Wednesday, 21 November 2018

Botanix (BOT)

Company Update

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Quick Read

BOT has four studies underway two clinical studies and one patient study and one lab-based investigation to test the efficacy of cannabidiol (CBD) in treating acne, atopic dermatitis, psoriasis as well testing the impact of CBD on anti-biotic resistance microbes. There is a growing interest in CBD as a therapy for a number of diseases, and to this end, there are currently 148 global CBD studies underway. BOT is the only dermatology study. BOT has also boosted its team with the appointment of industry veterans with extensive experience of getting drugs through the FDA approval process. We maintain our Speculative Buy recommendation with a price target of $0.20.

Event & Impact / Positive

BOT has four studies underway: BOT has four studies underway, two clinical studies and one patient study and one lab-based investigation.

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication</th>
<th>Stage</th>
<th>Expected Readout</th>
</tr>
</thead>
<tbody>
<tr>
<td>BTX 1503</td>
<td>Moderate to severe acne</td>
<td>Phase 2</td>
<td>Circa end Q2 CY2019</td>
</tr>
<tr>
<td>BTX 1204</td>
<td>Atopic dermatitis</td>
<td>Phase 2</td>
<td>Circa end Q2 CY2019</td>
</tr>
<tr>
<td>BTX1308</td>
<td>Psoriasis</td>
<td>Phase 1b</td>
<td>End Q1 2019</td>
</tr>
<tr>
<td>BTX 1801</td>
<td>Antimicrobial</td>
<td>Pre-Clinical</td>
<td>End Q4 CY2018</td>
</tr>
</tbody>
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Research Interest into Cannabidiol is Growing: The increasing interest in researching the potential of cannabidiol is demonstrated by the fact there are currently 148 Cannabinoind (CBD) based studies underway. BOT is currently the only group investigating the use of CBD for dermatological treatments giving BOT first-mover advantage in what is becoming an important new compound in medical science.

The Approval of Epidiolex paves the way for other CBD based products: The approval of Epidiolex for use in children for epilepsy is a positive step for other CBD based therapies because it means the FDA is comfortable with the safety profile of CBD for use in humans, particularly children. The FDA is also keen to promote the use of CBD therapies and is actively encouraging the use of FDA approved studies.

Expanded Team: BOT has expanded its team, and it now includes individuals with the skills needed to progress the company’s products towards FDA approval.

Recommendation

In our opinion BOT is a strong investment proposition as it is working in a developing drug area with strong macro tailwinds thanks to the increasing acceptance of CDB based therapies across a variety of diseases. There are many unmet needs that CBD can address thanks to its anti-inflammatory properties. BOT is pregnant with news flow, and from early next calendar year, there will be a number of key announcements that if positive, will further de-risk the company and set it up for the next iteration of growth. We maintain our Speculative Buy recommendation with a price target of $0.20, and we ascribe no value to BTX 1801 at this time.
**Investment Points**

**BOT has four studies underway**

BOT has four studies underway, two clinical studies and one patient study and one lab-based investigation.

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication</th>
<th>Stage</th>
<th>Study Design</th>
<th>Current Activity</th>
<th>Expected Readout</th>
</tr>
</thead>
<tbody>
<tr>
<td>BTX 1503</td>
<td>Moderate to severe acne</td>
<td>Phase 2</td>
<td>12 Week randomised, double-blind, vehicle-controlled</td>
<td>Study Underway</td>
<td>Circa end Q2 CY2019</td>
</tr>
<tr>
<td>BTX 1204</td>
<td>Atopic dermatitis</td>
<td>Phase 2</td>
<td>12 Week randomised, double-blind, vehicle-controlled</td>
<td>Study Pending – start Q4 CY2018</td>
<td>Circa end Q2 CY2019</td>
</tr>
<tr>
<td>BTX1308</td>
<td>Psoriasis</td>
<td>Phase 1b</td>
<td>A patient study using Bioskin</td>
<td>Study underway</td>
<td>End Q1 2019</td>
</tr>
<tr>
<td>BTX 1801</td>
<td>Antimicrobial</td>
<td>Pre-Clinical</td>
<td>Identification of skin disease indication</td>
<td>Lab study with U. Queensland</td>
<td>End Q4 CY2018</td>
</tr>
</tbody>
</table>

*Figure 1: Newly processed images from the Phase 1b study showing a reduction in pimplles over a week period.*

*Source: BOT*

*Figure 2: The bioskin patch being used in the Psoriasis study*

*Source: BOT*
Research interest into Cannabidiol is growing with 148 global studies underway.

Research Interest into Cannabidiol is Growing:

The increasing interest in researching the potential of cannabidiol is demonstrated by the fact there are currently 148 global Cannabinoid (CBD) based studies underway. A large proportion of these studies are focussed on epilepsy as there has been much interest in epilepsy, and the recent approval of Epidiolex by the US Food and Drug Administration (FDA) is a big step forward for the use of CBD based treatments.

The FDA approval of Epidiolex is helping to change the regulatory framework around cannabis making it easier for patients to access the medication. This easing of restrictions will make it easier for large drug companies to commercialise the product thereby making BOT more attractive to potential partners.

Israel is emerging a centre of cannabis research particularly with regards to autism and epilepsy. There are recorded instances of patients who suffered repeated seizures of up to one every hour and when treated with CBD, becoming seizure free allowing them to resume a normal life.

While researchers admit that they are at the beginning of the journey to understand the compounds in the cannabis plant, it is thought that the unique anti-inflammatory properties of CBD promote the healing process across a number of diseases.

BOT is currently the only group investigating the use of CBD for dermatological treatments giving BOT first-mover advantage in what is becoming an important new compound in medical science.

The Approval of Epidiolex paves the way for other CBD based products

The recent FDA approval of Epidiolex will make the approval of other CBD based treatments easier.

The FDA is supportive of CBD treatments as long as drug has been proven in a clinical study.

The FDA is also keen to promote the use of CBD therapies and is actively encouraging the use of FDA approved studies. The FDA Commissioner Scott Gottlieb, M.D said post the approval of the first Epidiolex.

“Controlled clinical trials are testing the safety and efficacy of a drug, along with careful review through the FDA’s drug approval process, is the most appropriate way to bring marijuana-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, prescribers can have confidence in the drug’s uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.”

Epidiolex has also been rescheduled from a schedule 1 drug to a schedule 5 drug making the distribution far easier as a lot of the restrictions have been removed. While the recreational use of THC laden marijuana is likely to remain contentious, the use of CBD based treatments is likely to become far more mainstream. 31 States have medical marijuana laws, and 60% of the US population live in states that have legalised marijuana making access to marijuana-based medication a lot simpler.
Expanded Team
BOT has expanded its team, and it now includes individuals with the skills needed to progress the company’s products towards FDA approval. Of particular interest is Dr Judith Plon who has 30 years regulatory experience with multiple FDA approved dermatology products. Another new hire Ms Jillian Chapas Reed also has 20 years of clinical trial experience across dermatology and immunology. The balance of the team all have experience in bringing new drugs to market.

BOT is a strong investment proposition
In our opinion BOT is a strong investment proposition as it is working in a developing drug area with strong macro tailwinds thanks to the increasing acceptance of CDB based therapies across a variety of diseases. There are many unmet needs that CBD can address thanks to its anti-inflammatory properties. Inflammation underpins a large number of disease states and CBD seems to be able to address a number of them which is more than likely due to humans having a large number of cannabinoid receptors.

We maintain our Speculative Buy recommendation and a price target of $0.20, we ascribe no value BTX 1801 at this time.
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