

Botanix Pharmaceuticals Ltd

(BOT \$0.067) Speculative Buy

EUROZ HARTLEYS

Analyst	Date	Price Target
Seth Lizee	7 th July 2022	\$0.25/sh

NDA filing Accelerated; Trials Fully Enrolled

Key Points

Sofpironium Bromide (SB)

- BOT announced it has accelerated its FDA filing timeline for Sofpironium Bromide
- The company is now targeting to file its New Drug Approval (NDA) in Q3 CY22
- Assuming a 12-month review process, Sofpironium Bromide could be approved by Q3 CY23, with key milestones in between being:
 - NDA submission;
 - Day 74 review letter;
 - FDA feedback on proposed trade name; and
 - FDA mid-cycle review
- As a result of this, BOT has ramped up commercial launch preparation activities.
- The company is also advancing a number of other manufacturing activities that are required for the FDA application. This will see BOT over the coming months commence the process of preparing for inspection of its contract manufacturing site and other FDA pre-approval activities
- As a reminder, Sofpironium Bromide gel 15% is the first and only new chemical entity developed to treat primary axillary hyperhidrosis, a medical condition which results in excessive underarm sweating.
 - **Registration Ready** - Sofpironium Bromide successfully completed its pivotal phase III studies, where it demonstrated ~85% of patients experienced a clinically meaningful improvement.
 - **New and better treatments needed** - Existing options suffer from various downfalls, either because of lacking efficacy, unfavourable side effects, risk of drug exposure to the skin, or pain from invasive procedures or surgery
 - **Significant market opportunity** - Hyperhidrosis affects upwards of 15 million people in the United States alone. The current treatment market is worth \$1.6 billion and expected to reach \$2.8 billion by 2030
 - **De-risked** - Sofpironium Bromide is already approved and launched in Japan with an existing partner
- BOT recently acquired Sofpironium Bromide in a transaction which we viewed as highly complementary to its existing dermatology pipeline, as well as being consistent with its strategy to be a leading dermatology

Other Clinical Programs

- BOT announced both its Rosacea (BTX 1702) phase 1/2 study and its Atopic Dermatitis (BTX 1204A) canine pilot study are now fully enrolled
- The company is now targeting study completion in Q3 CY22
- Both studies reached their target enrolment numbers
- Trial subjects will be completing their treatment in the coming weeks, following which data bases will be locked and activities finalised to report the outcome of the studies to the market

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 to file for FDA approval in Q3 CY22. 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.

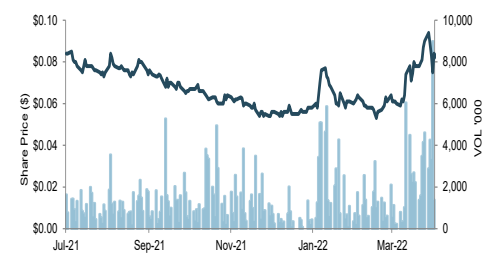
Botanix Pharmaceuticals Ltd (BOT)

Share Price	0.067	A\$/sh
Price Target	0.25	A\$/sh
Valuation	0.25	A\$/sh
Shares on issue	1,042	m(dil)
Market Capitalisation	69.8	A\$m

Enterprise Value	50.5	A\$/m
Debt	Nil	A\$/m
Cash (pro-forma*)	12.2	A\$/m
Unpaid Capital	7.1	

* Less US\$3m upfront payment

Share Price Chart



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