



THE GREENFUND

R E P O R T

BOTANIX  
PHARMA

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# BOTANIX

PHARMA

## Inspired by the Cannabis Plant

Botanix Pharma (BOT) state that their mission is “to improve the lives of patients suffering from serious skin diseases including acne, psoriasis and atopic dermatitis by providing new treatment options for conditions that currently are inadequately addressed or are treated with therapeutics that are burdened with side effects profiles.”

Simply put, this mission is the business.

And the business is preparing for some near term data read outs in the coming weeks, which if successful, will de-risk the company's portfolio of products with evidence as to how cannabis extracts produce the desired clinical effects BOT is striving for.

BOT is an Australian medical dermatology company engaged in the development of cannabinoid-based products for the treatment of a range of skin conditions and are working to get the first cannabinoid products approved by the FDA. If successful, they will dominate the multi-billion dollar dermatology market which largely has seen few new products approved in the last 20 years.

BOT is investigating the use of a synthetic active pharmaceutical ingredient, known as cannabidiol (CBD), which has a well-established safety profile, and is well documented in its ability to impact inflammation and potentially bacterial infection. However, BOT is not using the cannabis plant to obtain the CBD required for the formulation of their products.

*“The cannabis plant is the inspiration. We are just using a chemical that happens to be found in the plant.”*

Botanix Pharma Founder and CEO,  
Matt Callahan



All products made by BOT utilise synthetic CBD in conjunction with Permetrex™ skin delivery technology. Permetrex™ is a dermal delivery formulation technology that allows 10 to 20 times more of the active ingredient to get through the skin to better treat the disease. BOT has exclusive rights to this technology, developed by Dr Eugene Cooper, for all drugs that treat dermatological conditions.

Recently, BOT announced the results of a 3rd-party independent contract research report which was focused on showing the superior performance of Permetrex™ against a range of over the counter (OTC) CBD products. The comparative analysis demonstrated that, relative to the closest comparator CBD topical product, BOT's initial product (**BTX1503**) delivered:

- Over 5 times as much CBD to the epidermis, and
- Over 3 times as much CBD to the dermis, and
- Significantly more than other CBD topical creams and gels.

The first two products off the rank target the treatment of Acne (**BTX1503**) and Atopic Dermatitis (**BTX1204**). As it stands right now, there are no cannabis-based products approved for these markets and no-one else is studying the impact of CBD-based products on these conditions.

And this is what makes this company so exciting. They are operating in two very big markets—with combined Total Addressable Markets of over \$8 billion—and their products would really stand out in a market were the incumbents consist of generic brands, who to this day, still produce significant side effects and safety issues when used as a long term treatment method.

*“With acne, there has been no new approved drug for over 20 years.”*

Matt Callahan

As we will outline, the initial results from these clinical trials suggest that BOT products deliver on par efficacy-based results (even higher some of the time) as the incumbents, but (and it's a big one) with a statistically significant improvement in the safety profile. Same results, less side effects. Which would you rather your teenager use, if they both delivered successful treatment outcomes? Especially when some of those side effects include cancer risks, birth defects and risks of suicide?

Precedence for cannabis-based drugs gaining mainstream pharmaceutical acceptance was set when the FDA approved GW Pharmaceutical's Epidiolex in June last year. In general, the stigma surrounding cannabis and its legitimate ability to relieve the symptoms of a medical condition is rapidly reducing.

The lead asset **BTX1503** for the treatment of chronic acne – is currently in a phase II clinical trial that is expected to be completed and report in Q3.

The company's second asset, **BTX1204** for the treatment of Atopic Dermatitis (AD), which covers severe eczema, is currently in a Phase II clinical trial that is expected to be completed by the end of 2019. Both of the above Phase II studies are fully funded.

We believe the price targets set by both BellPotter and Argonaut to be fair and accurate. We see significant upside in the share price for investors prepared to take the speculative risk.

Should BOT deliver successful endpoints on the Phase II trials for their leading assets, then the most likely outcome from there would be a licensing deal with a global BIG Pharma player that would deliver significant upfront cash flow, and medium-term licensing royalties post successful Phase III study outcomes.

Recently, both BellPotter and Argonaut covered BOT and developed their own proprietary financial models. Both companies agreed that the most likely outcome post any successful Phase II studies would be a licensing deal. They each had their own metrics for the value of these deals and the discount rate that should be applied to the deal (based on uncertainty and risk)

Both recommended BOT as a speculative buy with target prices of \$0.15 and \$0.20 per share respectively.

### Why we like Botanix Pharma?

- Targeting two of the most common dermatological conditions with a total addressable market of over \$12 billion
- Synthetic cannabidiol means standardised production which greatly enhances the probability of clinical and regulatory success (FDA in the US)
- Strong global growth in CBD-based pharmaceutical products that drive social and medical acceptance of cannabinoids
- Exclusive global rights to use Permetrex™ delivery technology which is one of the primary factors in the successful outcomes of the clinical studies
- Two further products in initial stages of research and trials that could add tremendous long-term value, creating a substantial pipeline of commercial IP
- Strong management team with a proven track record of success in the drug development industry

## Further stats on the industry

More than



**3,000**

types of dermatological conditions exist ranging in severity and clinical presentation

Approximately



**1/3**  
of the

US population suffers from an active skin condition

By 2022



US  
**\$33.7B**

The global dermatology market is estimated to be worth by 2022 representing an increase of >65% from 2015



### Market Growth

expected to be driven by strong late-stage products in development

### There is a significant unmet medical need for treatment options that:

- > Improve patient compliance
- > Have improved safety/tolerability profiles
- > Allow for long-term use

## Industry Trends



Dermatology drug manufacturers are enjoying higher revenues than ever before,

and with increasing prevalence of skin diseases, this should continue across the next decade.



A number of leading drugs are set to come off of patent across the forecast period.

**BOTTOM  
LINE**



This is a very well-run company, operating in a very large market, with the ability to bring innovative change in treatment for the first time in over 20 years. The company has a strong pipeline of assets currently in study, each of which could be worth more than \$500 million in revenue to the company.

*“Botanix is uniquely positioned and poised for success with its pipeline of novel therapies that have the potential to meet many unmet patient needs. The Company is also way ahead of the curve with its delivery technology, Permetrex™, a highly elegant formulation with considerable potential across the broader dermatology space.”*

Vince Ippolito, President Botanix Pharma

Currently the only global player studying the effects of the CBD compound on dermatological diseases, this first-mover advantage creates an opportunity to really dominate the market in the plant-based products sector.

This also makes the company a very strong acquisition candidate, should they successfully license even the first product to market. One only needs to look to GW Pharmaceuticals (NYSE:GWPH) with its Epidiolex drug - the first ever FDA-approved cannabis-based drug. The company currently sports a \$5.5 billion market cap, and is the best proxy for how to model and evaluate the potential of BOT.

The ultimate value is heavily dependent on the outcomes of the Phase II studies for the **BTX1503** acne drug, and **BTX1204**, the psoriasis drug. Should these be positive, then look for the value of BOT to really take off, from its current worth of \$86 million. However, the same could not be said if the endpoints fail to find success. This would require additional funding (likely at a substantially discounted share price) in order to correct.



Given that we believe the outcome more than likely will be successful (based on the Phase Ib), then it is unlikely that the company would look to raise further capital and fund a Phase III study. We would expect a licensing deal, for short term capital gains, with long term royalty opportunities.

We like the experience and gravitas of the management team and board and see the recent appointment of Vince Ippolito to the board, as a strong indication that the company is looking to license its products, given his role in the sale of Anacor to Pfizer.

Their addressable market is huge, and the lack of innovation in the space glaringly obvious. There remains a substantial demand for new drugs to treat acne given that no drugs with a new mechanism of action have been approved by the FDA in more than 20 years.

In the Atopic Dermatitis patient base, long term usage of incumbent treatment products leads to signs of burning or local side effects. However early results suggest that the safety profile of both leadings assets could show potential for a longer treatment timeframe, a key unmet need in the current treatment of AD.

And with the Psoriasis study, BOT's third clinical program, there is a likelihood for BOT to learn a lot about the mechanism of action of CBD in skin disease, given the biopsies being undertaken as part of this study.

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