Phone: (+61 8) 9288 3388
Fax: (+61 8) 9321 6997
Email: broker@stateone.com.au

Level 14, State One House
172 St George's Terrace
Perth WA 6000

STATE ONE STOCKBROKING LTD
Participant of the ASX Group
AFSL 247100 ABN 95 092 989 083

# INITIATING COVERAGE — 6 December 2006

## Biota Holdings Ltd (BTA) – Speculative Buy

Price: $1.46
12 Mth Target: $1.85

### Investment Data:

| | |
|---|---|
| Share Price | $1.46 |
| Ord Shares | 179.3m |
| Market Capitalisation | $263m |
| Avg daily volume (6 mth) | 400k |
| 52 week Low/High | $1.13/ $2.00 |
| Net Cash (Sep 2006) | $42m |

### Major Shareholders:

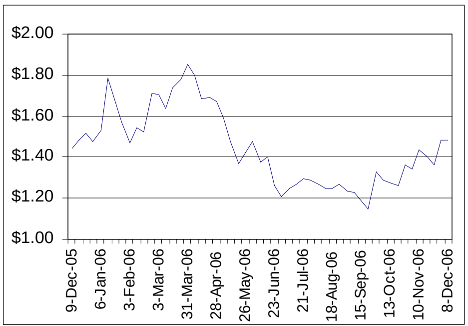
| | |
|---|---|
| Niako Investments | 7.7% |
| FMR Corp & Fidelity | 6.1% |

**Per share data**

| YE Jun | 2005 | 2006 | 2007F | 2008F |
|---|---|---|---|---|
| Book Value ($) | 0.19 | 0.26 | 0.30 | 0.37 |
| Cash Flow ($) | -0.11 | -0.04 | 0.06 | 0.09 |
| Earnings ($) | -0.12 | -0.07 | 0.04 | 0.07 |
| Dividend ($) | 0.00 | 0.00 | 0.00 | 0.00 |
| PER (x) | n/a | n/a | 37.4 | 19.7 |
| P/CF (x) | n/a | n/a | 24.7 | 15.9 |
| P/BV (x) | 7.6 | 5.6 | 4.9 | 3.9 |
| EV/EBITDA (x) | n/a | n/a | 48.6 | 23.0 |
| Div yield (%) | n/a | n/a | n/a | n/a |
| ROE (%) | n/a | n/a | 14.2% | 22.2% |

| YE Jun | 2005 | 2006 | 2007F | 2008F |
|---|---|---|---|---|
| Revenue | 5.05 | 14.97 | 38.68 | 49.00 |
| EBITDA | -15.34 | -12.31 | 5.48 | 11.60 |
| Net Profit | -15.06 | -11.31 | 7.15 | 13.48 |

### BTA – Share Price Graph




**Summary of Key Products**

(1) Relenza - generating income;
(2) Hepatitis C Virus - US$102m development/ licensing deal;
(3) RSV/Bronchiolitis - US$112m development/ licensing deal;
(4) LANI/ 2nd generation flu antivirals – early clinical stage; and
(5) HRV compounds for common cold complications - early clinical stage with Phase 1 dosing completed.

### "Rapidly rising" Relenza royalties boost outlook

- Biota specializes in respiratory diseases, particularly influenza.
- Biota is entering into a new phase in its corporate life, with a projected profit turnaround and positive cashflow in FY07, mostly on the back of rapidly rising royalty payments for its anti-influenza drug, marketed by GlaxoSmithKline (GSK) as Relenza.
- Not only is the stockpiling by governments boosting sales of Relenza, but Biota is also benefiting from major multi-million dollar licensing deals for two if its other products. These have boosted the company's profile as a biotech firm with valuable expertise, with the promise of significant further royalties if the other products are eventually commercialised.
- Since the announcement of the latest US$102m deal on 27 Nov, the stock price has jumped 7% to $1.46.
- In FY06, Biota lost $11.3m, down slightly from a loss of $15.1m in the previous year. It recorded a small loss of $0.8m in 1Q07. We expect Biota to be profitable in 1H07 with the surge in Relenza royalties. With its high growth stock status and turnaround story, attention is now turning to FY08 and beyond.
- For FY08, a key price catalyst would be the outcome of Biota's litigation against GSK for "failure to use best endeavors in the development and marketing of Relenza". The drug was licensed to GSK in 1990 and launched in 1999. Biota is claiming A$308m to A$430m from GSK and will submit an amended statement of claim in Mar 2007. The trial is set for 1 April 2008. Since FY04, Biota has expensed a total of $9m in litigation costs. As there are no counter-claims from GSK, the worst case scenario would be for Biota to lose the case and be required to pay GSK's legal expenses.
- As at 30 Sep 2006, debt-free Biota has $42m cash. $31m of the cash was raised in Nov 2005 from a" very successful" Share Purchase Plan involving 40.9m new shares at $0.76 apiece. The exercise was mainly a defensive move to provide funds for its GSK litigation.
- We estimate Biota will record a net profit of $7.2m in FY07, with a near-doubling to $13.5m in FY08. Contribution should come mainly from the surge in Relenza royalties to $23m and $28m respectively, assuming a progressive doubling of GSK's production capacity to 30m courses by Dec 2008. (Large government orders may well spur GSK to treble its capacity.) Combined revenues from other product segments and interest income should jump 60% to $15.3m in FY07 and 34% to $20.5m the following year. On the cost side, a major assumption is that the annual GSK litigation bill will amount to $6.5m for both years. The 90% spike in fully diluted EPS from 3.9¢ to 7.4¢ would bring FY08 PER down to a moderate 19.8x, compared with higher multiples that are typical for profitable healthcare-related stocks.
- We recommend BTA as a **Speculative Buy,** with a 12-month target price of $1.85, based on an FY08 PE multiple of 25x.

## RELENZA

**Booked In $5.3m Relenza Royalties In 1QFY07**

In FY6/06, Biota's revenues jumped three-fold to $15m, including $5.2m in royalties for Relenza from GSK, compared with only $0.5m royalties a year ago. MedImmune-related income of $5.1m was the second largest contributor, followed by interest income of $2.3m. Biota's flu diagnostic products (FLU OIA) contributed $1.2m, down 20%. In 1QFY07, Biota has recognised $5.3m in royalties from Relenza (ie more than the full year FY06).

**Main Cash Focus On Potential Payout From GSK Settlement**

GSK pays the royalties on Jun 30 each year for sales of Relenza recorded in the 12 months to April 30. The outstanding royalties due for the months of May and June 2006 were the main reason trade receivables surged to $5.1m as at 30 Jun 2006 from a mere $34,000 a year ago. Receipts from Relenza royalties should help to boost Biota's cash position to $55m by end-FY07 but the main cash focus would be on the size of the potential payout from GSK if Biota succeeds in its claim.

**Huge Pandemic Market With Stockpiling Of Relenza By Governments**

Relenza is one of the two antiviral drugs that the World Health Organisation recommends to countries for stockpiling - the other is Tamiflu. Biota estimates the global antiviral pandemic market could grow to $3.2b by 2008, with the US federal stockpile accounting for half of it. In June this year, the US Department of Health & Human Services announced its intention to have Relenza make up 20% of its stockpile, or 16.2m treatment courses, by the end of 2008. At US$21.72 per course and a net royalty rate of 6% (gross rate: 7%) , the US$350m sales value could generate potential royalties of about US$21m. Orders from the US commenced in July this year. Relenza has a 5-year shelf life, which means that the replacement of stockpiles on a five-year cycle further enhances Biota's earnings quality. However, the royalties will cease in mid-2014 when Biota's patents expire.

A key development leading to the higher Relenza stockpile by the US government was the approval given by its Food and Drug Administration, in March this year, for the use of Relenza in prophylaxis, or prevention, of flu infection in addition to just flu treatment. This approval removed a major disadvantage facing Relenza relative to Tamiflu.

The announcement in May this year by the Canadian government to order 5.5m courses of Relenza to make up 10% of its antiviral stockpile, again underscores the potential royalty bonanza for Biota. Biota expects the sales will generate royalties "in excess of A$9m", based on a price of about A$25 per course. Our earnings forecasts is based on the A$25 selling price; any changes would significantly affect Biota's earnings. We estimate a 5% fall in price to $23.75 would lower full-year net profit by 14% to $6.1m for FY07 and by 10% to $12.1m for FY08.

**Main Differences Between Relenza And Tamiflu**

There are two major differences between Relenza and Tamiflu:

(a) Relenza is effective against some Tamiflu-resistant strains, as cited by the US Department of Health and Human Services (US DHHS). Given the early proven efficacy of Tamiflu, the US DHHS has indicated that Tamiflu "should be the primary drug stockpiled". Biota however believes Relenza is less likely to develop resistance than Tamiflu and has said "We are seeing increasing evidence of this."

(b) Relenza is inhaled, unlike Tamiflu which is taken orally. Biota says this direct delivery to the lung (where the virus replicates) allows for high concentrations at the site of action and limits the risk of systemic side effects.

**Potential US$1b Seasonal Market**

On top of the pandemic market, the seasonal market (both retail and for seasonal government stockpile) is also a potentially large segment. Supply restriction means there is currently no retail supply but, according to pharmaceutical and healthcare consultancy firm IMS, the market size is in excess of US$1b.

**GSK's Capacity Expansion To Boost Royalties For Biota**

Sales of Relenza have been limited by GSK's production capacity constraints. The annual capacity should rise from 12m treatment courses currently, to 15m by end-Dec 2006, with further expansion in 2007. GSK has announced that it may subsequently "double or treble" production. The incentive to do so must be high in view of large government orders in the pipeline.

Based on an average production volume of 6m courses in the Jul-Dec 2006 period and full-production capacity of 8.25m in the Jan-Jun 2007 period, we estimate the total Relenza volume for FY07 will be 14.25m, increasing to 19.00m in FY08.

## HEPATITIS C VIRUS

**US$102m Licensing Deal With Boehringer On Hepatitis C Virus**

Under the deal announced on 27 November, Biota stands to receive up to US$102m from a global research collaboration and licensing agreement with the German firm Boehringer Ingelheim (BI) to treat Hepatitis C Virus (HCV) infections. Biota is to be responsible for drug discovery research whereas BI is to be responsible for worldwide development of potential compounds and their commercialisation. According to Biota, fast growing BI has the financial capacity to support late-stage trials in Hepatitis C, which are "particularly difficult and expensive." Biota's CEO said it may take 4-6 years before a licensing deal starts to generate royalties.

Biota's CEO said the size of the HCV deal, in addition to its US$112m deal last year with MedImmune - for Respiratory Syncytial Virus (RSV) compounds – and the fact that Biota's HCV compounds are "appreciably earlier in the drug discovery process", reflects the "strong global interest in HCV programs by big pharma and the potential market for any likely product".

Biota's capex for FY07 will only be around $1m to $2m, depending on whether it decides to expand its laboratory following the announcement of the HCV deal.

## RESPIRATORY SYNCYTIAL VIRUS (BRONCHIOLITIS)

**Potential $5m Cash Inflow From MedImmune Milestone By Early FY08**

Under Biota's US$112m licensing deal with MedImmune to develop and commercialise Biota's RSV compounds to treat bronchiolitis, Biota expects to commence Phase 1 around the middle of next year. Achievement of certain technical milestones at this pre-clinical stage could bring in revenue of about $5m in the early part of FY08. Subsequent milestones would likely spell higher payouts. RSV is the most common respiratory infection in infancy or childhood. Nasdaq-listed MedImmune dominates the US$1b RSV market in the US with its Synagis drug, which is administered by injection. Both Biota and MedImmune are therefore keen to exploit the wider market potential for Biota's compounds which are orally administered.

## SECOND GENERATION FLU ANTIVIRALS

**Promising 2nd Generation Anti-Flu Compounds, LANI**

Biota is making progress on its second generation flu antivirals, or long-acting neuraminidase inhibitors (LANI), which are targeted at the pandemic stockpiling market. The two compounds – FLUNET and CS8958 - use different active ingredients compared with Relenza and, according to management, both could be 1,000 times more potent than Relenza. The CS8958 program has completed its Phase 1 study and targets a launch date between 2010 and 2012. In August 2005, Biota won a US$8.5m grant from US National Institutes of Health (NIH) for FLUNET. It had earlier secured a US$5.6m grant for CS8958 in 2004. The winning of such grants from NIH, amid stiff competition, again speaks highly of Biota's capabilities. Biota co-owns the LANI program (on an "approximately 50:50" basis), with Sankyo Co, Ltd (Japan), which will fund the second phase of its development. Biota expects the US$8.5m grant will be expended at a rate of about US$2m per year.

## HRV COMPOUNDS FOR COMMON COLD COMPLICATIONS

**Results From Phase 1 Trials Expected By Mar 2007**

Biota's Human Rhinovirus (HRV) project deals with compounds for treatment of complications arising from common cold for high-risk patients, such as those with chronic respiratory disease or asthma. Management has indicated that its compound could be 10 times more potent than a competing product now being developed. It has completed Phase 1 dosing, at the early clinical stage. Management expects to report on the results by March 2007.

**Does Not Capitalise Expenses, For Now**

According to Biota's accounting policy, it does not capitalize its clinical expenses but may do so for expenditure before the start of commercial production or use "if the product or service is technically and commercially feasible and adequate resources are available to complete development." Should any of Biota's projects reach such a stage, not only will it benefit from the commercial potential but also from the capitalisation of such expenses, which could be significant given its high R&D expenses, which amounted to $7.7m in FY06.

## BALANCE SHEET

**Negative $111m Revenue Reserves A Barrier To Dividends But $57m Tax Loss A "Hidden Asset"**

Reflecting Biota's improvement on the earnings and cashflow fronts, its balance sheet should also be strengthening. We estimate shareholders' funds will grow 15% to $54m (30.1 cps) by Jun 2007 and another 25% to $67m (37.4 cps) a year later, on the back of rising Relenza royalties and income from its development/ licensing deals, coupled with the fact that part of its product research and development costs will be borne by its licensing partners.

Nevertheless, Biota's negative revenue reserves - which stand at $111m as at 30 Jun 2006 - means that no dividends should be expected over the next few years. On the other hand, we do not expect Biota to undertake any more capital raising exercises in the near future, following the $31m raised in Nov 2005 and an earlier $19.8m collected in Nov 2004.

On the other hand, in the event that Biota succeeds in its claim of up to A$430m ($2.40 per share) against GSK, there could be potential for either a sizeable capital return, that can capitalize on the $57m tax loss on Biota's books, or an acquisition.

## MANAGEMENT

**Revamped 6-Member Board**

Biota's board had undergone a major changeover over the past year with two departures and three additions. Its CEO and Managing Director, Peter Cook, 59, was appointed to his post just about a year ago in Dec 2005. Prior to that, he held a similar post at Perth-based Orbital Corporation Ltd., which develops engine and related technologies. Cook had also been the CEO of Faulding Pharmaceuticals and President of Ansell Protective Products Division.

Grant Latta, who joined the board in Feb this year, was a former Chairman on the Grains Research and Development Corporation and Deputy Chairman of Food Science Australia. Paul Bell, a former President of Merck & Co's Asia Pacific Region, was recently elected at Biota's AGM in October.

The board is chaired by John Grant, who has extensive experience in the venture capital, investment banking, management consultancy and public accounting sectors. The other two board members are Barbara Gibson, formerly General Manager of the Chemicals Group of Orica Ltd. and Professor Ian Gust, a consultant to the Bill and Melinda Gates Foundation, UNICEF, the World Bank and WHO. Professor Gust was the former Director of Research and Development at CSL Ltd.

## DISPERSED SHAREHOLDING

**Stock Accumulation By Largest Shareholder**

Biota's shareholders base is widely dispersed. Niako Investments, the single largest shareholder, has been picking up shares in the open market, raising its stake to 7.7% as at 9 November 2006 from 5.3% in August. Niako is controlled by Nick Mitris and Nick Balagiannis, former owners of Olympic Video Gaming company. Fidelity holds the second largest stake, with 6.1%.

**PROFIT & LOSS**

| YE Jun ($m) | 2005 | 2006 | 2007F | 2008F |
|---|---|---|---|---|
| Relenza Revenue | 0.53 | 5.19 | 23.38 | 28.50 |
| Others Revenue | 4.52 | 9.78 | 15.30 | 20.50 |
| **Total Revenue** | **5.05** | **14.97** | **38.68** | **49.00** |
| | | | | |
| EBITDA | (15.34) | (12.31) | 5.48 | 11.60 |
| Depreciation | (0.87) | (0.99) | (1.10) | (1.30) |
| EBIT | (16.21) | (13.29) | 4.38 | 10.30 |
| Net interest inc | 1.29 | 2.26 | 3.00 | 3.60 |
| Pretax profit/(loss) | (14.92) | (11.04) | 7.38 | 13.90 |
| Tax | - | - | (0.22) | (0.42) |
| Minorities | - | - | - | - |
| Adj net profit | (14.92) | (11.04) | 7.15 | 13.48 |
| Abnormals | (0.14) | (0.27) | - | - |
| **Reported net profit** | **(15.06)** | **(11.31)** | **7.15** | **13.48** |

**BALANCE SHEET**

| YE Jun ($m) | 2005 | 2006 | 2007F | 2008F |
|---|---|---|---|---|
| Property, plant & equip | 4.70 | 5.51 | 6.41 | 7.11 |
| | | | | |
| **Current Assets:** | | | | |
| Cash | 24.75 | 46.18 | 53.91 | 67.63 |
| Trade receivables | 0.03 | 5.11 | 6.50 | 6.50 |
| Others | 0.94 | 0.75 | 1.00 | 1.20 |
| Total | 25.73 | 52.05 | 61.41 | 75.33 |
| | | | | |
| **Current Liabilities:** | | | | |
| Payables | 3.17 | 4.03 | 5.50 | 6.50 |
| Deferred revenue | - | 6.01 | 7.26 | 4.51 |
| Borrowings | 0.37 | - | - | - |
| Provisions | 0.56 | 0.52 | 0.60 | 0.70 |
| Total | 4.09 | 10.56 | 13.36 | 11.71 |
| | | | | |
| **Non-Current Liabilities:** | | | | |
| Borrowings | 0.26 | 0.00 | 0.00 | 0.00 |
| Provisions | 0.04 | 0.10 | 0.15 | 0.20 |
| Total | 0.30 | 0.10 | 0.15 | 0.20 |
| | | | | |
| **Shareholders' Funds:** | | | | |
| Contributed equity | 125.95 | 157.97 | 157.97 | 157.97 |
| Reserves | (0.29) | (0.12) | (0.12) | (0.29) |
| Accumulated losses | (99.63) | (110.95) | (103.80) | (90.32) |
| Total | 26.04 | 46.90 | 54.05 | 67.37 |

**CASHFLOW**

| YE Jun ($m) | 2005 | 2006 | 2007F | 2008F |
|---|---|---|---|---|
| **Receipts** | | | | |
| Relenza | 0.53 | 5.19 | 23.38 | 28.50 |
| Others | 3.11 | 8.51 | 9.38 | 12.70 |
| Total | 3.64 | 13.70 | 32.75 | 41.20 |
| Net interest received | 1.26 | 2.11 | 3.00 | 3.60 |
| Payments | (17.89) | (23.49) | (25.04) | (28.08) |
| **Net cash from operation** | **(12.99)** | **(7.68)** | **10.71** | **16.72** |
| | | | | |
| **EBIT** | (16.35) | (13.56) | 4.38 | 10.30 |
| Add: | | | | |
| Depreciation | 0.87 | 0.99 | 1.10 | 1.30 |
| Other non-cash items | 0.83 | 0.25 | - | - |
| Chg in working cap | 0.40 | 2.54 | 2.24 | 1.52 |
| Net interest received | 1.26 | 2.11 | 3.00 | 3.60 |
| Net cash from operation | (12.99) | (7.68) | 10.71 | 16.72 |
| | | | | |
| Capex | 4.32 | (1.99) | (2.00) | (2.00) |
| Share issue | 19.77 | 31.84 | - | - |
| Sale of fixed assets | 0.13 | 0.06 | - | - |
| Loan repayment | (0.53) | (0.79) | - | - |
| Others | (8.65) | (0.02) | | |
| Dividends | - | - | - | - |
| | | | | |
| Net cashflow | 2.06 | 21.43 | 8.71 | 14.72 |
| Beginning cash | 22.70 | 24.75 | 46.19 | 54.90 |
| Cash carried fwd | 24.75 | 46.19 | 54.90 | 69.62 |

Francis Tan
Senior Equities Analyst

Phone: (02) 9024 9112
E-mail: ftan@stateone.com.au

STATE ONE STOCKBROKING LTD
Participant of the ASX Group
AFSL 247100 ABN 95 092 989 083

## Authorised Representatives


Alan Hill
Managing Director
Phone: +61 8 9288 3388
ahill@stateone.com.au

Ryan Davis
Equities & Derivatives Advisor
Phone: +61 2 9024 9106
rdavis@stateone.com.au

Brendan Fogarty
Equities & Derivatives Advisor
Phone: +61 8 9288 3304
bfogarty@stateone.com.au

Jason Fung
Equities Advisor
Phone: +61 8 9288 3328
jfung@stateone.com.au

Geoff Hart
Dealers Assistant
Phone: +61 8 9288 3313
ghart@stateone.com.au

John Haddad
Senior Industrial analyst
Phone: +61 2 9024 9121
jhaddad@stateone.com.au

Graeme Johnson
Equities Advisor
Phone: +61 8 9288 3316
gjohnson@stateone.com.au

Eugene Loy
Equities & Derivatives Advisor
Phone: +61 2 9024 9109
eloy@stateone.com.au

Tim Shrimpton
Equities & Derivatives Advisor
Phone: +61 2 9024 9107
tshrimpton@stateone.com.au

George de san Miguel
Equities Advisor
Phone: +61 8 9288 3334
gmiguel@stateone.com.au

Xuan Khoa Pham
Equities & Derivatives Advisor
Phone: +61 2 9024 9110
xpham@stateone.com.au

Matthew Racovalis
Equities Advisor
Phone: +61 8 9288 3307
mracovalis@stateone.com.au

Kenny Siew
Executive Director
Phone: +61 8 9288 3318
ksiew@stateone.com.au

Francis Tan
Senior Equities Analyst
Phone: +61 2 9024 9112
ftan@stateone.com.au

Charles Thomas
Equities & Derivatives Advisor
Phone: +61 8 9288 3308
cthomas@stateone.com.au

Brett Walker
Equities Advisor
Phone: +61 8 9288 3337
bwalker@stateone.com.au

Peter Wong
Equities Advisor
Phone: +61 8 9288 3318
pwong@stateone.com.au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