

# Quick Comment

## Botanix Pharmaceuticals Ltd (BOT \$0.08) Speculative Buy



Analyst	Date	Price Target
Seth Lizee	28 <sup>th</sup> April 2022	\$0.17/sh

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### US FDA grants new QIPD Status: BTX1801

#### Key Points

- The US FDA has granted BOT Qualified Infectious Disease Product (QIPD) designation for BTX1801
- The designation applies to the use of BTX1801 to: *"reduce the risk of Staph. aureus bloodstream infection in colonized patients dependent on central venous catheters-for-haemodialysis"*
- The BTX1801 program is designed to target nasal decolonisation of staph aureus and MRSA in patients undergoing haemodialysis with a view to reduce the incidence of life threatening blood stream infections
- The QIPD program is designed to provide incentives for the development of novel antibacterial or antifungal products
- Specifically, QIPD provides an additional 5 years of regulatory exclusivity, on top of existing FDA exclusivity, implying a total of 8 years potential exclusivity for BOT
- QIPD Recipients are further eligible for:
  - NDA "priority review" – Expedited 6 month FDA review period (vs standard 12 month); and
  - "Fast-track designation" – Enables more frequent communication with the FDA during the drug development and review process (enabling valuable guidance)
- Overall, this enhances the potential value potential of BTX1810 if shown to be clinically successful
- The designation requires fulfilling a strict set of qualifying criteria, demonstrating the products novelty and potential to treat serious or life-threatening diseases
- BOT notes, this new designation represents the first ever granted for a nasal decolonization agent for haemodialysis patients
- The new designation is supported by BOTs phase 2 clinical study results and its recent health outcomes study which highlighted the impact of bloodstream infections in haemodialysis patients that use central venous catheters
- This new designation adds onto a previous QIPD status granted to BOT for BTX1801 in the prevention of post-surgical infections
- The company notes these life-threatening infections are estimated to cost the US health system more than US\$360 million per annum
- The company has stated its recently completed additional pre-clinical and animal studies to support its planned phase 2b, which remains on track to initiate in 2Q'CY22
- Outside of this, BOT has a number of near term catalysts ahead, with:
  - BTX1702 (Rosacea) phase 1b/2a results – Mid 2022
  - BTX1204A (Atopic Dermatitis) Proof of concept results – Q2 CY22
- We maintain our Speculative buy recommendation and \$0.17/sh. Price Target

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### Investment Thesis

Botanix Pharmaceuticals Ltd (BOT) is a clinical stage pharmaceutical company. The company is looking to shake up big markets in dermatology and antimicrobials with its four clinical programs 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 clinically successful, is huge. We anticipate the stock will trade up as we approach the multiple catalyst due early to mid-next year, if BOT can deliver successful clinical outcomes, we believe the stock can trade above our price target, perhaps substantially.

### Botanix Pharmaceuticals Ltd (BOT)

Share Price	0.08	A\$/sh	Enterprise Value	56.7	A\$/m
Price Target	0.17	A\$/sh	Debt	Nil	A\$/m
Valuation	0.17	A\$/sh	Cash (pro-forma)	19.6	A\$/m
Shares on issue	1041.6	m(dil)	Unpaid cap.	7.1	m(dil)
Market Capitalisation	83.3	A\$m			

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