

SPEC BUY

Current Price 5.3c
Valuation 8.0c

Ticker:	BOT.ASX		
Sector:	Biotechnology		
Shares on Issue (m):	543.1		
Market Cap (\$m):	28.2		
Net Debt / (Cash) (\$m):	-5.7		
Enterprise Value (\$m):	22.5		
52 wk High/Low:	0.07	0.03	
12m Av Daily Vol (m):	2.58		
Risk adjusted valuation:			
BTX 1503 (\$m)	26.2		
BTX 1204 (\$m)	13.4		
BTX 1308 (\$m)	10.6		
BTX 1701 (\$m)	8.9		
Less: PV (Corporate Costs)	-6.1		
Add: PV (Cash Raised)	20.0		
Total portfolio (\$m)	73.1		
Assumed dilution (%)	40%		
Diluted portfolio value (\$m)	43.7		

Financials:	2Q FY17	3Q FY17	4Q FY17
Op CF (\$m)	-0.8	-0.8	-2.8
Inv CF (\$m)	0.0	0.0	0.0
Fin CF (\$m)	0.0	0.0	7.0
Net CF (\$m)	-0.8	-0.8	4.2
Cash (\$m)	2.4	1.5	5.7

Shareholders:	
Matthew Callahan (Exec Director)	13.0%
Caperi Pty Ltd (Co-founder)	13.0%
Other board & management	3.0%

Share Price Graph



Company Summary: Botanix (BOT) is a biotech company developing new topical drugs for the treatment of serious skin diseases. The Company's development products use 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.

Thursday, 17 August 2017

Botanix (BOT)

Clearing Regulatory Hurdles

Analysts | Daniel Williamson | Ian Christie, CFA

Quick Read

BOT has made significant progress since listing 12 months ago, and importantly de-risked its pipeline of products through successful Phase 1 safety trials for its lead candidate product (BTX 1503). An expanded portfolio adds to BOT's investment appeal and diversifies risks associated with the FDA approval process. Substantial news flow in 2H CY2017 should drive further value. We have valued BOT shares for the first time with a current valuation of 8 cents per share, underpinning our SPEC BUY call.

Event & Impact | Positive

Phase 1 complete: BOT has completed a Phase 1 safety, tolerability and pharmacokinetics study for its BTX 1503 acne treatment. BTX 1503 was found to have "an excellent safety profile, with little to no skin irritation and no severe adverse events recorded."

Expanded Portfolio: BOT's portfolio of candidate products has expanded since we initiated coverage ([Botanix Initiation Report](#)) back in March. The expanded portfolio enabled by a strengthened Permetrex license, encompassing the use of the Permetrex chemical to treat all skin diseases (previously the license only covered cannabidiol-based treatments). BOT has now filed five patent applications for Permetrex-enabled products.

Next cab off the rank: BOT is targeting the US\$4bn per annum prescription dermatitis market with its pipeline product BTX 1204. Initial patient studies for BTX 1204 are expected to commence in 2H CY2017. Importantly, the Company can progress BTX 1204 straight to a Phase 1b pilot study due to the formulations similarities with BTX 1503.

Potential medium-term revenues: The next candidate from BOT's expanded portfolio, BTX 1701, targets the \$1.5bn+ OTC acne cleanser market. Importantly, BTX 1701 does not necessarily require FDA approval and can therefore potentially provide nearer-term revenues. A commercial review and patient study for BTX 1701 will commence in 2H CY2017, with results expected in Q1 CY2018.

What's it worth? Putting a value on BOT shares, or any early-stage biotech for that matter, is difficult given the high levels of risk and lengthy timelines associated with the arduous FDA approval process. We have calculated "risk-adjusted values" for each of BOT's portfolio assets. From that we get a portfolio value of \$73m. Taking into account dilution for assumed future capital raisings we value BOT shares at 8 cents per share.

Recommendation

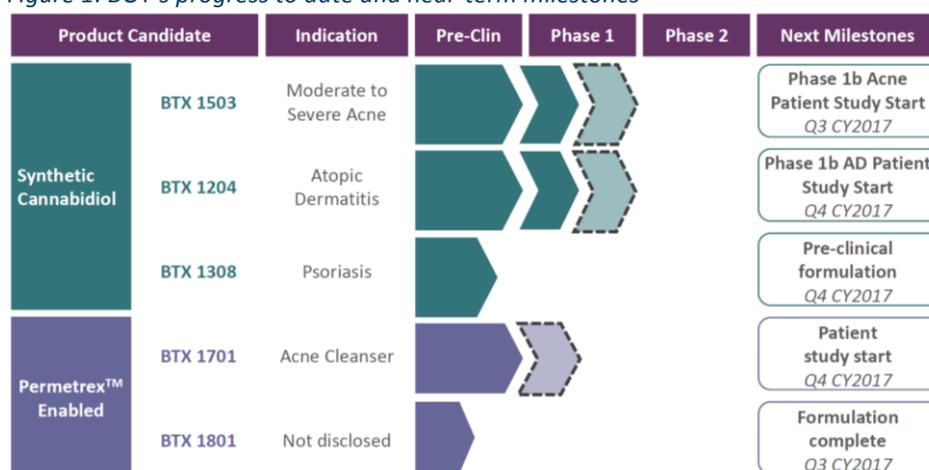
We maintain a SPEC BUY call on an initial valuation of 8 cents per share. *It should be noted that the valuation increases substantially as the Company moves through the approvals process, due to the significant de-risking at each Phase.*

Rapid Progress

BOT has maintained a strict development timeline...

BOT has maintained a strict development timeline since listing 12 months ago. The Company has progressed its flagship drug (BTX 1503), for the treatment of moderate to severe acne, through pre-clinical drug development and a Phase 1 safety study to now be in a position to commence a Phase 1b pilot study in Q3 CY2017. Results from the pilot study should be available before the end of this calendar year.

Figure 1: BOT's progress to date and near-term milestones



Source: BOT company presentation

...with significant news flow expected in the next 12 months

Key Inflection Point

Completed Phase II trials by the end of CY2018 will provide significant value uplift, if successful

Data from the Phase 1b pilot study for BTX 1503 will, if successful, feed into a Phase II study commencing at the start of CY2018. The Company targets Q4 CY2018 for completion of Phase II trials. Successful results for Phase II would represent a key inflection point for BOT and provide significant value uplift for investors. It would also put BOT on the radar of large pharma companies as a potential take-over target or asset sale of BTX 1503.

BOT's acne cleanser has the potential to provide near-term revenues

At the same time BOT aims to advance its acne cleanser (BTX 1701) through patient studies in late CY2017, with data expected in early CY2018. The Company is yet to decide the commercial pathway for the drug, but it is likely to target the "over-the-counter" acne cleanser market. Importantly, if this is the commercial path taken, BTX 1701 will not need to endure the lengthy approvals process and may generate potential near-term revenues.

Many Irons in the Fire

An expanded Permetrex license provides third party collaboration opportunities

BOT has broadened its scope through the strengthened Permetrex licensing agreement (the Permetrex patent is owned by Dr Eugene Cooper who in turn licenses it to BOT for milestone payments and royalties on Permetrex-enabled products). The Permetrex license now covers exclusive world-wide use for the topical treatment of skin diseases. This positions BOT perfectly to collaborate with companies that have difficulty delivering active ingredients into the skin. The Company is already working with multiple parties to combine Permetrex with existing products.

Further results expected from BTX 1204 trials in Q4 CY2017

BOT is also advancing its treatment for atopic dermatitis (BTX 1204) into a Phase 1b pilot study in Q4 CY2017. Due to the similarities between the BTX 1204 and BTX 1503 formulations, this product does not require a Phase 1 safety study.

Valuation Process

Valuing early-stage biotech companies is difficult due to the lengthy FDA approvals process

Valuing Early Stage Biotech's

Valuing early stage biotech companies is difficult given the long timelines to cash flow and the high risk of failure as the companies navigate the arduous FDA approval process. Traditional discounted cash flow or multiple valuation is not possible at these early stages.

Further muddying the waters is the reality that the biotech company will, in all likelihood, not commercialise the product. The most probable outcome is the drug will be sold to a large pharma company at some stage in late clinical development, and the pharma company will then market and commercialise the drug.

We value BOT shares on a risk-adjusted basis...

We have valued BOT's portfolio of candidate products on the basis that it takes drugs through to full FDA approval at which point the Company receives cash through an asset sale to large pharma. The underlying principal of our valuation is that each asset has a "risk-adjusted value" (RAV):

$$RAV = \text{Likelihood of Approval (LOA)} \times \text{Approved Asset Value}$$

...taking into account the likelihood of approval and likelihood of phase success during clinical trials

Likelihood of Approval (LOA)

All future cash flows, including cash payments for clinical trials and cash receipts for an eventual asset sale, need to be adjusted for the likelihood the cash flow will actually occur. For example, for a drug about to commence Phase 1 trials, the likelihood the Company will spend capital on Phase 2 trials is 66.7% and the likelihood the drug will progress all the way to approval is 16.3%.

Table 1: The probability of success at each FDA approval phase, and the likelihood of approval prior to commencing each phase

	Phase I	Phase II	Phase III	NDA*
Probability of phase success	66.7%	39.7%	69.6%	88.4%
Likelihood of approval	16.3%	24.4%	61.5%	88.4%

*NDA = New Drug Application

Source: Biotechnology Innovation Organization, Biomedtracker, Amplion

The probabilities of success were derived from a study conducted by the Biotechnology Innovation Organization (in conjunction with Amplion and Biomedtracker). Data was analysed from 9,985 transitions in the Biomedtracker database over a ten-year period from January 1st 2006 to December 31st 2015. It is the largest study of clinical drug development success rates to date.

Forecast FCF's are based on an assumed market size and market share for each portfolio drug

Forecast Free Cash Flows

The approved asset value, the price tag that big pharma would likely pay for the approved drug, has been estimated as the discount of estimated future cash flows from the drug. Annual free cash flows (FCFs) are estimated as follows:

$$FCF_{drug} = \text{Annual Global Sales} \times (\text{Market Share})_{drug} \times \text{Free Cash Profile}$$

The Free Cash Profile estimates the additional FCF generated from each additional dollar revenue added for big pharma

The “free cash profile” (FCP) measures how much free cash a big pharma company will generate for each additional dollar revenue generated. It is the ratio of free cash flow to revenue for the company. We analysed the 15 largest pharmaceutical companies globally from FY13 to FY16 and determined the average FCP to be 22%. In other words, 22% of each dollar revenue added will flow through to big pharma’s free cash flow.

Market Value and Market Share

We assumed a constant growth rate for annual global sales to forecast sales out to 2037 (the year current patents will expire). The market share estimate was based on current top selling brands and respective market shares.

Table 2: Global annual sales and assumed market share

	2017 Global Sales (\$bn)	CAGR	BOT Market Share
Acne			
Prescription	4.4	2.8%	8.0%
Over the Counter	1.5	2.5%	5.0%
Atopic Dermatitis	4.7	3.8%	5.0%
Psoriasis	10.5	1.7%	4.0%

Source: BOT releases, World Health Organisation, EpiCast, GlobalData, Argonaut estimates

Approved asset value is calculated as the likely value a large pharma company will pay for the drug once approved

Approved Asset Value

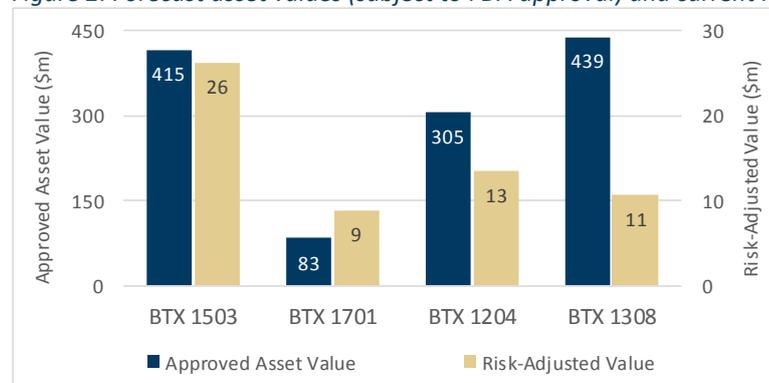
We then calculate the “approved asset value” as the discount of forecast future free cash flows. We assumed a discount rate of 17%, which is the average IRR for the top 25% pharma companies in terms of return on research and development (according to Deloitte’s report “Measuring the return from pharmaceutical innovation 2015”).

Risk-Adjusted Value

To obtain the RAV for each portfolio asset we then discount the approved asset value by the likelihood of approval. We also subtract the costs of clinical development to determine annual cash flows to BOT. These cash flows were discounted at a cost of equity of 20%, which we think is appropriate given the high level of risk associated with BOT shares.

The difference between approved asset value and risk-adjusted value reflects the level of risk inherent in each drug

Figure 2: Forecast asset values (subject to FDA approval) and current risk-adjusted values



Source: Argonaut forecasts

The result is a risk-adjusted portfolio value of ~\$73m and a fully diluted value per share of \$0.08

Valuation

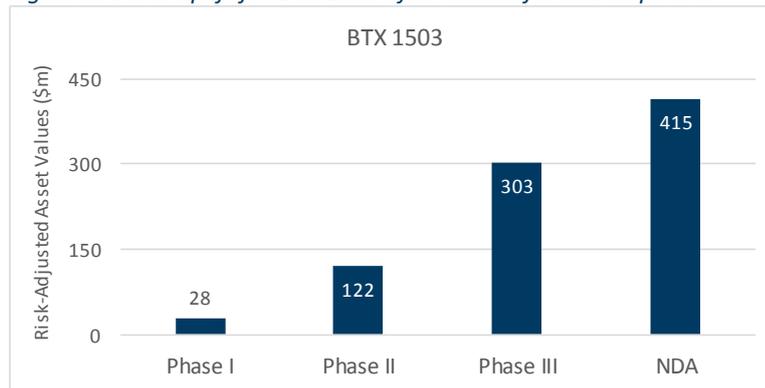
We calculate a risk-adjusted portfolio value (for BOT’s four current candidate products) of approximately A\$73m. We assume a dilution of 40%, equating to 908M fully diluted shares (compared with 543M current shares outstanding). **Therefore, we get a fully diluted valuation of \$0.08/share.**

It should be noted that the valuation increases substantially as the Company moves through the approvals process. This is because successful clinical trials substantially de-risk the candidate drug and, as such, the LOA increases significantly from phase to phase.

The value uplift as products progress through clinical trials is demonstrated in Figure 3 below. For BOT’s flagship acne product (BTX 1503) the risk-adjusted asset value increases from A\$28m post successful Phase 1 trials, to A\$122m post successful Phase 2 trials, to over A\$300m post successful Phase 3 trials. The final approved asset value to BOT shareholders is potentially A\$415m (pending a successful New Drug Application [NDA]).

Value uplift for BOT’s flagship BTX 1503 acne treatment as it progresses clinical trials

Figure 3: Value uplift for BTX 1503 after successful clinical phases



Source: Argonaut forecasts

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

Several large deals were completed in 2016 in the dermatology space

Anterios provides a strong comparable for BOT in its current stage of development

Comparable Transactions

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 3: 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®), currently 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

Allergan's acquisition of Anterios in January 2016 offers the best comparable to BOT at this early stage of development. Encouragingly, the upfront payment of US\$90m is broadly in-line with our estimated portfolio value of ~A\$73m (if you take into account a premium required to purchase a portfolio at such an early stage of development).

The transactions also highlight the significant value uplift as respective drugs move through the FDA approvals process. Late CY2018 represents a key inflection point for BOT as it targets completion of Phase II trials; the success of which would provide substantial value uplift for the Company.

RESEARCH:

Ian Christie | Director, Industrial Research
+61 8 9224 6872 ichristie@argonaut.com

Matthew Keane | Director, Metals & Mining Research
+61 8 9224 6869 mkeane@argonaut.com

James Wilson | Analyst, Metals & Mining Research
+61 8 9224 6835 jwilson@argonaut.com

Helen Lau | Analyst, Metals & Mining Research
+852 3557 4804 hlau@argonaut.com

Daniel Williamson | Analyst, Industrial Research
+61 8 9224 6831 dwilliamson@argonaut.com

INSTITUTIONAL SALES - PERTH:

Chris Wippl | Executive Director, Head of Sales & Research
+61 8 9224 6875 cwippl@argonaut.com

John Santul | Consultant, Sales & Research
+61 8 9224 6859 jsantul@argonaut.com

Damian Rooney | Director, Institutional Sales
+61 8 9224 6862 drooney@argonaut.com

Ben Willoughby | Institutional Dealer
+61 8 9224 6876 bwilloughby@argonaut.com

Phil Russo | Institutional Dealer
+61 8 9224 6813 prusso@argonaut.com

Josh Welch | Institutional Dealer
+61 8 9224 6868 jwelch@argonaut.com

George Ogilvie | Institutional Dealer
+61 8 9224 6871 gogilvie@argonaut.com

INSTITUTIONAL SALES – HONG KONG:

Travis Smithson | Managing Director - Asia
+852 9832 0852 tsmithson@argonaut.com

CORPORATE AND PRIVATE CLIENT SALES:

Glen Colgan | Executive Director, Desk Manager
+61 8 9224 6874 gcolgan@argonaut.com

Kevin Johnson | Executive Director, Corporate Stockbroking
+61 8 9224 6880 kjohnson@argonaut.com

James McGlew | Executive Director, Corporate Stockbroking
+61 8 9224 6866 jmcglew@argonaut.com

Ian Dorrington | Director, Corporate Stockbroking
+61 8 9224 6865 idorrington@argonaut.com

Geoff Barnesby-Johnson | Senior Dealer, Corporate Stockbroking
+61 8 9224 6854 bj@argonaut.com

Rob Healy | Dealer, Private Clients
+61 8 9224 6873, rhealy@argonaut.com

Cameron Prunster | Dealer, Private Clients
+61 8 9224 6853 cprunster@argonaut.com

James Massey | Dealer, Private Clients
+61 8 9224 6849 jmassey@argonaut.com

Chris Hill | Dealer, Private Clients
+61 8 9224 6830, chill@argonaut.com

Important Disclosure

Argonaut acted as the Lead Manager to the Placement that raised \$7.4M in April 2017 and will receive fees commensurate with this service. 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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