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CEO on Outlook

Open Briefing with CEO Peter Cook

Biota Holdings Limited
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In this Open Briefing®, Biota CEO Peter Cook discusses

- Strong H1 10 result, reflecting the substantial increase in Relenza royalties
- Progress in current development programs
- Outlook for costs, program funding

Open Briefing interview:

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Biota Holdings Limited today reported NPAT of $33.5 million for the first half ended December 2009, up from $7.2 million for the previous corresponding period. If earnings are maintained at this level in the current second half, you'd book NPAT of over $65 million for the full year ending June 2010, up from $38 million last year. Would this be a reasonable expectation? To what extent is this indicative of the likely level of earnings going forward?

CEO Peter Cook
Based on the first half alone we'll have a record year. We're very pleased with the progress we've made and the impetus the first half gives us for the full year.

However, we're not prepared to provide full-year guidance given GlaxoSmithKline (GSK) has control over the sale and delivery process for Relenza, the main source of our royalty income. No-one, not even GSK customers buying Relenza, can forecast the course of the current influenza pandemic. We'll continue to update the market quarterly on our indicative Relenza royalties, which we expect to remain solid.

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Sales revenue was $58.1 million, up from $10.5 million, including $56.7 million of Relenza royalties, up from $3.8 million. GSK last year announced plans to increase its Relenza production capacity to 90 million courses per year by December 2009, up from 60 million, and to offer an additional 100 million courses of Relenza in Rotahaler form, in response to the Swine Flu pandemic and resistance issues and side-effects with Tamiflu. Given this and that governments worldwide are seeking higher proportions of Relenza in their anti-viral stockpiles, what is the outlook for revenue for the current year?

CEO Peter Cook
All of the factors you've identified support our view that income from Relenza will remain strong, including the increase in capacity GSK has now successfully brought on line for Relenza Diskhaler. GSK's capital investment in the flagship Diskhaler product has been significant and based on the most recent quarter's sales, it has met its 90 million course annual capacity ahead of 31 December, as planned. To date, only the European Union has approved the Rotahaler form and has done so only for the duration of the current pandemic.

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Biota's partner Daiichi Sankyo this month filed a new drug application (NDA) in Japan for second-generation flu drug laninamivir (CS-8958) after the successful completion of Phase III clinical trials in Asia. What are the next steps towards commercialising laninamivir in Japan and to what extent would the drug's commercial prospects be enhanced if the recently commenced Phase III prevention studies are successful?

CEO Peter Cook
Commercialisation is well underway, given the NDA was filed ahead of plan in February. As soon as the NDA is approved the product will be available for sale for its first indication, treatment. The successful completion of the prevention studies will depend on access to flu sufferers towards the end of the current Northern Hemisphere winter. Once these studies are completed and the indication approved, we'll be able to make a broader label claim for the commercial product.

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Bridging Western early phase clinical studies with laninamivir, funded by the US National Institutes of Health, were also completed in the first half. It's your intention to secure a licensee for laninamivir outside Japan in the near future. Will you need to complete further bridging studies before securing a partner?

CEO Peter Cook
We've indicated it's our intention to seek a rest-of-the-world licensee for laninamivir in the near future. We're pleased with the level of interest being shown in the product, and the diversity of interested parties. Any rest-of-the-world licensee would have to undertake further clinical studies before approval is likely in Western markets. Whether these are undertaken by the licensee or ourselves will be a matter of timing and practicality and the terms of any licensing agreement.

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In November 2009, Biota announced the acquisition of the assets and drug development programs of two companies involved in developing antibacterial agents, Prolysis Limited in the UK and MaxThera, Inc in the US. Why were these programs attractive to you given your traditional focus on anti-viral compounds? To what extent do these acquisitions represent a change in strategy for Biota?

CEO Peter Cook
Biota has always been a small molecule drug discovery company with a focus on anti-infectives. It just so happened that our initial success was with anti-virals. So there's been no fundamental change in our strategy: the Prolysis and MaxThera programs fill specific gaps

in our pipeline; they do so cost effectively but still provide us with the opportunity to add considerable value.

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You expect to invest about $25 million and $15 million respectively in the Prolysis and MaxThera programs over the next three years. Can your current resources support this level of investment? To what extent can the investment be funded by your royalty stream from Relenza, whose patent expires in 2014?

CEO Peter Cook
We expect to be able to resource both the Prolysis and the MaxThera programs, but we also shouldn't lose sight that those programs are only part of our total development portfolio. Our pipeline is extensive, balanced and well funded from our forward revenue streams.

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What stage of development are you targeting with the planned investment in the Prolysis and MaxThera programs? What is your licensing strategy for the programs and what are the key factors you will consider in deciding whether to retain development internally or license to a third party?

CEO Peter Cook
Our intention is to take all of our programs to a significant value inflection point before seeking a licensee. The earliest of these value inflection points is usually proof-of-concept in humans. It's unlikely we'd significantly change that strategy with either the Prolysis or the MaxThera programs.

We view each licence opportunity on a case by case basis and there's always the opportunity to achieve a better risk-reward outcome for our shareholders by remaining flexible.

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Expenses totalled $20.3 million in the first half, down from $23.4 million in the previous corresponding period. What is the outlook for costs given the likely increase in development activity?

CEO Peter Cook
We've indicated we expect to support average project expenditure of approximately $50 million per annum over the next few years. That's for all our programs, not just the Prolysis or MaxThera programs. However, there will be considerable variation in the actual costs from year to year to accommodate the large, one off expenses characteristic of clinical trials. Indeed, the significantly higher clinical expenditure in the first half of fiscal 2009 compared with the recent first half, was the primary reason for the decline in expenses.

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Biota's reported first-half profit included a provision for income tax of $7.9 million, which assumes full-year profitability and recovery of all tax losses. What is the extent of the tax losses you carry and when is Biota likely to start paying cash taxes? What is the expected effective tax rate?

CEO Peter Cook

We carried approximately $40 million of tax losses into the 2010 financial year. We expect to pay tax on any profits in excess of this amount and that will be due for payment in December. After the recovery of our tax losses, we'd expect to pay at a 30 percent tax rate on any excess.

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Cash totalled $52.0 million as at the end of December, down from $86.7 million six months earlier, reflecting operating cash outflow of $14.5 million in the first half and a capital return of $20.0 million to shareholders in December. Given the investment needs of your portfolio of development programs, what scope do you see for further returns of funds to your shareholders?

CEO Peter Cook
It's our intention to return excess cash, beyond that required by our programs, and to do so in the most efficient manner. Franked dividends have considerable appeal to Australian shareholders however they will only be possible when we've cleared our tax losses and paid our tax.

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Thank you Peter.

For more information about Biota Holdings Limited, 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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