

# **EQUITY RESEARCH**

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# **SPEC BUY**

Current Price \$0.12 Target Price \$0.29

Ticker: Sector:		Biote	BOT.ASX echnology
Shares on Issu Market Cap (\$n Net Debt / (Cas Enterprise Valu	n): sh) (\$m):		964.0 120.5 -40.0 80.5
52 wk High/Lov 12m Av Daily V		0.27	0.07 3.98
Risk adjusted va BTX 1503 (\$m) BTX 1204 (\$m) BTX 1308 (\$m) BTX 1701 (\$m) BTX 1801 (\$m) Less: Corporate Add: Unpaid Ca	e Costs (\$n	n)	141.4 33.0 41.0 6.8 28.7 -32.5 68.1
Total portfolio (\$m) Assumed dilution (%)			286.4 16%
Diluted Portfolio Value (\$m) Add: Current Cash (\$m)			239.7 40.0
Valuation (\$m)			279.7
Financials:	2Q19A	3Q19A	4Q19A
Op CF (\$m)	-0.7	-4.6	-4.8
Inv CF (\$m)	-0.0	0.0	-0.0

Financials:			
	2Q19A	3Q19A	4Q19A
Op CF (\$m)	-0.7	-4.6	-4.8
Inv CF (\$m)	-0.0	0.0	-0.0
Fin CF (\$m)	0.0	0.3	0.3
Net CF (\$m)	-0.7	-4.3	-4.6
Cash (\$m)	13.5	9.3	4.7



Please refer to important disclosures at end of the report (from page 2)

Wednesday, 23 October 2019

## **Botanix Pharmaceuticals (BOT)**

## BTX 1503 Acne Study Read Out

Analyst | Michael Eidne

### **Quick Read**

The BTX 1503 study results are mixed as there is a material difference between the top line results in the US compared to Australia in terms of separation from vehicle. Overall BTX 1503 is effective with an average  $^{\sim}40\%$  reduction in lesions with very low adverse events across the total patient population. We maintain our SPEC BUY recommendation and price target of \$0.29 and view the short-term volatility as a buying opportunity.

## **BTX1503 Study Read Out**

**BOT Phase 2 acne study reads out:** BOT recently completed a Phase 2 study on its BTX 1503 acne formulation. This was a double-blind vehicle-controlled study with 368 patients, of which 50% were under the age of 18. The study was split between US and Australian sites with three different doses and two control groups. The control group was treated with delivery formulation Permetrex ™ without the active CDB ingredient.

Primary endpoint results are mixed: Of the 368 patients only a small percentage reported any adverse events which is a positive outcome considering the importance of safety in dermatological studies. The overall efficacy of BTX1503 was proven with an average 37% reduction in inflammatory lesions across all doses. There was however a significant difference between the US and Australian results. The US results show almost no separation from vehicle with the vehicle showing a 40% reduction in inflammatory lesions while the Australian results show a clear separation between vehicle and active. In Australia, which accounted for about a third of the patients, the active showed efficacy of an average of 41% reduction in inflammatory lesions and the vehicle showed a 26% reduction in inflammatory lesions. This is a statistically significant result.

**Secondary endpoint data results confirm separation:** A secondary endpoint was the reduction in non-inflammatory lesions ("blackheads"). The data across both the US and Australia showed clear separation between vehicle (-19%) and active (-24% to -35%). When the data is broken out by country Australian data shows a very large separation between vehicle (-5.5%) and active (-32% to -39%). The Australian response is almost four times the US response.

**Next Steps:** The variability in results could be due to manufacturing differences between the US and Australia and BOT is now using a single manufacturer for Permetrex <sup>™</sup> and CBD (see report: <u>BOT secures its Synthetic CBD supply</u>). Based on these results, BOT is planning to take BTX 1503 to Phase 3 and will be working with FDA on the next steps in the process.

### Recommendation

While the results are mixed due to the difference between the US and Australian results, we believe the result to be an overall positive. BOT owns Permetrex  $^{\text{TM}}$  and BTX 1503, and together they are safe and show an efficacy that rivals competing products in the market. We are sure there will be an explanation forthcoming that will explain the anomalous US inflammatory results. We, therefore, maintain our SPEC BUY recommendation and price target of \$0.29 and view the short-term volatility as a buying opportunity.



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Argonaut acted as Joint Lead Manager in respect of the Placement that raised \$40M in July 2019 and received fees commensurate with this service. Argonaut holds or controls 5,000,000 BOT shares.

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