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SPEC BUY

Current Price \$0.15 Valuation \$0.225

Ticker: Sector:		BOT-AU Biotechnology		
Shares on Issue (m): Market Cap (\$m): Cash (\$m): Enterprise Value (\$m):			973.1 146.0 22.1 123.9	
52 wk High/Low: 12m Av Daily Vol (m):		0.175	0.023 5.35	
Risk adjusted valuation (NP BTX 1503 (\$m) BTX 1801 (\$m) Corp Costs (\$m) Unpaid Capital (\$m)	PVs):		56.8 185.7 -33.4 2.7	
Portfolio (\$m) Dilution (%)			211.8 5%	
Dil. Portfolio Value (\$m) Current Cash (\$m)			201.2 19.2	
Valuation (\$m)			220.4	
Financials:				
Op CF (\$m) Inv CF (\$m) Fin CF (\$m)	3Q20A 3.1 -0.0 3.1	-5.9 0.0 -5.9	-2.6 -0.0 -2.6	
Net CF (\$m)	3.1	-5.9	-2.6	
Cash (\$m)	30.4	24.6	22.1	

Share Price Graph



Please refer to important disclosures at end of the report (from page 4)

Thursday, 4 February 2021

Botanix Pharmaceuticals (BOT)

Positive BTX 1801 study results

Analyst | Ian Christie

Quick Read

BOT announced positive results from its BTX 1801 Phase 2a nasal decolonisation proof of concept study. We upgrade to SPEC BUY (prior HOLD) as these results highlight CBD's potential as a new treatment for resistant bacteria.

Validates CBD effectiveness against Staph

Study objectives: The randomised, vehicle-controlled, double-blind, 66-participant study had primary objectives focusing on evaluating BTX 1801's safety and tolerability, and its effectiveness in eradicating *Staphylococcus aureus* ("Staph") bacteria from the noses of healthy participants.

Successful: Top line data shows the two BTX 1801 formulations (ointment and gel) were safe and well tolerated, with only mild adverse events, and successfully eradicated *Staph*. In this first human study to assess clinical utility of synthetic CBD as an antimicrobial agent, results after an initial 5 days of treatment showed that at day 7 *Staph* was eradicated in 76.2% (ointment) and 68.8% (gel) of participants, compared to 27.8% of participants in the combined vehicle group. The eradication rate at day 28 was 23.8% for the ointment (vehicle 12.5%) despite no treatment after day 5. See further detail on page 2.

Significant: There was significant separation from vehicle, notably at day 7 (two days after treatment ended), but also over longer periods. Rates of *Staph* eradication validate CBD as a potential new class of antibiotic, providing strong encouragement for further study.

Positive timing: This study comes at a time when antibiotic resistance is emerging as a growing global health challenge. It is important to note therefore that data from this study backs up published research (see our <u>recent note</u>) that concluded CBD "showed a low tendency to cause resistance in bacteria". Further, there has been excellent safety and tolerability results from all BOT's topical CBD studies.

Next steps: Prior research and study data will inform BOT's forward antimicrobial development strategy, with Qualified Infectious Disease Product (QIPD) status helping fast-track future studies (COVID permitting). We expect a Phase 2b study as the next step to help determine optimal effective dosages. We note that while no results were reported for methicillin-resistant *Staphylococcus aureus (MRSA)* in the Phase 2a study, previous pre-clinical data has demonstrated BTX 1801 eliminated *MRSA* from human skin (see page 2) and we expect future clinical studies will address this.

Recommendation

We upgrade to SPEC BUY (prior HOLD) on the back of these positive results. We additionally note considerable M&A activity and investor interest in CBD (Jazz this week bid US\$7.2B for GW Pharma). See page 3 for further comments.

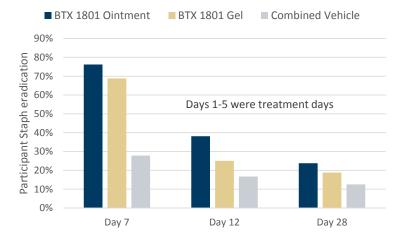


Study and research data

Figure 1: BTX 1801 Phase 2a study results

Percentage Staph eradication amongst trial participants					
	Day 7	Day 12	Day 28		
BTX 1801 Ointment	76.2%	38.1%	23.8%		
BTX 1801 Gel	68.8%	25.0%	18.8%		
Combined Vehicle	27.8%	16.7%	12.5%		

BOT produced BTX 1801 Phase 2a study results that showed significant separation from vehicle



Source: BOT, Argonaut

Figure 2: Prior research showing efficacy of different concentrations of BTX 1801 in MRSA infected human skin explants



Prior human explant pre-clinical data demonstrated that BTX 1801 eliminated MRSA from infected human skin

Complete eradication of MRSA from human skin explants was evident with the high dose BTX 1801 to be used in the Phase 2a clinical study

Source: BOT



Sector M&A activity and interest

Jazz (market cap US\$8.4B) acquires GW Pharmaceuticals (market cap US\$6.4B)

Jazz Pharmaceuticals this week agreed to buy GW Pharmaceuticals in a US\$7.2B cash and scrip deal at a 50% premium to GW's prior closing price. GW's cannabis-based epilepsy treatment (*Epidiolex*) has "blockbuster potential" according to Jazz and will bolster Jazz's existing neuroscience and oncology portfolios.

GW had 2020 sales of US\$526M, had cash of US\$486M at end December, and in addition to commercial products has eight additional cannabinoid development programmes at various stages of clinical development. Jazz anticipates GW's industry leading cannabinoid platform and scientific expertise to significantly expand its neuroscience pipeline.

The deal demonstrates growing pharma interest in cannabidiols and their potential medical attributes.

Other CBD stocks react

The GW announcement had a positive impact on the share prices of other CBD stocks.

Figure 3: Selected CBD companies and one-day share price reaction to Jazz / GW deal

Company	Description	Market	Share
		Сар	Price
			reaction
Corbus Pharma	Clinical stage; lead product candidate <i>lenabasum</i> ; CBD type 2 agonist that resolves chronic inflammation and limits fibrosis; products in Phase 2 and Phase 3 plus pre-clinical evaluations	US\$226m	4.3%
Zynerba Pharma	Clinical stage; focus on neuropsychiatric disorders; development of cannabinoid therapeutics for transdermal delivery; lead candidate <i>Zygel</i> ; 3 products Phase 2 ongoing or complete	US\$134M	27.4%

Source: Argonaut, FactSet, Company websites

Other Companies with ties to the cannabis space also reacted positively on 3rd February, with Cara Therapeutics +5.6%, Hexo Corp +11.7%, Tilray +12.0% and Aphria +12.5% as investors were encouraged by the corporate activity.

Valuation

Our valuation climbs from \$0.140 to \$0.225 for the following reasons:

- We assume the likelihood of potential cash flows associated with BTX 1801 increases to 24.4% (previously 16.3%) following the successful Phase 2a study. This is based on prior broad analysis of the likelihood of FDA studies progressing through clinical trial phases to commercialisation. All other assumptions regarding potential market size and possible BTX 1801 penetration are unchanged on prior.
- We have reduced the rate at which cash flows are discounted to 15.0% (prior 17.5%) to reflect generally lower discount rates globally.

Jazz Pharma will buy GW Pharma in a US\$7.2B deal at a 50% premium to GW's prior closing price

cannabis space climbed on the back of the news

Other stocks with links to the

Our valuation increases to \$0.225 (prior \$0.140) due to increased chance of successful progress through FDA phases and a lower discount rate on risked cash flows



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Argonaut holds or controls 1,400,000 BOT shares.

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