Biotech Daily
Marc Sinatra's Bioguide

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BIOTA: LEGAL RISK WITH SOME UPSIDE

Overview: Over the last few years, Biota's share price has been fuelled by news surrounding its influenza drug, Relenza. Stockpiling of drugs to defend against influenza pandemics by governments worldwide has seen sales of Relenza skyrocket from almost nothing. In addition, Biota's lawsuit against Glaxosmithkline (GSK) alleging that they failed to use their best endeavors in developing and marketing Relenza has had investors pondering a possible windfall of up to $430 million.

While the sales of Relenza are good news and the lawsuit against GSK could provide a very big lump sum of cash, neither really testifies to Biota's ability to be a successful drug development company. When you look beyond Relenza, however, you do glimpse a company that is putting itself in a position to be successful. It has consolidated in a purpose built facility in Melbourne, raised capital, built a local team, taken advantage of government funding, done licencing deals and moved their lead rhinovirus project up to phase II clinical trials.

So what value have these activities added to the company beyond Relenza?

Financials: Market cap: $333 million; cash: $60 million; last half cash burn: $16.7 million.

Directors & Management: non-executive chairman, John Grant; CEO, Peter Cook; non-executive directors: Paul Bell, Barbara Gibson, Dr Ian Gust and Grant Latta.

The Biota board has a mix of pharmaceutical, finance, medical research, commercialization and general business experience.

Products on Market: Biota has three US FDA approved products. They are:
1) Relenza - flu drug marketed by GSK. Sales generated $16 million in royalties last quarter.
2) FLU OIA - flu diagnostic marketed by Thermo Electron.
3) FLU OIA A/B - flu diagnostic marketed by Thermo Electron.
*The total profit share for diagnostics was $400,000 for the last half of 2006.

Products in Development: The following are Biota's main products in development, the indication they target and their current developmental stage.
1) HRV project - human rhinovirus infection in patients with respiratory conditions. Phase IIa trial starting late 2008;
2) RSV project - respiratory syncytial virus infection in children, elderly and immuno-compromised. Phase I trial just started.
3) HCV Project - hepatitis C virus infection. Discovery.
4) LANI (CS8598 and Flunet) – influenza. Phase II trials starting late this year.

Biota intends to take the HRV project through phase IIa trials on its own. The RSV and HCV projects are licensed to Medimmune and Boehringer Ingelheim, respectively. The licensors in both cases are covering all significant costs. CS8598 and Flunet are second-generation flu drugs and are co-owned with Japan's Daiichi-Sankyo Corporation.

Product Markets: Roche's Tamiflu completely dominates the flu drug market. Its 2006 sales were $US2.1 billion and first quarter 2007 sales were 47 percent above 2006. About one third of 2006 sales were for seasonal influenza. The likely approval of the first pre-pandemic influenza vaccines later this year is expected to impact the flu drug market. Little other product development is going on.

In 2000, there were 840,000 hospital admissions for chronic obstructive pulmonary disease (COPD) in the US, 60 percent of which were likely due to rhinovirus. In 2006, there were 400,000 admissions for asthma, 80 percent likely due to rhinovirus. The average cost per admission is about $US7000 for COPD and $US3000 for asthma.

Datamonitor put the potential RSV market at $US800 million in 2004, with a much larger market available to a drug suitable for lower risk groups. There are only a few new drugs in development, with many companies ceasing work in the area.

Estimates put the HCV market at about $US2.5-3 billion, but the use of combination therapies means the actual market for a single drug is likely to be considerably smaller. There are a reasonable number of new drugs in development.

Verdict: Using risk-adjusted discounted cash flow (DCF) analysis; I have calculated values for Biota's various projects. The RSV, HCV, HRV and LANI projects attracted values of $45 million, $18 million, $37 million and $33 million, respectively; with the RSV project with Medimmune the most promising and a great example of a value-adding licencing deal. Clearly, Biota's activities beyond Relenza have added significant value to the company.

Adding a value of $62 million for the Relenza royalties, $4 million for the diagnostics and $60 million in cash to the values above you get a total of $259 million. Biota's final value is dependent upon their lawsuit with GSK.

Unfortunately, I have been unable to find good data on lawsuits of this nature, while the lawyers I have consulted have advised me that you really need to be on the inside to predict the likely outcome. My guess is that Biota has a reasonably good case because it risks having to pay GSK's very significant costs (currently $40 million) if they lose. How much Biota will get, however, I don't know.

Biota is not for the faint-hearted right now. Based on today's numbers, a decision in the lawsuit could see Biota's market cap end up anywhere between $219 million ($259m - $40m) and $699 million ($259m + $430m + $10m, where $10m is Biota's expenses so far). Given Biota's current market cap of $333 million, I believe there is more upside than downside, but you must be willing to wear the risk.

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