BELL POTTER

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Botanix Pharmaceuticals (BOT)

Synthetic CBD for Dermatology

Speculative
See key risks on Page 3 and Biotechnology Risk Warning on Page 17. Speculative securities may not be suitable for Retail Clients.

Recommendation
Buy (Initiation)
Price
$0.077
Valuation (12 months)
$0.15 (Initiation)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**94.8%**
Dividend yield	**0.0%**
Total expected return	**94.8%**

Company Data & Ratios	
Enterprise value	**$44.1m**
Market cap	**$58.3m**
Issued capital	**757.4m**
Free float	**88%**
Avg. daily val. (52wk)	**$402,000**
12 month price range	**$0.051 - $0.21**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.09	0.11	0.05
Absolute (%)	-9.1	-23.8	60.0
Rel market (%)	-6.6	-15.0	65.1

Absolute Price

SOURCE: IRESS

Headway in clinical trials unlocking Botanix's potential

Botanix Pharmaceuticals is an Australian biotech company engaged in the development of novel compounds for the treatment of a range of dermatological conditions. All products utilise synthetic cannabidiol (CBD) in conjunction with Permetrex™ skin delivery technology. The company has exclusive rights to this technology for all drugs that treat dermatology conditions. The first two indications are for chronic acne and atopic dermatitis (AD).

The use of CBD to treat these conditions is novel. There are no approved medicinal cannabis products for these indications. This represents a crucial element of our Buy rating, as Botanix's products are likely to be highly differentiated in market that is crowded with generic versions of generally old molecules, many of which have side effects that prevent their long term use.

Initial signs point to Botanix's topical products having an excellent safety profile with, at worst, similar efficacy to on market topical products. In general, the stigma surrounding cannabis and its legitimate ability to relieve symptoms of a medical condition is rapidly reducing. Additionally, the FDA has now approved the first plant derived medicinal cannabis product in an unrelated treatment area (epilepsy).

The leading 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 mid 2019. The company's second asset, BTX1204 for the treatment of AD recently completed a successful IND meeting with the FDA. The company intends to commence a phase II trial in CY19.

As at 30 September 2018, the company had cash of $14.2m which is sufficient to complete the phase II study in BTX1503 and the phase II study for BTX1204.

We initiate coverage with a Buy (speculative) recommendation and valuation of $0.15.

Earnings Forecast

June Year End	FY18	FY19e	FY20e	FY21e
Revenues	1.8	3.3	21.0	14.0
EBITDA $m	-11.1	-11.7	10.4	6.7
NPAT (underlying) $m	-11.0	-11.7	10.4	6.7
NPAT (reported) $m	-11.0	-11.7	10.4	6.7
EPS underlying (cps)	-2.3	-1.5	1.3	0.8
EPS growth %	-108%	35%	189%	-36%
PER (x)	nm	nm	5.9	9.2
FCF yield (%)	nm	nm	nm	12%
EV/EBITDA (x)	nm	(3.8)	4.2	6.6
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0%	0%	0%	0%
ROE %	0%	-266%	70%	31%

SOURCE: BELL POTTER SECURITIES ESTIMATES

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Investment Overview

Botanix is an Australian biotech company engaged in the development of novel compounds for the treatment of a range of dermatological conditions. All products utilise synthetic cannabidiol (CBD) in conjunction with Permetrex^{TM} delivery technology. The company has exclusive global rights to this technology for all drugs that treat skin disease.

CBD has gained much publicity over the last 2 years following the legalisation of the hemp industry in Canada and the FDA's approval of the first medicinal cannabis product in the US. CBD is becoming well known for its strong anti-inflammatory and immunosuppressant effects. There are no side effects and no addiction risks with CBD. These effects are driving enormous growth for over the counter products and Botanix is seeking to capitalise on this popularity with more potent prescription products.

The key distinction between synthetic CBD and plant derived CBD is its purity - i.e. the synthetic product is 100% pure and is free of any other compound (including the psychoactive THC). Synthetic CBD is readily available. It is also likely that synthetic CBD will be more economical to produce in commercial pharmaceutical grade quantities than plant derived product.

In general, topical administration of a drug onto the skin has distinct advantages over oral and injectable drugs in dermatology. Topical products tend to cause fewer side effects and are more successful at delivering drug to the targeted disease area as compared to orally administered CBD where around 6% of the drug reaches the bloodstream. Additionally, Botanix assert that 5% Permetrex CBD formulation delivers more drug to the target area than regular 20% and 10% CBD topical formulations using traditional skin delivery technologies.

The company has three assets in the clinic and a further asset in the preclinical stage. The leading asset is BTX1503 – for the treatment of moderate to severe chronic acne. BTX1503 is currently recruiting a phase II clinical trial that is expected to be completed in mid-2019. Its efficacy profile is comparable to current topical products although initial signs point to a superior safety profile (based on phase 1b data).

The second asset, BTX1204 treats atopic dermatitis. The company recently held a successful pre IND meeting with the FDA allowing commencement of a phase II clinical trial in the USA. Botanix expect this trial to cost ~$US6m commencing in 4Q CY2018.

The third asset BTX1308 is targeting mild to moderate psoriasis. BOT has recently enrolled the first of 15 patients in a phase 1b study being conducted in Australia. Data is expected in 1Q CY19.

Botanix is currently in preclinical testing of pipeline product BTX1801, being a new antibiotic aimed at treating antimicrobial resistance for a variety of skin infections.

Data from the phase II acne study is due in mid CY2019 with the AD trial due to report in 2H CY2019. The most likely path to commercialisation is a partnering deal with a larger pharma group. We consider both indications are highly attractive for potential partners due to the very large market size and chronic nature of both indications. Most drugs to treat these conditions have been off patent for many years and are highly genericised. CBD is a new active pharmaceutical ingredient and in our view highly differentiated from the remainder of the treatment market.

We initiate coverage with a Buy (Speculative) recommendation and valuation of $0.15.

Key Risk Areas

Over the counter competition: The burgeoning market for nutraceutical CBD products presents a potential risk. These over the counter (OTC) formulations of plant derived CBD are gaining in popularity every quarter. OTC products are widely available throughout the US (by mail order) and in retail outlets and are relatively cheap, particularly for US patients without health insurance cover. It is likely there will be markets for both OTC products and pharmaceutical grade products. Competition may also emerge from other drug developers seeking to develop products involving synthetic CBD.

Efficacy remains unproven: Plant derived CBD products consist of well over 100 different types of CBD in a single product. Industry literature indicates the presence of an entourage effect whereby each of these compounds work together to generate the general healing effect whereas the Botanix products consist of a single synthetic cannabinoid. While the safety and efficacy data from clinical trials is encouraging, the long term efficacy and safety from BOT's products are yet to be studied in a large randomised trial.

Intellectual Property: The strength of the patents and other instruments protecting the intellectual property of Botanix are yet to be tested in the court. If Botanix's registered intellectual property is invalidated or removed from intellectual property registers this will adversely impact the long term earnings capacity of the company. The company also relies the Permetrex technology as its drug delivery platform. If the licensor fails to enforce or defend the intellectual property rights associated with Permetrex, this may affect Botanix's ability to develop and commercialise its product candidates.

Clinical Risk: All of Botanix's products are a variation in dosage of the same active compound (CBD). Hence, if the company's leading asset BTX1503 is unsuccessful in phase II, this may increase the likelihood of further clinical failure in BTX1204, BTX1308 and BTX1801.

Financing Risk: The company is likely to require further capital from shareholders in order to progress its clinical program. The need for additional capital depends on numerous factors including the results from clinical studies and the willingness of development partners to engage in discussion for the commercialisation of BOT's various assets.

Regulatory Risk: The use of CBD for medicinal purposes remains at the fringe of mainstream medicine, hence there is no certainty that even with appropriate evidence from clinical trials that the company will secure a deal to commercialise these drugs. This risk is likely to dissipate if the US Farm Bill is passed. This includes legislation to legalise the cultivation of low THC (industrial) hemp.

DEA: Synthetic cannabidiol is a "Schedule 1" drug substance under the Controlled Substances Act (US) and is subject to strict control and regulation by the US DEA (Drug Enforcement Agency). The manufacture and handling of controlled substances is subject to strict limitations. Should any 3rd party be involved in the manufacture, handling or clinical trials involving the Botanix drugs lose their accreditation, these many hamper or halt entirely the development and commercialisation process.

Commercialisation: The company will almost certainly require a distribution partner in each market around the world. In the United States the ability of a distribution partner to sell these drugs will depend upon inclusion on various private payer formulary lists. Ultimately the distribution partner and the payers will determine the net price for each sale and this process is generally outside of the control of drug developers like Botanix.

About BTX1503

BTX1503 is the company's leading drug candidate and is being developed for the treatment of chronic mild to severe acne.

CLINICAL DATA

The IND (investigational new drug) application was approved by the FDA in May 2018. A Phase II study is currently underway and is expected to be completed in mid 2019.

- This randomised, controlled, blinded study will enrol 360 patients and run for 12 weeks across 28 sites in Australia and the US and is expected to cost ~$8m ($22k/patient);
- The primary endpoint of the trial is absolute change from baseline to week 12 in inflammatory lesions and involves three separate dosing regimens and a control; and
- Secondary endpoints include a) absolute change from baseline to week 12 in non-inflammatory lesions, b) percentage change from baseline to week 12 in inflammatory and non-inflammatory lesions, and c) proportion of successfully treated patients.

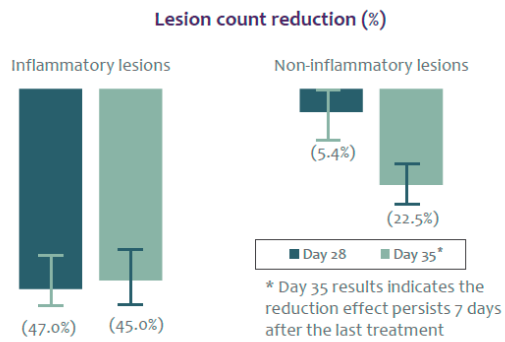
We expect that with 360 patients the trial is powered for statistical difference in at least the primary endpoint.

EARLIER CLINICAL TRIALS

The phase II study follows the recent phase 1b study in 21 patients over 4 weeks. The key data from the phase 1b study was:

- The drug reduced inflammatory lesions by 47% and non-inflammatory lesions by 5.4%;
- There were no adverse safety effects associated with BTX1503; and
- The drug modestly outperformed leading topical products Epiduo (marketed by Galderma) and Aczone (marketed by Allergan).

Figure 1 - BTX1503 Lesion Count Reduction in Phase 1b Trial



SOURCE: BOTANIX INVESTOR PRESENTATION 05/02/18

Figure 1 indicates a potential for long-lasting efficacy following last treatment. For the seven days following treatment inflammatory lesions reduced by approximately 45%. Additionally, the 'reduction effect' actually improves for non-inflammatory lesions in the week following treatment from 5.4% at day 28 to 22.5% at day 35.

TREATMENT LANDSCAPE FOR ACNE

The standard of care for patients with mild to severe chronic acne is a range of topical products that include benzoyl peroxide, antibiotics and topical retinoids. Despite mixed efficacy these generally tend to have moderate side effects relative to oral drugs.

- Benzoyl Peroxide works by inhibiting the formation of skin blemishes that form when oil and skin cells become trapped in the pore. Although it shows strong efficacy in treating mild acne it is typically ineffective on its own at treating more severe, chronic cases;
- Topical antibiotics are an effective short-term treatment for inflammatory (deep lying) acne although long-term use must be avoided when feasible due to the potential of bacterial resistance;
- Topical retinoids are proven to be effective at unblocking and preventing comedonal (surface) acne such as 'whitehead' and 'blackhead' pimples. However, patients' skin tends to be overly sensitive to light and many patients also find that their acne actually gets worse at the 4-week mark before improvement.

Figure 2 - Branded Topical Treatment Options for Mild to Severe Chronic Acne

		Indications at 4 Weeks			
Agents	Lesion Count Reduction	Oil Reduction	Acne Proliferation Reduction	Inflammation	Key Considerations
BTX 1503	47%	Yes	Yes	Yes	Dryness of Skin
Benzoyl Peroxide (Epiduo)	42%	No	Yes	Possibly	Irritation
Topical Antibiotic (Aczone)	38%	No	Yes	Possibly	Irritation; Potential Anti-biotic Resistance
Topical Retinoid (Retin-A)	35%-60%	No	No	Possibly	Irritation; Phototoxic

SOURCE: BOTANIX INVESTOR PRESENTATION 05/02/18

If topical treatment options are ineffective, the next line of treatment includes oral medication such as anti-biotics and isotretinoin. In general, the poor safety profile of these treatment options undermines their strong efficacy. Patients are often left with long-term side effects which may include skin scarring and depression. Further treatment options tend to be gender specific. For example, oral contraceptives have been found to have moderate, indirect effectiveness at reducing oily skin for women. Similarly, anti-androgens also decrease skin oil despite several systemic side effects.

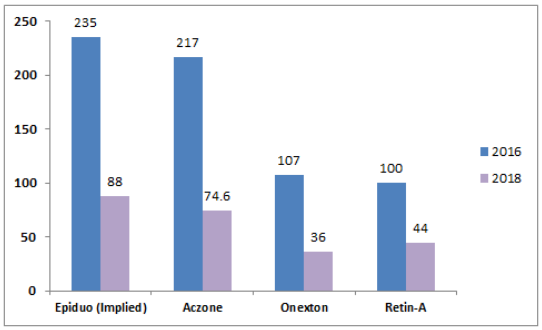
We conclude there is a clear unmet need for long-term safe treatment of mild to severe chronic acne. If the superior safety profile of BTX1503 compared to standard of care can be further substantiated in the current phase II trial, Botanix will be well positioned to secure a licensing deal or indeed a sale of the company to a global pharmaceutical company.

MARKET SIZE

Gross sales value of the US prescription acne market is estimated by the company at US$4.9b inclusive of both topical and oral medications. The topical prescription market alone is estimated at US$2.65b and is expected to increase at a CAGR of 3% in the forecast period. We estimate the market wide gross to net discount to be approximately 47%. Revenues for the abovementioned leading topical brands are all substantially down from pre-2016 figures following the loss of exclusivity and the introduction of generics.

For the brands owned by listed companies (with the exception of Epiduo) estimated revenues are as follows:

Figure 3 - Implied Topical Acne Product Revenue in 2016 and 2018 ($USm)



NOTE: 2018 REVENUES ARE ANNUALISED FROM 6 MONTH REPORTED REVENUES ON JUNE 30 2018

SOURCE: ALLERGAN Q2 2018 EARNINGS RELEASE & BAUSCH HEALTH 2Q EARNINGS RELEASE

The above graph shows estimated revenues for branded topical products Epiduo (owned by Galderma), Aczone (owned by Aczone), Onexton (Bauch Health) and Retin-A (also owned by Bauch Health) in the prescription acne market in 2016 and 2018.

Branded products have lost both market share and experienced pricing decline due to the entry of generic competitors. Despite the revenue declines experienced by these leading brands, the market volume of prescriptions written for acne treatment continues to grow by approximately 3.3% per annum.

PRICING

The leading topical products in acne were priced in the range of ~US$3,000 to $3,200 in 2016 although it is likely that the realised price is considerably lower. In our view, BTX1503, if approved, will be highly differentiated because of the novel nature of CBD as the active pharmaceutical ingredient and therefore likely able to command higher pricing - similar to the range noted above. For BTX1503 the annual cost per user is estimated at US$3,000.

PARTNERING PROSPECTS

For the purposes of this discussion we assume the Phase II study produces data which shows a statistical difference between the control and active arm of the trial in the primary endpoint. The strength of that signal will influence the level of competitive tension in the negotiation of any transaction.

Botanix has a number of options for commercialisation of BTX1503, however the most likely option is that it executes a licencing deal at the end of the phase II study. It is also possible (but unlikely) that a larger group may acquire the company. Alternatively BOT may sell the country rights to its formulations to a 3rd party as a means of raising non dilutive capital.

In addition to the quality of the clinical trial data, other factors may include the following:

- The stigma surrounding cannabis and its ability to relieve the symptoms of a variety of medical conditions, including epileptic seizure, anxiety, depression and general inflammation is dissipating. We draw this conclusion based on the FDA's recent approval of the first medicinal cannabis product in the US (epidiolex) and the explosive growth currently being experienced in the market for over the counter CBD products in the USA;
- The pending re-scheduling of industrial hemp (off schedule 1 of the Controlled Substance Act) at the Federal level in the US will be a major catalyst for development partners to take a fresh look at CBD based medicinal products; and

- Even though the Botanix products are synthetic (man made), the stigma of being a cannabidiol is likely to remain until the Federal laws are changed.

MILESTONE REVENUE

Assuming the company partners the drug at completion of the current phase II study, the forecast milestone revenues for BTX1503 are as follows:

- Upfront milestone revenue of US$30m in 2020 following the completion of the phase II clinical trial in mid-late 2019;
- Revenue of US$10m in 2020 upon first enrolment in a phase III trial;
- Revenue of US$10m in 2021 upon successful phase III data readout; and
- Revenue of US$50m in 2022 subject to FDA approval of the drug.

Figure 4 - BTX1503 Predicted Milestone Revenue (Gross – before risk adjustment)

US$m Fiscal Year	2019	2020	2021	2022	2023
Upfront payment	-	30.0	-	-	-
Upon first enrolment in Phase III	-	10.0		-	-
Data readout from phase III	-	-	10.0	-	-
Upon FDA approval	-	-	-	50.0	-

SOURCE: BELL POTTER SECURITIES ESTIMATES

If the company decides to partner at the end of phase II, the development partner would normally absorb the cost of the approval study.

ROYALTY REVENUE & MARKET SHARE

We further assume a 12% royalty based on sales revenues beginning in 2023. BTX1503 is expected to hold a modest initial market share in the low single digit percentage range from years 2023-2027.

The abovementioned milestone and royalty revenues for BTX1503 are discounted by 70% in our DCF model in order to reflect the development risk associated with this drug. As each milestone is met, it is reasonable to expect the discount rate will reduce.

INTELLECTUAL PROPERT PROTECTION

The two original patents (as listed in the 2016 prospectus) are proceeding towards grant in the US and other jurisdictions. The patent portfolio has now expanded to 9 different families covering compositions for treating each of acne, dermatitis, psoriasis and other inflammatory conditions, dose range patents for each of these diseases and a number of antibacterial patents for cannabidiol as well as other cannabinoids. All of these patent families are being prosecuted in the US, Australia and 23 other countries.

MANUFACTURING

The company has used 3 manufacturing sites, 2 in the US and 1 in Australia. All are GMP qualified and have made clinical materials. The 2 US sites are commercial scale. Of these the company has installed proprietary mixing equipment at one site which may be used for the production of commercial quantities depending on partnering arrangements.

About BTX 1204

BTX1204 is a synthetic cannabinoid being developed for the treatment of Atopic Dermatitis (AD) – a chronic skin condition usually diagnosed during infancy. AD is the most common form of eczema and generally involves inflammation of the skin which tends to worsen when the immune system is weak. Researchers believe that approximately 50% of moderate-severe diagnoses are genetic.

CLINICAL DATA

In August 2018 the company held a successful pre IND meeting with the FDA which will allow commencement of a phase II clinical trial in the USA. We note the following about the phase II trial:

- The Phase II clinical trial will be randomised, vehicle controlled and double blinded. The study will be across 200 patients with moderate AD across 25 sites in the US and Australia;
- The primary endpoint will look at the proportion of subjects with Investigator's Static Global Assessment (ISGA) success – which is subjectively defined as AD being "clear" or "almost clear". Secondary endpoints include a) change from baseline in the signs of AD, b) eczema area severity index score, c) percentage of body surface area affected by AD, and d) the time taken to achieve success; and
- Botanix expects to begin the trial in 4Q18 and expects to have the study fully recruited in mid-2019 with data available soon thereafter.

EARLIER CLINICAL TRIALS

BTX1204 is the identical chemical entity to BTX1503 and is, therefore, not required to undertake a separate safety study. In June 2018 Botanix successfully completed a phase 1b study in AD. The trial was a randomised, controlled, double blind study in 36 patients over 4 weeks in Australia. The data was reported as follows:

- BTX1204 was twice as effective over the vehicle (placebo) with "substantial improvement" in key signs of AD including itch and underlying inflammation; and
- Efficacy was increasing at the 4-week time point. In this small study tolerability was established with no signs of burning or local side effects. This suggests potential for a longer treatment timeframe - a key unmet need in the treatment of AD.

TREATMENT LANDSCAPE & COMPETITION

Topical corticosteroids in combination with Vitamin D creams and antihistamines are the first line of treatment for AD. They aim to provide short-term itch relief in order to break the itch-scratch reflex cycle – the primary cause of reinfection. Although in more mild cases, these therapies may be effective, in moderate/severe cases long-term use (of steroids) tends to do more harm than benefit. Prolonged use damages and dries out the epidermal layer of skin which, somewhat paradoxically, ends up actually worsening the itch-scratch complex.

- Most of these medicines are now off patent and consequently have generic competitors; and
- Pfizer's new topical ointment Eucrisa is the latest branded product for the treatment of AD. Pfizer acquired the developer (Anacor Pharmaceuticals) for US$4.5bn and the drug was initially expected to become a blockbuster (expected annual revenue of US$2b), however in 2Q18 its worldwide revenues were just US$39m. Eucrisa has a good safety profile – however, many patients reported

that it has little to no effect on itch. A significant number of patients also reportedly experience severe local pain following application of Eucrisa which is a major concern as paediatrics is the primary target market. The API in Eucrisa is Crisaborole which is in a class of medicines knows as phosphodiesterase inhibitors. It is a non-steroid topical anti-inflammatory, hence it should be safe for long term use.

Second-line agents include immunosuppressant medications such as topical calcineurin inhibitors. Branded products including Elidel and Protopic are expected to reach peak sales of US$350m and US$175m in 2018, respectively. These treatments reportedly have improved efficacy compared to Eucrisa and BTX1204, however their use comes with a 'black box' warning regarding elevated risk of skin cancer and lymphoma.

Another relatively new systemic treatment option is Dupixent - a monoclonal antibody administered via bi-weekly injection. Dupixent is currently the most effective treatment for AD and is marketed by Sanofi and Regeneron Pharmaceuticals. It is indicated to treat adults with moderate to severe AD that is not well controlled with topical prescription therapies. In order to be considered for this drug other treatment options must fail. The drug generated 3Q18 revenue of US$219m is still well below estimated peak sales of US$4.2b. The FDA have also recently approved Dupixent for the treatment of asthma – a common succession of AD in children.

It is important to note the difference between AD and other forms of eczema, such as contact dermatitis, which instead occurs when the patient comes into contact with an allergen or irritant (these include pets, certain foods, grass, dust etc). The condition is the second most common form of eczema and currently managed by avoiding the allergen if possible as it is considerably harder to treat with drugs. Botanix has not yet conducted any testing for other forms of eczema other than AD, however this is likely, pending the outcome of the AD study.

MARKET SIZE

The gross value of sales for the treatment of atopic dermatitis is estimated to be in excess of US$4.0b annually and predicted to reach over US$6.0b by 2022. Once again, the net value of revenues is likely to be less than half of this sum due to the large gross to net discount which applies in this (dermatology) section of the market. Botanix estimate that, of the amount of diagnosed AD patients who fill their prescription, 25% have severe AD, 41% have moderate AD, and 34% have mild AD.

PRICING

The leading topical products in AD are priced in the range of ~US$2,500 to US7,200 per annum in 2018. In our view, BTX1204 should command a premium to Elidel ($US3,840 per annum) and Protopic ($US2,520 per annum) as it is highly unlikely to have the same adverse long- term side effects.

BTX1204 is likely to be highly differentiated from its competitors as it is a new agent with a novel mechanism of action. For BTX1204 we estimate the annual revenue per user to be approximately US$4,500.

KEY ASSUMPTIONS ON PARTNERING

We believe that the most likely option is that Botanix executes a licensing deal at the end of a phase II study in 2020.

MILESTONE REVENUE

The forecast milestone revenues for BTX1204 are as follows:

Figure 7 - BTX1204 Predicted Milestone Revenue

US$m (fiscal year) 1204	2019	2020	2021	2022	2023	2024
Upfront payment	-	-	30	-	-	-
Upon First Enrolment in Phase III	-	-	-	10	-	-
Upon Following Successful Phase III Data	-	-	-	-	10	-
Upon FDA approval	-	-	-	-	-	50

SOURCE: BELL POTTER SECURITIES ESTIMATES

ROYALTY REVENUE & MARKET SHARE

We further assume a 12% royalty based on sales revenues beginning in 2024. We forecast low single digit share of the market in this indication from 2024-2026.

The abovementioned milestone and royalty revenues for BTX1204 are discounted at a risk adjustment rate of 80% reflecting the associated risks of drug development.

Summary Financial Data

The company was recapitalised and renamed to Botanix in May 2016. This transaction also signalled the appointment of the current US based management team. The listed entity acquired Botanix via the issue of 153m shares valued at ~$3m. The listed entity was then renamed Botanix Pharmaceuticals Limited. The company raised a further $3m cash at this time.

Figure 2 - History of capital raising

Fiscal Year	Capital Raised $m	Issue Price $	
May-16	3.0	0.02	Recapitalisation
Apr-17	7.4	0.055	Placement
Feb-18	15.0	0.11	Placement
	25.4		

SOURCE: COMPANY ANNOUNCEMENTS

The most recent quarterly showed a net cash burn of $3.0m (for the quarter) including R&D spend on clinical trials of $2.6m. Since its recapitalisation the company has spent $11.2m in total, the vast majority of which has been development spend.

As at 30 September 2018 Botanix held A$14.2m in cash, and is expecting to receive approximately A$4m from the R&D tax incentive refund from the ATO during the coming quarter.

Forecast cash outflows for the December quarter are estimated to be approximately A$5.35m with approximately A$4.75m planned to be spent on R&D, primarily associated with the two Phase 2 clinical trials (BTX 1503 for acne and BTX 1204 for atopic dermatitis), the Phase 1b patient study for BTX 1308 (psoriasis) and progressing other pipeline products (including BTX 1801 for bacterial skin infections).

Based on these projections the company should have $12.9m in cash at 31 December 2018. We expect this is sufficient to complete the two phase II studies.

The timing and extent of further capital raising (if any) will depend on the quality of the upcoming clinical result in BTX1503. The data will drive any transaction. We do not anticipate BOT will undertake an approval study by itself, therefore a licencing deal(s) is more likely.

In our view it is most likely that a partner will want to acquire exclusive country rights, to the molecule rather than for a specific indication. This would not prohibit the negotiation of specific milestones on each indication as outlined in this report – i.e. separate studies and approvals are required for each indication and therefore it is reasonable to assume separate milestones for each.

The other key factor in partnering discussions is the fact that the phase III approval studies are neither long or expensive (in comparison to say oncology or CNS drug trials).

Our forecast includes cash receipts from a licencing transaction in FY20. The company's ability to complete this transaction remains highly uncertain and will depend on a number of factors including (but not limited to) the quality of the data from the clinical program. If the company is unable to execute a suitable licencing deal, then it will almost certainly require further equity capital from shareholders.

Valuation

The following table summarises key deal terms of relevant transactions in the dermatology pace. These comparables are relevant to the forecast milestone revenues and an underlying driver of our valuation.

Figure 9 - Related Transactions and Licensed Deals

Year of Deal	Drug Name	Treatment Use	Deal Type	Acquirer	Licensor/Vendor	Clinical Stage	Upfront Payment ($US)	Potential Deal Value (Excl. Upfront)
2010	Axiron	Low Testosterone	License	Ely Lilly	Acrux	Post Phase III	$50m	$282m Milestones + Royalties
2015	Doryx	Acne	Acquisition	Mayne Pharma	Actavis	On Market	$50m	N/A
2015	Siliq	Psoriasis	License	Valeant	Astra Zeneca	Post Phase III	$100m	$170m Milestones + Royalties
2016	Tralokinumab	AD & Psoriasis	License	Leo Pharma	Astra Zeneca	Post Phase IIb	$115m	$1b Royalties
2016	Pegcantratinib	AD & Psoriasis	Acquisition	Sienna Pharma	Creabilis	Phase IIb	Undisclosed	$150m Milestones
2016	Eucrisa	AD	Acquisition	Pfizer	Anacor	Post Phase III	$4.5b	N/A
2018	**Halobetasol Foam**	**Plaque psoriasis**	**Acquisition**	**Mayne Pharma**	**Private company**	**Approved**	**US$10m**	**US$22m in milestones plus annual earnout payments over 10 years**
2018	JW1601	AD	License	Leo Pharma	JW Pharmaceutical	Pre IND	$17m	US$385m plus 2% royalty

SOURCE: BELL POTTER SECURITIES

With the exception of Axiron, the peer group is comprised of products for dermatological conditions.

- We note the US$115m paid by Leo Pharma for Kyntheum (tralokinumab). This drug is a monoclonal antibody. Leo Pharma has numerous clinical studies under way in the US to evaluate this drug including a phase III trial in adolescents with AD which commenced in July 2018. The drug is not yet approved in any country;
- Leo Pharma's US$17m upfront payment for JW1601 is relevant. JW1601 is a novel atopic dermatitis drug candidate intended for oral treatment of atopic dermatitis which is expected to maximize efficacy by dual action of anti-pruritus (anti-itch) and anti-inflammation and minimize adverse events by high selectivity on the target. The drug was developed in Korea and does not yet have an IND for the US. The drug is an oral anti histamine; and
- We note Pfizer's acquisition of biopharmaceutical conglomerate Anacor for US$4.5b – of which the majority of value was initially thought to be attributable to Eucrisa. In 3Q 2018 Eucrisa generated US$104m of revenues, still well below pre-acquisition revenue expectations.

The Denmark based Leo Pharmaceuticals continues to invest heavily in its dermatology franchise as does Mayne Pharma. The high level of corporate activity in this area highlights the still unmet need to long term, safe treatments of this condition.

We are cautious on the valuation for the following key reasons:

- Despite recent regulatory success with the FDA for the first plant derived medicinal cannabis product (Epidiolex), the inertia of government to fully legalise the cultivation of industrial hemp is a threat to the commercial viability of CBD;
- Botanix is a small company that has not previously had a drug that it has developed come to market; and
- We know very little about the chemical composition of the synthetic CBD being tested by Botanix. We are unaware of whether the Botanix drug is a virtual copy of a particular cannabinoid (in which case it is dubbed an "isolate" or slightly modified from the plant version (an "analog"). Either way the risk of a paragraph IV challenge on the validity of the patent is a real threat. The value of patents on any small molecule drug in increasingly questionable and we note this it likely to have been a factor in the October 2018 acquisition by Mayne Pharma of the Halobetasol Foam product for which is paid just US$10m upfront.

The basis of our valuation is a DCF model. The key assumptions are as follows:

- The model assumes an equity cost of capital of 15.25%;
- A terminal growth rate of 2.0%; and
- BTX1503 and BTX1204 revenues were discounted at 70% and 80%, respectively. The discounts reflect the risk attached to future cash flows associated with drug development. In the event that phase II results are supportive of phase III studies the valuation may rise.

Figure 3 - DCF Valuation

DCF Valuation - Firm Value	($1,000,000)
$million	
Total PV of Explicit Free Cashflow	55.5
Total PV of Continuing Year	52.2
Enterprise Value	107.7
Less Net Debt	-14.2
Equity Value	121.9
Number of Shares (million)	797.5
Equity Value Per Share	$0.15
Dividends prior to valuation base date yet to be received	$0.00
Net cashflow valuation per share incl cum dividends	$0.15
Franking Credits per share (valued at 30¢ in the $)	$0.00
Total Value Per Share	$0.15

SOURCE: BELL POTTER SECURITIES ESTIMATES

The implied EV is A$108m. This is relative to the combined US$200m in forecast milestone receipts if the clinical trial program proceeds as planned. We conclude there is potential for further valuation uplift as the clinical program meets various hurdles throughout development.

Board and Leadership

BOARD OF DIRECTORS

Graham Griffiths: Chairman and Non-Executive Director

Mr Graham Griffiths was appointed as Non-Executive Director and Chairman in July 2016. His executive career spans 40 years in technology-based companies, including various senior executive sales, marketing and product development positions with multi-nationals in the USA and Asia Pacific region. He was formerly Managing Director of ASX listed company Ipernica Ltd, a diversified technology and intellectual property commercialisation group and was responsible for the acquisition and commercialisation of Nearmap (ASX:NEA), a global geospatial mapping technology company.

Matthew Callahan: Executive Director

Mr Matthew Callahan was appointed Executive Director in July 2016 and is also the founding director of Botanix. He is also the founding CEO of iCeutica, and a co-inventor of technologies that comprise the SoluMatrix Fine Particle Technology™ for improving the bioavailability of pharmaceuticals. He has more than 20 years legal, licensing and investment management experience and is a director of Orthocell Ltd (ASX:OCC).

Dr William Bosch: Executive Director and Chief Scientific Officer

Dr William Bosch was appointed Executive Director in July 2016. He has more than 25 years of experience in the industry, focusing on applications of drug delivery technology to Pharmaceuticals product development. Dr Bosch also works with iCeutica Inc. and is a co-inventor of the SoluMatrix™ technology and has been instrumental in the development of three FDA approved products that use the drug delivery technology. Dr Bosch was also co-founder of NanoSystems LLC in 1995 and a co-inventor of NanoCrystal® Technology.

Robert Towner: Non-Executive Director

Mr Robert Towner was appointed Non-Executive Director in January 2016. He has over 20 years corporate advisory and executive experience in the financial markets. Mr Towner's skills include maintaining board awareness of financial markets, corporate governance, capital structuring and working capital requirements. In addition, Mr Towner has considerable experience in public and private capital raising initiatives.

Figure 4 - Directors Shareholding

Director	Holding Shares (m)	Holding Options
Matthew Callahan	70.7	-
Graham Griffiths	3.7	4.1
William Bosch	15.5	8.1
Robert Towner	0.75	4.1
	90.6	16.3
Shares on issue (m)	757.4	
Free float	88.0%	
Fully diluted shares on issue	773.7	

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Botanix Pharmaceuticals

as at 21 November 2018

Recommendation	Buy (Speculative)
Price	$0.077
Valuation (12 months)	$0.15

Table 1 - Financial summary

Profit & Loss (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Year Ending June					
BTX1503 - Acne	-	-	-	16.0	4.0
BTX1204 - AD	-	-	-	-	8.0
BTX1308 - Psoriasis	-	-	-	-	-
R&D incentive	-	1.8	3.3	5.0	2.0
Total Revenue	-	1.8	3.3	21.0	14.0
COGS	-	-	-	-	-
Gross profit	-	1.8	3.3	21.0	14.0
GP margin	0%	100%	100%	100%	100%
Expenses Net of R&D	1.1	1.9	2.3	2.3	2.3
Total Clinical R&D Expense	3.7	11.0	12.7	8.3	5.0
Total Expenses	4.8	12.9	15.0	10.6	7.3
EBITDA	(4.8)	(11.1)	(11.7)	10.4	6.7
Depreciation	-	-	-	-	-
Amortisation	-	-	-	-	-
EBIT	-4.8	-11.1	-11.7	10.4	6.7
Interest expense	0.0	0.0	0.0	0.0	0.0
Pre tax profit	(4.7)	(11.0)	(11.7)	10.4	6.7
Tax expense	-	-	-	-	-
NPAT- normalised	(4.7)	(11.0)	(11.7)	10.4	6.7
Reported NPAT	(4.7)	(11.0)	(11.7)	10.4	6.7

Cashflow (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Gross cashflow	-4.7	-10.1	-11.8	8.9	7.3
Net interest	0.0	0.1	0.0	0.0	0.0
Operating cash flow	-4.7	-9.9	-11.8	8.9	7.3
Proceeds from asset sales	0.0	0.0	0.0	0.0	0.0
Free cash flow	-4.7	-9.9	-11.8	8.9	7.3
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	6.9	21.6	0.0	0.0	0.0
Movement in borrowings	-0.2	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Change in cash held	2.0	11.6	-11.8	8.9	7.3
Cash at beginning of period	3.7	5.7	17.3	5.5	14.4
FX adjustment	0.0	0.0	0.0	0.0	0.0
Cash at year end	**5.7**	**17.3**	**5.5**	**14.4**	**21.7**

Balance Sheet (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Cash	5.7	17.3	5.5	14.4	21.7
Receivables	0.2	0.4	0.3	1.8	1.2
Short term investments	-	0.0	0.0	0.0	0.0
Other current assets	-	-	-	-	-
Property, Plant and Equipment	-	-	-	-	-
Intangible assets	-	-	-	-	-
Total assets	5.9	17.7	5.8	16.2	22.9
Trade payables	0.5	1.4	1.4	1.4	1.4
Debt	-	-	-	-	-
Other provisions	-	-	-	-	-
Total Liabilities	0.5	1.4	1.4	1.4	1.4
Net Assets	5.4	16.3	4.4	14.8	21.5
Share capital	11.6	33.3	33.3	33.3	33.3
Retained earnings	(6.4)	(17.5)	(29.1)	(18.7)	(12.0)
Reserves	0.2	0.4	0.2	0.2	0.2
Shareholders Equity	5.4	16.3	4.4	14.8	21.5

Valuation Ratios (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Reported EPS (cps)	-1.1	-2.3	-1.5	1.3	0.8
Normalised EPS (cps)	-1.1	-2.3	-1.5	1.3	0.8
EPS growth (%)	0%	-108%	35%	189%	-36%
PE(x)	**nm**	**nm**	**nm**	**5.9**	**9.2**
EV/EBITDA (x)	nm	nm	-3.8	4.2	6.6
EV/EBIT (x)	nm	nm	-3.8	4.2	6.6
P/NTA (x)	7.7	3.6	13.3	3.9	2.7
Book Value Per Share (cps)	1.0	2.1	0.6	2.0	2.8
Price/Book (x)	7.7	3.6	13.3	3.9	2.7
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	nm	nm	nm	nm	12%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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