

# Quick Comment

## Botanix Pharmaceuticals Ltd (BOT \$0.085) Speculative Buy



Analyst	Date	Price Target
Seth Lizee	4 <sup>th</sup> May 2022	Under Review (prev. \$0.17/sh.)

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## Dermatology Asset Acquired

### Key Points

BOT has announced an acquisition:

- The company will acquire Sofpironium Bromide, a novel dermatology asset
- The drug is the first and only new chemical entity developed to treat primary axillary hyperhidrosis, a medical condition which results in excessive underarm sweating
- Sofpironium Bromide gel 15% has been developed to be a best-in-class, once daily, topically administered therapy
- Hyperhidrosis represents a significant new market opportunity for BOT, with:
  - An estimated 15m people suffering from the disease in the U.S. alone
  - Existing treatment options lack efficacy, come with poor side effect profiles, and lack insurance coverage
  - Hyperhidrosis market forecasted to reach \$2.8 billion per annum by 2030 (from current \$1.6 billion per annum)
- BOT is acquiring the asset from US listed company Brickell Biotech Inc. (NASDAQ: BBI) in a attractively structured deal with minimal upfront payments
- The late stage asset recently completed two successful pivotal Phase 3 studies, achieving statistically significant efficacy with favourable safety profiles
- The asset is de-risked, having already been approved by the Japanese equivalent of FDA (PMDA) and recently launched by the existing partner, Kaken Pharmaceuticals (Kaken) in Japan
  - Kaken is a \$1.7bn Japanese Pharmaceutical company
  - Under this existing licensing agreement, Kaken has rights to commercialise Sofpironium Bromide in Japan (recently launched), as well as South Korea, China and certain other Asian Countries
  - BOT is entitled to 25% of the royalties and milestone payments received from Kaken
- Plans are now to submit a New Drug Approval (NDA) to the FDA in 2H 2022, with anticipated approval in 2H 2023 (assuming 12 month review process)
- Key milestones for Sofpironium Bromide include:
  - NDA submission – 2H 2022
  - Day 74 review letter from FDA – 2H 2022
  - FDA feedback on proposed trade name – 1H 2023
  - FDA mid-cycle review – 1H 2023
  - Commercial manufacturing for launch – 2H 2023
  - FDA approval – 2H 2023

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### Transaction Overview – Attractive terms

- BOT has acquired all assets owned or controlled by Brickell primarily related to Sofpironium Bromide, including its interest in a license for Sofpironium Bromide
- The transaction includes an upfront payment, milestone payments and royalties payable to Brickell, structured as follows:
  - US\$3m upfront
  - US\$2m if positive 'Day-74 letter' received from FDA (after NDA filing)
  - Up to US\$4m if FDA approval received before 30th September 2023 (down to zero if after 17th Feb 2024)
  - US\$4m upon EU/UK marketing approval (from regulatory agencies)
  - Milestone payments when net sales exceed US\$75m, capped at US\$160m (which imply more than US\$1.8bn in net sales to BOT); and
  - Aggregate royalties payable from 12%, rising towards 20%, above US\$500m annual net sales
- The company will additionally reimburse some development expenses incurred in recent months
- BOT will assume responsibility for future development of Sofpironium Bromide, including filing for approval with the FDA and other international regulatory authorities (ex. far east Asia)

### Clinical Data – Ready for regulatory submission

- Positive results from Phase 3 studies were recently reported for Sofpironium Bromide
  - Two pivotal Phase 3 studies (Cardigan I and II) evaluated a total of 700 patients
  - Further ~300 patients participated in a 48-week safety study
  - All of this is in addition to Kaken, which ran and successfully completed their own pivotal phase 3 trials for Japanese registration
- Overall, results showed a once a day topical admission of Sofpironium Bromide gel 15% elicited early, sustained, and significant improvements in signs and symptoms of primary axillary hyperhidrosis across all efficacy measures
- Across all studies, there were no treatment related serious adverse events, with any adverse events being transient and mild to moderate in nature
- Highlights of pooled data from the Cardigan I and II studies include:
  - All Primary and secondary endpoints achieved statistical significance
  - 85% of subjects had a clinically meaningful 1-point change in the patient reported outcome measure, with 55% registering a more rigorous 2-point change
  - Over 60% had a 50% or greater reduction in sweat production and the clinically meaningful 1-grade change
    - Average reduction in sweat at week 6 was ~138mg
- Additionally, efficacy in the long-term safety study continued to improve on average from commencement to week 48

### Other

- BOT has updated its development pipeline, as shown below:

INDICATION	PRODUCT	PHASE 1	PHASE 1B	PHASE 2	PHASE 3	APPROVED	STATUS
Axillary Hyperhidrosis (excessive underarm sweating)	Sofpironium Bromide						FDA approval filing planned 2H 2022
Moderate to severe acne	BTX 1503						Phase 3 commencement pending
Rosacea	BTX 1702						Phase 2 study underway - enrollment complete mid 2022
Atopic Dermatitis	BTX 1204A						Canine study complete 2Q 2022
Antimicrobial	BTX 1801						Phase 2 study commencing 2Q 2022

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- A number of major catalyst approach as we enter CY2022, we estimate timing as follows:

Timeline	CY'2022			CY'2023+	
	Jun'Q	Sep'Q	Dec'Q	Mar'Q	Jun'Q+
<b>Sofprlonum Bromide</b>					
NDA					
<b>BTX1503 (Acne)</b>					
Phase 3 Study					
<b>BTX1801 (Antimicrobial)</b>					
Phase 2b Study					
Phase 3 Study					
<b>BTX1702 (Rosacea)</b>					
Phase 1b Study					
Phase 3 Study					
<b>BTX1204A (Atopic Derm.)</b>					
Canine Follow up Study					
INAD					
Commercial Partner (Cannine)					
Phase 2b Study					
Phase 3 Study					
<b>Permetrex (Delivery Tech.)</b>					
Licensing Agreements					

- We maintain our Speculative Buy recommendation, with our price target under review (previously \$0.17/sh.) pending the addition of the Sofpironium Bromide into our sum-of-the-parts valuation

### 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 be filled for FDA approval in 2H 2022. 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	0.085	A\$/sh	Enterprise Value	69.3	A\$/m
Price Target	Under Review	A\$/sh	Debt	Nil	A\$/m
Valuation	Under Review	A\$/sh	Cash (pro-forma*)	12.2	A\$/m
Shares on issue	1,041.6	m(dil)	Unpaid Capital	7.1	
Market Capitalisation	88.5	A\$m			

\* Less US\$3m upfront payment

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