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Biota Holdings Limited
10/585 Blackburn Road
Notting Hill, VIC 3168

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Biota Holdings Limited today reported NPAT of \$7.2 million for the first half ended December 2008, up 31 percent from the previous corresponding period. Excluding the \$20 million GlaxoSmithKline (GSK) litigation settlement, the underlying business booked a net loss of \$12.8 million for the half versus net profit of \$5.5 million previously. Is the underlying result indicative of the earnings trend going forward?

CEO Peter Cook

As we have high expenses in some halves and low expenses in others, and vice versa, our earnings can seem quite volatile on a half-yearly comparative basis. It would be inappropriate to extrapolate too much from any one half's result and see that as establishing a trend. It's simply the nature of our business.

Our aim is to manage the movements so that over a year we're around breakeven and in a balanced cash position.

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Sales revenue for the half-year was \$10.5 million down 60 percent, reflecting the fall in Relenza royalties to \$3.8 million from \$16.5 million and the absence of a milestone payment, which totalled \$3.4 million in the previous corresponding period. Given recent announcements by GSK of a contract with the UK Department of Health for 10.6 million treatment courses of Relenza, and plans to increase supply of Relenza to Japan this flu season, what's the outlook for revenue for the full year ending June 2009?

CEO Peter Cook

Beyond the orders for Relenza GSK has already taken, it's difficult to provide further comment on our revenue outlook. This is due to the uncertainty of delivery timetables under contracts we're not privy to, and the fact that royalties are calculated at the prevailing exchange rate at the time of delivery. Our expectation is that a reasonable portion of the large UK and Japanese orders will be delivered in the second half of this financial year.

During the first half we secured a US\$3.5 million payment for an extension of our respiratory syncytial virus (RSV) program with AstraZeneca. But because the accounting treatment of that payment is significantly different from the accounting treatment of the milestone payment we received in the previous first half, you see a radically different contribution to the revenue line.

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You estimate that the UK contract may represent royalty income of up to \$18 million. What is the typical time line for delivery under government stockpiling contracts such as this and when do you expect to receive the royalties?

CEO Peter Cook

The terms of supply under the UK contract are confidential and have been agreed between the UK Department of Health and GSK. Given we're not party to those terms, we can't comment on the timelines or the timing of royalty payments.

The UK government indicated its intention to double its stockpile of neuraminidase inhibitors some 18 months ago. The tenders weren't called until September or October 2008 and contracts weren't awarded until January. These protracted cycle times make it difficult for us to estimate timelines.

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R&D expenses rose to \$6.3 million in the first half from \$4.6 million in the previous corresponding period. How do these costs relate to your current development projects? With four compounds being developed in-house, what's the expected trend in R&D costs going forward?

CEO Peter Cook

The increase in R&D expenditure is associated with the acceleration of AstraZeneca's RSV program. Forward trends in R&D costs will vary as they depend on the stage of development we're at with each compound and the requirements of the licensee.

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Biota booked operating cash flow of \$0.6 million in the first half versus outflow of \$8.7 million in the previous corresponding period. Based on your estimate that the GSK settlement would have a net positive cash flow effect of \$12 million, this implies underlying cash outflow for the first half of \$11.4 million. How does this compare with your cash burn targets?

CEO Peter Cook

As I've stated before, the intrinsic volatility of our underlying revenue and expenditure and the resultant profit and cash flow makes it extremely difficult if not impossible to extrapolate from a single half. I'm comfortable we're on track with our previously announced cash burn targets, and our cash balances are ahead of budget. Given the stage of our programs, we're tracking within our expectations.

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As at the end of December 2008 Biota had cash of \$55.4 million, down from \$60.2 million six months earlier. In light of the cash flow trend, how comfortable are you with cash at this level?

CEO Peter Cook

Our priority in these uncertain times is to maintain sufficient cash to fund our worst case operational scenarios. The nature of our business means the vast majority of the work we undertake is experimental. By implication, the results of our experiments aren't known to us in advance, so we have to carry sufficient contingency to address any potential outcome. We're comfortable with our current cash position and believe it's adequate.

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In October you completed an on-market share buyback of 5 percent of Biota's share capital. In total, 9.2 million shares were bought back and cancelled. What are your current capital management priorities?

CEO Peter Cook

Our current priority is to make certain we have sufficient cash to meet any reasonable contingency resulting from our development programs. The retention of an adequate cash balance is of paramount importance, as attempting to raise capital in the current market isn't an appealing option.

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Daiichi-Sankyo, the co-owner of your long acting neuraminidase inhibitor (LANI) CS8958, recently commenced a pivotal Phase III study of the compound in Asia after completing an initial Phase II study of in Japan. What further steps are needed for eventual commercialisation of LANI CS8958?

CEO Peter Cook

The successful completion of the Phase III work that's currently underway is the first step. The second step is the preparation of registration documentation from the results of that study, and the final step is approval from the Japanese health authorities to market the drug in Japan. If the product is to be commercialised beyond Japan, those steps will need to be repeated in other markets such as North America and Europe.

A pivotal Phase III study aims to prove both an adequate level of efficacy and an acceptable level of side effects in a significantly large population. As influenza seems to be quite prevalent this year in Japan, we expect to be able to recruit an adequate number of patients to meet these requirements.

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You're currently conducting Phase IIa trials of your human rhinovirus (HRV) compound. You've previously indicated you'd complete these trials before partnering development of the compound. What are the partnering prospects for the compound and how might they be impacted by the current global economic slowdown?

CEO Peter Cook

I don't believe the current global economic slowdown is relevant to this. The very long lead time associated with product development means that big pharmaceutical companies are used to dealing with economic ups and downs. In fact, big pharma has known pipeline shortfalls and filling those shortfalls is more important to the sector than the impact of an economic slowdown.

In order to interest big pharma however, the study has to produce positive results. As this is a study of *human* rhinovirus, efficacy must be established in man. It's a critical experiment and until it's results are delivered, it won't be clear whether a potential product even exists.

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Can you comment on recent progress in your other development projects and the expected milestones over the next 12 to 18 months?

CEO Peter Cook

The LANI enrolments should be complete by the end of the northern hemisphere winter and the results are expected to follow later this calendar year. Both the RSV and HCV programs are licensed and we're restricted on what we can say on them. The achievement of milestones will be announced in line with our contractual obligations and in conjunction with our licensees.

The HRV Phase IIa challenge study has been completed in the first cohort but the results will not be available until mid year.

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Thank you Peter.

For more information about Biota, 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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