

Botanix Pharmaceuticals

Getting under the skin

Botanix Pharmaceuticals (ASX:BOT) is a clinical stage synthetic cannabinoid pharmaceutical company with a targeted pipeline of dermatological and antimicrobial products. Botanix's clinical development pipeline includes clinical programs which leverage synthetic cannabidiol in the topical treatment of serious skin diseases and for antimicrobial applications. The company has recently had clinical success with positive Phase 2a results from two different BTX 1801 formulations (ointment and gel) which were demonstrated as safe, well tolerated and successful at eradicating *Staphylococcus aureus*. This is particularly relevant to the global public health sector which battles with antibiotic resistance to *Staphylococcus aureus* and to methicillin resistant Staph (MRSA), both classed as superbugs. The company has identified a near term plan for its three areas of focus including launching in H1 CY2021 the Phase 1b clinical study for BTX 1702 and its ability to treat rosacea. A timetable for the progression of the BTX 1503 Phase 3 study is under review, pending the completion of the BTX 1702 Phase 1b clinical study and lifting of travel and clinical trial conduct restrictions across the US where clinical trials were planned.

Business model

Botanix is focussed on progressing its clinical development pipeline with three key programs. BTX 1503, which is focused on moderate to severe acne, has achieved the completion of a successful end of Phase 2 meeting with the FDA, which will enable BOT to seek confirmation from the FDA on a drug development plan which in turn will support registration of BTX 1503. BTX 1801 has just completed a successful Phase 2b clinical study which demonstrated eradication rates as high as 76.2% at Day 7 for the BTX 1801 ointment, with eradication effects through to day 28 of the study to 23.8% despite no treatment after day 5. The gel demonstrated Staph eradication in 68.8% of participants at day 7 and 18.8% at day 28. This is significant because antibiotic resistance is a major challenge for public health authorities globally with the UN forecasting that drug resistant diseases could cause 10m deaths a year by 2050. Staph and methicillin-resistant Staph (MRSA) are a leading cause of surgical site infections. The third key program is the Phase 1b clinical study for BTX 1702 and its efficacy with the treatment of popular pustular rosacea.

Interim result commentary

Botanix ended H1 FY21 with cash of \$19.2m and subsequently has received an R&D tax incentive refund of \$6.88m for the FY19/20 financial year. This company invested \$4.35m in R&D in H1, which was substantially down on the \$8.38m expended in H1 FY20 and reflects the delays that COVID has created for the company in conducting clinical trials.

Anti-inflammatory biotechs are likely the closest peers

We look to biotechs focused on antimicrobial and anti-inflammatory products for peers for Botanix. Some that come to mind in the Australian market include Dimerix and Paradigm Biopharmaceuticals, although neither are focussed on topical products.

Biotech

12th March 2021

Share details

ASX Code	BOT
Share price	\$0.11
Market Capitalisation	\$102.2M
Shares on issue	973.1M
Net cash at 31/12/2020	\$19.2M
Free float	74.96%

Share performance (12 months)



Upside Case

- Advanced clinical pipeline across three clinical programs
- Significant upside and application should BTX 1801 (successful at eradicating Staph) progress to commercialisation
- Well-funded (\$19.2m at 31 Dec and \$6.87m R&D grant in Feb 2021)

Downside Case

- BTX 1702 Phase 1b Rosacea study fails to meet its end points
- COVID has disrupted clinical trials in US
- Long time line to commercial success

Catalysts/upcoming events

Launch of 1b rosacea study, planning and timing of Phase 3 acne study, advancement of Phase 2b antimicrobial study

Comparable companies (Aust/NZ)

Dimerix (ASX:DXB), Paradigm Biopharmaceuticals (ASX:PAR)

Top 5 shareholders

Shenasaby Investments	7.27%
Caperi Pty Ltd	6.12%
Dr William Bosch	1.64%
Yarraandoo	1.03%
Sweet As Developments	1.01%

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FINANCIAL SERVICES GUIDE

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