

Botanix Pharmaceuticals

New dermatological and antimicrobial agents

Botanix Pharmaceuticals is a clinical-stage biotech company focused on the development of novel treatments for common skin conditions. Its approach combines synthetic cannabidiol (CBD) and a patented skin delivery technology, Permetrex, for which Botanix has an exclusive licence in dermatology. After demonstrating encouraging human safety data in Phase I/II, the company has a busy pipeline for 2022, with a Phase IIb antimicrobial trial due to commence in Q122 and a Phase I/II trial for rosacea already underway, along with plans for Phase III trials in acne and Phase IIb studies in atopic dermatitis. Key to its success will be continued clinical validation of the efficacy of CBD in humans in the chosen indications.

Opportunities for synthetic CBD

Botanix is focused on four main indications: acne, atopic dermatitis, rosacea and MRSA/Staphylococcus aureus infection. Its most advanced asset, BTX1503, is for the treatment of acne, although the largest targeted market is for BTX1204A in atopic dermatitis (US\$4.1bn 2020). Despite the high worldwide prevalence of these conditions, there have been little in the way of new treatment modalities developed over the last decade. Botanix combines the reported anti-inflammatory and antimicrobial properties of CBD with a proprietary skin delivery platform called Permetrex (for which it has an exclusive development licence) to treat these common inflammatory skin conditions and bacterial infections. Importantly, CBD/Permetrex formulations may offer a new class of antibacterial agent to address the growing problem of antibacterial resistance.

The components

Permetrex, the skin delivery technology that underlies the pipeline, is a topical formulation that can deliver high doses of a compound into the skin without the use of irritating levels of alcohols or petroleum derivatives often found in current dermatological preparations. Botanix's second component is synthetic CBD, the man-made equivalent of the compound found in the Cannabis sativa plant. The company's BTX1503 Phase II trials have shown this to be safe and well tolerated in humans, and to have efficacy in anti-inflammatory and antimicrobial settings.

A busy pipeline for 2022

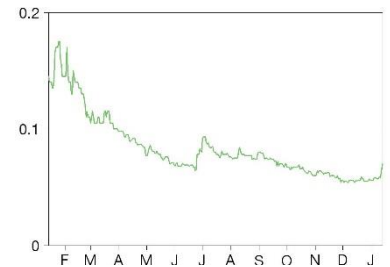
Botanix has a busy clinical pipeline. Results from the BTX1801 Phase IIa trial showed a 76% eradication rate of Staphylococcus aureus from the nasal passage of healthy, colonised volunteers on day 7, after five days' treatment. This extended to 23% at day 28 compared to 12% in the control arm. Phase IIb studies are planned for Q122. All three dermatology trials should provide considerable data in 2022. The company has confirmed plans for its most advanced asset, BTX1503 for acne, to enter Phase III trials following contradictory but resolved data from Phase II. Potentially the largest value driver for the company, BTX1204A for atopic dermatitis, is expected to advance to Phase IIb given positive data from a canine pilot study. Given the market size of the targeted indications, we assume that Botanix would likely aim to out-license assets following Phase II proof-of-concept.

Healthcare
14 January 2022

Price **A\$0.07**
Market cap **A\$68m**

A\$/US\$0.7159

Share price graph



Share details

Code	BOT
Listing	ASX
Shares in issue	973.14m

Business description

Botanix is a clinical-stage biotech company engaged in the research and development of topical synthetic cannabinoid-based treatments for dermatological and antimicrobial applications. The company has four active clinical programmes in its pipeline aimed at addressing significant needs in these markets.

Bull

- Large unmet need for new dermatological and antimicrobial agents.
- Demonstrated an encouraging safety profile for CBD-based formulations.
- Cash position of A\$21.55m (30 June 2021) sufficient to fund R&D through 2023.

Bear

- Lack of reputable clinical data on CBD-based therapeutics increases R&D risk.
- R&D cost base will significantly increase as assets progress into Phase III.
- Impact of COVID-19 could unexpectedly delay clinical timelines.

Analysts

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