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# Botanix Pharmaceuticals (BOT)

## Phase III In Acne To Proceed

**Speculative**
**See key risks on Page 6 and Biotechnology Risk Warning on Page 9. Speculative securities may not be suitable for Retail Clients.**

Recommendation
Buy (unchanged)
Price
$0.125
Valuation
$0.25 (previously $0.33)
Risk
Speculative

**GICS Sector**

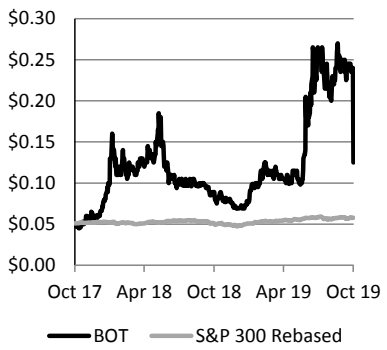
**Pharmaceuticals & Biotechnology**

| Expected Return | |
|---|---|
| Capital growth | **124%** |
| Dividend yield | **0%** |
| Total expected return | **124%** |
| **Company Data & Ratios** | |
| Enterprise value | **$76.6m** |
| Market cap | **$120.6m** |
| Issued capital | **964.5m** |
| Free float | **91%** |
| Avg. daily val. (52wk) | **$710,000** |
| 12 month price range | **$0.067 - $0.29** |

**Price Performance**

| | (1m) | (3m) | (12m) |
|---|---|---|---|
| Price (A$) | 0.24 | 0.23 | 0.09 |
| Absolute (%) | -46.8 | -44.4 | 40.4 |
| Rel market (%) | -46.1 | -44.9 | 28.1 |

**Absolute Price**




SOURCE: IRESS

## Miss On Primary Clinical Endpoint

BOT reported the headline results from its 368 patient double blinded, randomised clinical trial investigating the use of BTX1503 in the treatment of moderate to severe acne. The primary endpoint was reduction in the absolute count of inflammatory lesions over a 12 week period. The drug achieved a 40.5% reduction in the number of lesions, however, relative to vehicle the result was not statistically significant. The failure to achieve statistical significance in this measure caused the stock price to fall by 48% following the announcement.

In relation to safety, the results in the active arm were outstanding. There were no serious adverse events and very few adverse events of any consequence. The drug is very well tolerated and suitable for sustained long term use. The safety profile compares well with marketed products in this indication.

The key secondary endpoint was reduction in non-inflammatory lesions and for this measure the results were highly statistically significant and supportive of further investigation.

The major driver of the failure to achieve statistical significance in the primary endpoint was the better than expected vehicle response at the US clinical sites. The vehicle response at these sites was unusual and generally between 2x and 4x higher than that seen in Australia for inflammatory and non-inflammatory lesions respectively. The company theorises that this was due to batch differences in the vehicle between sites. In our view this reflects poorly on the conduct of the trial and the QA procedures in manufacturing. Fortunately the results from the clinical sites in Australia were consistent with expectation and supportive of further analysis. For this reason the company has indicated its intention to pursue an approval study in acne.

## Retain Buy Speculative Recommendation

We retain our Buy (Speculative) recommendation. As BOT has announced its intention to conduct approval studies with BTX1503 there are significant changes to earnings in the forecast period. We have also included the dilution from the recent capital raise and accordingly the valuation is reduced to $0.25 from $0.33.

**Earnings Forecast**

| June Year End | FY19 | FY20e | FY21e | FY22e |
|---|---|---|---|---|
| Revenues | 4.8 | 5.0 | 14.0 | 40.0 |
| EBITDA $m | -17.0 | -13.6 | -6.5 | 29.3 |
| NPAT (underlying) $m | -17.0 | -13.6 | -6.5 | 29.3 |
| NPAT (reported) $m | -17.0 | -13.6 | -6.5 | 29.3 |
| EPS underlying (cps) | -2.2 | -1.4 | -0.6 | 2.9 |
| EPS growth % | 1% | nm | nm | nm |
| PER (x) | nm | nm | nm | 4.3 |
| FCF yield (%) | nm | nm | -6% | 23% |
| EV/EBITDA (x) | (4.5) | (5.6) | (11.8) | 2.6 |
| Dividend (cps) | - | - | - | - |
| Franking | 0% | 0% | 0% | 0% |
| Yield % | 0% | 0% | 0% | 0% |
| ROE % | -2549% | -50% | -32% | 59% |

SOURCE: BELL POTTER SECURITIES ESTIMATES

# Poor QA Spoils A Promising Result

BOT has now released the headline results of its phase II study which examined the effect of BTX1503 in the treatment of moderate to severe acne.

The headline results were:

- All doses of BTX1503 achieved a reduction in the number of inflammatory lesions with the highest efficacy obtained for the 5% BTX1503 group which achieved an average reduction in inflammatory lesions of 40.54%;
- The combined vehicle group, however, achieved an average reduction in inflammatory lesions of 40.15%. This was an unusually high response from the vehicle group and consequently the primary endpoint of reduction in inflammatory lesions did not achieve statistical significance. The control group was treated with permetrex excluding the active drug;
- It appears there was a substantial difference between the responses recorded at the Australian sites (11) vs the US sites (25). Looking at the Australian sites only, there was a statistically significant reduction in inflammatory and non inflammatory lesions;
- The study saw no serious adverse events and very low incidence of treatment related adverse events of any nature.

Despite the failure to achieve a statistically significant result in the primary outcome, Botanix has announced its intention to move forward with its preparations for a phase 3 clinical program in the acne indication. The company now intends to seek an end of phase 2 meeting with the FDA.

## Trial Design

This phase II study enrolled a total of 368 patients across 5 cohorts:

- 5% BTX 1503 twice a day (BID);
- 5% BTX 1503 once a day (QD);
- 2.5% BTX 1503 once a day (QD);
- Vehicle once a day (QD); and
- Vehicle twice a day (BID).

11 sites participated in Australia and 25 sites in the US. In this 12 week, double blind study patients were randomly allocated to each group.

Throughout the course of this analysis we refer to the combined vehicle group – which refers to the cumulative response rate of the once a day and twice a day vehicle groups.

The primary end point was absolute change (by number) from Baseline to week 12 inflammatory lesion count. Safety was also a primary end point[1].

- Secondary endpoints were absolute change from Baseline to week 12 in non-inflammatory lesions;
- Percentage change in non inflammatory lesions at week 12; and
- Proportion of patients with clear/almost clear and grade 2 reductions from baseline Investigators Global Assessment (IGA) of acne severity at week 12.

[1] Adverse events, tolerability

## Key results in more detail

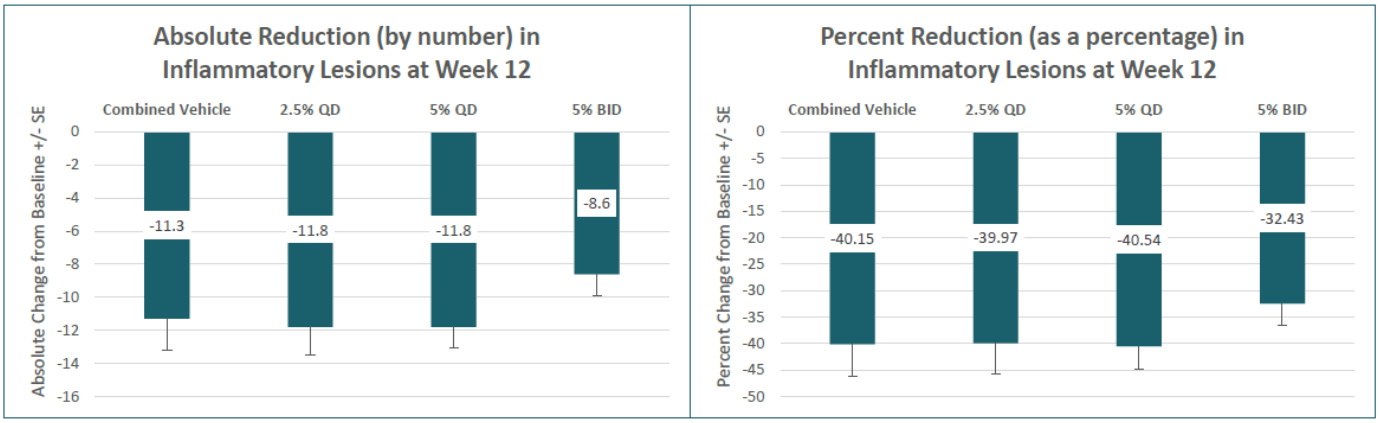
### EFFICACY

For the purposes of brevity, our analysis is limited to the discussion of the efficacy data from the 5% once a day (QD) treatment cohort.

For the primary endpoint – inflammatory lesion count:

- 5% QD reduced the number of lesions by 11.8 relative to the control of 11.3 (figure 1 – chart on the LHS);
- The result did not achieve statistical significance; but
- Efficacy (5% QD) was in line with leading topical acne products.

**Figure 1 - Primary endpoint summary**



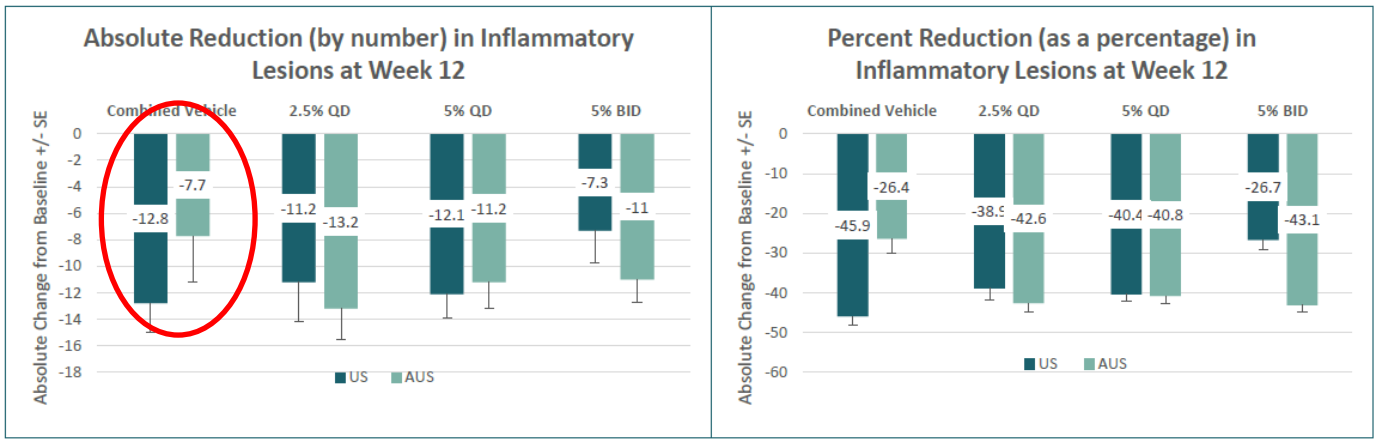

SOURCE: COMPANY DATA

In the chart on the RHS, there was practically no difference between the active drug result and the combined vehicle response.

Normally this result would be enough to terminate a clinical program, however, in this case further analysis was warranted for the reason that the vehicle response rate was far higher than had been expected.

The sub groups of Australia and the US trial sites were examined in more detail with the following results.

**Figure 2 - Inflammatory lesions - Australia and US Sub Groups**



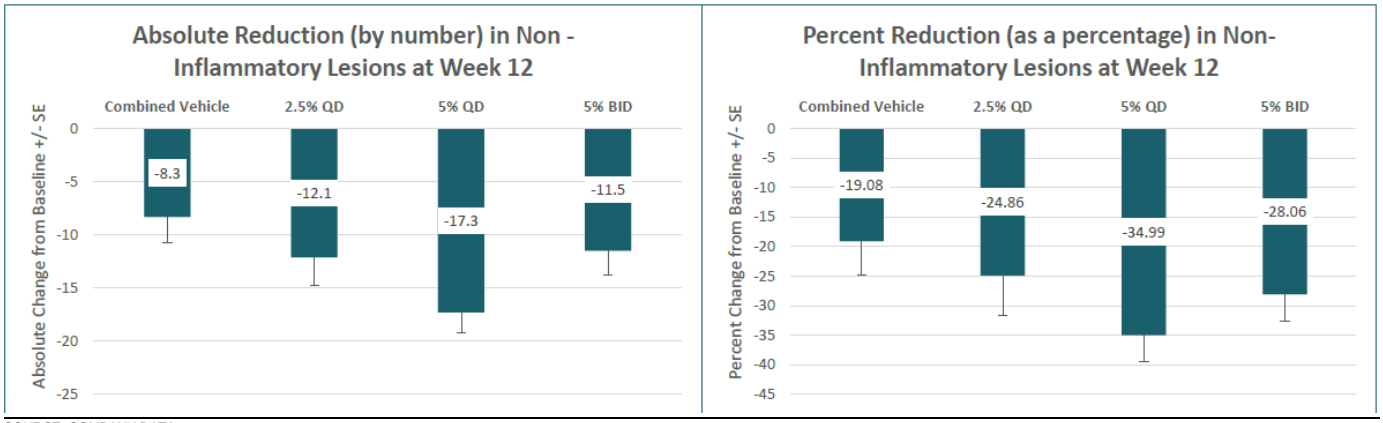

SOURCE: COMPANY DATA

In the chart on the LHS, in the 5% QD cohort, the US and Australia recorded absolute reductions of 12.1 and 11.2 lesions respectively. However, the combined vehicle response showed a significant difference with the vehicle response in Australia at 7.7 lesions being well below the 11.2 lesions in the active group. This result is clinically significant.

In contrast the vehicle response in the US group (12.8) actually exceeded the result from the active group (12.1). Based on this result, it was fairly obvious to the investigators that there was a problem with the vehicle group in the US.

This conclusion was supported by the outcomes in the secondary endpoints which we summarise as follows.

**Figure 3 - Combined non inflammatory lesion response**



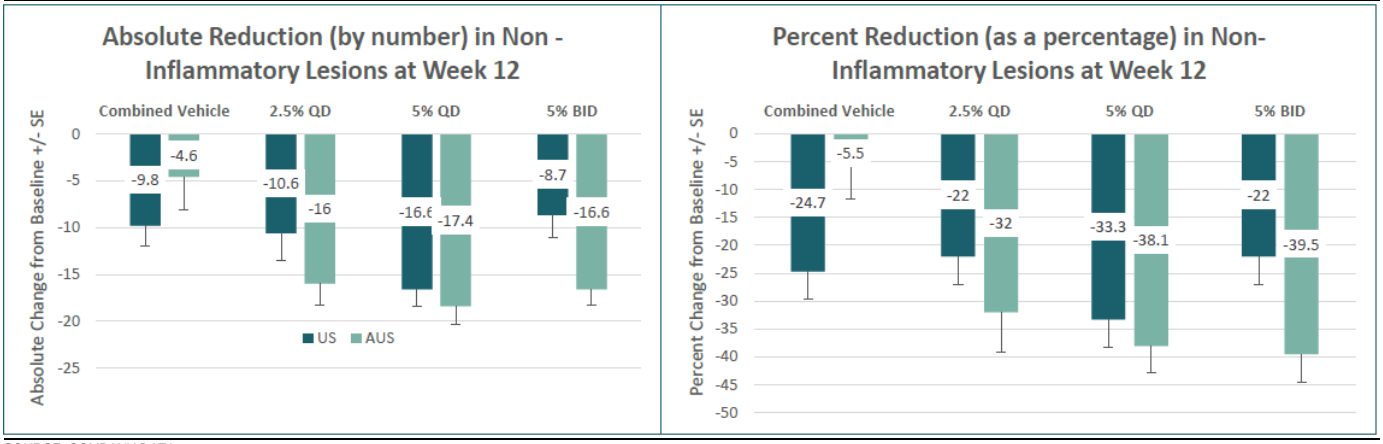

SOURCE: COMPANY DATA

The response in non-inflammatory lesions was the secondary endpoint.

All BTX1503 dose groups in both Australia and the US reduced the number of non-inflammatory lesions with 5% QD showing a 35% reduction vs vehicle 19%. This result was highly statistically significant (p=0.0007).

Within the sub groups the vehicle response in the US was greater than 4x higher than seen in the Australian sites.

**Figure 4 - Secondary endpoints - non inflammatory lesions**




SOURCE: COMPANY DATA

In the chart on the RHS, note the combined vehicle response rate of 5.5% reduction in non-inflammatory lesions at the Australian sites vs 24.7% reduction in the US sites. In the active arm, the 5% QD cohort achieved 33.3% and 38.1% reductions in non-inflammatory lesions in the US and Australia respectively.

In the Australian sites the 38.1% reduction in lesions vs the 5.5% reduction in the control group was key data to support the company's view that the phase 3 approval study should continue. This outcome is clearly not due to chance. The percentage changes in non-inflammatory lesions reported here is supported by the absolute reduction in lesions shown on the LHS.

The 11 sites in Australia recruited a total of 118 patients across all 5 cohorts.

## High Vehicle Response in the US Trial Sites

The rate of response in the combined vehicle group was the factor which led to this clinical trial not achieving statistical significance in the primary endpoint.

The vehicle in this case was a formulation of permetrex that excluded the active synthetic CBD, nevertheless it had a remarkable impact on patient acne in the US trial sites. Some part of the formulation clearly has an anti inflammatory or antimicrobial effect.

The analysis provided by BOT states that there were 11 different batches of product used to compete this study across both the active and the vehicle. This was necessary due to a confluence of factors including the following:

- DEA regulations in the US prevented the import of the drug substance into the US. Accordingly different batches of active drug were used across clinical sites in each country; and
- The contract manufacturers responsible for manufacturing CBD products for Botanix in the US did not have prior experience in the manufacture of the product in addition to lacking the facilities and equipment to manufacture commercial quantities. Differences in manufacturing conditions and equipment are thought to have led to inconsistencies in the active product and the vehicle between the various clinical trial sites.

In the absence of further explanation, these factors reflect poorly on the conduct of the trial. Ideally the manufacturing of the active drug for each country should have been completed in a single batch for each dose strength. As there is no active content in the vehicle, it is not unreasonable to estimate that the entire batch could have been produced by one contract manufacturer in one or two batches, therefore ruling out inconsistencies in manufacturing.

Fortunately the data from the Australian sites for both the inflammatory lesions and non inflammatory lesions is sufficiently strong to warrant further investigation. The secondary endpoint measure reduction in inflammatory lesions (across all sites) was a highly statistically significant result (refer to figure 3).

BOT will not be repeating this trial on the basis that the results from the Australian sites and those of the US sites (as far as the active arm were concerned) were consistent with expectation.

## Atopic Dermatitis

The company is expected to report headline results from the Atopic Dermatitis trial (AD) in early 2020. This 200 patient study was recruited patients across 25 sites in Australia and the US and is also a randomised double blind study.

We note the following key points:

- There is a single cohort in each arm; and
- There are two batches for each country – one for the vehicle and one for the active.

The restrictions around the manufacture and transport of CBD in the US necessitated the production of multiple batches for this trial also. While this is not ideal, it is largely unavoidable.

Going forward, the manufacturing process has been optimised over the last year. In particular commercial supplies of synthetic cannabidiol are now available in the United States and changes to the DEA's classification of CBD have eased the restrictions around the transportation and storage of drug at clinical trial sites.

These factors should facilitate a less complicated supply route for the approval studies in Acne and AD (assuming the company decides to also take AD to an approval study).

**CONCLUSIONS**

- The drug showed strong efficacy in the reduction of both inflammatory and non-inflammatory lesion at all sites and all dose levels;
- The failure to achieve statistical significance in the primary endpoint in the overall intent to treat group was disappointing, however, the 118 patients from the Australian sites showed a clear advantage over the vehicle with an average reduction in inflammatory lesion of 11.2 vs 7.7 in the control group; and
- The reduction on non-inflammatory lesions across the ITT group was highly statistically significant.

These final two bullet points are the key drivers of the company's decision to pursue an approval study. The decision to proceed to an approval study in the absence of unequivocal data from the phase II study is not ideal. In an approval study the FDA will generally only consider the results from the entire population, therefore, there can be no repeat of manufacturing problems noted in this phase II trial.

BOT will report its September 30 4C cash flow statement in the next few days. We expect the company will report cash of $44m which should be sufficient to fund the approval study in Acne. BOT also has an extensive development pipeline for other indications.

In relation to earnings forecasts, based on this result we now consider it is unlikely the company will seek to partner the Acne indication in FY20, especially since it has announced plans to take BOT1503 through to an approval study. We have removed the upfront milestone receipt from the income statement in FY20 but have stepped up the forecast royalty on sales following an assumed launch of the Acne product. We have also increased the level of non R&D expenses to be in line with the expense levels reported in FY19. We have added an additional $20m over three years to cover the expected cost of two phase III trials required for the approval of BTX1503.

**Figure 5 - Summary of earnings changes**

| | 2020 | | | 2021 | | |
|---|---|---|---|---|---|---|
| | New | Old | % change | New | Old | % change |
| Revenues | 5.0 | 26.3 | -81% | 14.0 | 14.0 | 0% |
| EBIT | -13.6 | 15.7 | large | -6.5 | 6.7 | large |
| NPAT | -13.6 | 15.7 | large | -6.5 | 6.7 | large |
| EPS | -1.4 | 2.0 | large | -0.6 | 0.8 | large |

SOURCE: BELL POTTER SECURITIES ESTIMATES

As a result of the changes to earnings forecasts and the dilution from the recent $40m capital raise, the valuation is reduced from $0.33 to $0.25.

# Botanix Pharmaceuticals

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).

**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

**Clinical Risk:** BTX1503, BTX1204 and BTX1308 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 the other indications.

**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.

**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.

# Botanix Pharmaceuticals
as at 24 October 2019

| | |
|---|---|
| Recommendation | Buy, Speculative |
| Price | $0.125 |
| Valuation | $0.25 |

## Table 1 - Financial summary

| Profit & Loss (A$m) | FY18 | FY19 | FY20e | FY21e | FY22e |
|---|---|---|---|---|---|
| **Year Ending June** | | | | | |
| BTX1503 - Acne | - | - | - | - | 26.7 |
| BTX1204 - AD | - | - | - | 12.0 | 4.0 |
| BTX1308 - Psoriasis | - | - | - | - | 5.3 |
| R&D incentive | 1.8 | 4.6 | 5.0 | 2.0 | - |
| **Total Revenue** | 1.8 | 4.8 | 5.0 | 14.0 | 40.0 |
| **COGS** | - | - | - | - | - |
| **Gross profit** | 1.8 | 4.8 | 5.0 | 14.0 | 40.0 |
| **GP margin** | 100% | 100% | 100% | 100% | 100% |
| | | | | | |
| **Expenses Net of R&D** | 1.9 | 5.2 | 5.3 | 5.5 | 5.7 |
| **Total Clinical R&D Expense** | 11.0 | 16.6 | 13.3 | 15.0 | 5.0 |
| **Total Expenses** | 12.9 | 21.8 | 18.6 | 20.5 | 10.7 |
| **EBITDA** | (11.1) | (17.0) | (13.6) | (6.5) | 29.3 |
| Depreciation | - | - | - | - | - |
| Amortisation | - | - | - | - | - |
| **EBIT** | -11.1 | -17.0 | -13.6 | -6.5 | 29.3 |
| Interest expense | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Pre tax profit | (11.0) | (17.0) | (13.6) | (6.5) | 29.3 |
| Tax expense | - | - | - | - | - |
| **NPAT- normalised** | (11.0) | (17.0) | (13.6) | (6.5) | 29.3 |
| **Reported NPAT** | (11.0) | (17.0) | (13.6) | (6.5) | 29.3 |

| Cashflow (A$m) | FY18 | FY19 | FY20e | FY21e | FY22e |
|---|---|---|---|---|---|
| Gross cashflow | -10.1 | -13.1 | -13.6 | -7.3 | 27.1 |
| Net interest | 0.1 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Operating cash flow** | -9.9 | -13.1 | -13.6 | -7.3 | 27.1 |
| Proceeds from asset sales | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Free cash flow** | -9.9 | -13.1 | -13.6 | -7.3 | 27.1 |
| Business acquistions | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Proceeds from issuance | 21.6 | 0.6 | 40.0 | 0.0 | 0.0 |
| Movement in borrow ings | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Change in cash held** | 11.6 | -12.5 | 26.4 | -7.3 | 27.1 |
| Cash at beginning of period | 5.7 | 17.3 | 4.8 | 31.2 | 24.0 |
| FX adjustment | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Cash at year end** | **17.3** | **4.8** | **31.2** | **24.0** | **51.1** |

| Balance Sheet (A$m) | FY18 | FY19 | FY20e | FY21e | FY22e |
|---|---|---|---|---|---|
| Cash | 17.3 | 4.8 | 31.2 | 24.0 | 51.1 |
| Receivables | 0.4 | 0.5 | 0.4 | 1.2 | 3.3 |
| Short term investments | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other current assets | - | - | - | - | - |
| Property, Plant and Equipment | - | - | - | - | - |
| Intangible assets | - | - | - | - | - |
| **Total assets** | 17.7 | 5.3 | 31.7 | 25.1 | 54.5 |
| Trade payables | 1.4 | 4.5 | 4.5 | 4.5 | 4.5 |
| Debt | - | - | - | - | - |
| Other provisions | - | 0.1 | 0.1 | 0.1 | 0.1 |
| **Total Liabilities** | 1.4 | 4.6 | 4.6 | 4.6 | 4.6 |
| **Net Assets** | 16.3 | 0.7 | 27.1 | 20.6 | 49.9 |
| Share capital | 33.3 | 33.9 | 73.9 | 73.9 | 73.9 |
| Retained earnings | (17.5) | (34.5) | (48.1) | (54.6) | (25.3) |
| Reserves | 0.4 | 1.3 | 1.3 | 1.3 | 1.3 |
| **Shareholders Equity** | 16.3 | 0.7 | 27.0 | 20.5 | 49.8 |

| Valuation Ratios (A$m) | FY18 | FY19 | FY20e | FY21e | FY22e |
|---|---|---|---|---|---|
| Reported EPS (cps) | -2.3 | -2.2 | -1.4 | -0.6 | 2.9 |
| Normalised EPS (cps) | -2.3 | -2.2 | -1.4 | -0.6 | 2.9 |
| EPS grow th (%) | -108% | 1% | nm | nm | nm |
| | | | | | |
| **PE(x)** | **nm** | **nm** | **nm** | **nm** | **4.3** |
| **EV/EBITDA (x)** | nm | -4.5 | -5.6 | -11.8 | 2.6 |
| **EV/EBIT (x)** | nm | -4.5 | -5.6 | -11.8 | 2.6 |
| | | | | | |
| P/NTA (x) | 5.8 | 145.5 | 4.5 | 5.9 | 2.4 |
| Book Value Per Share (cps) | 2.1 | 0.1 | 2.8 | 2.1 | 5.2 |
| Price/Book (x) | 5.8 | 145.5 | 4.5 | 5.9 | 2.4 |
| | | | | | |
| 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 | -6% | 23% |
| | | | | | |
| 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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