Botanix Pharmaceuticals Ltd

(BOT $0.063) Speculative Buy

EUROZ HARTLEYS

Analyst	Date	Price Target
Seth Lizee	**14th October 2022**	**$0.27/sh**

BTX 1702 Phase 1b/2 Clinical Study for Rosacea: SUCCESSFUL RESULTS

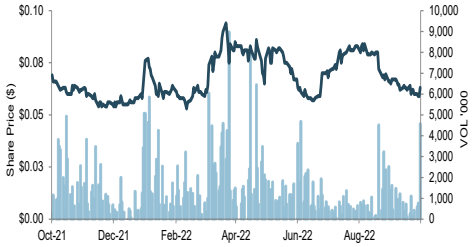
Key Points

- BOT has announced the successful results of its BTX 1702 Phase 1b/2 clinical trial for rosacea
- Papulopustular rosacea (rosacea) is a chronic skin disease characterized by redness (inflammation) and acne like break outs
- The trial was successful in meeting its primary endpoint of safety and tolerability across all arms
- Additionally, clinically meaningful improvements were demonstrated across several exploratory efficacy endpoints evaluated, particularly in the 10% BTX 1702 arm, with results comparable to competing products in market (as explored below)
- Furthermore, efficacy continued to improve at each time point assessed, indicating it could potentially improve further over time
- The 8-week, randomised, double blind, vehicle controlled study was designed to evaluate patients with moderate to severe papulopustular rosacea (rosacea) across two different concentrations of BTX 1702 (10%, 20%) alongside a vehicle control arm (cream with no drug)
- Rosacea affects an estimated 430 million individuals globally (~5.5% of population), with women more likely to be affected and 85% of patients over the age of 30 years old
- In the United States alone, rosacea affects an estimated 16 million Americans, with ~5 million medical treatment prescription made
- The current treatment market is worth an estimated US$1.9 billion pa, and forecasted to reach US$2.6 billion by 2025 (~6.8% CAGR)
- Current treatments look to manage the underlying symptoms, such as redness or the acne like break outs, with topical and oral options available. Whilst some of these drugs are effective, they come with a number of side effects and long term use limitation (i.e. antibiotics)
  - We note a 2019 demand (FMX103) study highlighted 73% of patients indicated they are likely to seek better solutions than their current treatment, and
  - A 2015-18 symphony health analysis showed over 70% of patients switch or discontinue therapy after their first diagnosis
- As a result, we believe the rosacea treatment universe is prime for disruption, with a gap in the market for drugs that can deliver similar efficacy without the side effects and limitations
- Whilst more studies need to be done, these results show BTX 1702 has the potential to combine reduction in inflammatory lesions, antimicrobial effects and general improvements in skin condition into a single product, all whilst maintaining an excellent safety and tolerability profile – overall demonstrating the potential for BTX 1702 to be a best-in-class treatment for rosacea
- Beyond this, we believe the results potentially provide BOT supporting information to progress its BTX1503 Acne program, and in our view further de-risk the program
- Overall, these results strengthen BOTs already valuable pipeline of products, led by its lead asset Sofpironium Bromide, which the company recently submitted a New Drug Application (NDA) for to the FDA (12 month review process)

Botanix Pharmaceuticals Ltd (BOT)

Share Price	0.063	A$/sh
Price Target	0.27	A$/sh
Valuation	0.27	A$/sh
Shares on issue	1,196	m(dil)
Market Capitalisation	75.3	A$m
Enterprise Value	49.7	A$/m
Debt	0.0	A$/m
Cash (pro-forma, inc R&D)	17.9	A$/m
Unpaid capital	7.8	m(dil)

Share Price Chart



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Euroz Hartleys declares that it has acted as underwriter to and/or arranged an equity issue in and/or provided corporate advice to BOT during the last year. Euroz Hartleys has received a fee for these services.

This analyst declares that he has a beneficial interest in BOT.

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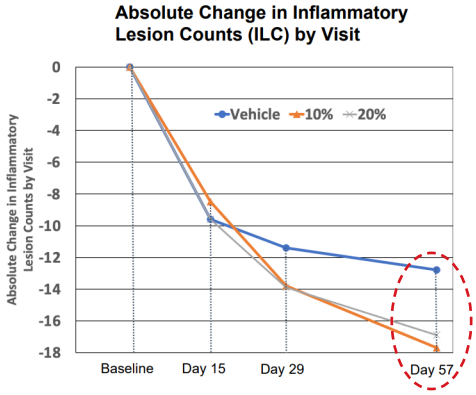
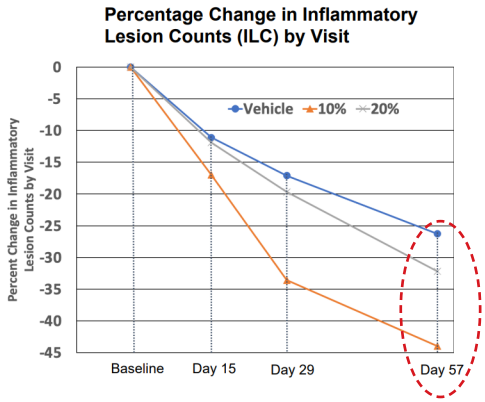
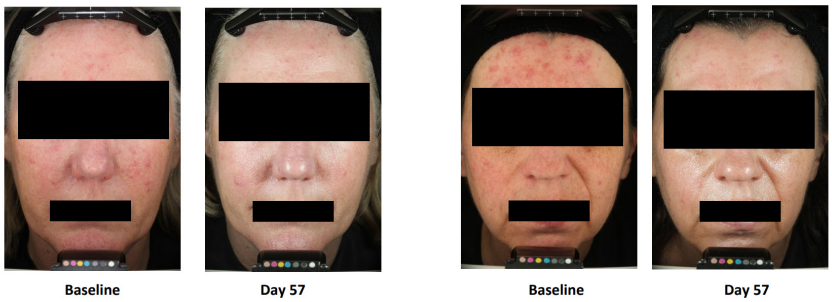
Study Results Discussion

- The primary endpoint of safety and tolerability was met across all arms, noting:
  - No treatment related serious adverse events were reported; and
  - Patients in the 10% BTX 1702 arm reported no burning or stinging whatsoever (significant achievement when compared to existing treatment options), and with only 5% in the 20% arm reporting minor burning or stinging
- We highlight the 10% BTX 1702 dose showed statistically significant results in the FDA designated endpoint of reduction in inflammatory lesions (both absolute, P=0.02, and percentage reduction, p=0.03), as shown below:





- In addition to this, clinically meaningful results were further observed in the subjective IGA and CEA endpoints, where:
  - Both treatment arms demonstrated solid efficacy in the improvement of the investigators global assessment (IGA) endpoints, with clear separation from the vehicle (24.4% vs 9.3% and near statistical significance (P=0.059, P=0.059) in the 10% arm; and
  - Clinically meaningful results were observed from the 10% arm in the CEA (Clinicians Erythema Assessment) endpoint, with clear separation from vehicle (23.8% vs 15.4%), however not meeting statistical significance
  - We believe the study's ability to generate statistical significance across these endpoints was potentially held back by study size, with the relatively small treatment arm size (n=45) used
- Further to this, examining photo evidence from the clinical study demonstrates the significant reduction of redness in target patients and reduction in visible lesions, as shown below:



- As a result of all this, BOT believes the 10% BTX 1702 dose to be the superior formulation with the most attractive safety and efficacy profile to take into further clinical development
- Furthermore, when compared against competitor products (with published efficacy outcomes at 8 weeks), today's data suggests BTX 1702 is potentially comparable in lesion reduction with possible improvement in safety and tolerability, as shown below:

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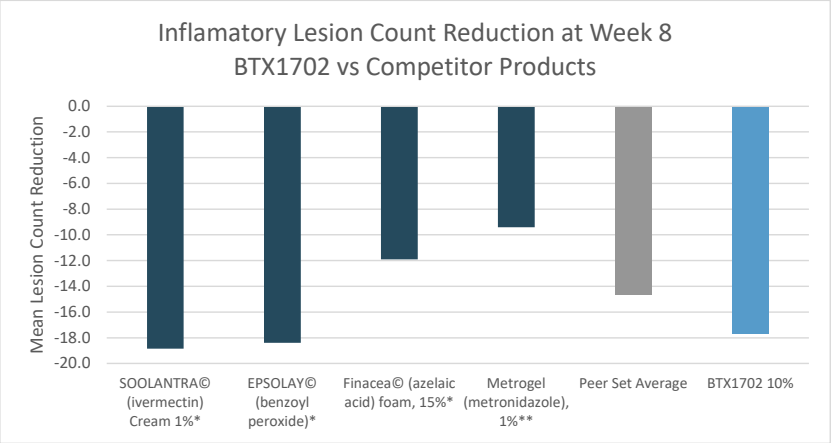

***using study mid-point results; *Data at 10 weeks*

- We note Ivermectin cream alone generated ~US$176 million in annual sales within the United States alone as of June 2022 (per IQVIA)

- Next steps from here will see BOT review the full data set for the study once the final clinical study report is complete and engage with the FDA on the development program

BTX 1204A

- BOT has confirmed its BTX 1204A canine dermatitis pilot study has been completed
- However, the company states based on an initial review of the data that a significant number of dogs enrolled in the study did not meet the specific inclusion criteria. As a result, the company may not gain useful efficacy data from this study
- The company notes the active arm appears to be safe and well tolerated, and that it will continue to review the study to establish if any additional insights can be gained

Catalyst

Near term catalysts ahead:

- FDA Day-74 Letter (Sofpironium Bromide) – 4QCY22
- FDA Mid-cycle Review (Sofpironium Bromide) – 1H CY23
- FDA Approval (Sofpironium Bromide) – 4QCY23
- BTX1801 (Antimicrobial) Phase 2 launch – 2H CY22

Investment Thesis

Botanix Pharmaceuticals Ltd (BOT) is a pharmaceutical company looking shake up big markets in dermatology and antimicrobials. The company has a mature development pipeline, with its lead product Sofpironium Bromide targeting FDA approval in 4Q CY23. This is in addition to a series of other programs in clinical studies, which leverage the unique properties of synthetic cannabinoid, in conjunction with a proprietary drug delivery system.

We believe the market is pricing these programs as failures, or close to it, whereas our analysis suggest the opposite. The prize, should individual programs ultimately be successful, is huge. We anticipate the stock will trade up as we approach the multiple catalyst due this year, if BOT can deliver successful clinical and commercial outcomes, we believe the stock can trade above our price target, perhaps substantially

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Contact Details

Euroz Hartleys Limited **+61 8 9488 1400**

Research Analysts

Gavin Allen - Head of Research	+61 8 9488 1413
Mike Millikan - Resources Analyst	+61 8 9268 2805
Declan Bonnick - Resources Analyst	+61 8 9488 1481
Kyle De Souza - Resources Analyst	+61 8 9488 1427
Michael Scantlebury - Resources Analyst	+61 8 9268 2837
Steven Clark - Resources Analyst	+61 8 9488 1430
Trent Barnett - Senior Analyst	+61 8 9268 3052
Harry Stevenson - Industrials Analyst	+61 8 9488 1429
Seth Lizee - Research Analyst	+61 8 9488 1414