

**Attention ASX Company Announcements Platform
Lodgement of Open Briefing®**



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

Date of lodgement: 06-Sep-2006

Title: Open Briefing®. Biota. CEO on Results & Outlook

Record of interview:

corporatefile.com.au

Biota Holdings Limited today reported a net loss of \$11.3 million for the year ended June 2006, compared with a loss of \$15.1 million in the previous year. Revenue from continuing operations was \$13.9 million 3.7 times that of the previous year, driven by royalties for the flu drug Relenza and income from the MedImmune licensing deal for Biota's lead compounds for Respiratory Syncytial Virus (RSV). To what extent are these revenues recurring in nature?

CEO Peter Cook

Revenue from Relenza is, and will continue to be, a significant portion of our income. Given the stockpiling of the drug by governments on the back of concerns about a potential avian influenza pandemic, we expect our income from Relenza to increase significantly over the next two to three years. You need to be aware there's a fairly substantial time lag from a government's announcement of its intention to stockpile, to orders being placed with GlaxoSmithKline (GSK), the licensee of the drug, and delivery. It's only at the end of that process that a Relenza sale is reflected as a royalty in our accounts.

Our income from the MedImmune deal included a substantial upfront licence payment, which under AIFRS will be recognised in our accounts over the period of our R&D collaboration, to June 2007. There's also a recurring element to the MedImmune income, which is the reimbursement of our expenses associated with the project. In addition, we'd expect to receive a milestone payment under the MedImmune arrangement some time during the current fiscal year.

corporatefile.com.au

What's the outlook for revenue and earnings in the current year ending June 2007?

CEO Peter Cook

We expect revenue growth to be driven by royalties from Relenza, continuing income from MedImmune, plus a milestone payment assuming milestones are met, and grants from the National Institutes of Health (NIH) relating to our LANI (long-acting neuraminidase inhibitor) program. We expect our expenses to increase, but not to the extent they negate the growth in revenue.

corporatefile.com.au

Biota's total expenditure increased to \$26.3 million in 2006, up from \$20.1 million in the previous year, primarily reflecting an increase in product development expense to \$9.1 million from \$3.6 million. What was behind this increase given expenses such as R&D and business development spending have been cut?

CEO Peter Cook

Last year we closed our R&D facility in California because it was a relatively expensive site for laboratory work and we've shifted those programs back to Australia to maintain our overall R&D effort, but at lower cost. That was also reflected in our business development costs, which previously had a significant US dollar-based component.

The major increase in our product development expenses came from two main areas. One was in getting our Human Rhinovirus (HRV) compound into the clinic, and it's now in Phase I clinical studies. The second related to our expenditure associated with the MedImmune project, which was correspondingly reflected in our revenue line.

corporatefile.com.au

Cash outflow from operations was \$7.7 million in 2006, down from outflow of \$13.0 million in the previous year. What's your expected cash burn in 2007?

CEO Peter Cook

As we've previously advised the market, we expect our underlying operations be cash flow positive for fiscal 2007. That assumes normal working capital demands. In the event a particular opportunity presented itself, for example securing additional IP, our cash burn would obviously change.

corporatefile.com.au

In July GSK notified you that indicative royalties relating to sales of Relenza for the June quarter were \$3.4 million. This was on top of the \$2.2 million received for the year ended April 2006. How does this reconcile with the \$5.2 million in Relenza royalties you booked in your June 2006 accounts and what level of unit sales does it relate to?

CEO Peter Cook

GSK reports to us a calculation of royalties for Relenza based on a year end of April. It also gives us an estimate for royalties for the quarter ending June, so

there's an overlap in the figures for the month of April. Internally we try to adjust for that; the \$5.2 million we booked in June 2006 is our best estimate.

On units sold, I should stress that we don't know GSK's average selling price so can't calculate volumes. But we estimate that for the year to 30 April GSK sold approximately 3 million courses and based on the information available for the June quarter, GSK ended the fiscal year with a sales run rate of up to 10 million courses per annum. That would be approximately in line with GSK's target of increasing production capacity to 15 million courses by December of this year. That compares with actual production capacity of 1 million courses in 2005.

corporatefile.com.au

You've previously indicated that based on GSK's intention to increase its Relenza production capacity, you expect to earn \$18 million of royalties in the current financial year. What assumptions is this based on?

CEO Peter Cook

We've based our estimate on GSK continuing for a 12-month period at the run rate achieved in May and June this year, that is an annual rate of around 10 million courses. If that occurs we should earn \$18 million of royalties. The 10 million run rate isn't at the upper limit of GSK's capacity given its publicly stated aim of achieving annualised production of 15 million courses by the end of the calendar year. At the same time, we've annualised what might be a period of relatively heavy production. We believe those are fair and reasonable off-sets.

corporatefile.com.au

The US Department of Health and Human Services (HSS) recently advised its intention to increase its stockpile of Relenza by an additional 12.3 million courses, to 16.2 million courses, by the end of 2008. If HHS orders in line with this intention, what are the implications for Biota's cash flow and revenues over the stockpiling period?

CEO Peter Cook

Bear in mind that of the 16.2 million courses that have to be delivered by the end of 2008, 3.9 million have to be delivered by December 2006. Assuming the 12.3 million courses are spread evenly over the period, although there's no guarantee that would happen, these orders would represent a \$7 million cash flow to us in the June 2007 year, followed by a \$10 million cash flow in 2008 and a further \$10 million in 2009. This takes into account that GSK pays royalties to the year ended April, 60 days in arrears.

corporatefile.com.au

To what extent are other countries stockpiling Relenza and what's GSK's ability to fulfil its current backlog of orders for the drug?

CEO Peter Cook

GSK's contracts with governments are generally confidential but some countries, including Australia, the US and France, have made some of the information public. From this we've identified confirmed orders totalling nearly 30 million courses, including the US's 16.2 million courses, 9 million

courses from France, 1.7 million courses from Germany and 1.8 million courses from Australia, although delivery dates aren't known. There are also unconfirmed orders from Ireland, Canada, Holland and Singapore which have ordered both Tamiflu and Relenza, but haven't disclosed the proportions. Based on the confirmed orders, GSK appears to have orders equivalent to about double its intended production capacity as at December 2006.

corporatefile.com.au

In the 2006 year Biota spent \$4.4 million on its legal action against GSK, in which you're seeking damages for GSK's handling of the early marketing of Relenza. This was up from \$3.7 million in the previous year. What's the expected cost of the litigation going forward, and will costs increase as you near the expected trial date in April 2008?

CEO Peter Cook

First let me clarify that we've taken legal action against GSK not simply for its handling of the early marketing of Relenza. Quite specifically we contend that GSK failed to use its best endeavours to develop the drug and its delivery device, conduct appropriate clinical trials and market it.

Our litigation costs are running between \$4 million and \$5 million annually. In the year in which the trial occurs, and we're pleased the trial date is now locked into the court register on 1 April 2008, we expect the cost of the trial itself to be somewhere in the range of \$2 million to \$3 million. We've entered a risk-sharing arrangement with our key advisors in the case, so we're defraying some of the cash costs associated with the trial until its completion. This ensures we've aligned our advisors' interests totally with ours.

corporatefile.com.au

Biota signed its RSV licensing deal with MedImmune in December and revenue from the deal totalled \$5.1 million in 2006. What's the current progress of the RSV project and what's the expected profile of revenue from the deal as it goes forward into clinical trials?

CEO Peter Cook

The \$5.1 million was in part the upfront payment and in part the ongoing meeting of our costs associated with the development program, and for the six months to June that represented \$2.9 million. We'd expect a similar rate of activity to continue over the full year, not just six months. As I already indicated, we also could potentially receive a milestone payment, due at the commencement of the Phase I study which may occur in the current financial year.

corporatefile.com.au

You recently announced you'd started the Phase Ib clinical trial of your HRV drug BTA798 after the successful completion earlier this month of the Phase Ia human safety trial in the UK. What are the main objectives of the Phase Ib trial and when do you expect it to be completed?

CEO Peter Cook

In the Phase Ib study we go to multiple doses of the compound, as opposed to Phase Ia where we tested single doses. The Phase Ib trial is around safety and

pharmacokinetics; we're trying to see if there are any problems in repeat doses of the compound and whether the quantitative information in man resembles the data in pre-clinical work. At this stage, the trial is still in healthy people and therefore isn't about efficacy.

We'd expect the Phase Ib work to be completed by the end of December this year but there'll be a number of months of work to fully interpret the study and establish whether we're in a position to proceed to the next phase of clinical studies. We'd expect the results to be available in the second quarter of calendar 2007.

corporatefile.com.au

Are you seeking a licensee to help fund the development of the HRV drug? What's your ability to continue self-funding its development?

CEO Peter Cook

It's our intention to keep self-funding HRV and we've based our cash flow projections on this assumption. We'll continue to fund development until at least the completion of Phase IIa studies to demonstrate the efficacy of the drug.

HRV, probably better recognised as the frequent causal virus of the common cold, is a relatively minor disease in healthy people, but it causes serious complications in other patients, notably those with asthma, chronic obstructive pulmonary disease, or a compromised immune system. In these cases it can be a very dangerous virus and this will be our target market. Because of the nature of the disease, we expect to be able to undertake a challenge study under clinical conditions, giving healthy patients a cold and treating them with the drug to prove its efficacy, which can be done relatively inexpensively. We believe we'll have added significant value at that point. We won't license the compound until we've reached that inflection point in value.

corporatefile.com.au

Sankyo, Biota's partner in the development of second generation anti-influenza compounds, LANI, announced in March an accelerated development program, focused on the Japanese market, for the lead compound CS 8958. How's this program being funded and what are the potential revenue opportunities for Biota?

CEO Peter Cook

The program is being completely funded by Sankyo, which will meet the costs of developing a new dry powder inhaler and the associated clinical studies in Japan. Additionally, we've received two grants from the US NIH for that program. One covers LANI in a nebulised version of CS8958, which is our lead compound, and the other the FLUNET compounds, our back-up compounds in the program.

The potential revenue opportunities for us include the NIH work, and income from a licence for the program to another pharmaceutical company for the rest of the world, beyond Japan.

corporatefile.com.au

As at the end of June 2006, Biota had no debt and cash in hand of \$46.2 million, compared with \$24.8 million a year earlier. This partly reflects the raising of \$31.8 million via a share purchase plan offered to shareholders in November 2005. Do you have adequate cash to fund ongoing development and operating activities over the current year? When do you expect the business to be self-funding?

CEO Peter Cook

We expect to be cash neutral this year and that includes all the programs we've already discussed. We believe we have sufficient working capital and that the underlying business will be cash neutral. In terms of reported earnings, we believe we'll be fairly close to break-even this year in our underlying operations.

corporatefile.com.au

Peter, you were appointed CEO of Biota in December 2005. What's been your initial focus at the company and what's your strategy for the business?

CEO Peter Cook

Our strategy has been clear: to continue our drug discovery and product development programs in antivirals, particularly respiratory antivirals, and to release shareholder value from our existing pipeline as quickly, as fulsomely and as sustainably as possible. In my brief period with the company I've ensured that the management team stays focussed on achieving our key milestones and we've been successful in that to date.

We're driving our development programs as hard as we can and increasing expenditure, where appropriate, to reach value-add points. We're also building good relationships with our partners, MedImmune and Sankyo, and delivery within those partnership programs is tracking to plan.

As part of our focus to release value for our shareholders, we've also sought to ensure our litigation against GSK is effectively funded and that costs are controlled. We're managing this like any other project – it's something we have to ensure we get value from.

corporatefile.com.au

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.

To receive future Open Briefings by e-mail, visit www.corporatefile.com.au

DISCLAIMER: Corporate File Pty Ltd has taken reasonable care in publishing the information contained in this Open Briefing®. It is information given in a summary form and does not purport to be complete. The information contained is not intended to be used as the basis for making any investment decision and you are solely responsible for any use you choose to make of the information. We strongly advise that you seek independent professional advice before making any investment decisions. Corporate File Pty Ltd is not responsible for any consequences of the use you make of the information, including any loss or damage you or a third party might suffer as a result of that use.