CEO on FY2012 Result

Open Briefing interview with CEO Peter Cook

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In this Open Briefing®, Peter discusses:

- First revenue under BARDA contract
- Cash burn management
- Positioning of Biota in US post merger with Nabi

Record of interview:

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Biota Holdings Limited (ASX: BTA) today reported a net loss after tax of $18.8 million for the year ended June 2012, compared with a loss of $28.1 million in the previous year. The key feature of the result was Biota's booking of its first revenue under its US$231 million contract with the US Office of Biomedical Advanced Research and Development Authority (BARDA) to develop long acting neuraminidase inhibitor laninamivir for the US market. As of 30 June, you had delivered four of the five BARDA contract milestones, with the fifth milestone ongoing. What is the outlook for BARDA revenue as you work through the fifth milestone?

CEO Peter Cook
In general terms, our revenue from the BARDA contract will double each year through to the fourth year of the program. We booked revenue of around $10 million in FY2012, and that should ramp up to around $25 million this year, then $50 million next year and over $100 million in the following year, with the remainder falling into the final year of the contract.

That revenue profile is only a guide and will be determined, ultimately, by the scheduling. Clearly, the biggest task under the contract will be the Phase III clinical trials, which have to be global in reach, and will occur late in the piece.

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Royalty income was $8.6 million, down 11 percent, comprising Relenza royalties of $4.3 million, down from $6.1 million in the previous year, and Inavir royalties, from sales in Japan, of $4.3 million, up from $2.9 million. What visibility do you have on royalties in the nearer term? Can you comment on the maturity and competitive position of Inavir in the Japanese market?

CEO Peter Cook
As usual, we don't have a high degree of visibility around royalties: even world health authorities are unable to adequately forecast what's going to occur in the next influenza season. However, over the eight years we've been earning royalties from Relenza, we've achieved around $20 million to $30 million per annum in royalty income. On this measure, royalties were relatively low in FY2012.

Inavir performed well in its first full season since its launch in the Japanese market. Based on the six months to the end of June, Inavir was the largest selling neuraminidase inhibitor in

Japan, with sales of around $114 million, compared with about $97 million for Tamiflu. So Inavir appears to have won a market share in the order of 50 percent in year two, which is a great result.

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Product development costs, which appear to be related primarily to the BARDA contract, totalled $16.6 million in FY2012, up from $15.6 million in FY2011. To what extent do payments from BARDA lag Biota's expenses under the contract? To what extent is the increase in Biota's receivables, to $7.2 million as at 30 June from $4.1 million a year earlier, attributable to the BARDA contract?

CEO Peter Cook
Work on our human rhinovirus (HRV) antiviral vapendavir, which accounted for much of our product development expenses in FY2011, reduced in FY2012, but was replaced almost dollar for dollar by expenditure under the BARDA contract.

Of the $3.1 million year on year increase in receivables, $2.9 million relates to the BARDA contract. The increase is a function of the increasing revenue flowing under the contract, which was about $10.6 million in FY2012, up from about $0.6 million the year before. Under the agreement with BARDA, we invoice 15 days after month-end and we're paid typically after a further 30 days. Clearly, as the contract ramps up, our receivables will reflect that increase in revenues.

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R&D expenses were $16.4 million for FY2012, down from $20.7 million. Post its proposed merger with US-based Nabi Biopharmaceuticals, Biota will have about $100 million in cash, versus $52.9 million at 30 June. What is your plan for R&D, particularly for your programs at clinical stage, given an apparent focus on laninamivir product development?

CEO Peter Cook
The reduction in R&D expenditure in FY2012 was partly due to the completion of our RSV program, which has moved into product development, but also reflected a deliberate refocusing of our research activities. We focused our early stage research work on our gyrase program and turned off our other competing antibacterial programs, driven by the progress with gyrase. Our other antibacterial programs have been suspended unless they have attracted external funding.

Under our current plan, our clinical stage programs will focus on laninamivir. Because it's fully funded, we'll give maximum attention to that program. In the near term – six to nine months – we'll be looking to advance one or more of the earlier stage, pre-clinical programs like RSV, or hepatitis C or gyrase programs. We have yet to decide which of these programs we'll advance into the clinic. We're looking to maintain cash burn at around $20 million a year; but at this stage we haven't identified the specific programs or the extent of any clinical expenditure.

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As at 30 June, Biota had accumulated tax losses of $51.7 million and franking credits of $4.2 million. To what extent will Biota be able to utilise these following the proposed merger?

CEO Peter Cook
The tax losses and franking credits will remain with the Australian companies which will continue to exist, but will be under the ownership of a US holding company. So long as the existing assets of the Australian companies generate a profit, the tax losses will be available to us. However, our ability to recover those tax losses will be dependent upon continuity of ownership tests, continuity of business tests and that current legislation remains in place.

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Post the proposed merger with Nabi and formation of NADAQ-listed Biota Pharmaceuticals, what is the expected contribution to earnings and cash flows of the Nabi assets? What assumptions underlie your expectation that the $100 million cash holding post merger will be adequate for at least three years of operation?

CEO Peter Cook
We've taken a very conservative approach and are being prudent in terms of risk adjusted forward cash flows. Other than Nabi's cash and the earnings ability of that cash, we've ascribed minimal value to any other Nabi assets. Even though on FY2012 figures we have a burn rate of approximately $15 million, we've applied our highest annual cash burn rate of the last three years as the basis for our estimate that $100 million in cash will be adequate for three years of operation. We believe the number is highly conservative.

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How do you expect the merged company, Biota Pharmaceuticals, to be positioned versus comparable US companies in terms of financial metrics such as cash holdings and cash burn, as well as clinical news flow?

CEO Peter Cook
Our first priority was to have sufficient cash. As a rule, Australian biotechnology companies carry about a year of cash reserve, and here any additional cash is considered lazy money that should be returned to shareholders. The US biotechnology view is different: most US biotechs try to carry three years of cash reserve, and due to the unpredictability of the forward markets, their view is that money should be raised when it's available and timing is appropriate.

Our financial metrics will look fairly similar to comparable US companies. While our current cash burn might look a little light in US terms, after we go through the transition process, we'd expect to crank up one or more of our early stage programs we think have the best chance of success. That means our cash burn will increase, but not within our first 12 months as a US company.

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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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