Biota

Buy around $1.70

Bargain biotech

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SYMBOL DEFINITIONS

SPECIALTY DISH | HIGH RISK | MARKET CAP $310m

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Biotech companies are not renowned for having earnings. More commonly, the average biotech firm chews through significant amounts of investor capital in attempting to take a drug from development through to the commercialisation stage. Considering this, a good deal of patience is required before an investor will see any earnings.

> *"Biota has de-risked most of its other major drug developments by partnering with large pharmaceutical companies"*

Biota (BTA), on the other hand represents something of a rarity in the biotech sector. That is, the company generates earnings for investors and is set to deliver a maiden profit in the year to June 2007. And what's more, we believe the market is not factoring in the company's earnings potential.

While we previously thought the words biotech and cheap were mutually exclusive, Biota appears to be the exception to the rule.

Based in Melbourne, Biota describes itself as an antiviral drug development company. Biota's most successful drug to date is zanamivir, the first-in-class neuraminidase inhibitor for the treatment and prevention of influenza.

Biota licensed zanamivir to GlaxoSmithKline (GSK) way back in 1990 and the British pharmaceutical giant began marketing the drug as Relenza in 1999. Relenza is used to treat seasonal influenza and is currently being stockpiled by various governments for defence against possible pandemic outbreaks of avian (bird) influenza.

And this is where the story becomes interesting for Biota. Governments around the world are stockpiling influenza drugs and this large and growing market is shared between Relenza and Tamiflu. Relenza is delivered through a disk inhaler device, while Tamiflu is taken orally.

In the early stages of the stockpiling process, Tamiflu grabbed the majority market share, partly because GSK wasn't prepared for the surge in demand. (This is now subject to a legal battle between the two parties, which we discuss below) However, there have since been some side effect issues with the Tamiflu drug. In consequence, orders of Relenza are now picking up strongly and GSK is looking to ramp up production to meet the increase in demand.

GSK have increased their production of Relenza from 1 million courses in 2005 to 30 million courses (annualised) in the first quarter of 2007. This will translate into a significant increase in royalty payments for Biota in 2008.

Each sale of the Relenza product generates a net royalty fee of around 6.75 percent for Biota. GSK makes the payment annually in arrears, skewing royalty payments and cash flows towards the second half of the year.

As mentioned, the market for Relenza consists of the 'seasonal' and the pandemic market. The seasonal market relates to the standard winter 'flu and has a market size of around US$1 billion. Biota estimates the pandemic stockpiling will total around US$4-5 billion by 2009, with an annual replenishment market of US$1 billion after governments finish building their stockpiles.

Biota's patent protection on the zanamivir/Relenza product comes off progressively from 2011 through to 2014. The size of these markets, along with GSK increasing production to meet strong demand, represents a significant opportunity for Biota. We will discuss the impact on the financials in a moment, but first, let's examine Biota's other products.

Still on influenza, the company is working on the next generation of products, known as LANIs (long-acting neuraminidase inhibitors). Also inhaled, LANIs provide more potency and a longer period of action. This allows them to be administered only once a week, instead of twice daily as is the case with Relenza.

While still in the early stages of development, LANIs' high potency and reduced frequency of administration offers an advantage over Relenza in that the product requires less storage space for stockpiling.

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Biota has a joint ownership with Japan-based Daiichi-Sankyo for the development of LANIs. Phase I testing in Japan is complete and funding of US$5.6 million has been secured from the US National Institute of Health to commence Phase I Western trials. UK testing has already commenced.

LANIs are likely to supersede Relenza in the pandemic/stockpiling market. However, provided the trials go according to plan, LANIs will not hit the market until around 2010 - 2011. This is to coincide with the replenishment of government pandemic stockpiles, given that both Relenza and Tamiflu have a five year shelf life.

From a shareholder perspective, Biota has de-risked most of its other major drug developments by partnering with large pharmaceutical companies. While the end result may not be as spectacular in the event of a successful commercialisation, the company will not chew through so much capital throughout the development process.

Biota has a partnership with MedImmune Inc, a US-based company currently being absorbed by European giant Astra Zeneca. MedImmune has a licence and collaboration agreement to develop Biota's lead compounds aimed at RSV (respiratory syncytial virus).

Respiratory syncytial virus (RSV) infects people of all ages, particularly infants, causing similar symptoms to influenza and occurring at about the same frequency. The virus is highly contagious and according to Biota, roughly 50 percent of children will experience two RSV infections by the age of two.

The World Health Organisation estimates global annual infection and mortality figures for RSV to be 64 million and 160,000 respectively. In the U.S., estimates put RSV-associated hospitalisations at between 125,000 and 250,000 per annum.

With the market for RSV therapies at around $1.1 billion, MedImmune dominates the market with their Synagis product. Biota's licensing agreement with MedImmune has the potential to deliver US$107 million in milestone payments (as certain development stages are achieved). MedImmune will fund development costs and Biota stands to earn any future royalties from the successful sale of the drug.

In November 2006, Biota signed a licensing and research collaboration agreement with Boehringer Ingelheim to develop and commercialise Biota's novel nucleoside analogues designed to treat Hepatitis C Virus (HCV) infections. Biota stands to earn $US102 million in milestone payments and research support. In addition, Biota will enjoy royalty payments in the event of successful commercialisation.

Lastly, Biota is developing a treatment for Human Rhinovirus (HRV) also known as the common cold. While common and generally self-limiting, HRV is a major cause of hospitalisation for patients with underlying respiratory conditions. This is Biota's target market.
Phase I trials are complete, and the company plans on completing Phase IIa trials before looking for a development partner.

So Biota may be packed with potential, but how do the financials look? Well, surprisingly good for a biotech.

Biota is on track to report before tax earnings of around $18 million for the year to June 2007. Considering the company has around $70 million in accumulated tax losses, tax shouldn't be a problem in the foreseeable future.

Giving some idea of the recent pick up in Biota's profitability, half year earnings were $4.1 million, therefore the second half contribution is significant. With GSK now ramping up production of Relenza, we would expect royalty payments to continue growing throughout 2008.

Biota's financial statements provide some visibility as to future royalty payments. Because Relenza royalties are paid in arrears, the real indicator of royalty payments is in the receivables line of the balance sheet. Growing receivables indicate Biota expects to book future revenues from accrued Relenza royalties.

In addition to increased royalty payments, Biota should also continue to generate revenue from partnerships after reaching defined development milestones.

Of course, expenses will also increase as the company progresses its various drug programs through the development phases. Nevertheless, Biota is confident that revenues will increase faster than expenses, leading to an expansion of profit margins.

There are few mainstream analysts who cover Biota, so there are no consensus earnings forecasts. However, given projections of $18 million in earnings for this financial year, the company trades on an earnings multiple of around 17 times. In our view, given the expected growth in Relanza royalties, Biota is very cheap.

The stock also looks good from a balance sheet perspective. At December 31, the company had around $42 million in cash and a total equity base of $51.3 million. This signifies that the company's asset base is very profitable. That is, Biota can generate significant cash flows from a small equity base.

As the company does not need much in the way of fresh injections of capital to maintain operations, we believe capital management initiatives may come into play in the future.

However, in the near term Biota will be maintaining a large cash balance to fund its operations (given the way GSK pays royalties annually in arrears) and to fight a legal battle with GSK. Biota is taking GSK to court for 'failing to use best endeavours in the development and marketing of Relenza'. A trial date has been set for April 1, 2008, although it is possible that an out-of-court settlement will be reached beforehand.

Biota is claiming up to $430 million in damages and has built up extensive documentation to argue its case against GSK. While Biota remains confident that the claim will be successful, Members should be aware that litigation costs will continue to constrain the company's ability to utilise excess cash for the benefit of shareholders.

From a charting perspective, growing investor support has seen Biota gain around 50 percent since September. This marks a significant improvement in the longer-term outlook, reviving the upward trend that commenced in 2005.

As displayed on the daily chart, the latest gains have been characterised by a series of sharp rallies followed by periods of consolidation at successively higher levels. Since achieving a 13-month high of $1.89 in May, Biota has been consolidating above $1.62. We expect that this level will continue supporting prices in the near term, with additional support at $1.51 underpinning the upward trend.

In the months ahead, we expect the long-term re-rating of Biota to continue. A break above $1.89 will initially target the $2 region with longer-term potential for gains toward $2.75 and beyond.

As such, we recommend Biota as a buy to all Members around $1.70.

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