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CEO on H1 Results & Outlook

Open Briefing with CEO Peter Cook

Biota Holdings Limited
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In this Open Briefing®, Peter discusses:

- Loss reflecting lower royalty income, offset by first revenue from BARDA
- Management of costs while advancing programs with maximum shareholder value
- Progressing toward proposal to optimise company value

Open Briefing interview:

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Biota Holdings Limited (ASX: BTA) today reported a net loss after tax of $11.0 million for the first half ended December 2011, compared with a loss of $15.9 million in the previous corresponding period. The result reflected a fall in royalty income, only partially offset by first revenue under your contract with the US Office of Biomedical Advanced Research and Development Authority (BARDA) to develop long acting neuraminidase inhibitor laninamivir for the US market. Are these trends indicative of your expected performance over the remainder of the year?

CEO Peter Cook
We've always found it difficult to provide a reliable forecast for royalty income: it depends on the severity and incidence of influenza outbreaks. We expect increasing revenue from BARDA as the work program accelerates and more resources are committed. The first half represents the first full six month period since we secured the BARDA contract, and while initial revenues are relatively low, we expect them to grow significantly, reaching a peak annual amount of US$60 million to US$70 million.

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Revenue from the BARDA contract was $4.3 million in the first half and you delivered three contract milestones. What are the specific milestones you delivered and what milestones are you working toward currently? What will be the impact on revenue and expenses relating to the BARDA contract when you start Phase I studies around June?

CEO Peter Cook
Our first three contract milestones under the BARDA contract involved the preparation of

detailed plans covering the various aspects of delivering a new drug application (NDA) to the US Food and Drug Administration (FDA) in the first quarter of 2016.

The first three milestones were the preparation of plans for product development, clinical development and regulatory licensure, and manufacturing facilities. The next milestone is the manufacturing feasibility plan which will ensure we have the capability to manufacture sufficient product to take into the clinic. These planning stages of the program were expected to take about nine months. The final contract milestone is the implementation of the full program which will involve about four years of work.

It's not the case that our Phase I studies will be the first trigger for revenues and costs under the BARDA program. Delivering our manufacturing facilities plan, which has to occur before the clinical studies, will also incur significant expenditure and much of that work is already underway. This will be followed by the transfer of manufacturing to the US and the manufacture of sufficient product to undertake the clinical trials.

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Relenza royalties for the first half were $0.7 million, down from $3.3 million in the previous corresponding period, in the absence of any significant government restocking of neuraminidase inhibitor stockpiles. What visibility do you have on potential stockpiling activity in the nearer term?

CEO Peter Cook
Our understanding is derived from governments' public indications of their intention to add to or replenish their stockpiles. Both the US and the UK governments have inventory in their stockpiles expiring in the 2011/12 period. However, timing is difficult to forecast.

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First half royalty revenue from Inavir was $0.7 million, down from $1.2 million. Inavir (laninamivir) was launched in the Japanese market in late 2011 and your partner Daiichi Sankyo expects sales to total approximately US$125 million this flu season, up from just over US$90 million last year. What assumptions underlie this forecast?

CEO Peter Cook
The product was launched during the first half of the 2011 financial year and was a period of pipeline fill. In contrast, the December 2011 quarter saw a relatively mild and late start to the seasonal influenza market in the northern hemisphere. However, that situation changed early in the New Year, with conditions favourable to a surge in influenza, particularly in Japan.

After the reporting period, Daiichi Sankyo has again confirmed it still expects sales of approximately US$125 million in the 2011/2012 flu season. The key driver of the sales increase will be Daiichi Sankyo's larger penetration of the Japanese neuraminidase inhibitor market compared with the launch year. To do so it will need to secure over 30 percent of the market this season.

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Daiichi Sankyo has initiated an Inavir prophylaxis trial in Japan. It is seeking to recruit 1,500 subjects to evaluate Inavir's ability to prevent transmission of influenza A and B within families with a confirmed sufferer. Given Inavir has approval in a treatment application,

what testing is needed to gain approval for prophylaxis and what is the time line? What implications might this trial have for the development of laninamivir in the US?

CEO Peter Cook
Daiichi Sankyo has previously completed a prophylaxis study on 600 subjects. The mild circulating influenza strain and high incidence of antibodies to that strain in the study group made a definitive outcome difficult to achieve with the number of subjects. The new study is larger to provide more power. A prophylaxis study measures how well a drug protects a subject after they have been exposed to the disease; usually from another member of the family.

Predicting a concluding time for the study is difficult; influenza has a highly variable disease pattern in the community every season. If flu is common, it's relatively easy to get 1,500 subjects into a study but in a year when flu is not common, that can be a lot harder. We expect the trial to be completed in the current flu season but that can't be assured.

All the work we do on our products, anywhere in the world, adds value. Even though the Japanese study can't be directly submitted to the FDA for laninamivir, the work will add to the information we have on the safety of the product. The BARDA contract requires the completion of additional clinical programs on subjects representative of North American ethnic groups and not restricted to a single Asian ethnic group.

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R&D expenses were $8.1 million for the first half, down from $12.9 million in the previous corresponding period and product development expenses were $7.8 million, down from $8.4 million. Given plans to commence Phase I trials of laninamivir under the BARDA contract around June, as well as ongoing progress in your other programs, what is the outlook for R&D and product development costs for the remainder of the year?

CEO Peter Cook
The guidance we've provided to shareholders is for an overall decline in research expenditure. This is primarily because our gyrase broad spectrum antibiotic program has almost completed this phase of its development, and our respiratory syncytial virus (RSV) program is at a stage of shifting into the clinic.

While we expect a progressive downward shift in research expenditure, there will be a significant increase in our product development expenses. All our work under the BARDA program, for example, will appear in the product development expense line.

In the first half, product development expense was down on the corresponding period, reflecting the timing of payments for our HRV clinical program.

We're always focused on containing and controlling our costs. Our plan over the medium term is to trend towards a breakeven outcome on expenditure against revenue.

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Biota's Phase IIb clinical study of the HRV antiviral BTA798 (vapendavir) in asthmatic subjects has completed recruitment and results are expected to be announced in the June quarter. What are next steps in the development of vapendavir and what is the potential market for the antiviral? What is your intention with regard to licensing development of vapendavir?

CEO Peter Cook
Essentially we're conducting a clinical proof of concept for vapendavir in stable asthmatics who contract a naturally circulating HRV infection.

The study results will guide us on the design of any ultimate Phase III study and which subject group to address. For example, if we demonstrate antiviral activity that doesn't provide any improvement in the underlying asthma, we'd look to align the product into a specific anti-viral claim, most likely for transplant or immuno-compromised patients.

We'd expect to attract some licensing interest from "big pharma" once we've successfully demonstrated proof of concept. Whether we move to a licence at that point will depend on the attractiveness of any offer and how many of the potential indications the licensee is interested in taking up.

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Cash at 31 December 2011 was $56.5 million, down from $70.0 million six months earlier while cash burn was $12.6 million in the first half, down from $26.4 million in the previous corresponding period. You've stated that your cash position allows you to advance programs while also managing the variability inherent in the royalty streams. Are you adequately funded for the short to medium term?

CEO Peter Cook
Yes, we're comfortable that we're adequately funded for the short to medium term and will remain in a position to focus on those programs we want to advance. Typically we're not in a position to advance all our programs at maximum speed and we're selective on which programs advance.

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You've indicated that the board, in conjunction with advisor Piper Jaffray, has made solid progress in putting together a proposal that optimises the commercial opportunities associated with laninamivir and Biota's other products. What options are you looking at and why has such an exercise been necessary: won't the market appropriately price Biota once the value of its development portfolio is proven?

CEO Peter Cook
The reason the board has engaged Piper Jaffray is the attractiveness of the US market's ability to provide appropriate amounts of capital to the drug discovery sector. Ultimately, and assuming successful programs, this should lead to more stable, improved valuations.

We've never been in a position to advance our projects as far as we'd like. The board believes this has placed a capital market-imposed glass ceiling on our valuation. Typically we've licensed our products at the pre-clinical or early clinical stage to reduce our demand for capital. Adequate levels of funding would allow us to advance more projects to a later stage, like we're doing with laninamivir under the BARDA contract. This should generate larger returns for shareholders.

The BARDA contract provides US$231 million to advance laninamivir from early clinical stage to the lodgement of an NDA for a single indication. If we included expenses for prophylaxis studies, the overall program would cost between US$300 and US$350 million. The Australian

market has demonstrated historically, with us and other biotech companies, it's unable to absorb funding of that magnitude for a single product, let alone multiple products with similar funding requirements.

We believe it is in shareholders' interests for us to gain access to the deeper capital market of the US. At the moment, without access to adequate funding, we're leaving too much money on the table by licensing our programs early.

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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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