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CEO on Outlook, LANI Potential

Open Briefing with CEO Peter Cook

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In this Open Briefing®, Peter discusses:

- Net loss reflects lower Relenza royalties, costs related to HRV programme
- Initial LANI royalty received from Japanese market
- Continuing to review options for rest-of-world approval for LANI

Open Briefing interview:

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Biota Holdings Limited today reported a net loss after tax of $15.9 million for the first half ended December 2010, compared with profit of $33.4 million in the previous corresponding period. The result primarily reflected the fall in Relenza royalty income to $3.3 million from $56.7 million. Can you comment on the market conditions behind this decline and the extent to which Relenza has lost market share?

CEO Peter Cook
Royalty income in the first half of the 2010 financial year reflected the height of the global swine-flu pandemic. Those conditions can't be expected to occur every year but when they do, our earnings can be substantial. For Roche and Relenza licensee GlaxoSmithKline (GSK), the two key market contenders, the value of the influenza market during the pandemic year was over US$4 billion. In that year, Relenza secured some 27 percent market share by value.

Although pandemic timing is impossible to predict, Relenza's demand fundamentals are sound given official government policy is supportive. A number of governments have formally stated their intention to increase their influenza drug stockpiles to cover more than the original 25 percent of the population targeted in 2004. Additionally, there's a significant amount of aging stock, particularly of Tamiflu, in many government stockpiles that will need replacing within the next three years, and that's taking into account an already extended shelf life.

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What insight do you have in relation to Relenza royalties over the remainder of the current year ending June 2011?

CEO Peter Cook
Governments seem to have taken comfort from having avoided a swine-flu crisis and in the aftermath of the global financial crisis, or in the case of Australia after other national calamities, have shifted their attention to other areas. But the reality is that influenza hasn't gone away and will recur.

Given the uncertainty, the best insight into the outlook we can give investors is to provide timely publication of our most recent historical royalties data, and that's what we'll continue to do.

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In the first half Biota booked its first royalty revenue from its long acting neuraminidase inhibitor (LANI), which is sold as Inavir, totalling $1.2 million. The drug was developed with Daiichi Sankyo and launched in the Japanese market in mid October. How indicative is this first royalty payment of the expected royalty flow from Inavir?

CEO Peter Cook
Our partner Daiichi Sankyo has done a very good job launching Inavir and obtaining a good price for it. The peak of the Japanese flu season is in February and so the March quarter will be critical for first season sales.

While we'll need to see more supporting evidence before drawing any conclusions, preliminary data suggests that Inavir has outsold each of Tamiflu, Relenza and Rapiacta during the quarter. If that's confirmed in the current quarter, we'd conclude we were off to a good start.

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To what extent might the track record of sales in Japan impact the progress of your negotiations with an overseas agency to provide funding for the approval process for LANI outside Japan or increase the attractiveness of the drug to potential licencees ex-Japan?

CEO Peter Cook
Obtaining funding for the programme of clinical studies and related manufacturing and good manufacturing practice (GMP) approvals we've got to undertake in the West is central to potential licensees extracting value from Inavir. There's interest in the product, but the level of interest is dependent on whether or not there's agency funding for the Western trials. Early success in Japan may be the icing on the cake for a potential licensee, but it's the agency funding for the trials that will determine the nature and timing of any commercialising partner interest.

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Cash at 31 December 2010 stood at $77.5 million, down from $104.9 million six months earlier. Given cash burn of $26.8 million in the first half, up from $14.4 million in the previous corresponding period, you retain cash equivalent to 1.4 years of operation. Can you comment on the adequacy of this cash buffer? What are Biota's funding options if you decide to undertake the rest-of-world LANI approval process in-house?

CEO Peter Cook
Given the time lines in relation to gaining agency funding and the progress of LANI and the alternative opportunities we see, the Board is comfortable with our current cash reserve and isn't seeing the need to pursue additional funding at this juncture.

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The primary reason for the uplift in Biota's cash expenses was the increase in R&D expenses and product development costs, which totalled $21.3 million, up 38 percent. What specific programmes does this increased spending relate to and what is the expected trend in these costs over the remainder of the year?

CEO Peter Cook
The specific and major item of increase was spending on our human rhinovirus (HRV) Phase IIb study in chronic asthmatics. We announced the commencement of the study in July and at the time indicated we'd potentially spend $25 million on the programme over a two year period. Clinical studies tend to be front-end loaded: you incur a lot of costs setting them up before you even dose the first patient. Those upfront costs won't recur in the second half.

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Biota booked a tax credit of $0.8 million for the first half, versus an expense of $7.9 million in the previous corresponding period. However, actual cash tax paid was $3.7 million, versus nil. What did this tax payment relate to given Biota retains significant unrecognised tax losses?

CEO Peter Cook
The tax credit of $0.8 million largely reflected a cash refund related to UK R&D investment. The tax expense of $7.9 million in the previous first half was a provision for the 2010 financial year based on an assumption of continued strong pandemic sales of Relenza in the second half. The actual tax paid for 2010 was $3.7 million, reflecting lower than assumed royalties for the total year. That amount was actually paid in the first half of 2011.

The unrecognised tax losses we hold relate to the pre-2003 operations of the Company and are subject to continuity of ownership tests and other conditions. Those tax losses are currently recoverable at 53 cents in the dollar.

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Since the end of the first half, Biota has announced that licensee GlaxoSmithKline (GSK) has commenced a pivotal Phase III study comparing intravenous (IV) zanamivir (Relenza) with oseltamivir in hospitalised patients with influenza. What is the expected time line for gaining approval for IV zanamivir, what is the potential market and what would be the structure of Biota's royalty payments from sales of an IV version of the drug?

CEO Peter Cook
GSK has had a long standing interest in this study, recognising the clinical need for a dose form of the drug for patients who are acutely ill and unable to take a pill or use an inhaled product. During the flu pandemic a number of "named patient" approvals were granted, allowing clinicians specific use of the unapproved product. The results were outstanding: there were cases where the product was given to comatose patients in intensive care wards who most likely would have died had the product not been used.

During the height of the pandemic the US government considered placing orders for 30,000 courses of IV products, to be supplied by GSK, Roche and BioCryst. To put this in perspective, the US market overall bought 55 million courses of Tamiflu and Relenza in the same period. On that basis, this class of products represents less than 0.05 percent market share by volume. The IV form will be relatively expensive given the large amount of the drug required and our standard royalty payment of 7 percent will apply in most markets, with 10 percent applying in some markets including in Australia. Even so, sales of this product aren't expected to substantially impact our total royalty payments.

GSK expects the study to take about three years to complete, followed by a further 12 month approval period before the product is available for use.

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What specific shareholder value-enhancing milestones do you expect to achieve over the next six to 12 months?

CEO Peter Cook
We expect a number of milestones over that period. As I mentioned, a significant update on our financing options and opportunities around LANI will most likely occur in the next six months. In the next 12 months we'll also most likely complete our Phase IIb HRV study and have made significant progress in commercialising our respiratory syncytial virus (RSV) programme, where we've now formally identified a molecule for pre-clinical development. In six months we'll have another couple of quarters of data on Inavir's progress in its first influenza season in Japan, and in 12 months we'll be able to see how it's shaping up in its second season.

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Thank you Peter.

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

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