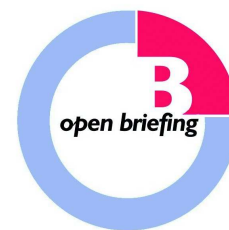


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Biota Holdings Limited today reported NPAT of \$38.2 million for the year ended June 2009, compared with a loss of \$6.5 million in the previous year. Excluding the \$20 million settlement received from GlaxoSmithKline (GSK) and related litigation costs, net profit was \$25.4 million, up from \$15.3 million. How indicative is the 2009 underlying result of the earnings outlook for the current year ending June 2010?

CEO Peter Cook

Since the beginning of May we've provided a number of updates to the market on the plans of GSK to increase its production capacity for Relenza, both in the current Diskhaler delivery format and also in the Rotocap/Rotohaler format, a novel inhaler device that at the moment is restricted to use in pandemics and within Europe. Since the beginning of the Swine Flu outbreak in late April, GSK has indicated that its order book for Relenza was strong and limited only by available capacity, which was being aggressively expanded.

Capacity and orders, of course, aren't sales. However, our shareholders should expect our results in FY2010 to benefit from a stronger royalty flow from Relenza than we received in FY2009 due to the known impact of Swine Flu thus far on government demand for Relenza pandemic stockpiles. The best way to monitor Relenza sales will be through our quarterly announcements and those of GSK.

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You recently announced a cash return of \$20 million to shareholders in December 2009, pending shareholder approval if needed. What's the rationale

behind the quantum of the return and why aren't you returning more to shareholders given cash of \$86.7 million at the end of June?

CEO Peter Cook

The last time we raised capital from our shareholders was October 2005, when we sought to strengthen our balance sheet in preparation for the litigation against GSK. That litigation was finally resolved in the 2009 financial year. As a result, we see it as appropriate that our surplus funds are returned to shareholders, particularly as the near term revenue outlook is sufficiently encouraging to give us confidence we'll be able to retain the capital we need to meet our growth plans.

The proposed capital return is not our only attempt to reward shareholders. We undertook an on-market share buyback from February to October 2008, during which we acquired 9.2 million shares, or about 5 percent of issued capital, at a cost of \$7.8 million.

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Does the introduction of a dividend remain off the agenda?

CEO Peter Cook

Capital management is constantly under review by the Board, so nothing is off the agenda. However, we're not in a position to pay franked dividends until the company becomes a tax-payer which should occur in the not too distant future. That would allow us to consider franked dividends should the Board determine we have cash in excess of our requirements. However, external factors also dictate the balance that needs to be struck between retaining earnings, for both balance sheet strength and to fund growth, and providing a return to shareholders. In the current environment our conservative financial structure has allowed us to avoid the funding issues that have affected many in our sector.

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Sales revenue for 2009 was \$57.6 million up 59.8 percent from the previous year mainly due to the increase in Relenza royalties in the second half to \$41.2 million, versus \$3.8 million in the first half. GSK intends to increase Relenza production capacity to 190 million courses by the end of the 2009 calendar year, up from 60 million courses currently. Do you have any indication of the likely royalty flow in 2010?

CEO Peter Cook

Analysts who've closely studied GSK's Relenza expansion plans are forecasting our royalties to be in the range of \$80 million and \$130 million in FY2010. These forecasts assume GSK's capacity can be built as planned and that declared government orders actually become sales. They also assume GSK can get regulatory approval for the Relenza Rotahaler.

The \$80 million and \$130 million forecast would seem reasonable based on what we know at this time, but we should also note that the course of any Swine Flu pandemic in the northern hemisphere winter cannot be forecast: it could dissipate, it could become more virulent, or it could become resistant to all approved drugs. Each of those different scenarios would affect our royalties – particularly in the second half of FY2010.

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After the successful Phase III clinical evaluation of laninamivir (CS-8958) in August 2009, Daiichi Sankyo has elected to market laninamivir in Japan, which will result in a new royalty flow to Biota on all Japanese sales. What processes need to be completed before laninamivir can be marketed in Japan and what is the potential market in Japan?

CEO Peter Cook

The next key step in the process is the submission of a new drug application (NDA) to the Japanese health authorities. Daiichi Sankyo has indicated it intends to complete that by March 2010, and the typical lead time to approve a new drug application would be approximately 18 months.

Daiichi Sankyo has indicated it will also commence a prevention study with laninamivir – the current NDA relates to laninamivir as a *treatment* for flu. We'll keep our shareholders informed as progress is made on both these matters.

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What is your strategy for laninamivir outside Japan and what are the next steps before you could get approval for the drug in other markets?

CEO Peter Cook

At the clinical level, our strategy outside Japan has been to complete “bridging studies” in the West which in conjunction with the major studies from Japan, should allow for Western registration. We've attempted to do this on a cost effective basis for our shareholders by using funds predominantly from the US National Institutes of Health.

At the commercial level we've been actively seeking potential licensees for the rest of the world. One of the reasons we were pleased to get the results of the Phase III study released in mid August, was that a number of the companies that have expressed interest in the product wanted to see those results before offering a term sheet or a more formal expression of interest.

Overlaying all this has been the issue of the Swine Flu pandemic. A number of countries have actively sought to identify drugs in the late stage of development that could be rapidly deployed to the public's benefit should the pandemic move into crisis. The US Centre for Disease Control for example, has screened laninamivir against Swine Flu strains as part of its contingency strategies. It's worth pointing out that laninamivir, being clinically the most advanced of the unapproved influenza anti-virals, has attracted particular interest and we and Daiichi Sankyo have set out to assist public health authorities wherever possible.

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You completed the Phase IIa clinical trial of your human rhinovirus drug (BTA798) in June 2009. What are the next steps in your clinical development plans for the drug and what's the expected time line? What are the partnering prospects for the HRV program?

CEO Peter Cook

As we've previously indicated would be the case, with proof of concept established, we're now actively seeking to identify suitable licensing partners. That could be a six to 12 month process. Meanwhile we'll continue to develop our plans for a full Phase II study in actual patients – the Phase IIa study was a challenge study, so it was around an induced disease – which will involve a consultative process with the regulators whilst the licensing is being established. I should point out that there's a considerable commercial interest in HRV because it seems to be emerging as the principal, but untreatable, cause of complications in patients with pre-existing asthma.

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In August, AstraZeneca returned the rights to the Respiratory Syncytial Virus (RSV) program to Biota due to the Phase 1a trial not meeting the required safety margin. You intend to spend about \$3 million in 2010 to develop "promising" back-up compounds and re-licence the program. What gives you confidence to put additional development costs into the program when AstraZeneca has discontinued it?

CEO Peter Cook

The drug profile of BTA9881 overall did not meet AstraZeneca's commercial safety margin, that is, its test of whether the drug is more likely to get to market than less likely to get to market. However, we see commercial opportunities in the back-up program behind BTA9881, particularly given the knowledge we've accumulated working with AstraZeneca over the last couple of years. We remain confident that within the back-up compounds, albeit they're not as advanced as the lead compound, there will be compounds that will meet or exceed AstraZeneca's commercial safety criteria.

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Biota's operating costs, excluding litigation costs, were \$34.2 million in 2009, up only 7 percent. Can you continue to contain costs as activity in your clinical programs increases?

CEO Peter Cook

This question is at the core of our business and development strategy. Our fixed costs are reasonably well contained and we can continue to contain them. Our project costs however, are usually met by our licensees or from grant monies, and therefore are always fully recovered. That strategy differentiates us from many other companies in the biotech sector.

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Excluding the litigation settlement, Biota booked operating cash flow of \$12.5 million in 2009, up from \$4.8 million in the previous year, and cash of \$86.7 million as at 30 June was up from \$60.2 million a year earlier. What is the outlook for cash at the end of the current year?

CEO Peter Cook

We'd expect the business to remain cash accretive with a cash balance significantly ahead of June 2009, even allowing for the \$20 million return to shareholders planned for December. The principal driver of that will be Relenza, our major cash generator.

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What potential milestones do you expect over the next 12 months?

CEO Peter Cook

First, we'll be very carefully monitoring Relenza royalties each quarter and informing our shareholders about that. Second, with laninamavir we'd expect to see progress towards a rest-of-the-world partner and also to see progress toward the commercial introduction of the product in Japan, including the NDA submission and commencement of the prophylaxis study. Additionally, we'll see progress on the clinical studies of laninamivir underway in the West. Third, we'd expect to see progress on the licensing of the HRV program and fourth we'd expect progress around the Hepatitis C program we've licensed to Boehringer Ingelheim, which we've not had a lot to say about in the recent period.

In addition, we've spent a considerable amount of time on strategy in the last few months and we've identified that as quickly as possible we want to be in the position of having two or three products out in the market generating royalties at any one point in time. That's going to require the addition of appropriate programs to our portfolio.

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Given Relenza patents are due to start expiring in many of the major markets in 2014, can you realistically expect to have two or more royalty-generating products on the market?

CEO Peter Cook

Laninamavir should be in one or more of the major markets before Relenza patents expire. In our significant markets, the earliest Relenza patent expiry is December 2014 but there are a couple of big markets, like Japan, where the patents run later. Also, given our HRV program is in Phase II, it's conceivable it could get to market during the lifespan of laninamavir. In addition, we'll need to undertake some form of expansion. We'll be looking to license or acquire appropriate additional programs, for example late pre-clinical programs, that we could see out in the market within a four to five year window.

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Thank you Peter.

For more information about Biota, visit www.biota.com.au or call CEO Peter Cook on +61 3 9915 3720 or CFO Damian Lismore on +61 3 9915 3721.

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