

SPEC BUY

Current Price \$0.11
Target Price \$0.29

Shares on Issue (m): 964.0
Market Cap (\$m): 106.0
Net Debt / (Cash) (\$m): -37.3
Enterprise Value (\$m): 68.7

52 wk High/Low: 0.27 0.07
12m Av Daily Vol (m): 3.42

Risk adjusted valuation (NPVs):

BTX 1503 (\$m) 142.6
BTX 1204 (\$m) 33.3
BTX 1308 (\$m) 41.4
BTX 1701 (\$m) 6.8
BTX 1801 (\$m) 28.9
Less: Corporate Costs (\$m) -32.5
Add: Unpaid Capital (\$m) 68.6

Total portfolio (\$m) 289.1
Assumed dilution (%) 16%

Diluted Portfolio Value (\$m) 242.0
Add: Current Cash (\$m) 40.0

Valuation (\$m) 282.0

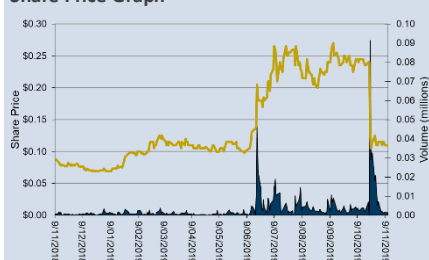
Financials:

	3Q19A	4Q19A	1Q20A
Op CF (\$m)	-4.6	-4.8	-6.9
Inv CF (\$m)	0.0	-0.0	-0.0
Fin CF (\$m)	0.3	0.3	32.6

Net CF (\$m) -4.3 -4.6 32.6

Cash (\$m) 9.3 4.7 37.3

Share Price Graph



Please refer to important disclosures at end of the report (from page 15)

Thursday, 14 November 2019

Botanix Pharmaceuticals (BOT)

A deep dive into the BTX 1503 Study Results

Analyst | Michael Eidne

Quick Read

In this report, we take a deep dive into the recently released BTX 1503 phase 2 acne results. We compare each arm of the study with five other acne products that are either in development or are fully commercialised. We also review the share price performance of two other ASX listed biotech stocks, Paradigm (PAR) and ResApp (RAP) who also had anomalous results but have since recovered. We are expecting the readout from the Atopic Dermatitis study early next year with a Rosacea and anti-microbial study about to kick off. We maintain our SPEC BUY recommendation and price target of \$0.29.

BTX 1503 Results Review

Key Takeaways from the BTX1503 Acne Phase 2 Study: There were no adverse events or treatment-related discontinuations across the 368 patients. A phase 2 study focuses on safety and efficacy, so one of the outcomes was met across all study arms.

A Comparison with other Acne Studies: We looked at several other acne products study results to compare the BTX1503 results across the different study arms.

Figure 1. Summary of Inflammatory findings – (Green is good, red is negative)

Drug	Efficacy (Lesion reduction, %)	Separation from Vehicle (Lesion reduction, %)	Adverse Events (%)
ameeq™	High (-16.93, -56%)	Low (-13.4, -43%)	High (24.5%)
AOBiome	Medium (-9.6)	Low (-6.7)	High (25%)
Aczone™	High (-15.6, -52.7%)	Low (-14, -46.7%)	Low (0.36%)
Epiduo™	Low (-7.4)	High (-0.7)	High (26.06%)
BTX 1503	High (-11.8, -40.5%)	Low (-11.3, -40.15%)	Low (2.2%)
BTX1503 - US	High (-12.1 -40.4%)	Negative (-12.8, -45.9%)	Low (2.2%)
BTX1503 - AU	High (-11.2, -40.8%)	High (-7.7, -26.4%)	Low (2.2%)

Source: US National Library of Medicine, BOT, Argonaut Research

We conclude that if the results of the BTX 1503 Australian arm were to be taken in isolation, then it would be a class leader due to efficacy and safety based on the comparative data presented in this discussion. Also, the overall efficacy of BTX 1503 across all arms compares favourably with other products that are commercialised or in development.

Post ambiguous results release case study: We review the long-term share performance of Paradigm (PAR) and ResApp (RAP) who released ambiguous study results.

Upcoming news flow: The BTX 1204 atopic dermatitis study is on track to complete recruitment this quarter and readout is expected in Q1 CY2020. The company is about to commence a Phase 1b study on rosacea and on an anti-microbial formulation.

Recommendation

We maintain our SPEC BUY recommendation and price target of \$0.29.

A Closer Look at the Acne Trial Results

Quarterly Cash Position

During the quarter the company raised \$40m before costs and is currently holding \$37.3m in cash

During the quarter the company raised \$40m before costs and is currently holding \$37.3m in cash and expecting outflows of \$7.2m in R&D activities and \$4.1m in other costs in the current quarter.

BTX 1503 Acne Trial Results

BOT completed its BTX1503 acne clinical study with readout post the end of the quarter

BOT completed its BTX1503 acne clinical study with readout post the end of the quarter. The results were mixed with a good result recorded in Australia with a clear separation between vehicle and active, but in the US arm there was very little separation between the vehicle and active arms. These results were anomalous, and they still have to be adequately explained by the company. However, the study did show good efficacy and safety of active across both the US and Australian sites and based on these outcomes BOT is planning to proceed to a Phase 3 acne study.

Key Takeaways from the Study:

There were no adverse events or treatment related discontinuations across the 368 patients

Safety: There were no adverse events or treatment-related discontinuations across the 368 patients. A phase 2 study focuses on safety and efficacy, so one of the outcomes were met.

Efficacy: There are two ways to look at efficacy when conducting a study on the pharmacological action of a drug; the absolute change in the condition that is being treated and a comparison to a placebo that compares the outcomes in the patient population where some patients were treated with the drug and a control group with a placebo. Generally, there is always some reaction on the control arm of a study, and that is why a key step is the statistical analysis of the results to determine if the difference between the active arm and vehicle arms of a study is statistically significant across the patient population.

From the study results it was clear that the Australian arm of the study performed very well and was in fact in line with the results from other acne studies

In an internal medicine study generally, though not always, there is a less of a vehicle response to external factors, but in a dermatological study, external factors play a much bigger role. This is because often patients will take better care of their skins which could lead to a false positive response of the control arm of the study.

When comparing the results of the two arms it is clear that something went wrong with the Permatix[®] vehicle arm of the study in the US

From the study results, it was clear that that the Australian arm of the study performed very well and was in fact in line with the results from other acne studies which we will look at in detail later. The overall study results and US arm results if taken at face value would give one the impression that BTX1503 does not provide any differentiation to the Permatix[®] vehicle response. However, patients being treated with Permatix[®] and BTX1503 combination or just with Permatix[®] recorded a circa 40% reduction in inflammatory acne lesions.

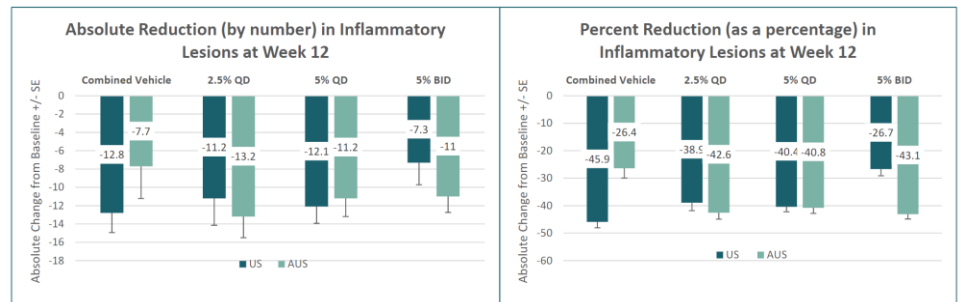
When comparing the results of the two arms, it is clear that something went wrong with the Permatix[®] vehicle arm of the study in the US. BOT has not yet explained what went wrong as they are still investigating. On a close examination of the results from the active

It is however clear that a level of uncertainty has been introduced by the inability of the company to explain the US vehicle results and it will be important for BOT to communicate its findings to the investment community.

arm of the study it is important to note that the results from the active arms are consistent across both the US and the Australian studies which provides confirmation of the efficacy of BTX 1503.

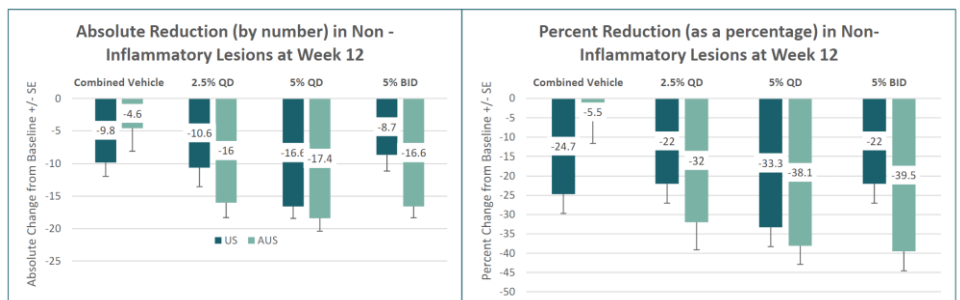
It is however clear that a level of uncertainty has been introduced by the inability of the company to explain the US vehicle results and it will be important for BOT to communicate its findings to the investment community.

Figure 2. Inflammatory Results



Source: BOT

Figure 3. Non-Inflammatory Results



Source: BOT

Is the problem fixed?

BOT has made several key changes to its material supply agreements in that both BTX1503 and Permatrex® are now sourced from a single manufacturer

BOT has made several key changes to its material supply agreements in that both BTX1503 and Permatrex® are now sourced from a single manufacturer. BOT suspects that the issues are with Permatrex® used in the US arm because it was sourced from multiple contract manufacturing organisations (CMO's). The material used in the Australian arm of the study was sourced from a single CMO, and this model has been replicated with Purisys being appointed to supply the API. Purisys is cGMP certified and audited by the FDA to produce APIs for human consumption. Permatrex® manufacturing has been outsourced to a single large chemicals manufacturer.

A Comparison with other Acne Studies

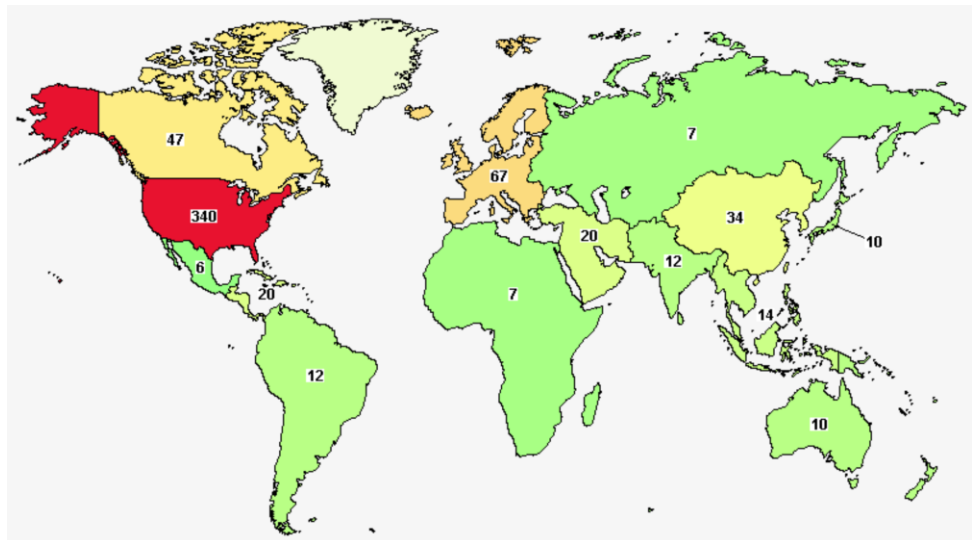
We wanted to put these results into context with the results from other vehicle controlled acne studies

We wanted to put these results into context with the results from other vehicle-controlled acne studies. To achieve a meaningful comparison, we compared the BTX 1503 results to other acne studies across the key metrics; efficacy on inflammatory lesions, efficacy on non-inflammatory lesions, separation from a benign vehicle and the % adverse events reported. We used the results from the 5% CDB once a day application in our comparison as it's BOTs preferred treatment model.

We used the US National Library of Medicine database as our primary source as well as information published by the drug companies who own the products.

There are some 589 acne or acne-related studies captured in the system from about 2002 until the current day, including new studies that are currently recruiting. About 60% of these studies have been conducted in the US, and only ten have been conducted in Australia.

Figure 4. Map showing the geographical location of acne studies



Source: US National Library of Medicine

To make a comparison to the BOT results we selected studies that have been conducted in the last several years

To make a comparison to the BOT results, we selected studies that have been conducted in the last several years, had a similar study design to the BOT study and had published results. We also included Epiduo™ and Aczone™ which are referenced in the BOT releases. We limited our study to five comparators and acknowledge that this is not an exhaustive list. We also excluded studies that used a medical device such as acne masks as we do not believe this is comparable to BTX 1503.

One of our observations is that there does not seem to be a large universe of recently completed studies with results that can be compared to the BOT results

One of our observations is that there does not seem to be a large universe of recently completed studies with results that can be compared to the BOT results. We also attempted to find acne treatments with a novel delivery method (e.g. Foamix) or with a novel API (e.g. AOBiome). We wanted something different from the plethora of accepted Benzoyl Peroxide and anti-biotic treatments. A cursory review of the dataset seems to show that a large proportion of the acne studies that have been completed are variations of already existing treatments. There were also a large number of product comparison

studies, so we limited our review to vehicle-controlled studies. We also found that only 148 of the 598 acne studies on the system have published results.

Comparing the Results with other acne products

Pharma Companies in this report

Figure 5. Comparator companies featured in this report

Name	Code	Market Cap (AU\$m)	FY1 Revenue (AU\$m)	FY1 EBITDA (AU\$m)
Foamix Pharmaceuticals Ltd.	FOMX	386.0	6.7	(76.7)
AOBiome	Private	NA	NA	NA
Bausch Health Companies Inc.	BHC-US	13,461.2	12,474.6	5,220.3
Galderma (subsidiary of Nestlé)	Subsidiary	NA	NA	NA
Almirall SA	ALM-ES	4,860.3	1,395.9	489.7
Botanix Pharmaceuticals Limited	BOT-AU	106.1	5.0	(13.6)

Source: Factset

Foamix Pharmaceuticals Ltd

Foamix Pharmaceuticals Ltd

Foamix Pharmaceuticals Ltd. is a pharmaceutical company, which focuses on the development and commercialisation of proprietary, innovative and differentiated topical drugs for dermatological therapy. Its product portfolios include minocycline foam, minocycline gel, mometasone foam, calcipotriene foam, triamcinolone acetonide foam, betamethasone valerate foam, and betamethasone dipropionate. The company was founded by Dov Tamarkin and Meir Eini on January 19, 2003 and is headquartered in Rehovot, Israel. Foamix is listed in the United States and has market capitalisation of AU\$386m. Its key acne product, Amzeeq, uses a foam-based delivery system for a broad spectrum anti-biotic Minocycline to the skin. It received FDA approval for the product in October 2019. Normally Minocycline is taken orally, and it has been challenging to deliver the drug topically due to instability, but its propriety Molecule Stabilising Technology allows the effective application of the drug. Foamix is also developing a treatment for Rosacea.

AOBiome Therapeutics

AOBiome Therapeutics, Inc

AOBiome Therapeutics, Inc. develops microbiome-targeted therapies for local, nasal and systemic inflammatory conditions. Its portfolio includes three clinical-stage programs, a Phase 2b study to treat patients with acne vulgaris, a Phase 2 trial to reduce elevated blood pressure, and a Phase 1b/2a clinical trial in allergic rhinitis, as well as earlier-stage preclinical programs targeting diverse inflammatory indications. The company was founded by Jamie Heywood, David Whitlock and Lenny Barshack in 2013 and is headquartered in Cambridge, MA. It's a private VC backed company that has raised US\$100m since 2013 and recorded \$20m in revenue 2017. It was planning to IPO in December 2018 on the Hong Kong market, but this was withdrawn. AOBiome has a novel API of Ammonia Oxidising Bacteria that it is currently studying. It also has an Atopic Dermatitis study in children and adults in progress with an imminent readout.

Galderma SA**Galderma SA**

Galderma SA develops and markets therapeutic and aesthetic solutions for dermatology. It provides medical dermatological solutions that meet the needs of patients and physicians with a particular focus on acne, rosacea, psoriasis and other steroid-responsive dermatoses, onychomycosis (fungal nail infections), pigmentary disorders, skin cancer and medical aesthetic and corrective solutions for skin senescence. The company was founded in 1981 and is headquartered in Paris, France and is a subsidiary of Nestlé. Galderma's flagship acne product is Epiduo that had a peak revenue of circa US\$700m.




Almirall SA**Almirall SA**

Almirall SA engages in the development, manufacture, storage, commercialisation and sale of pharmaceutical and cosmetic products, as well as of the raw materials used in production. The company operates through the following segments: Marketing through Own Network, Marketing by Licensees, Research and Development Activity, Therapeutic Area of Dermatology in the United States, and Corporate Management and Results not assigned to Other Segments. Its products include treatments for respiratory, autoimmune, dermatological and gastrointestinal diseases. The company was founded in 1943 and is headquartered in Barcelona, Spain.

One of Almirall's key acne products is Aczone™ which it bought from Allergan as part of a portfolio of dermatological products in a transaction that was finalised in September 2018. Allergan sold a portfolio five products for US\$550m with earn-outs of up to US\$100m. The product set had annual sales of circa US\$150m.

Inflammatory Comparison

Figure 6. Comparator Inflammatory lesion results comparison

Inflammatory Lesion Comparison		Study Details				Active Arm			Vehicle Arm			
Company Name	Product	Phase	API ¹	Study Length	Patients (n)	Lesion Reduction	% Reduction	Adverse Events %	Lesion Reduction	% Reduction	Adverse Events %	Lesion Diff
Foamix Pharmaceuticals	 amzeeq [™] (minocycline) topical foam, 4%	Phase 3	Minocycline (Broad Spectrum Antibiotic)	12 weeks	1,507	-16.93	(56.0%)	26.20%	-13.4	(43.0%)	24.5%	-3.53
AOBiome	AOB101	Phase 2	Ammonia oxidizing bacteria	4 weeks	36	-9.6		25%	-6.7		22%	-2.9
Almirall SA/Allergan Plc	 Aczone [™] (dapsone) 7.5%	Phase 3	Dapsone 7.5% (antibiotic)	12 weeks	2,238	-15.6	(52.7%)	0.36%	-14	(46.7%)	0.36%	-1.6
Galderma	 EPIDUO FORTE [™] (adapalene and benzoyl peroxide)	Phase 4	Epiduo [®] (adapalene and benzoyl peroxide)	12 weeks	285	-7.4		26.06%	-0.7		12.59%	-6.7
Botanix Pharmaceuticals Limited	BTX 1503	Phase 2 - Total	CBD	12 weeks	368	-11.8	(40.5%)	2.20%	-11.3	(40.2%)	1.10%	-0.5
Botanix Pharmaceuticals Limited	BTX 1503	Phase 2 - US Arm	CBD	12 weeks	257	-12.1	(40.4%)	2.20%	-12.8	(45.9%)	1.10%	0.7
Botanix Pharmaceuticals Limited	BTX 1503	Phase 2 - AUS Arm	CBD	12 weeks	111	-11.2	(43.1%)	2.20%	-7.7	(26.4%)	1.10%	-3.5

¹ Active Pharmaceutical Ingredient

Source: US National Library of Medicine, BOT

When comparing BTX 1503 overall efficacy results to Epiduo, Aczone and amzeeq and AOBiome's phase 2 product we can see that in terms of active arm efficacy results, BTX 1503 is in line with comparator topical acne treatments.

The Aczone[™] vehicle response was in a similar percentage range to the US arm of the BTX 1503 study

It is also of interest to note that in the amzeeq[™] and Aczone[™] studies, the vehicle response was in a similar percentage range to the US arm of the BTX 1503 study. The percentage change in lesions in the vehicle arm of the Aczone[™] study (-46.7%) was greater than Permetrex[™] (-45.9%) vehicle response in the BTX 1503 study. This shows that a high vehicle response is not unknown, and even with a high vehicle response, products are approved and can become successful treatments. Aczone[™] reached peak revenue of US\$300m and was sold as a key part of a drug portfolio for US\$550m.

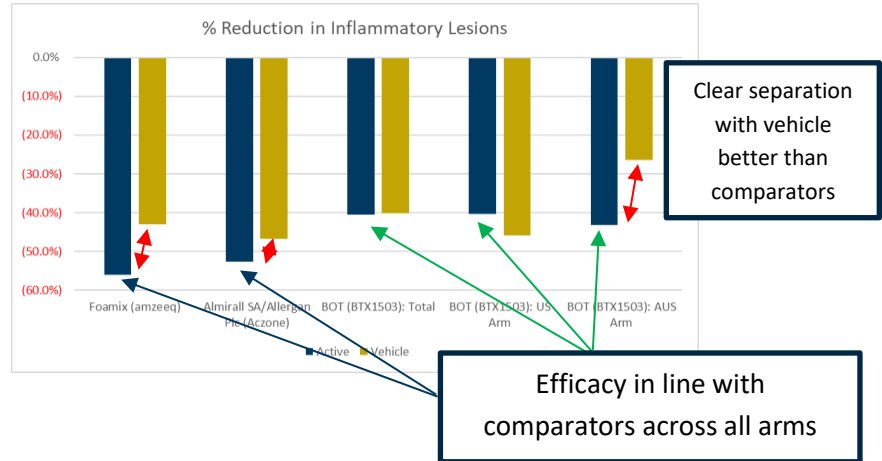
The stand out result is the Australian BTX1503 study arm where Permetrex[™] vehicle only recorded a -26.4% reduction in lesions vs a -43.1% reduction in lesions on the active arm

The standout result is the Australian BTX1503 study arm where Permetrex[™] vehicle only recorded a -26.4% reduction in lesions vs a -43.1% reduction in lesions on the active arm. This gives very good separation between active and vehicle with an active result in line with current products on the market or in testing.

As a crude measure we also looked at the absolute change in lesions, and on this basis, the Australian arm of the BTX 1503 score of -3.5 compares very favourably with amzeeq's[™] -3.53, AOBiome's -2.9 and Aczone's[™] -1.6. Only Epiduo outperforms all its competitors with a score of -6.7. However, the overall efficacy of Epiduo[™] is lower than all products with the lowest absolute decline in lesions of -7.4 compared to the other in this review. Epiduo did not release the percentage fall in lesions as part of their study.

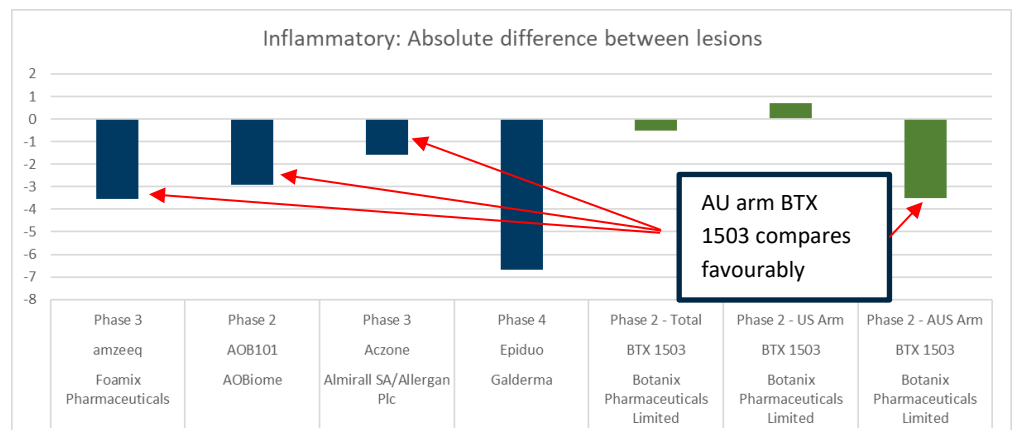
Figure 7. The absolute difference between inflammatory lesions

When we compare the percentage change of BTX 1503 to amzeeq™ and Acxzone™ we can see that the BTX 1503 Australian arm has very clear separation between active and vehicle which is a very encouraging



Source: US National Library of Medicine, BOT

Figure 8. Reduction in the % of inflammatory lesions




Source: US National Library of Medicine, BOT

Not all the studies report a percentage change from baseline and not knowing the baseline makes it impossible to calculate a percentage change from the change in lesions. However, when we compare the percentage change of BTX 1503 to amzeeq™ and Aczone™ we can see that the BTX 1503 Australian arm has a very clear separation between active and vehicle which is very encouraging.

By comparing the BTX 1503 to other acne study results for comparator products, we can see that while the result for the US arm is anomalous, the results from the Australian arm place BTX 1503 in a very good position particularly when taking the safety results into account. We discuss this in detail later on.

Non-Inflammatory Comparison

Figure 9. Comparator Non-Inflammatory lesion results from comparison

Non-Inflammatory Lesion Comparison		Study Details				Active Arm			Vehicle Arm			Diff
Company Name	Product	Phase	API	Study Length	Patients (n)	Lesion Reduction	% Reduction	Adverse Events %	Lesion Reduction	% Reduction	Adverse Events %	
Almirall SA/Allergan Plc	 Aczone 75	Phase 3	Dapsone 7.5% (anti-biotic)	12 weeks	2,238	-20.8	(44.5%)	0.36%	-18.7	(40.0%)	0.36%	-2.10
Bausch Health Companies Inc.	ACYC	Phase 3	ACYC	12 weeks	498	-16.3		15.60%	-8.3		13.40%	-8.00
Botanix Pharmaceuticals Limited	BTX 1503	Phase 2 - Total	CBD	12 weeks	368	-17.3	(35.0%)	2.20%	-8.3	(19.1%)	1.10%	-9.00
Botanix Pharmaceuticals Limited	BTX 1503	Phase 2 - US Arm	CBD	12 weeks	257	-16.6	(33.3%)	2.20%	-9.8	(24.7%)	1.10%	-6.80
Botanix Pharmaceuticals Limited	BTX 1503	Phase 2 - AUS Arm	CBD	12 weeks	111	-17.4	(38.1%)	2.20%	-4.6	(5.5%)	1.10%	-12.80

Source: US National Library of Medicine, BOT

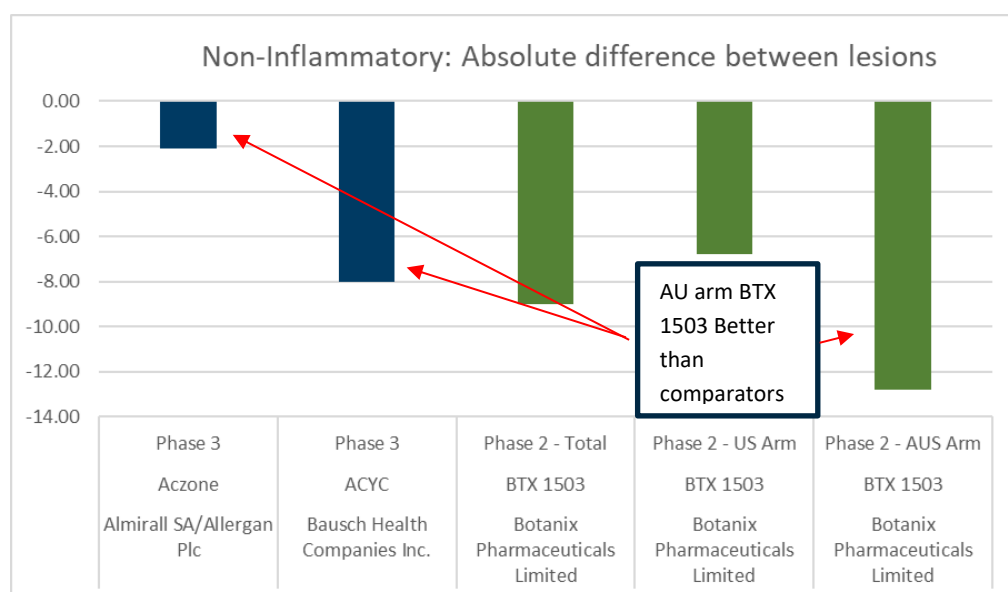
We have broken out the non-inflammatory BTX 1503 results and looked at them in isolation

We have broken out the non-inflammatory BTX 1503 results and looked at them in isolation because they do show separation from the vehicle across the US and Australian arms. The Aczone™ study also reported a separate set of results for non-inflammatory that we could compare to the BTX 1503 study results. Bausch Health companies also did a study with a sole focus on non-inflammatory lesions testing a drug ACYC which we believe it is yet to be commercialised.

We can see from these results that BTX 1503 performed well across both the US and Australian study arms. The Australian arm performed extremely well and could be viewed as a best in class result from this comparison.

Aczone™ shows a similar outcome in terms of separation from the vehicle between the inflammatory and non-inflammatory endpoints although with a good overall efficacy score.

Figure 10. Reduction in the % of non-inflammatory lesions

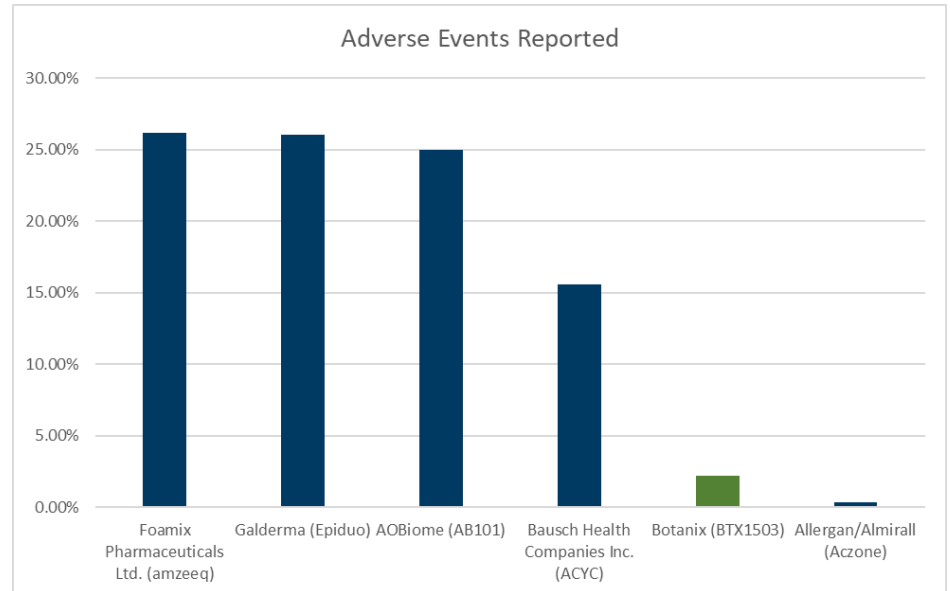


Aczone™ shows a similar outcome in terms of separation from vehicle between the inflammatory and non-inflammatory end points although with a good overall efficacy score.

Source: US National Library of Medicine, BOT

Adverse Events

Figure 11. % Adverse events reported



Source: US National Library of Medicine, BOT

An important measure that is reported in FDA studies is the incidence of adverse events reported by the patient population

BOT 1503 stands out compared to to the comparators we have included in this analysis.

An important measure that is reported in FDA studies is the incidence of adverse events reported by the patient population. These adverse events range from mortality, serious adverse events and non-serious adverse events. Mortality and serious adverse events would more than likely be very rare and almost unknown in a dermatological study, so we compared the total non-serious adverse events reported with BTX 1503 outcomes.

No serious adverse events include gastrointestinal disorders, general disorders, infections such as influenza, sinusitis and upper respiratory infections. These events are recorded as a percentage of the patient population.

It is on this measure that BOT 1503 stands out compared to the comparators we have included in this analysis. Only Aczone™ has a better record than BTX 1503. What also stands out is the gap between BTX 1503 and the other drugs that may have a similar efficacy range but a substantially larger amount of reported adverse events. A quarter of the patients on amzeeq™ and Epiduo™ reported adverse events. Therefore BTX 1503 2.2% adverse events is a very good result, particularly when coupled with the strong efficacy result of circa -40% reduction in lesions.

Our Conclusions

While this analysis is not exhaustive it has provided some interesting comparisons

Anti-biotics are clearly an effective treatment for acne but considering the issues around the overuse of anti-biotics could mean that over time they will lose efficacy

If the results of the BTX 1503 Australian arm were to be taken in isolation then it would be a class leader

While this analysis is not exhaustive, it has provided some interesting comparisons. BTX 1503 is a new novel treatment, but there are other groups pursuing acne treatments that are not anti-biotic or benzoyl peroxide-based as well. However, in this limited group of novel and more traditional treatments, BTX 1503 low incidence of adverse events stand out.

Antibiotics are an effective treatment for acne, but there are growing concerns in the medical fraternity over the issues around the overuse of antibiotics which could mean that over time they will lose efficacy.

Another key takeaway is that the FDA has approved drugs even if they have a high incidence of minor adverse events, and these formulations will go on to be commercial successes such as Epiduo™.

If the results of the BTX 1503 Australian arm were to be taken in isolation, then it would be a class leader due to efficacy and safety based on the comparative data presented in this discussion. To provide an overview of the data we have broken out each element in our analysis and given each factor a score of High, Medium, Low and Negative and the BTX 1503 Australian arm scores all greens across the board.

Figure 12. (Green is good, red is negative. Please note: our score is not a scientific measure)

Drug	Efficacy (Lesion reduction, %)	Separation from Vehicle (Lesion reduction, %)	Adverse Events (%)	Comments
ameeq™	High (-16.93, -56%)	Low (-13.4, -43%)	High (24.5%)	Novel delivery, antibiotic
AOBiome	Medium (-9.6)	Low (-6.7)	High (25%)	Novel, Phase 2
Aczone™	High (-15.6, -52.7%)	Low (-14, -46.7%)	Low (0.36%)	Anti-biotic
Epiduo™	Low (-7.4)	High (-0.7)	High (26.06%)	Low relative efficacy
BTX 1503 (Total)	High (-11.8, -40.5%)	Low (-11.3, -40.15%)	Low (2.2%)	Novel, Phase 2
BTX1503 - US	High (-12.1 -40.4%)	Negative (-12.8, -45.9%)	Low (2.2%)	Novel, Phase 2
BTX1503 - Australia	High (-11.2, -40.8%)	High (-7.7, -26.4%)	Low (2.2%)	Novel, Phase 2

Source: US National Library of Medicine, Argonaut research, BOT

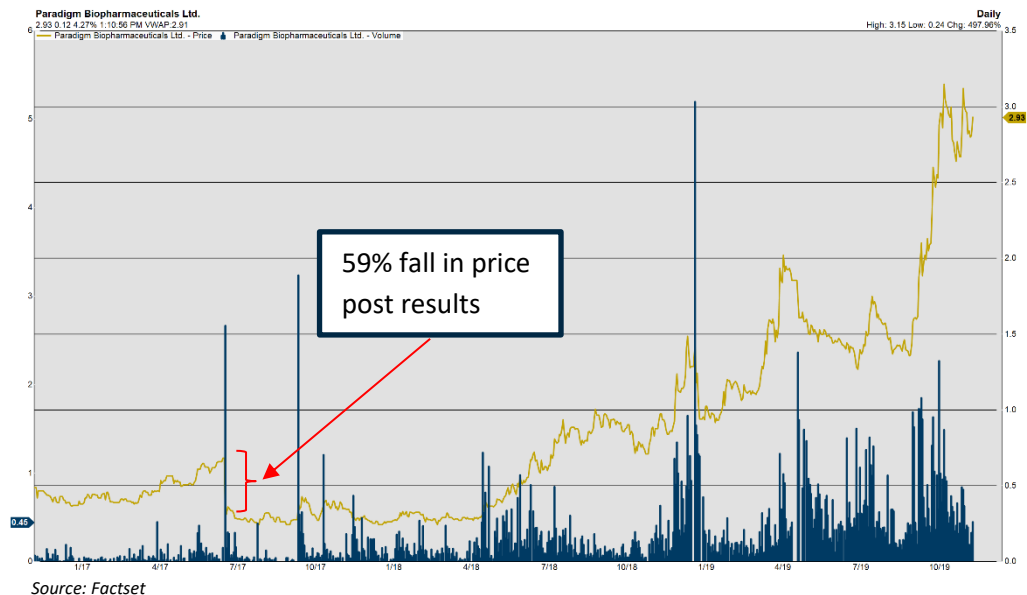
Case Studies – Other ASX listed Biotechs with ambiguous study outcomes

The BTX 1503 study results were not clear cut, so we have looked at two case studies where a study has produced ambiguous results that do not disprove the science but has been the result of some external issue. Due to the fact the core science behind these drugs or products is viable, the share prices have recovered and in some case far surpassed the prices before the release of results. We believe that BOT is in the same position and with some more data will recover its lost ground.

Paradigm (PAR)

Figure 13. PAR Price chart

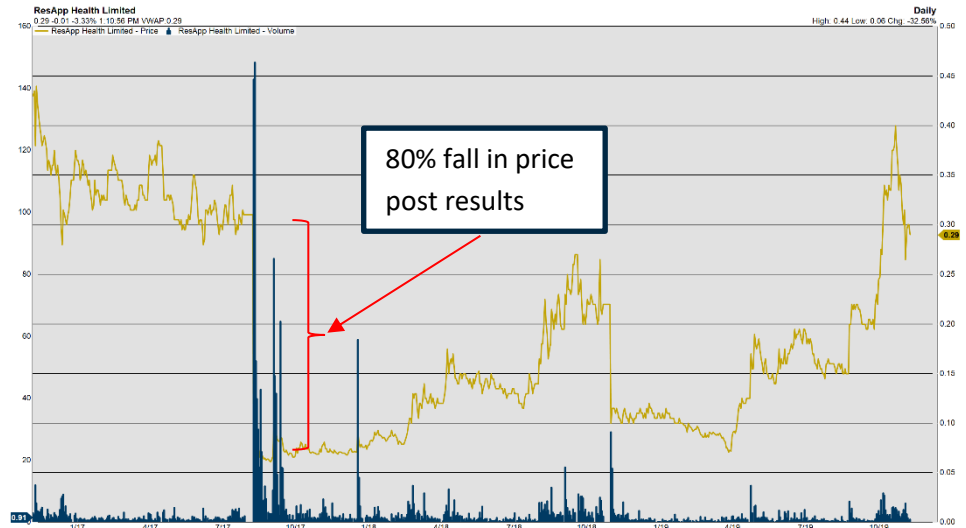
Good phase 2 results were achieved with the Osteoarthritis study and since the fall the share price has rallied 1,090%.



PAR is in the process of re-purposing the API PPS for use in hay fever and Osteoarthritis. In 2017 PAR conducted a Phase 2a allergic rhinitis trial which despite promising results before the phase 2 study failed to meet its endpoints. The issue was not PPS but rather that the drug formulation was at fault, and as a result the treatment was not effective. The share price fell 59% on the news. The company then focussed on using PPS for Osteoarthritis and put hay fever on the back burner. Good phase 2 results were achieved in the Osteoarthritis study, and the share price has rallied 1,090% from its lowest point.

ResApp Health (RAP)

Figure 14. RAP Price chart



The stock fell 80% but has since recovered by 375% due to the fact the study was repeated in which the correct protocols were followed and the end points were achieved

Source: Factset

RAP is a medical device company that has technology that enables the diagnosis of lung conditions such as bronchitis and pneumonia by coughing into a smartphone running its proprietary software. A study was conducted at the Joondalup Hospital in Perth, which had very strong results. A study was then undertaken in the US which had poor results due to the fact study protocols were not followed. The stock fell 80% but has since recovered by 375% due to the fact the study was repeated in which the correct protocols were followed, and the endpoints were achieved.

BOT Upcoming News Flow

Atopic Dermatitis Study

The BTX 1204 atopic dermatitis study is on track to complete recruitment this quarter

The BTX 1204 atopic dermatitis study is on track to complete recruitment this quarter and readout is expected in Q1 CY2020. There are approximately 200 patients taking part in the randomised double-blind vehicle-controlled study.

Rosacea

The company is about to commence a Phase 1b study on papulopustular rosacea

The company is about to commence a Phase 1b study on papulopustular rosacea. The study aims to enrol 36 patients in a double-blind, vehicle-controlled study. The primary endpoint will be the safety and the tolerability of BTX 1702 formulation. Exploratory endpoints will be the absolute change and percentage change in lesion counts and an IGA score.

Anti-Microbial

BOT is continuing its development of its BTX 1801 anti-microbial platform. It is expecting to start a study in the current quarter.

Valuation and Recommendation

The Australian arm of the BTX 1503 study and the overall non-inflammatory results are very compelling

BOT is planning to take BTX 1503 to a phase 3 study. We believe our review of comparator data validates this view. The Australian arm of the BTX 1503 study and the overall non-inflammatory results are very compelling and are a standout compared to other products in the universe that are FDA approved and commercialised. The fact that BTX 1503 is a non-traditional anti-biotic treatment and has a very low occurrence of adverse events makes it a compelling and novel treatment.

We maintain our SPEC BUY recommendation and price target of \$0.29.

BOT also has a phase 2 atopic dermatitis study reading out early next year. While it is possible to treat acne with anti-biotics over the longer term, the same can not be said of Atopic Dermatitis. The most effective treatment for Atopic Dermatitis, steroids, cannot be used over the long term due to severe side effects. Therefore, if CBD is effective on Atopic Dermatitis and with the safety profile that has been demonstrated across the large patient population in the acne study, CBD as a long term treatment for Atopic Dermatitis could be a blockbuster product. As we have seen from the case studies of PAR and RAP, negative study results due to an anomaly are often buying opportunities for investors. We, therefore, maintain our SPEC BUY recommendation and price target of \$0.29.

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Important Disclosure

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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