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# Biota Holdings Limited (BTA)

Outperform

LANI (CS-8958) Phase 3 Influenza Trial Delivers; RSV License Terminated

\$2.17

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## Key Points

Daiichi Sankyo has announced the results of its multinational Phase 3 MARVEL study of CS-8958 (LANI) in treating seasonal influenza.

The trial met its primary endpoint of "non-inferiority" to Tamiflu in both adults and children using both a 20mg and 40mg single inhaled dose.

Daiichi re-iterated an intention to file for approval of LANI in treating influenza by March 2010, with Biota retaining an est. <5% royalty on Japanese sales.

Biota also announced that AstraZeneca (AZ) has terminated the license agreement over its respiratory syncytial virus (RSV) program.

## Summary

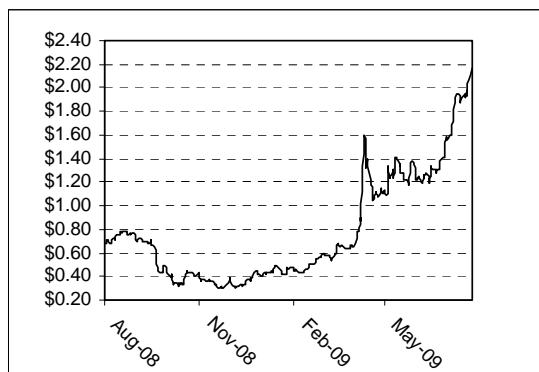
|  |                |
|--|----------------|
| <b>Market Capitalisation (M)</b>           | <b>\$360.4</b> |
| <b>Share Price</b>                         | <b>\$2.17</b>  |
| Shares on Issue (M)                        | 174.9          |
| Av. Monthly Volume (Yr Rolling)(M)         | 14.4           |
| 52 Week High                               | \$2.25         |
| 52 Week Low                                | \$0.29         |
| <b>Valuation Per Share (fully diluted)</b> | <b>\$2.66</b>  |
| <b>Cash (M) as at 31/12/08</b>             | <b>\$55.4</b>  |

## Key Financials (A\$'000)

| Year End             | FY08<br>Actual | FY09<br>Est.  | FY10<br>Est.   |
|----------------------|----------------|---------------|----------------|
| Relenza Royalties    | 20,544         | 45,019        | 134,503        |
| Partnering Income*   | 5,871          | 4,069         | 7,467          |
| <b>Total Revenue</b> | <b>44,989</b>  | <b>64,224</b> | <b>147,124</b> |
| Total Op. Expenses   | (41,397)       | (20,868)      | (12,163)       |
| R&D Expenses         | (10,287)       | (13,621)      | (12,774)       |
| <b>EBITDA</b>        | <b>(9,897)</b> | <b>39,626</b> | <b>118,742</b> |
| Normalised NPAT      | 10,735         | 17,291        | 88,243         |
| <b>Adj. NPAT</b>     | <b>(6,489)</b> | <b>31,870</b> | <b>88,243</b>  |
| Adj. EPS (c)         | (3.5)          | 18.3          | 50.4           |
| Adj. PE Ratio (x)    | n/a            | 11.9          | 4.3            |

\* Upfront/Milestones only (ex-R&amp;D income)

## Share Price Graph (A\$)



## Our View

- Daiichi also indicated it will conduct a Phase 3 prophylaxis study for LANI in late CY09, which would both broaden the label claim, but also drive government stockpiling, in our view. As a result of Phase 3 success, we have upgraded our risk weighting to 95% for market approvals and launch of LANI in Japan. Given the resistance issues plaguing seasonal use of Tamiflu in Japan, coupled with a continued ban on teenage use by the Ministry of Health, we see Japanese seasonal sales of LANI reaching A\$200m in FY17. With the current pandemic running its course, we suspect traditionally long Japanese approval timelines will be expedited for LANI. For ROW clinical studies of LANI, the developmental history of Tamiflu/Relenza in Asian/Caucasian populations, suggests no reason why similar efficacy results cannot be replicated in late stage trials in Europe/US. We anticipate Biota/Daiichi will license the rights to LANI prior to any major efficacy studies commencing (Phase 2b) during FY10. Biota retains a 50% stake in all jurisdictions ex-Japan. We have upgraded our est. US\$105m ROW licence deal to US\$225m, given the Phase 3 data and interest in influenza globally. Our risk-adjusted valuation on LANI is \$183.5m (\$1.05 per share).
- We had anticipated US\$5.0m in milestones payments under the AZ license deal during FY10, which we have now stripped from our estimates and reduced our risk-adjusted valuation of the program from \$63.7m to \$15m. The license was terminated due to the lead Phase 1a drug BTA9881 not meeting an undisclosed safety margin to continue development. We note AZ purchased Arrow Therapeutics in 1Q CY07 for US\$150m, acquiring three RSV programs, with a single license to Novartis (worth up to US\$227m) which may have also impacted the decision to continue working with Biota. One should not discount Biota's ability to re-package and license its RSV program once again, given it successfully re-licensed its Hepatitis C (HCV) program for US\$102m in 4Q CY06 after re-acquiring the rights from GSK. The Company will spend \$3m on the program, essentially to move early stage RSV drug candidates into pre-clinical studies, prior to seeking a second license deal.
- The changes to our FY10, FY11 estimates are shown in Appendix 1. Biota currently trades on a forecast FY10 EV/EBITDA of 1.7x and a PER of 4.3x. As a result of the favourable LANI result and expectation of Japanese registration, substantially offset by a downgrade in RSV value, we have increased our price target by 2.3% to \$2.66. Despite the significant (+70%) uplift in price thus far in FY10, we maintain our Outperform recommendation on further developments in pandemic stockpiling and LANI licensing.

## Appendix 1

### Changes to Forecasts

|                          | FY09E    |         |        | FY10E    |         |        | FY11E    |         |        |
|--------------------------|----------|---------|--------|----------|---------|--------|----------|---------|--------|
|                          | Previous | Revised | Change | Previous | Revised | Change | Previous | Revised | Change |
| Relenza Volumes (m)      | 25.7     | 25.7    | 0.0%   | 76.9     | 76.9    | -0.1%  | 31.1     | 31.1    | 0.0%   |
| Relenza Royalties (A\$m) | 45.0     | 45.0    | 0.0%   | 134.5    | 134.5   | 0.0%   | 54.4     | 54.4    | 0.0%   |
| EBITDA                   | 39.6     | 39.6    | 0.0%   | 126.8    | 118.7   | -6.4%  | 42.3     | 40.8    | -3.4%  |
| Adj. NPAT                | 31.9     | 31.9    | 0.0%   | 93.9     | 88.2    | -6.0%  | 33.0     | 31.8    | -3.7%  |
| Adj. EPS (c)             | 18.3     | 18.3    | 0.0%   | 53.8     | 50.4    | -6.2%  | 18.9     | 18.2    | -3.9%  |

Source: Taylor Collison estimates

### Biota Holdings Limited - Summary of Forecasts

BTA \$2.17

#### PROFIT & LOSS SUMMARY (A\$'000)

|                              | FY08A           | FY09E         | FY10E          | FY11E         |
|------------------------------|-----------------|---------------|----------------|---------------|
| Relenza Royalties            | 20,544          | 45,019        | 134,503        | 54,417        |
| Partnering (Licence) Income  | 5,871           | 4,069         | 7,467          | 10,667        |
| Research income (inc Grants) | 15,042          | 12,171        | 1,624          | 700           |
| <b>Total Revenue</b>         | <b>44,989</b>   | <b>64,224</b> | <b>147,124</b> | <b>72,695</b> |
| <i>Growth (pcp)</i>          | -21.5%          | 42.8%         | 129.1%         | -50.6%        |
| Net Gain on GSK Settlement   | 0               | 12,736        | 0              | 0             |
| <b>Net Operating Revenue</b> | <b>3,592</b>    | <b>56,092</b> | <b>134,961</b> | <b>60,408</b> |
| R&D Expenses                 | (10,287)        | (13,621)      | (12,774)       | (13,403)      |
| <b>EBITDA</b>                | <b>(9,897)</b>  | <b>39,626</b> | <b>118,742</b> | <b>40,849</b> |
| Depreciation                 | (933)           | (1,207)       | (1,254)        | (1,616)       |
| Amortisation                 | (1,681)         | (3,827)       | (8,286)        | 0             |
| <b>EBIT</b>                  | <b>(12,511)</b> | <b>34,593</b> | <b>109,202</b> | <b>39,233</b> |
| Net Interest                 | 3,202           | 2,845         | 3,445          | 6,157         |
| <b>Pre-Tax Profit</b>        | <b>(9,309)</b>  | <b>37,438</b> | <b>112,647</b> | <b>45,389</b> |
| Tax Expense                  | 2,820           | (5,568)       | (24,404)       | (13,617)      |
| Minorities                   | 0               | 0             | 0              | 0             |
| <b>NPAT Normalised *</b>     | <b>10,735</b>   | <b>17,291</b> | <b>88,243</b>  | <b>31,773</b> |
| <b>NPAT Adj.</b>             | <b>(6,489)</b>  | <b>31,870</b> | <b>88,243</b>  | <b>31,773</b> |
| <i>Growth (pcp)</i>          | n/a             | n/a           | 176.9%         | -64.0%        |
| Net Adjustments              | 0               | 0             | 0              | 0             |
| <b>Reported Profit</b>       | <b>(6,489)</b>  | <b>31,870</b> | <b>88,243</b>  | <b>31,773</b> |

#### PER SHARE DATA

| Period                  | FY08A        | FY09E       | FY10E       | FY11E       |
|-------------------------|--------------|-------------|-------------|-------------|
| <b>Adjusted EPS (c)</b> | <b>(3.5)</b> | <b>18.3</b> | <b>50.4</b> | <b>18.2</b> |
| <i>Growth (pcp)</i>     | n/a          | n/a         | 176.3%      | -64.0%      |
| <b>Reported EPS (c)</b> | <b>(3.5)</b> | <b>18.3</b> | <b>50.4</b> | <b>18.2</b> |
| <i>Growth (pcp)</i>     | n/a          | n/a         | 176.3%      | -64.0%      |
| Dividend (c)            | 0.0          | 0.0         | 0.0         | 0.0         |
| Franking                | 0%           | 0%          | 0%          | 0%          |
| Gross CF per Share (c)  | 2.6          | 19.5        | 49.7        | 28.1        |
| NTA per share (c)       | 28.0         | 50.2        | 109.0       | 127.2       |

#### VALUATION MULTIPLES

| Period                | FY08A | FY09E | FY10E | FY11E |
|-----------------------|-------|-------|-------|-------|
| Adjusted PE Ratio (x) | n/a   | 11.9  | 4.3   | 11.9  |
| PE Ratio (x)          | n/a   | 11.9  | 4.3   | 11.9  |
| Dividend Yield (%)    | n/a   | 0.0%  | 0.0%  | 0.0%  |
| EV/EBITDA (x)         | n/a   | 7.4   | 1.7   | 3.9   |
| EV/EBIT (x)           | n/a   | 8.4   | 1.9   | 4.0   |

#### CAPITAL RAISING ASSUMPTIONS

| Period             | FY08A | FY09E | FY10E | FY11E |
|--------------------|-------|-------|-------|-------|
| Shares Issued (m)  | 0.0   | 0.0   | 0.0   | 0.0   |
| Issue Price (A\$)  | 0.0   | 0.0   | 0.0   | 0.0   |
| Cash Raised (A\$m) | 0.0   | 0.0   | 0.0   | 0.0   |

#### KEY RATIOS

| Period                    | FY08A  | FY09E  | FY10E  | FY11E  |
|---------------------------|--------|--------|--------|--------|
| EBITDA/Sales Margin %     | -22.0% | 61.7%  | 80.7%  | 56.2%  |
| EBIT/Sales Margin %       | -27.8% | 53.9%  | 74.2%  | 54.0%  |
| Current ratio (x)         | 3.4    | 5.5    | 17.6   | 19.2   |
| Net Debt : Equity (%)     | -94.8% | -91.5% | -90.9% | -99.3% |
| ROE (%)                   | -9.6%  | 40.0%  | 61.6%  | 15.4%  |
| Dividend Payout Ratio (%) | n/a    | 0.0%   | 0.0%   | 0.0%   |

\*Excluding litigation expense and settlement, tax effected at 30%

#### BALANCE SHEET SUMMARY (A\$'000)

| Period                          | FY08A         | FY09E          | FY10E          | FY11E          |
|---------------------------------|---------------|----------------|----------------|----------------|
| Cash                            | 60,164        | 87,775         | 173,280        | 220,923        |
| Receivables                     | 4,270         | 16,056         | 27,954         | 13,812         |
| Inventories                     | 0             | 0              | 0              | 0              |
| Other                           | 0             | 0              | 0              | 0              |
| <b>Total Current Assets</b>     | <b>64,434</b> | <b>103,832</b> | <b>201,234</b> | <b>234,736</b> |
| Inventories                     | 0             | 0              | 0              | 0              |
| Property Plant & Equip          | 7,543         | 7,836          | 8,082          | 7,966          |
| Intangibles                     | 12,113        | 8,286          | 0              | 0              |
| Other                           | 5,168         | 1,720          | 0              | 0              |
| <b>Total Non-Current Assets</b> | <b>24,824</b> | <b>17,843</b>  | <b>8,082</b>   | <b>7,966</b>   |
| <b>TOTAL ASSETS</b>             | <b>89,258</b> | <b>121,674</b> | <b>209,316</b> | <b>242,701</b> |
| Accounts Payable                | 12,023        | 14,772         | 10,299         | 10,904         |
| Borrowings                      | 0             | 0              | 0              | 0              |
| Provisions                      | 1,122         | 1,122          | 1,122          | 1,330          |
| Other                           | 6,059         | 3,125          | 0              | 0              |
| <b>Total Current Liab</b>       | <b>19,204</b> | <b>19,019</b>  | <b>11,421</b>  | <b>12,235</b>  |
| Borrowings                      | 132           | 0              | 0              | 0              |
| Provisions                      | 6,622         | 6,752          | 7,183          | 7,982          |
| Other                           | 0             | 0              | 0              | 0              |
| <b>Total Non-Current Liab</b>   | <b>6,754</b>  | <b>6,752</b>   | <b>7,183</b>   | <b>7,982</b>   |
| <b>TOTAL LIABILITIES</b>        | <b>25,958</b> | <b>25,771</b>  | <b>18,603</b>  | <b>20,216</b>  |
| <b>TOTAL EQUITY</b>             | <b>63,300</b> | <b>95,904</b>  | <b>190,713</b> | <b>222,485</b> |

#### CASH FLOW SUMMARY (A\$'000)

| Period                      | FY08A           | FY09E         | FY10E          | FY11E         |
|-----------------------------|-----------------|---------------|----------------|---------------|
| <b>EBIT (excl Abs/Extr)</b> | <b>(12,511)</b> | <b>34,593</b> | <b>109,202</b> | <b>39,233</b> |
| Add: Depreciation           | 933             | 1,207         | 1,254          | 1,616         |
| Amortisation                | 1,681           | 3,827         | 8,286          | 0             |
| Change in Pay.              | 6,019           | 2,749         | (4,473)        | 606           |
| Less: Tax paid              | 2,820           | (5,568)       | (24,404)       | (13,617)      |
| Net Interest                | 3,202           | 2,845         | 3,445          | 6,157         |
| Change in Rec.              | 5,080           | (11,786)      | (11,897)       | 14,141        |
| Change in Inv.              | 0               | 0             | 0              | 0             |
| Other                       | (4,090)         | 2,364         | (2,694)        | 1,007         |
| <b>Gross Cashflows</b>      | <b>4,815</b>    | <b>34,056</b> | <b>87,005</b>  | <b>49,143</b> |
| Capex                       | (3,785)         | (1,500)       | (1,500)        | (1,500)       |
| <b>Free Cashflows</b>       | <b>1,030</b>    | <b>32,556</b> | <b>85,505</b>  | <b>47,643</b> |
| Re-Purchase of Shares**     | (3,022)         | (4,945)       | 0              | 0             |
| <b>Net Cash Flow</b>        | <b>(1,992)</b>  | <b>27,611</b> | <b>85,505</b>  | <b>47,643</b> |

\*\* Biota bought back 9.17m shares, or 5% of its issued capital, ending 7th Oct 2008

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