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CEO on FY Results, BARDA Contract

Open Briefing with CEO Peter Cook

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In this Open Briefing®, Peter discusses

- **Net loss reflects reduced Relenza royalties**
- **Significance of US$231 million flu drug development grant from US**
- **Strength of balance sheet with $70 million cash**

Open Briefing interview:

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Biota Holdings Limited yesterday reported a net loss after tax of $28.1 million for the year ended June 2011, compared with profit of $16.2 million in the previous year. The result reflected lower Relenza royalty income, which fell to $6.6 million from $63.7 million, partially offset by first royalties from sales of Inavir in Japan, which totalled $2.9 million. How did royalties from Relenza and Inavir compare with your expectations and what is the outlook for royalty income for the current year ending June 2012?

CEO Peter Cook
Relenza had a big year in FY2010 as it was the year of the swine flu pandemic. We expected royalties to be subdued this year: influenza drugs are both seasonal and cyclical products and royalties are a function of that. The way we respond to these cycles is by carrying appropriate cash reserves.

We were pleased to have launched Inavir in Japan in FY2011, ahead of schedule. Japan is one of the two largest markets for influenza drugs and we expect the future contribution of Inavir in Japan to be significant.

Over the last six years, we've seen at least three cycles of building influenza drug stockpiles, reflecting the threats from severe acute respiratory syndrome (SARS), bird flu and last year the swine flu pandemic. Given that the earliest of our major Relenza patents does not terminate until December 2014 and in Japan until 2019, there is every chance that another of those cycles will again influence sales. For the record, our Inavir patents run until 2027.

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In April Biota announced it had been awarded a contract of up to US$231 million by the Office of Biomedical Advanced Research and Development Authority (BARDA) of the US

Department of Health and Human Services to develop laninamivir for the US market. The funding is to cover Phase II and III trials of the drug and lodge a new drug application (NDA) with the US Food and Drug Administration (FDA). What has been the progress in this project and what is the expected time line for the major clinical trials?

CEO Peter Cook
The BARDA contract covers more than Phase II and III trials. It requires the availability of laninamivir to the US stockpile, sourced from domestic US manufacturers. This covers the scale-up and commissioning of manufacturing plants to produce both the active pharmaceutical ingredient and the final dose form. This won't be Biota's plant, but a combination of US contract manufacturing plants.

Once the manufacturing capability is available, a suite of clinical trials are planned to be undertaken including Phase I, Phase II and Phase III trials as ultimately agreed with the FDA.

The time line for the project is five years with the first year devoted to planning and the last four years to execution. Under our contract with BARDA, there are five major milestones with the first four related to planning and only the fifth with execution. The first milestone has been delivered ahead of time. We're in active dialogue with BARDA on such matters as manufacturing, clinical trial design and location, who will be handling the trials and scheduling.

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What implications does the approval of laninamivir in Japan (as Inavir) have for the clinical trials required to lodge an NDA in the US?

CEO Peter Cook
Japan's clinical trials are non-inferiority studies and not double blinded as they generally are in the West. As a result very little is directly useable in the US from the trials Daiichi Sankyo has done in Japan. Additionally, there are advantages if the trials are run with product manufactured in the US to US good manufacturing practice (GMP) standards. However, the clinical use of the product in Japan adds considerable value to the total NDA package in terms of safety, potentially removing the need for post-marketing Phase IV safety studies.

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What level of up-front investment will Biota have to make in order to progress the US trials of laninamivir? How will payments under the BARDA contract be received and booked by Biota?

CEO Peter Cook
There is a small amount of cost that will be directly borne by us under the contract but predominantly all costs will be met by BARDA. We will be reimbursed by BARDA for work completed under a comprehensive, agreed plan that includes all the work we subcontract.

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What implications does the BARDA contract have for rest-of-world marketing of laninamivir? To what extent will the US clinical trial results be relevant to regulatory approval in other markets?

CEO Peter Cook
BARDA has awarded this contract for the ultimate benefit of US citizens. The product has to meet the needs of the US population under emergency conditions, such as during an influenza pandemic.

Very few Western regulators have requirements that differ significantly from the US, so while this isn't the purpose of the contract, we're hopeful much of the work we undertake will be relevant in other regulatory environments. Potentially, US approval would allow us, with very minimal changes or additions, to access the rest of the world.

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To what extent is the BARDA contract a funding model for other compounds in your development pipeline?

CEO Peter Cook
BARDA's charter addresses bio-defence or disease outbreaks that require a bio-defence type of response from the US government. Bio-defence strategies include the development and stockpiling of drugs for emergency purposes; they may never be deployed but are ready in the event of a crisis. Clearly most drug products don't fit into that category and governments don't provide funding for products that are likely to be developed, supplied and used under normal commercial terms.

The rest of Biota's development programs tend not to fit into the bio-defence category. What we've secured with BARDA should be seen as only relevant to our influenza antivirals.

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Is there any risk to the BARDA funding due to current volatile market conditions and the debt crisis in the US?

CEO Peter Cook
We have no specific reason to suspect such a risk. We believe that at the time of the contract award there were intense pressures on costs, yet the program was still given priority.

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Cash at 31 December 2010 stood at $70.0 million, down from $104.9 million a year earlier. Given cash burn of $34.4 million for the year, Biota holds cash equivalent to two years of operation. What is Biota's expected annual cash burn for the near term and what are the funding options for your development pipeline?

CEO Peter Cook
Cash burn in FY2011 was atypically high because we invested in a Phase IIb study for our human rhinovirus (HRV) product and there was a concurrent downturn in royalties from Relenza. Over time, we adjust the level of activity in our programs and rebalance our phasing so that our cash burn rates are not excessive relative to our reserves.

We intend to reduce our cash burn in FY2012 and carry a cash reserve of greater than two years.

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Biota continues to work with Piper Jaffray on a strategy to maximise and release shareholder value. Where do you see the most significant anomalies in the current stock market valuation of Biota?

CEO Peter Cook
We don't believe the market has appreciated the significance of the BARDA contract, which relates to a program that's also largely derisked because of laninamivir's approval in Japan. While over the life of Biota shareholders have made a net contribution $70 million, we've just secured about three times that amount to allow us to take our second product through to market approval. We'll end up with a registered and approved product in the US, completely funded by non-dilutive external funding.

Piper Jaffray are advising us on how best to release shareholder value, given the BARDA contract. In addition Piper Jaffray's advice will consider the funding of the other products in our portfolio like our HRV and respiratory syncytial virus (RSV) programs, so that shareholders can get the maximum value from these programs as well.

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What are the key clinical and corporate milestones investors should look for from Biota over the next 12 months?

CEO Peter Cook
The BARDA contract means there will be a significant shift in the nature of our work. Instead of licensing a product whilst it's still in the early stages of development and taking a relatively low price for it, the BARDA funding will allow us to take laninamivir through to the completion of Phase III and registration. Obviously, progress against the BARDA milestones will be critical over the medium term.

We also have a couple of other clinical programs running over the current year. We've indicated that we expect enrolments to be completed in our HRV program during the later half of this calendar year and results from this trial to be available by the end of the financial year.

The BARDA program is long term and will involve the completion of a number of significant milestones. We will report these as they occur, balancing our obligations to BARDA and our shareholders.

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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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