTX-1503.

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Important Disclosure
Argonaut acted as the Lead Manager to the Offer that raised $3.5M in June 2016 and received fees commensurate with this service. Argonaut holds or controls 12.1M BOT Options exercisable at $0.03 on or before 30 June 2019.

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Purpose of the report: It provides a background and overview, or update, for a Company that is typically at an early stage of its life cycle. Argonaut *does* provide a view and recommendation based on Company review, the outlook and management discussion.
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