

Biota Holdings Ltd (BTA.ASX)

INITIATION OF COVERAGE

Thursday 28 June 2007
Healthcare

Biota was one of the first Australian biotechnology companies to sign a licensing deal with a major global pharmaceutical company, licensing zanamivir, a neuraminidase inhibitor (NAI), to Glaxo in 1990.

Biota currently has three products that are registered and selling across the world.

- zanamivir- now known as Relenza, and
- Flu OIA and OIA/B diagnostic tests, which are sold by Inverness Medical.

It is one of only a few profitable Australian biotechnology companies.

Market for Relenza US\$2b pa. Over the next few years, Governments worldwide will spend US\$4-5b to fill their neuraminidase stockpiles. Once this has been completed the annual stockpile replacement market is estimated to be US\$1bpa. The consumer (non-stockpile) market for NAI is also US\$1b, bringing the total market to US\$2bpa.

GSK legal battle could result in a large settlement. Biota currently estimates damages in its legal battle with GSK at between \$308-430m. We believe this will be revised upwards in the near term. We are confident that BTA's position is warranted.

Additional licensing deals of US\$200m. The company also has a strong product pipeline, the most advanced of which are entering Phase II trials. Two of their early stage products, treatments for RSV and HCV, are partnered with MedImmune and Boehringer Ingelheim respectively.

Our base case DCF valuation for Biota is \$2.83/share, assuming a \$100m settlement from GSK and that 2 of the company's development products achieve registration and sales.

We initiate coverage of Biota Holdings with a Buy recommendation and a price target of \$2.83/share. We believe the company is the best quality biotechnology company in Australia and with its strong history of licensing deals and deep product pipeline, it should continue to be profitable.

Rating: Buy
(previous): N/A

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Share price: \$1.74

Price target: \$2.83
NPV per share \$2.83
Risk: High

Shares on issue (m): 181.7
Shares on issue (diluted) (m): 182.7
Free float: 100%
Average daily volume: 286,539

Market cap (\$m): \$319.7
Enterprise value FY06e (\$m): \$273.5
Net Debt FY06e (\$m): -46.2
Gearing (ND/ND+E) FY06e: NA
S'holders equity FY06e (\$m): 46.9
NTA per share FY06e: \$0.26

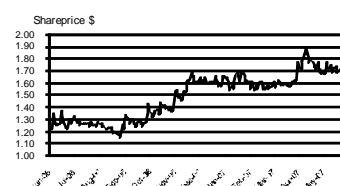
Forecast: 2007

Free cash flow (\$m): 8.1
Return on average equity: 38.1%
Net interest cover: NA

Forecast: 2008

Free cash flow (\$m): 21.5
Return on average equity: 33.4%
Net interest cover: NA

Shareprice (\$):



Year to Jun (\$m)	2005a	2006a	2007e	2008e	*2009e
Sales revenue	3.7	12.7	58.9	74.4	196.7
% change		246%	364%	26%	164%
EBITDA	-15.5	-12.6	18.6	19.2	175.9
EBITDA margin	-422%	-99%	32%	26%	89%
NPAT rep. (incl. sig items)	-15.1	-11.3	24.9	28.2	135.2
NPAT normalised	-15.1	-11.3	25.6	29.5	66.5
EPS diluted norm. (c)	-0.11	-0.06	0.14	0.16	0.36
% change	0%	-43%	NA	15%	125%
Dividend (c)	0	0	0	0	0
PER (x)	-15.8	-27.6	12.4	10.8	4.8
EV/EBITDA (x)	-13.8	-21.1	13.9	12.3	0.6
Yield (%)	0.00%	0.00%	0.00%	0.00%	0.00%

All numbers excl significant items expect for NPAT rep. *2009 estimate includes settlement from GSK in reported numbers.

Source: Company, Foster Stockbroking

www.fostock.com.au

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COMPANY HISTORY

Biota Holdings Ltd (BTA) is one of Australia’s oldest biotechnology companies, and was listed on the ASX in 1985. The company is based in Melbourne and focused on developing products to diagnose and treat viral diseases.

Biota was one of the first Australian biotechnology companies to sign a licensing deal with a major global pharmaceutical company, licensing zanamivir, a neuraminidase inhibitor (NAI), to Glaxo in 1990.

COMPANY DESCRIPTION




Biota currently has three products that are registered and selling across the world.

- zanamivir- now known as Relenza, and
- Flu OIA and OIA/B diagnostic tests, which are sold by Inverness Medical.

The company also has a strong product pipeline, the most advanced of which are entering Phase II trials. Biota’s product pipeline is shown in the following diagram.

Biota’s Product Pipeline

Stage of Development	In-house	Licensed	In market
Marketed			Relenza (Large market), FLU OIA (Small market)
Late Clinical			
Early Clinical	LANI (Large market), HRV (Medium market)		
Preclinical		RSV (Medium market)	
Lead			
Discovery		HCV (Large market)	

 Small market
  Medium market
  Large market

Source: Company

All of the products in Biota’s pipeline target significantly sized markets. In the following sections we further examine BTA’s product portfolio.

INFLUENZA DRUGS

The neuraminidase inhibitor market

The neuraminidase market has grown rapidly since the introduction of Biota's Relenza and its competitor Tamiflu in 1999, and is broken up into two areas:

- The pandemic stockpile market, and
- The consumer market.

The pandemic stockpile market

The flu, or influenza, is not one virus but many. Each year, numerous mutations of the two most prevalent flu types, Influenza A and Influenza B, appear. These mutations are of varying severity.

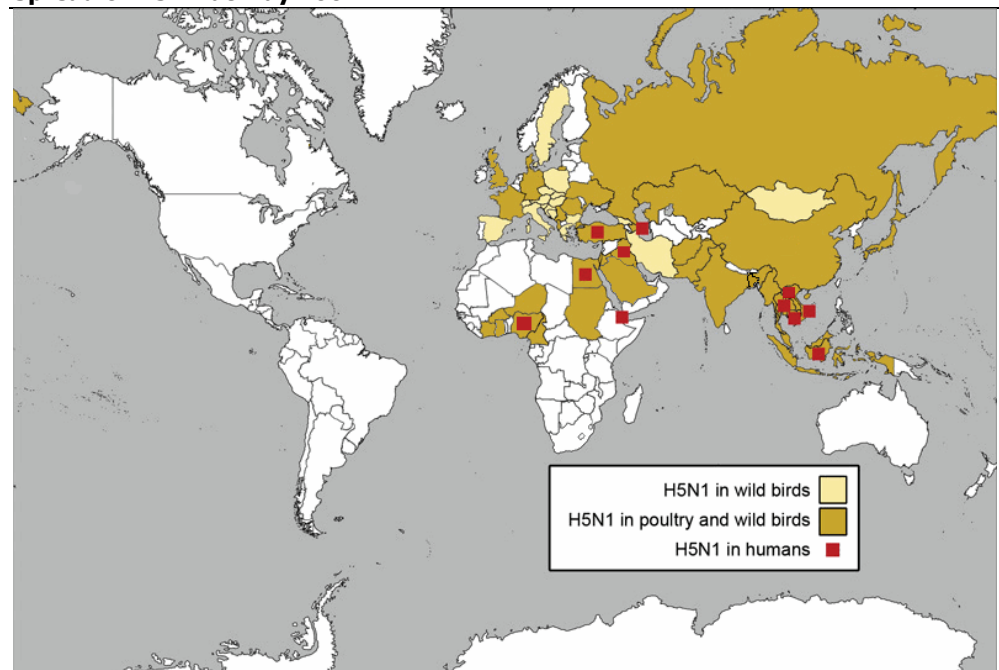
Flu season occurs throughout autumn and winter in both the Northern Hemisphere and the Southern Hemisphere. The severity of the flu season depends on the harshness of the weather and the severity of the prevalent flu strains. A particularly harsh winter, and a virulent new strain, can lead to an increased number of people suffering from the flu. This is called an epidemic. An example of this was in 2003, where epidemics occurred in both Japan and the United States.

Throughout history there have been a number of **pandemics**, where a large percentage of the population becomes infected with a deadly strain of the flu. The last of these was the outbreak of the Spanish Flu in 1918, as troops were returning from World War 1. This killed an estimated 20-40m people, particularly the young and the old. The next worldwide influenza pandemic is considered to be overdue.

The effect of Bird Flu

In 2004, concern started to grow over a particularly deadly new strain of Avian Flu, H5N1. This was spreading like wildfire through the bird populations of Asia, and also killed a number of people who had contact with infected birds. Panic spread, as many believed it would inevitably mutate to allow human-to-human transfer.

Spread of H5N1 at May 2007



Source: PandemicFlu.gov

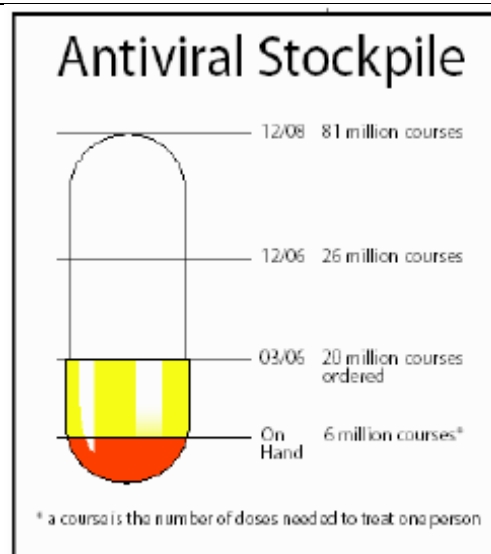
Although the majority of the world is now affected by Bird Flu, as far as we are aware it has not mutated to allow human to human transfer.

The creation of a pandemic stockpile

The fear of a flu pandemic has led to renewed acknowledgement by Governments over the need to prepare for an eventual flu pandemic. This has led to the development of new stockpiles of neuraminidase inhibitors, as well as vaccines. **Over the period 2006-2009, Governments worldwide will spend US\$4-5b to fill their neuraminidase stockpiles.**

The following diagram shows the state of the United States' stockpiling, as at July 2006.

US stockpiling of neuraminidase inhibitors



Source: HHS Pandemic Planning Update (July 2006)

Source: Company

The replacement market for these drugs as their five year expiries lapse (commencing in 2011) is expected to be US\$1b pa.

The seasonal (consumer) market

The most underrated market for neuraminidase inhibitors is the seasonal (consumer) market. This is the traditional market, where a patient sees a doctor, obtains a prescription and has it filled by a pharmacist. We estimate that this market grew around 40% over the last year.

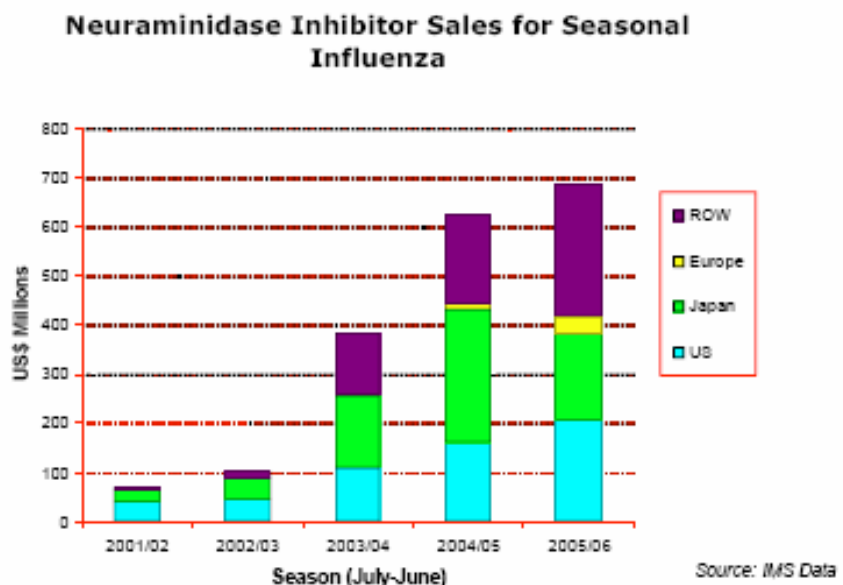
One of the reasons why this market originally grew slowly was the perception that sufferers had "just the flu". The flu was seen as a short term hindrance, rather than a potentially life threatening disease. In reality, every year between 3-5 million people contract the flu, and between 250,000 to 500,000 people die from it. Therefore NAI can be extremely useful even when there is no pandemic.

The growth in the seasonal market for NAI has been slower than the pandemic market, with Japan being the strongest market, but it is now growing strongly. This is partly due to the attention given to avian flu, and the new Government stockpiles. Customers now understand both the dangerous nature of the flu and the role neuraminidase inhibitors can play in helping to prevent flu and reduce symptoms.

There is potential upside to the seasonal market, as production capacity constraints, particularly for Relenza, are limiting growth.

The growth in the seasonal (consumer) market for neuraminidase inhibitors is shown below.

Seasonal sales of neuraminidase inhibitors



Excludes pandemic stockpiling

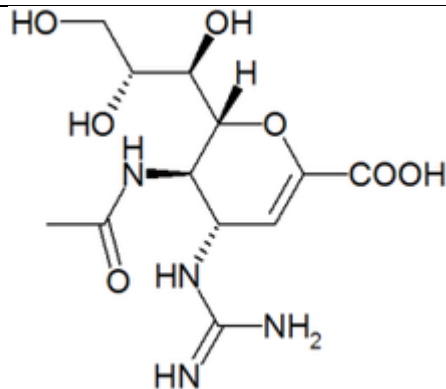
Source: Company

The consumer market is now estimated at US\$1b, bringing the overall market for neuraminidase inhibitors to US\$2b pa once initial stockpiling has been completed.

zanamivir (Relenza)

zanamivir is used for the treatment and prophylaxis of Influenza viruses. It is sold by GlaxoSmithKline under the brand name Relenza. zanamivir entered Phase I trials in 1993, and received its first approval in Australia in 1999. It has subsequently received approval in over 70 countries. It was launched in both the US and Europe in 1999, and has been launched in 30 countries.

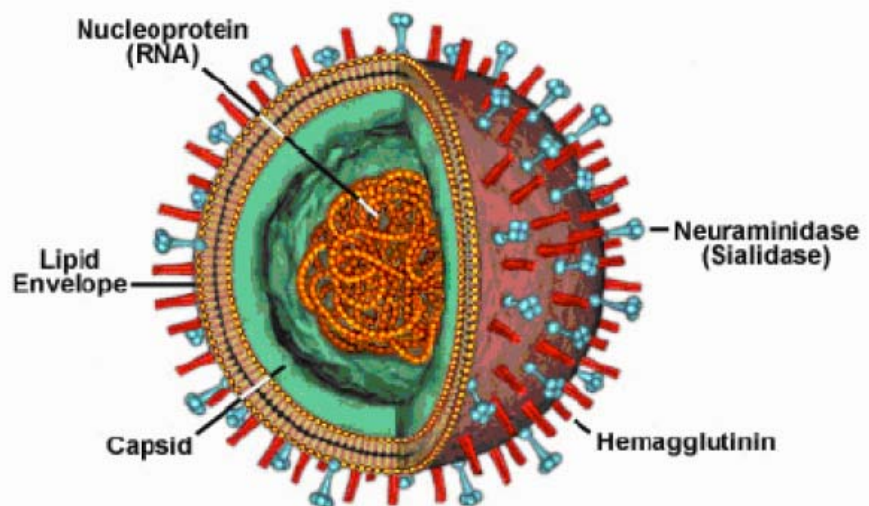
zanamivir chemical formula



Source: Company

zanamivir was the first in a class of drugs called neuraminidase inhibitors (NAI), named such because they prevent the action of neuraminidase, an enzyme on the surface of influenza viruses that assists the virus to spread. It was discovered in 1989 by Biota funded scientists from the Victorian College of Pharmacy (VCP) and the CSIRO.

Neuraminidase on the outside of the influenza virus



Source: Roche

A timeline for the development of Relenza is shown in Appendix A.

Licensed to Glaxo in return for 7% royalty

Biota successfully licensed zanamivir to Glaxo in 1990, while it was still in discovery. The licensing agreement for Relenza was very good for a product licensed at such an early stage of development. Until the end of zanamivir's patent life, Biota is entitled to a 7% royalty on sales worldwide, with the exception of Australia, New Zealand and South Africa, where the company is entitled to a 10% royalty. This royalty is paid each year on the 30th June, 12-months in arrears.

In return for its early work, Biota passed a royalty of 1% GSK sales (14.3% Biota royalties) through to the CSIRO and the VCP. The company has recently purchased CSIRO's royalty, and will only have to make an additional payment if certain sales targets are met. We believe this was a clever move for Biota, as sales of Relenza are increasing and the company would in all likelihood have needed to pay more in the future. It also means that in the event of a successful claim against GSK, the company will not have to pay CSIRO any part of the settlement. We have assumed that the company paid \$10m for this royalty.

Royalties until 2014

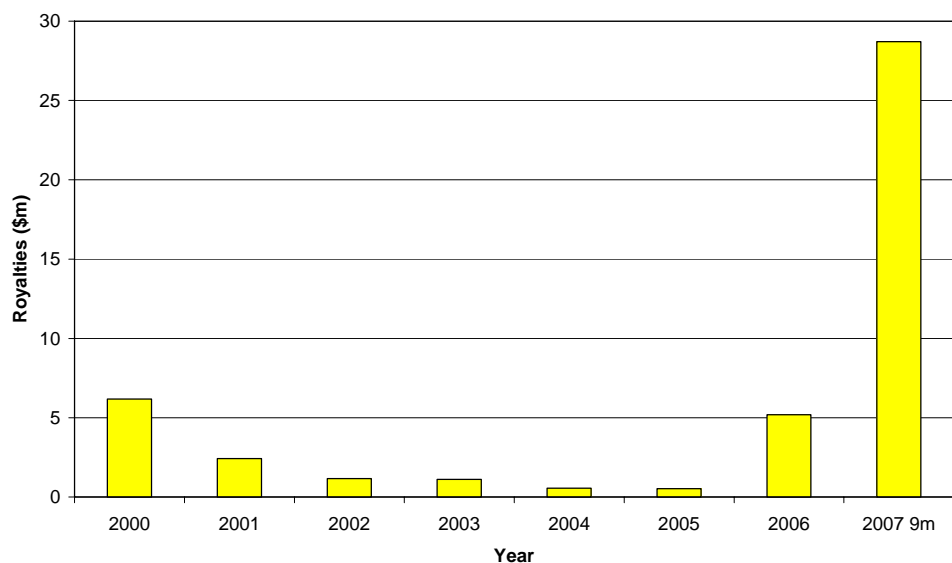
Biota will receive royalties for Relenza until its US patent expires in 2014. Relenza's European and Rest of World patents expire between 2011 and 2013.

Royalties so far

Despite gaining 40% share of the US market in its first year, and having 100% of the EU market in its first three years, Relenza's sales languished thereafter until 2006. In 2003, Relenza's competitor Tamiflu had over US\$300m in sales, whereas Relenza had only approximately AUD\$15-16m in sales. This disparity may be attributed to licensee GSK effectively abandoning Relenza. This is the subject of a court battle between Biota and GSK, and is discussed in more detail in later sections.

Below is a graph showing the royalties payable to BTA since the launch of Relenza. We note the rapid improvement over FY2006 and FY2007 (first 9 months).

Relenza Royalties



Source: Company

The growth in royalties over FY2006 corresponds with GSK's realisation that its mothballed drug Relenza had significant value. In FY2004-FY2005, when stockpiling of NAI began, only Tamiflu was stockpiled. In the past two years there has been increased stockpiling of Relenza.

GSK has dramatically lifted its production capability for Relenza over the past 2 years, from 1m courses pa at December 2005 to 15m courses at December 2006. **Estimated capacity is now thought to be close to 30m courses pa, and we believe GSK is considering lifting this significantly.** In our model we assume that GSK lifts production capacity to 45m doses by 2010.

We now examine Relenza's attributes in more detail, to determine if there is any other cause for the dropping sales over 2001-2005, other than GSK's alleged failure to commercialise.

Relenza's Dosage Form

Relenza has been formulated for delivery by an inhaler. This was because, as an inhaled drug, Relenza is delivered directly to the site of the infection, the lungs. Unlike an oral dosage, the drug does not pass through the systemic circulation, and this is said to reduce the potential for side effects. Patients use the inhaler twice daily for five days.

Relenza



Source: Company

Questions have been raised about the type of inhaler used by GSK for Relenza, with some saying that it has hindered patient approval of Relenza. Also, patients generally prefer an oral dose to an inhaler. However, asthma, which is a billion dollar market primarily treated using inhalers, has shown that inhalers are not a significant market deterrent.

While we believe the dosage form may have had a small detrimental effect on sales, it does not account for the 94% difference between Relenza's market share and that of its competitor.

Side Effects

The following table compares Relenza (zanamivir) to its main competitor Tamiflu (oseltamivir).

Side effects of Relenza

	zanamivir	oseltamivir
Age approved for prophylaxis	>5 years	> 13 years
Age approved for treatment	>5 years	>1 year
Renal impairment	No dose adjustment required	Adjustment if creatinine clearance 10-30 mL/min
Hepatic impairment	No dose adjustment required	Safety not established
Reduction of symptoms	By median of 1.5 day	By median of 1.3 day
Adverse reactions	Allergy – very rare Bronchospasm and dyspnoea – very rare Rash and urticaria – very rare	Nausea 7.0 – 10.7% subjects Vomiting 2.1 - 8.0% Diarrhoea 3.2 – 5.5% Bronchitis 0.7 – 3.7% Headache 1.6 - 20.1% Fatigue 0.8 – 7.9% Psychiatric disorders/ suicidal tendencies (over 200 cases)
Frequency of drug resistance	None reported	1.3 and 8.6 -18.0% in adults & children respectively

Source: *The Lancet* vol. 366 August 13, 2005; Foster Stockbroking

Clearly, side effects are far more common, and longer lasting, taking Tamiflu than with Relenza. Tamiflu can also be less widely used. It is not safe if the patient has hepatic impairment (reduced liver function) or renal impairment. Unlike Relenza, Tamiflu is also ineffective when the patient is using anti-clotting drug Plavix, and may be unsafe when the patient is in their first trimester of pregnancy.

We will discuss Tamiflu's most serious neurological side effects in a further section.

Bronchospasm

In Phase I trials, one of the trial patients, who had mild or moderate asthma, suffered from bronchospasm after taking Relenza. This was noted in the initial list of side effects on the 1999 FDA approved label for Relenza, which stated,

“any patient who develops bronchospasm or decline in lung function should stop the drug. Patients with underlying respiratory disease should be instructed to have a fast-acting bronchodilator available when treated with zanamivir.”

Despite this warning, shortly after Relenza was launched in the US, a doctor died from a bronchospasm after taking Relenza, and his family sued Glaxo Wellcome. After this a much stronger warning was placed on Relenza's label, suggesting that people with existing pulmonary conditions should not use Relenza.

It should be stressed that causality has not been found in cases where a patient has died after using Relenza, ie it was not proven that Relenza directly caused any deaths. Nor were the effects sufficient to cause the FDA to remove approval of the drug.

We do not believe that this side effect was the cause of Relenza’s languishing sales in its early years. Relenza’s side effects are far less concerning than those of its competitor Tamiflu.

Early Competitors

The introduction of neuraminidase inhibitors (also called anti-viral medicines) created a new market for flu treatment. Prior to the release of Relenza, flu sufferers were treated with over the counter cold and flu tablets, older drugs like amantadine, and ineffective antibiotics.

Amantadine and rimantadine are rarely used because they have serious side effects. They are known to cause behavioural changes, delirium, hallucinations, agitation, and seizures.

Common Flu Treatments

Options	Helps Prevent the Flu	Treats the Flu Virus	Eases Flu Symptoms
Antiviral Medicines (NAI) eg Relenza	✓	✓	✓
Flu Vaccines	✓		
OTC Treatments			✓

Source: Tamiflu.com

Vaccines can help to prevent the flu, but they can only be used to prevent a set number of mutations, and become rapidly out of date. It also takes a long time to develop new vaccines. This means that flu vaccines will never remove the need for flu treatments.

Over the counter treatments like cold-and-flu tablets have limited effectiveness, and cannot prevent the flu or reduce the time of infection.

Neuraminidase inhibitors like Relenza have been effective in all three treatment areas.

Tamiflu

Relenza’s largest competitor is fellow neuraminidase inhibitor Tamiflu. Tamiflu (oseltamivir) was discovered in 1996 by Gilead Sciences and was developed in conjunction with Roche, who now markets the drug.

Tamiflu

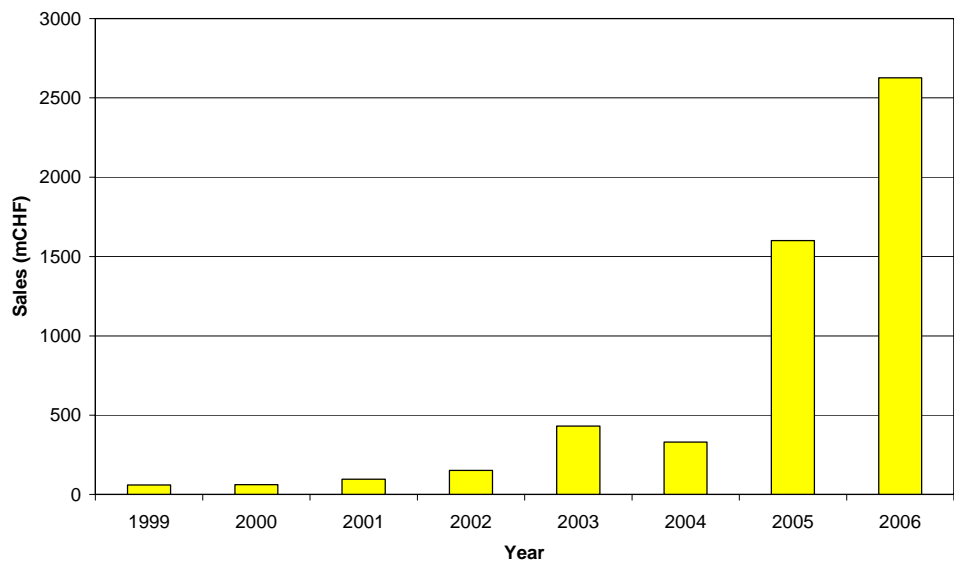


Source: Roche

Market share

The following graph shows Tamiflu’s sales growth since its launch in 1999 (calendar year sales).

Tamiflu sales



Source: Roche.

Tamiflu has successfully cornered the market in neuraminidase inhibitors, and now has 97% market share world-wide. The majority of the Government stockpiles are also made up of

Tamiflu, however this is now changing as resistance to Tamiflu grows, and production capacity for Relenza increases.

We do not believe that the quality of Tamiflu warrants such a large market share.

Comparison with Relenza

The following table provides a direct comparison of Relenza and Tamiflu.

	Relenza	Tamiflu
Discovered by	Biota	Gilead Sciences
Marketed by	GlaxoSmithKline	Roche
Launched in Europe	1999	2002
Launched in the US	1999	1999
Current Market Share	3%	97%
Dosage form	Inhaler	Oral capsule/ liquid
Benefits	Inhaler give dose directly to the site of infection, increases patient compliance and reduces potential for side effects	Oral dosage is patient preferred
Negatives	Inhaler system not patient preferred	Increased dose required for oral dosage increases likelihood of side effects.
Most serious reported side effects	Bronchospasm	Delirium induced suicide
Likelihood of Resistance	Considered to be lower than Tamiflu	Resistance already detected.

Source: FSB, Companies.

Fast Development Time

Tamiflu's development timeline was far faster than Relenza's. Human testing of Tamiflu commenced in March 1997, around the same time as Relenza's Phase 3 trial. However, the results of Tamiflu's phase 3 trials were released in September 1998, only 3 months after Relenza's second phase 3 trial was completed.

Tamiflu received its first approval in Switzerland in September 1999. FDA approval for Tamiflu was granted in October 1999, only 3 months after Relenza.

We question why GSK needed 5 years to progress Relenza through clinical trials, when Tamiflu's trials lasted only 1.5 years.

Oral Delivery

Tamiflu is taken orally. It is in capsule form for adults and liquid form for children. This is a patient preferred delivery system however it has a number of problems associated with it. For example, as it must pass through the circulation, an oral dosage:

- Requires a higher dosage than an inhalant , and
- Increases the probability of recurring side effects.

It also has an increased likelihood of the virus developing resistance to the drug.

While Tamiflu has the benefit of using a patient preferred dosage form, we do not believe that this accounts for the enormous disparity between Relenza's and Tamiflu's market shares.

Side Effects

As shown earlier, common side effects of Tamiflu include nausea, vomiting, diarrhea, abdominal pain, and headache. Less common side effects include hepatitis, elevated liver enzymes, rash, and allergic reactions. Post marketing surveillance has also uncovered the potential for toxic epidermal necrolysis, cardiac arrhythmia, seizure, confusion, haemorrhagic colitis and for the drug to aggravate existing diabetes conditions.

The most concerning side effects of Tamiflu are neurological effects. These were first discovered in Japan, where over 24m people have taken Tamiflu. Between 2004 and March 2007, 15 Japanese teenagers were reportedly injured or killed by jumps or falls from buildings after taking Tamiflu. A 17 year old is also reported to have thrown himself in front of a truck. Well over 200 reports have been made of people suffering from delirium, hallucinations, suicidal tendencies and/or other psychiatric disorders after taking Tamiflu. While no conclusive causal link has been established, the FDA requires that patients being treated with Tamiflu be monitored for abnormal behaviour.

The Japanese Health Ministry is undertaking a review of Tamiflu and its neurological effects. We note that this study has recently been widened to include Relenza, after 10 concerning incidents involving the drug. We note that none of these incidents involved injury to a patient. **While we are monitoring this study closely, we are not overly concerned, as Relenza's dosage form means that it is unlikely to cause neurological side effects.** For example, in animal studies Tamiflu was shown to breach the blood-brain barrier, whereas Relenza did not.

We believe that in comparison with Tamiflu, Relenza is well tolerated, and its safety profile should not have any significant effect on sales.

Resistance

A Japanese study by Kiso et al, published in Lancet in 2004, found resistance in 18% of a group of 50 Japanese children treated with Tamiflu. Similar studies elsewhere have shown that flu viruses fairly rapidly develop resistance to Tamiflu.

The level of resistance would develop even faster during a pandemic. For this reason it is important to stockpile more than one form of NAI. While the majority of the world stockpile is currently Tamiflu, over time we believe the stockpile will become closer to 50% Tamiflu: 50% Relenza. The US Govt has already stated that it would like 20% of its stockpile to be Relenza.

A benefit of Relenza is that the chemical formula for Relenza is thought to hinder the virus' ability to become resistant. This means that **viruses are believed to develop resistance to Relenza at a lower rate than Tamiflu. We see this as a significant benefit.**

Legal Battle with GlaxoSmithKline

In May 2004, Biota launched legal action against GlaxoSmithKline, the licensee of Relenza. Biota alleged that GSK failed in its contractual obligation to use "best endeavours in the development and marketing of Relenza". Biota claimed that:

- "GSK restricted Relenza to its proprietary Diskhaler system, and did not adequately pursue alternative or improved inhalation systems.
- GSK withdrew support for crucial post-approval clinical studies designed to expand the product's use and market acceptance.
- After the launch year, GSK failed to properly launch Relenza in a number of countries where the product was registered, and allowed registrations to be stopped, cancelled or scheduled for cancellation.
- After the launch year, GSK withdrew promotion support for Relenza, allowing the sales and market share to decline dramatically in all key markets, even in those where there was no direct competition."

Failure to Launch

Despite receiving approval in over 70 countries, market audits have only shown sales of Relenza in around 30. In addition to not launching Relenza in a number of key markets, including China, GSK also failed to extend the approved applications for Relenza. For example, despite receiving approval for paediatric use in the US, GSK initially withdrew its application for paediatric use in Europe, limiting Relenza's market.

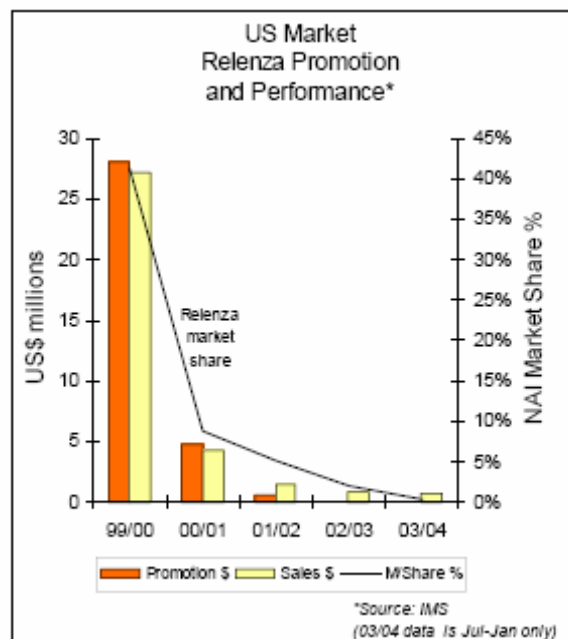
No marketing trials

GSK also failed to complete vital "phase 4" trials for Relenza. These are designed to build market awareness and doctor approval, and are particularly important when building a new market. We believe this would have diminished their ability to grow Relenza's sales.

Failed to supply promotional support

The most obvious consequence of GSK's actions is the collapse of Relenza's market share in the US from 40% in 1999/2000 to 1% in 2003/2004.

US Sales of Relenza, compared with promotional spend

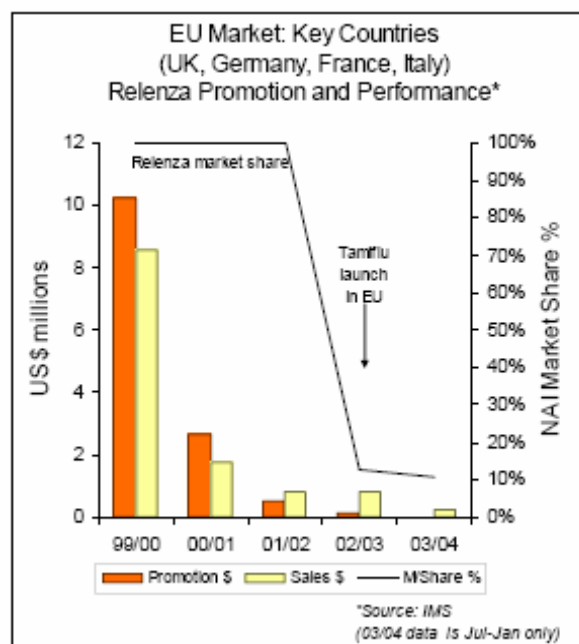


Source: Company

As is shown in the graph on the preceding page, Relenza's market share in the US fell in proportion with a reduction in promotional spending by GSK. In the early years new drugs, particularly those which are creating a new market, require large promotional spending. By comparison, in 2000/2001, when GSK's promotion budget for Relenza fell 83%, Roche increased its promotion spending for Tamiflu by 42%.

Some may suggest that this link to promotional spend was spurious, and that the fall in Relenza's sales was due to better patient acceptance of Tamiflu. In our opinion, Relenza's performance in the EU disproves this. Relenza launched in Europe in 1999, whereas Tamiflu did not launch until 2002. The graph below clearly shows that Relenza's sales fell before the introduction of Tamiflu, suggesting another reason for the drop. We believe that this was the lack of support from GSK.

EU Sales of Relenza, compared with promotional spend



Source: Company

The above graph shows that the launch of Tamiflu in 2002/2002 did not affect Relenza's sales, rather Tamiflu re-grew the market.

We are confident that the fall in Relenza's sales, and its inability to regain market share from Tamiflu, will be found to be related to GSK's failure to support the drug adequately.

GlaxoSmithKline’s likely defence

Of course, GSK will attest that they did use their best endeavours. We feel that GSK’s defence will likely centre on 3 areas:

- Concern over side effects;
- Patient preference for an oral dosage (ie Tamiflu); and
- The light flu seasons in 1999-2002.

We have already discussed the first two areas. Relenza has a superior safety profile to its far more successful competitor Tamiflu, so we do not believe that concern over side effects played any role in reducing sales of Relenza.

Although patients may prefer an oral dosage form like Tamiflu, we believe that given adequate promotion support this would have been offset by Relenza’s relative safety.

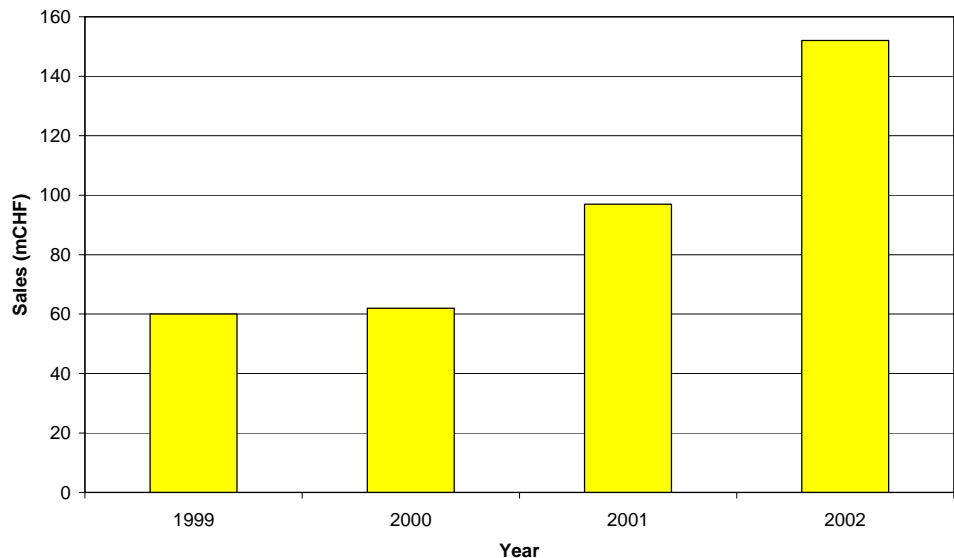
We also note the dramatic uplift in sales of Relenza over the last two years would not, in our opinion, have been possible if Relenza was a dud in the eyes of consumers.

We do not believe that either of these concerns warranted GSK putting Relenza on the backburner.

Mild flu seasons in 1999-2002

The four years following the launch of Relenza had mild flu seasons. As a result, the NAI market grew at a slower rate than had been initially expected. We believe GSK may use this as an excuse for withdrawing support for Relenza. However, as the sales graph for Tamiflu shows, the NAI market still grew.

Sales of Tamiflu from 2002-2003



Source: Roche

In addition, despite 1999 having the mildest winter in over 10 years, Relenza captured good initial US sales. **We therefore do not believe that this will be considered to be a valid defence.**

Overall, we believe that Biota was justified in launching its legal battle with GSK. We do not believe that GSK used “best endeavours in the development and marketing of Relenza”.

Trial in April 2008

Biota and GSK's case will be heard in the Victorian Supreme Court in April 2008. Prior to this we expect the following milestones.

Trial Milestones

Date	Milestone
Before end July 2007	Biota to release updated estimate of damages
August 2007	Biota witness statements due
December 2007	GSK witness statements due
April 2008	Trial commences

Source: FSB, company

The next milestone we are expecting is an announcement by Biota of its revised estimate of damages. **In December 2004, BTA released an initial estimate of \$308-430m. Since then the market for NAI has more than doubled. As a result we believe that Biota's amended damages claim will be significantly higher.**

In our forecasts we are assuming that the legal battle goes to trial. However, **there is a strong likelihood that the matter will be settled prior to trial.** In this case we believe BTA would accept a lower settlement than the claim estimate. This is because it would allow money to be more rapidly diverted to progressing the company's pipeline products.

LANI

In conjunction with Daiichi-Sankyo, Biota is also developing second generation NAI. These are being developed specifically to service the pandemic stockpile market.

Unlike Relenza, BTA's second generation NAI has significant benefits over Relenza and Tamiflu.

- First it is a long acting neuraminidase inhibitor (LANI) and is designed to last longer and require lower doses than either Tamiflu or Relenza.
- The dose will be once weekly rather than twice daily for 5 days.
- The drug will use a cheap, single dose inhaler, a significant improvement from the diskhaler.
- It will be also be sold in bulk form, and will be able to be administered using a nebuliser. This provides a significant benefit to Governments, as it allows rapid deployment and treatment in the event of a pandemic.

Biota and Daiichi-Sankyo's LANI project has been funded by a number of grants, including a US\$5.6m grant from the US NIH. Biota management believes that very little money will be needed from the company to develop this drug.

The most advanced of these compounds, CS8958, is being developed for launch in 2011. CS8958 has already completed Phase I clinical trials in Japan. There were no serious side effects reported in this initial Phase I trial. Phase II trials are due to commence in Japan in October. CS8958 is also due to commence Phase I trials in the UK. Daiichi-Sankyo is funding the Japanese trials, with NIH grant funding being used to fund the RoW trials.

Biota and Daiichi-Sankyo share all rights and royalties to this project. Daiichi-Sankyo will develop and market the product for the Japanese market, and the two companies are currently seeking a licensing partner for Rest of World.

CS8958 is only one of a number of second-generation NAI that Biota and Daiichi-Sankyo are developing. For example, Biota has been awarded a US\$8.5m NIH grant to progress its FLUNET NAI, which is currently in preclinical studies.

Influenza Diagnostics

In partnership with Inverness Medical, Biota markets the FLU OIA diagnostics systems for rapid detection of influenza. While flu testing is not an enormous market, and only contributed \$1.25m profit share to BTA in 2006, it has provided a continuous income stream to Biota for a number of years.

RESPIRATORY SYNCYTIAL VIRUS (RSV)

Biota is also developing a novel product for the treatment of Respiratory Syncytial Virus (RSV). RSV is the most common cause of serious lower respiratory tract infections in children under 1 year old, and results in the hospitalisation of over 250,000 US children each year. It also results in the hospitalisation of over 177,500 US adults per annum, with an estimated 14,000 elderly and high risk adults dying. The cost of adult hospitalisation alone in the US is over US\$1b.

Synagis, an injectable drug for prevention of RSV in high risk infants, has over US\$1b in annual sales. Biota has designed an oral drug to complement Synagis' market position. This new drug has been shown in animal studies to reduce the viral load of animals infected with RSV.

US\$107.5m partnering deal with MedImmune

Despite the drug not having entered clinical trials, BTA has successfully partnered its RSV drug to MedImmune (recently purchased by AstraZeneca), for an initial license fee of US\$5m, and a potential for up to US\$107.5m in milestone fees. The company will also receive a royalty on future sales. In addition, BTA will no longer need to spend any money on the development of the drug.

This is an outstanding deal for a product at this early stage. **We believe this deal is further proof of the quality of BTA's product portfolio, and its ability to form partnerships with major pharmaceutical companies.**

We note that Biota has chosen to exclude the Asian market, with the exception of Japan, from its deal with MedImmune, retaining it for its own or for further sale. We expect RSV to enter clinical trials shortly.

HEPATITIS C VIRUS (HCV)

4.1 million Americans, or 1.6% of the US population, have been infected with HCV. Of these people, 3.2 million are chronically infected, and 70% of these people will progress to chronic liver disease. 1-5% of infected patients die as a result of HCV infection.

The current treatment for HCV patients is a combination of ribavirin and interferon. Current sales of such products are in excess of US\$1bn per annum. However, ribavirin/interferon treatment has a number of side effects, which limits the amount of therapy a patient receives. We believe that a new drug, with a safer side effect profile could capture a large portion of, and indeed grow the market for HCV treatment.

Biota has discovered and is developing a novel class of antiviral nucleoside drugs which treats Hepatitis C. It does so by inhibiting the HCV polymerase, an enzyme involved in the replication of the virus.

US\$102m research collaboration and licensing deal

In November 2006, BTA entered into a world wide research collaboration and licensing agreement with Boehringer Ingelheim to develop their potential HCV therapies.

Under the terms of the agreement, Biota is eligible to receive payments up to US\$102 million based on products achieving certain clinical, regulatory and commercialisation milestones, including an initial technology access fee and research support. Biota will also receive royalties on future sales.

We note that under this agreement, Boehringer Ingelheim will not only pay the costs of any trials, but it will also pay for any work carried out by Biota.

Again, this is a phenomenal deal for a product at this stage of development. **Biota has consistently shown an ability to attract well regarded partners with deep pockets to fund its programs.**

HUMAN RHINOVIRUS

Biota has also been developing products to treat Human Rhinovirus (HRV), a major cause of the common cold. Although in many cases HRV infection only causes minor discomfort, over 150m patients annually seek medical attention or are hospitalised due to complications from HRV infection. This includes asthmatics and COPD sufferers, whose conditions are exacerbated by the virus. There is no treatment for HRV.

BTA's compounds are designed to bind to VP1, a protein which helps bind HRV to nasal cells. Their lead compound BTA798 is highly active against a range of rhinoviral serotypes, and has been found to be safe in Phase I trials. Subject to the results of this trial, a Phase IIa trial will commence in 2008.

Unlike its HCV and RSV programs, BTA has chosen to progress HRV to the end of challenge studies. Management believes that these trials can be completed relatively cheaply, and will allow the drug to be partnered at a much higher price and with a better royalty stream. We agree with this strategy.

VALUATION

The value of Biota is dependent on two key components,

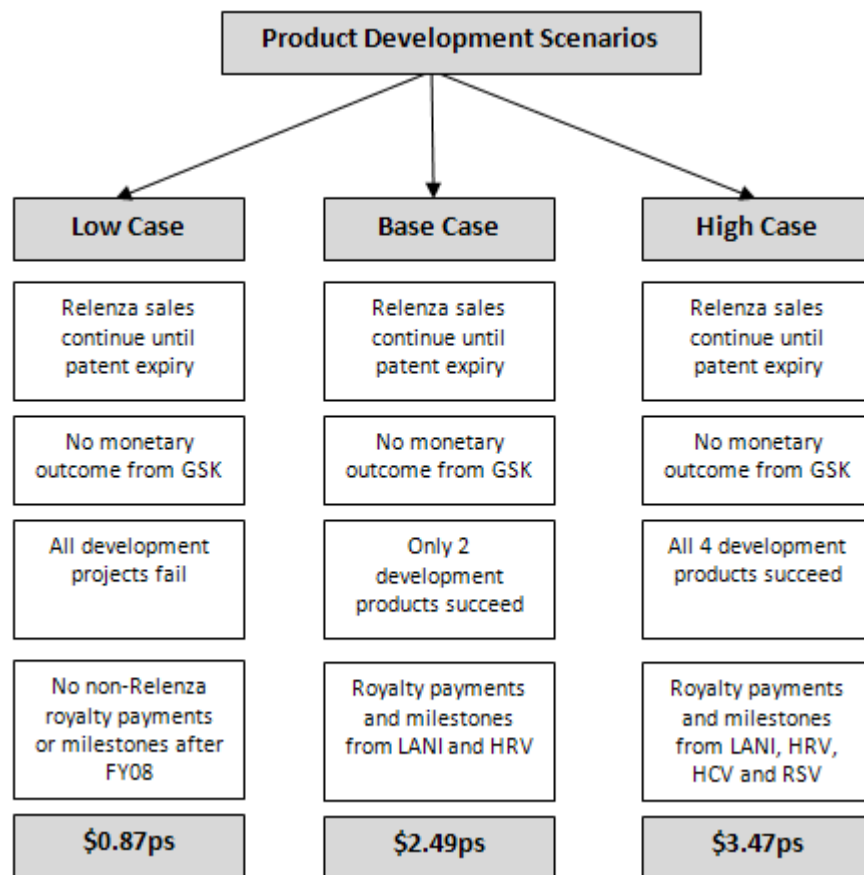
- The number of development products that are eventually approved; and
- The amount of any outcome from GSK.

Below we have used scenario analysis to determine the value of Biota using varying outcomes for both these components. In all cases we use DCF analysis with a WACC of 12%.

Development products

While Relenza is already approved and we are confident that strong revenues will continue until patent expiry in 2014, the success of Biota's development projects is less certain. In the following flow chart we examine the effect that development project success has on Biota's DCF. In this analysis we are assuming no monetary outcome from GSK.

Scenario Analysis- Product Development



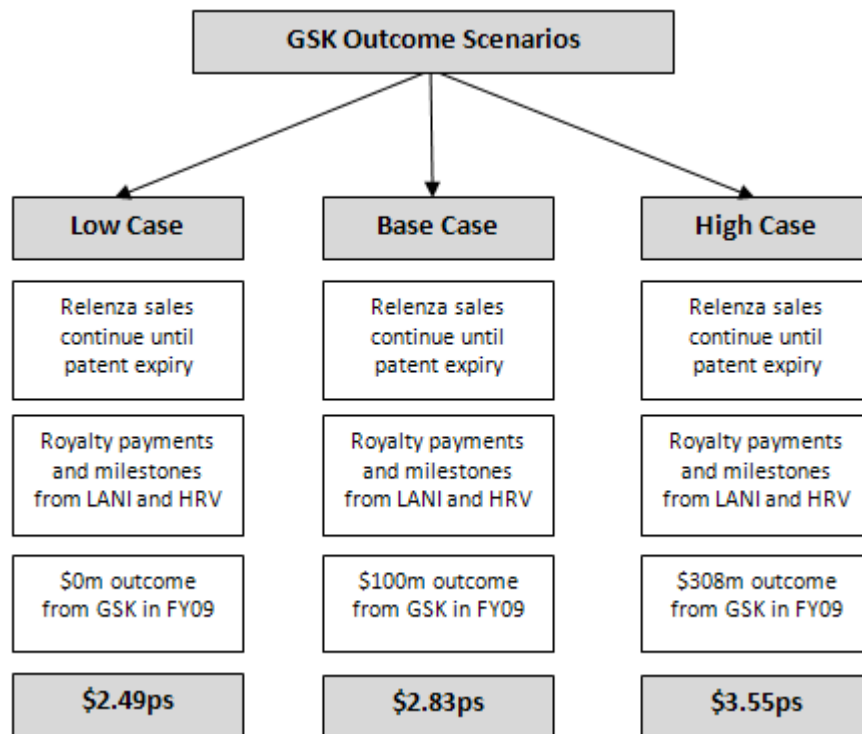
Source: Company

Given Biota's excellent development history, we do not believe that the low case is likely, and believe the most likely scenario is the base case. In our company valuation, we assume that LANI and HRV are successfully developed.

GlaxoSmithKline outcome

We have also examined three different outcomes from the legal battle with GSK. While we are confident that BTA will be successful, we have nonetheless included a scenario where no monetary payment is received. The base and upper cases represent Biota's current lower and upper estimates of damages. We note again that Biota is likely to increase these estimates in the near future.

Scenario Analysis- GSK outcome



Source: Company

We believe the most likely scenario is the base case, and have therefore used it in valuing Biota.

We note that in a blue sky scenario, where the monetary payment received from GSK is \$308m, and all 4 development products are commercialised, our valuation for Biota is \$4.53/share.

Final valuation

Our final valuation for Biota is \$2.83/share, assuming a \$100m settlement from GSK and that 2 of the company's development products achieve registration and sales.

Biota Valuation

	Now		In 1 year	
	\$m	per share	\$m	per share
DCF valuation	451.7	2.49	425.6	2.34
Net debt	-63.1	-0.35	-146.3	-0.81
Total valuation	514.8	2.83	572.0	3.15

Source: FSB estimates

The following table shows our key forecast parameters for Relenza, LANI and HRV. Note that we assume all products are licensed to major pharmaceutical companies, and that Biota receives royalties only up until the patent expiry date.

Key Development Parameters

Product	Forecast sales from	Patent expires	Estimated royalty
Relenza	1999	2014	7%
LANI	2011	2020	6%
HRV	2012	2020	6%

Source: FSB estimates.

Our valuation includes no terminal value, as we have only forecast sales for each product up until their patents expire.

EARNINGS FORECAST

Our forecasts for Biota over the next three years are as follows.

Biota Earnings Forecast

Y/e Jun	2007e	2008e	2009e
Sales revenue	58.9	74.4	196.7
Growth	364%	26%	164%
EBITDA	18.6	19.2	175.9
EBITDA margin	32%	26%	89%
Depreciation	1.0	1.0	1.1
EBITA	17.6	18.1	174.8
EBITA margin	30%	24%	89%
Amortisation	0.7	1.3	1.3
EBIT	16.9	16.8	173.5
EBIT margin	29%	23%	88%
Net interest expense	-3.0	-4.4	-7.3
PBT	19.9	21.2	180.7
Tax	-5.0	-7.0	45.6
NPAT	24.9	28.2	135.2
NPAT normalised	25.6	29.5	66.5

Source: Foster Stockbroking estimates.

We note that the company has provided guidance for the FY2007 PBT of greater than \$18m, however we believe this is likely to be exceeded. Given the benefit of unbooked tax losses, we are forecasting a reported NPAT of \$24.9m.

Sales growth of 26% in FY08 is due to GSK expanding its Relenza production capacity from 21m units pa to our estimates of 38m units pa. By FY2010 we are assuming that the GSK will have lifted capacity to 45m units pa.

FY2009 revenue growth is due largely to our estimated outcome of \$100m from GSK, but also from an increase in our forecast revenue from commercial partners as BTA meets its research milestones.

RECOMMENDATION

We initiate coverage of Biota Holdings with a Buy recommendation and a price target of \$2.83/share. We believe the company is the best quality biotechnology company in Australia, and with its strong history of licensing deals and deep product pipeline, should continue to be profitable.

RISKS AND REWARDS

Risks

- Our valuation for BTA is dependent on a \$100m outcome in the trial with GSK. Should this not eventuate, our valuation for BTA would diminish.
- Biota's development projects are at an early stage and, despite many being partnered, have a high degree of risk. Our valuation assumes some probability that two of these products being successful. Should one or both of these fail, our valuation for BTA would fall.

Rewards

- Our estimate for the eventual settlement with GSK is below BTA's damages claim. Should the eventual payout be higher, our valuation would rise.
- We have only assumed that 2 of Biota's current development projects succeed. Should the other two be successful, our valuation for Biota would rise. We also note that the company will in all likelihood develop new products that are not currently in the pipeline. These would also provide upside.

APPENDIX A- TIMELINE FOR THE DEVELOPMENT OF RELENZA

Date	Milestone
1989	zanamivir discovered
1990	zanamivir licensed to Glaxo
1990-1992	Preclinical studies
1993	Phase I study
June 1994	Phase IIa trial
October 1994	Glaxo moves zanamivir into full clinical development
March 1995	Glaxo merges with Wellcome to form Glaxo Wellcome
December 1995	Phase IIb trial of zanamivir commences
1996	Competitor Tamiflu discovered
March 1997	Human trials begin for Tamiflu
April 1997	1 st Phase 3 trial commences in Australia
June 1997	2 nd Phase 3 trial begins in the Northern Hemisphere
April 1998	1 st P3 trial completed
July 1998	2 nd P3 trial completed
March 1999	Relenza receives TGA approval
July 1999	Relenza receives FDA approval for those >12yo
1999	Relenza is launched in the US
October 1999	Tamiflu receives FDA approval and launches in the US
January 2000	Glaxo Wellcome merges with SmithKline Beecham to form GlaxoSmithKline (GSK).
May 2000	GSK withdraws the prophylaxis application in Europe, despite positive trial results
May 2000	Relenza receives FDA approval for children ≥7yo
June 2000	GSK withdraws the paediatric application for Relenza in Europe, despite having US approval
October 2000	GSK advises Biota that promotion of Relenza has been transferred to an external supplier
October 2000	The National Institute for Clinical Excellence (NICE) in the UK advises that Relenza can be prescribed prophylactically to protect at risk and elderly patients.
November 2000	GSK withdraws its prophylaxis FDA application for Relenza in the US.
2001	Relenza sales and market share decline.
2001	GSK terminates its research collaboration on 2 nd generation flu drugs with Biota.
2002	Relenza sales and market share continue to decline.
January 2003	Major flu epidemic in Japan.
December 2003	Major flu epidemic in the US.
2003	Competitor Tamiflu's sales grow to US\$330m for the 2003 calendar year, while Relenza's sales and market share continue to decline.
2004	Avian Flu outbreaks. Governments begin stockpiling NAI, in particular Tamiflu.
May 2004	BTA launches legal action against GSK for failing to support Relenza.
December 2004	BTA estimates damages at \$308-430m.
August 2005	GSK confirms German stockpiling of Relenza.
September 2005	Relenza Stockpiling in Holland.
November 2005	French stockpiling of Relenza.
December 2005	Australian Govt adds Relenza to stockpile.
April 2006	US Dept of Defence orders US\$5.2m Relenza.
July 2006	BTA reports FY2006 royalties of \$5.2m.
February 2007	BTA announces 1H royalties of \$12.7m.
April 2007	BTA announces Q3 Relenza royalties of \$16m.

Source: Company

APPENDIX B- BOARD AND MANAGEMENT

In our opinion, Biota has an outstanding board for a biotechnology company.

Chairman- John Grant

John Grant joined the Board 30 August 2001 and was elected Chairman. He was the joint founder in 1984 with Hambros Bank of Hambro-Grantham Limited, a venture capital firm which now operates as Colonial First State Private Equity and of which he was CEO and Executive Chairman until 2001. Previously he was CEO and Managing Director of International Pacific Corporation Limited, now Rothschild Australia Limited.

Managing Director- Peter Cook

Peter Cook was appointed Managing Director and Chief Executive Officer on 9 December 2005. Peter was formerly Chief Executive Officer and Managing Director of Orbital Corporation Limited. He previously held the positions of Chief Executive Officer of Faulding Pharmaceuticals, President of Ansell's Protective Products Division, Deputy Managing Director of Invetech and Director of Research and Development for Nicholas Kiwi.

CFO and Company Secretary- Damian Lismore

Damian Lismore was appointed Company Secretary on 26 August 2005. His commercial background includes ten years with Price Waterhouse (now PwC) in Australia and six years with Deloitte Haskins & Sells in the UK. More recently, he has served as Group Financial Controller and General Manager Buying & Finance for Sigma and as Managing Director of MNT Innovations, the commercial arm of the CRC (Co-operative Research Centre) for MicroTechnology.

Director- Barbara Gibson

Barbara Gibson was appointed a Director in April 1996. She was formerly the General Manager Chemicals Group of Orica Limited and a member of the Orica Group Executive. Prior to this role she was the General Manager of Advanced Sciences Group, which included the Pharmaceuticals, Diagnostics and other Healthcare businesses of Orica.

Director- Ian Gust

Ian Gust was appointed a Director on 27 July 2001. He was the former Director of Research and Development at CSL Limited, a position he held for ten years (1990-2000). He is currently a Professorial Fellow, Department of Microbiology and Immunology, University of Melbourne, a consultant to the Bill and Melinda Gates' Children's Vaccine Program, and a consultant to UNICEF, the World Bank and the World Health Organisation.

Director-Grant Latta

Grant Latta joined the Board on 9 February 2006. He is a member of the Australian Competition Tribunal to the Federal Court. He was formerly Chairman of the Grains Research and Development Corporation, Deputy Chairman of Food Science Australia, Deputy Chairman of Export Finance and Insurance Corporation and Director of Austrade.

Director- Mr Paul Bell

Mr Paul Bell was formerly President of Merck & Co Inc's Asia Pacific Human Health Division between 1997 and 2002 and a member of the international pharmaceutical company's Management Committee. Paul is currently a Director of Cochlear Limited and Bio-Link Partners Ltd. Mr Bell is also Chairman of Westmead Millennium Institute Advisory Board, a Member of the Pharmaceutical Partnerships Program Committee and a Member of the Business Development Advisory Board of Garvan Institute of Medical Research.

APPENDIX C- TOP 20 SHAREHOLDERS

Top Twenty Shareholders

Investor	Holding	%
Niako Investments Pty Ltd	12,880,000	7.16
National Nominees Limited	11,681,732	6.49
JP Morgan Nominees Australia Limited	6,558,349	3.64
ANZ Nominees Limited	4,562,709	2.54
Westpac Custodian Nominees Ltd	4,308,708	2.39
Arora Constructions Pty Ltd	3,550,000	1.97
Citicorp Nominees Pty Limited	3,510,448	1.95
AMP Life Limited	2,547,454	1.42
HSBC Custody Nominees (Australia) Limited	2,391,105	1.33
Mr Graeme A McDonald & Mrs Susan W McDonald	1,387,789	0.77
Mildura Equity Chambers Management Pty Ltd	1,291,420	0.72
New Age Amusements (Aust) Pty Ltd	1,120,000	0.62
LJ Thomson Pty Ltd	993,580	0.55
Ciach Holdings Pty Ltd	926,555	0.51
Cogent Nominees Pty Limited	829,811	0.46
HSBC Custody Nominees (Australia) Limited	811,601	0.45
Dr Kevin Anthony Glucina	808,000	0.45
Bellevue Investments Pty Ltd	790,961	0.44
UBS Wealth Management Australia Nominees Pty Ltd	732,800	0.41
Bellevue Investments Pty Ltd	700,000	0.39
Total	62,383,022	34.67

Source: Company

FINANCIALS

Biota Profit & Loss \$m						
Y/e Jun	2006a	2007e	2008e	2009e	1H 07a	2H 07e
Sales revenue	12.7	58.9	74.4	196.7	19.1	39.8
EBITDA	-12.6	18.6	19.2	175.9	2.9	15.7
EBITDA margin	-99%	32%	26%	89%	15%	39%
Depreciation	1.0	1.0	1.0	1.1	0.0	1.0
EBITA	-13.6	17.6	18.1	174.8	2.9	14.7
EBITA margin	-107%	30%	24%	89%	15%	37%
Amortisation	0.0	0.7	1.3	1.3	0.0	0.7
EBIT	-13.6	16.9	16.8	173.5	2.9	14.0
EBIT margin	-107%	29%	23%	88%	15%	35%
Net interest expense	-2.3	-3.0	-4.4	-7.3	-1.2	-1.9
PBT	-11.3	19.9	21.2	180.7	4.1	15.8
Tax	0.0	-5.0	-7.0	45.6	0.0	0.0
NPAT	-11.3	24.9	28.2	135.2	4.1	15.8
NPAT normalised	-11.3	25.6	29.5	66.5	4.1	16.5

Source: Company; Foster Stockbroking estimates.

Biota Cashflow \$m				
Y/e Jun	2006a	2007e	2008e	2009e
Receipts	7.0	42.9	73.4	190.5
Payments	-23.5	-30.6	-54.7	-17.4
Interest	2.1	-3.0	4.4	7.3
Tax	0.0	0.0	0.0	-45.6
Other	6.7	0.0	0.0	0.0
Operating cash flow	-7.7	9.3	23.1	134.8
Loans to related parties	0.0	0.0	0.0	0.0
Sale of PPE	0.1	0.0	0.0	0.0
Acquisitions	0.0	-4.0	0.0	-4.0
Capex	-2.0	-1.2	-1.6	-1.7
Investing Cashflow	-1.9	-5.2	-1.6	-5.7
Debt repayments	-0.8	0.0	0.0	0.0
Debt borrowed	0.0	0.0	0.0	0.0
Equity proceeds	31.8	46.0	0.0	0.0
Dividends	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Finance Cashflow	31.0	46.0	0.0	0.0

Source: Company; Foster Stockbroking estimates.

Biota Balance Sheet \$m

Y/e Jun	2006a	2007e	2008e	2009e
Cash and cash equivalents	46.2	60.3	81.8	210.9
Receivables	5.9	19.8	20.9	27.1
Inventories	0.0	0.0	0.0	0.0
PPE	5.5	5.1	5.7	6.3
Intangibles	0.0	10.0	9.3	8.0
Total Assets	57.6	95.2	117.0	252.3
Payables	4.0	10.9	11.5	15.0
Deferred revenue	6.0	0.0	0.0	0.0
Tax liabilities	0.0	0.0	0.0	11.4
Debt	0.0	0.0	0.0	0.0
Provisions	0.6	4.9	0.9	0.3
Other	0.0	12.2	16.3	2.1
Total Liabilities	10.7	28.1	28.7	28.8
Net assets	46.9	67.1	88.3	223.5
Contributed Equity	158.0	158.3	158.3	158.3
Reserves	-0.1	-0.2	-0.2	-0.2
Retained profits	-111.0	-91.0	-69.8	65.3
Total Equity	46.9	67.1	88.3	223.5

Source: Company; Foster stockbroking estimates.

Biota Financial Ratios

Y/e Jun	2006a	2007e	2008e	2009e
DPS c	0.0	0.0	0.0	0.0
Yield %	0.0	0.0	0.0	0.0
Ave wtd shares dil m	179.3	182.7	182.7	182.7
EPS rep c	-0.06	0.14	0.15	0.74
EPS normalised c	-0.06	0.14	0.16	0.36
PER x	-27.6	12.4	10.8	4.8
EPS growth %	-43%	NA	15%	125%
Interest cover x	6.0	-5.6	-3.8	-23.9
Ave RoE (%)	-24%	38%	33%	30%
Ave RoA (%)	-119%	48%	48%	419%
EV/EBITDA x	-21.1	13.9	12.3	0.6

Source: Company; Foster Stockbroking estimates.

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