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Botanix (BOT)

Successful Acne Patient Study

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Quick Read

BOT has successfully completed a Phase 1b acne patient study achieving all the Company’s BTX 1503 program goals. This provides significant value uplift by de-risking both the BTX 1503 acne program as well as BOT’s wider portfolio of cannabidiol-based dermatological products (for the treatment of atopic dermatitis and psoriasis). BOT’s ability to maintain a strict development timeline along with targeting large markets, that have seen little innovation over the last 20 years, underpin our positive view. We maintain our speculative buy call on a revised $0.20 per share valuation (previously $0.095 per share).

Event & Impact | Positive

Successful acne study results: BOT has completed its Phase 1b study in patients with moderate to severe acne for its flagship product, BTX 1503; meeting all designated endpoints. The study found that BTX 1503 has an excellent safety profile and is very effective at reducing the number of inflammatory and non-inflammatory acne lesions after 4 weeks of treatment. The pilot study enrolled 21 subjects, with 18 subjects completing the study.

Outperforming market leaders: On average inflammatory lesions decreased by ~47% by Day 28 of the study and, importantly, patients maintained a 45% reduction in inflammatory lesions at the follow up on Day 35 (after a week of no treatment with BTX 1503 at all). This reduction in lesions is better than the leading topical acne treatments currently on the market (see Figure 1 below). Non-inflammatory lesions, which traditionally are slower to respond to treatment, decreased in the patient study by ~5.4% at Day 28 and showed a larger decrease of ~22.5% at Day 35 of the study.

Figure 1: Four-week inflammatory lesion reductions of leading topical acne treatments

<table>
<thead>
<tr>
<th>Product</th>
<th>Owner</th>
<th>Average Inflammatory Lesion Reduction at 4 weeks (%)</th>
<th>2016 Annual Revenue in the US (US$m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epiduo®</td>
<td>Allergan</td>
<td>~42%1</td>
<td>~US$494m</td>
</tr>
<tr>
<td>Aczone®</td>
<td>Galderma</td>
<td>~38%2</td>
<td>~US$456m</td>
</tr>
</tbody>
</table>

Source: BOT market update – 29/01/2018

Maintaining a strict development timeline: BOT now plans to initiate a much larger Phase 2 study for BTX 1503 in 2Q CY2018, enrolling approximately 400 subjects in Australia and North America. The Company has previously indicated that results for this trial are likely in early-to-mid 2019, maintaining the expediated development timeline for BTX 1503.

Recommendation

We maintain our speculative buy recommendation on a revised $0.20 valuation.
Valuation

De-Risking Entire Portfolio

Whilst clearly positive for BTX 1503, the Phase 1b results also substantially de-risk BOT’s wider portfolio of cannabidiol-based dermatological products. The proven anti-inflammatory properties of BTX 1503 bodes well for the Company’s atopic dermatitis (BTX 1204) and psoriasis (BTX 1308) treatments as both skin diseases include inflammation as a key symptom.

We account for BOT’s somewhat de-risked portfolio by reducing our cost of equity. We now value BOT shares using a 15% cost of equity (previously 20%).

Less Dilution

Our model accounts for future capital raises and any subsequent dilution from those raises. Previously we were conservative in our assumed price that each raise was completed at. Given strong recent share price gains on the back of positive Phase 1b data, we are less conservative in our assumed dilution which has a significant impact on our valuation.

BTX 1503 – Potential Market Leader

Results from the Phase 1b study of an average ~47% reduction in inflammatory lesions outperforms the current market leading topical acne products (see Figure 1 above). Together these two products (Epiduo and Aczone) generated nearly US$1bn annual revenue in 2016.

We believe the initial results position BTX 1503 to potentially be the market leading acne treatment and have adjusted our market share forecasts accordingly. We now assume BTX 1503 secures 12% market share in the prescription acne space up from 8% assumed previously). This is in-line with Epiduo’s approximate market share in 2016.

It should be noted that our valuation increases substantially as BOT moves through the approvals process. This is because successful clinical trials substantially de-risk the candidate drug and, as such, the likelihood of approval increases from phase to phase.

*Figure 2: Value uplift for BTX 1503 after successful clinical phases*

Source: Argonaut forecasts
Positive Impact on Valuation

BOT’s first successful patient data represents a key inflection point for the Company, and the value uplift is reflected in our revised 20 cents per share valuation (previously 9.5 cents). The drivers of the value uplift include less assumed dilution, a significantly de-risked portfolio and BTX 1503’s potential to be a market leading acne treatment as described above.

Our ~A$105m portfolio valuation compares favourably with Allergan’s acquisition of Anterios in January 2016 for an upfront payment of US$90m (~A$110m). It should be noted that undisclosed milestone payments may significantly increase the final consideration Allergan pays for the acquisition of Anterios. Anterios offered a topical drug delivery technology and had a topical acne treatment in pre-clinical development (see detail in tables overleaf).
The potential prize for BOT shareholders is highlighted by market valuations of NASDAQ listed companies with products in latter stages of FDA approval.

Recent deals in the dermatology space range from US$90m in the pre-clinical stage to US$5.2bn for drugs completing Phase 3 trials.

### Table 1: Comparable dermatology focused biotech companies

<table>
<thead>
<tr>
<th>Company</th>
<th>Treatments</th>
<th>Market Cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sienna Biopharmaceuticals (NASDAQ:SNNA), IPO on NASDAQ in July 2017</td>
<td>Topical treatment for pruritus and psoriasis (SNA-120), currently in Phase IIb trials&lt;br&gt;Topical treatment for atopic dermatitis, psoriasis and pruritus (SNA-125), currently in pre-clinical development&lt;br&gt;Class II medical device for treatment of acne (SNA-001), application filed for FDA 510(k) clearance</td>
<td>US$368m</td>
</tr>
<tr>
<td>Dermira Inc (NASDAQ:DERM), IPO on NASDAQ in March 2017</td>
<td>Injectable treatment for plaque psoriasis (CIMZIA), completed Phase III and currently awaiting NDA approval&lt;br&gt;Topical treatment for primary axillary hyperhidrosis (or excessive sweating), completing Phase III trials&lt;br&gt;Topical treatment for acne, currently in Phase III trials&lt;br&gt;Injectable treatment for atopic dermatitis (Lebrikizumab), currently in Phase II trials</td>
<td>US$1.3bn</td>
</tr>
</tbody>
</table>

Source: pharmamedtechbi.com

### Table 2: Recent pharmaceutical deals in the dermatology space

<table>
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<tr>
<th>Deal</th>
<th>Treatments</th>
<th>Deal Value</th>
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<tbody>
<tr>
<td>Roche offloads Lebrikizumab drug rights to Dermira in August 2017</td>
<td>Repurposed atopic dermatitis treatment (IL-13 drug Lebrikizumab), expected to go straight into Phase IIb study</td>
<td>US$1.4bn</td>
</tr>
<tr>
<td>Allergan acquired Vitae Pharmaceuticals in October 2016</td>
<td>Oral psoriasis treatment (VTP-43742), in Phase II clinical trials&lt;br&gt;Topical atopic dermatitis treatment (VTP-38543), in Phase II clinical trials</td>
<td>US$639m</td>
</tr>
<tr>
<td>Sienna Biopharmaceuticals acquired Creabilis in December 2016</td>
<td>Topical psoriasis treatment (CT327), in Phase IIb clinical trials&lt;br&gt;Topical atopic dermatitis treatment (CT340), in pre-clinical development</td>
<td>US$150m</td>
</tr>
<tr>
<td>Allergan acquired Anterios in January 2016</td>
<td>Topical drug delivery technology (NDS™)&lt;br&gt;Topical acne treatment (ANT-1207), in pre-clinical development</td>
<td>US$90m</td>
</tr>
<tr>
<td>Leo Pharma acquired Astells global dermatology business in April 2016</td>
<td>Topical atopic dermatitis treatment (Protopic®), currently on the market...among other products for the treatment of acne and skin infections</td>
<td>~US$770m</td>
</tr>
<tr>
<td>Pfizer acquired Anacor in May 2016</td>
<td>Topical atopic dermatitis treatment (Crisabarole), completing Phase III clinical trials</td>
<td>US$5.2b</td>
</tr>
<tr>
<td>Purdue acquired drug rights from Exicure in December 2016</td>
<td>Topical psoriasis treatment (AST-005), completed Phase I clinical trials</td>
<td>US$790m</td>
</tr>
</tbody>
</table>

Source: pharmamedtechbi.com
RESEARCH:

Important Disclosure
Argonaut acted as the Lead Manager to the Placement that raised $7.4M in April 2017 and will receive fees commensurate with this service. Argonaut holds or controls 12.1M BOT Options exercisable at $0.03 on or before 30 June 2019.

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