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Biota Holdings Limited today reported profit after tax of \$20.2 million for the year ended June 2007, compared with a loss of \$11.3 million in the previous year. Sales revenue rose to \$53.3 million from \$11.6 million, driven primarily by growth in Relenza royalties to \$39.8 million from \$5.2 million in the previous year. In light of the slowing in Relenza royalties in the fourth quarter to \$11.1 million from \$16.0 million in the third quarter, what's the expected trend in Biota's Relenza receipts over the current year ending June 2008?

CEO Peter Cook

Whilst there is volatility in the quarterly payment of royalties, the real issue is that annual royalties rose last year to nearly \$40 million from \$5.2 million. Those royalties are flowing from GlaxoSmithKline's (GSK) sales of Relenza into various governments' stockpiles in preparation for a potential influenza pandemic. The stockpile has reached approximately US\$5.6 billion, about A\$6.5 billion.

GSK has been increasing its Relenza production capacity to meet this demand, which we estimate at 24 million to 30 million courses annually, up from around 15 million courses in December 2006. That's consistent with what GSK's Chief Executive has told the market: that the company would increase capacity to between 30 million and 45 million courses in calendar 2007.

We also know that the stockpile market is still active; the US government for example, won't complete its stockpile build until December 2008, and the UK

government has indicated as recently as May that it would consider stockpiling Relenza were GSK in a position to provide supply. Existing stockpiles will also need to be replenished – the product has a shelf life of only five years – and that cycle is expected to start in about 24 months. In summary, there's upside in the stockpile market.

Based on all of this, our expectation is that we should see modest growth in our Relenza receipts in the current year, and that there could be some upside if all goes well and GSK becomes aggressive about getting product out.

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What guidance can you provide regarding the outlook for earnings in the current year?

CEO Peter Cook

Aside from what we've just discussed in relation to what might occur with Relenza this year, the other driver of our revenue line is our collaboration income. Our guidance there is that you should expect an increase over 2007. That's because there'll be an increase in the value of the work we're undertaking for MedImmune, and our agreement with Boehringer Ingelheim (BI) will have a full-year impact in 2008, whereas there was only a six-month impact last financial year.

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Operating cash flow was \$21.0 million in 2007 compared with cash outflow of \$7.7 million in the previous year. To what extent is a positive operating cash flow sustainable?

CEO Peter Cook

I'd remind you that we receive our Relenza royalties as a lump sum paid annually in arrears, so we have an outflow of cash over most of the 12-month period, with a large inflow at the end of the financial year. Also, the nature of our work is such that you can get unexpected and/or lumpy cash expenditure. Those qualifications aside, at this stage we'd expect our cash flow to remain positive.

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Excluding litigation expenditure, Biota's total expenses increased to \$23.6 million in 2007, up from \$21.7 million in the previous year. This partly reflects increases in R&D costs, which were \$8.2 million, up from \$7.7 million, and product development costs, up to \$10.3 million from \$8.4 million, under your licence agreements with MedImmune and BI. Head office costs fell to \$3.9 million from \$4.3 million. To what extent is the level of expenses in 2007 indicative of annual expenses going forward?

CEO Peter Cook

We set out to balance our projects so that two or more large projects don't end up with heavy expenditures within the same year. The costs of running a business like ours are external costs, which can be very lumpy, for instance during a clinical trial, and internal costs, which are mostly staff related. In reality, we have to balance our external expenditure against what our internal

head count can cope with in terms of managing projects. So, our current costs are indicative.

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During the year Biota acquired the royalty rights to Relenza held by the CSIRO and the Victorian College of Pharmacy (VCP), and at the end of June there was a \$13.4 million intangible asset on the balance sheet relating to royalty prepayment. What was the rationale for acquiring the rights, what was the basis for your valuation of them and what impact will the acquisition have on earnings and cash flow going forward?

CEO Peter Cook

Although our arrangements with CSIRO and the VCP are substantially confidential, I'm able to explain these developments in broad outline. It was the litigation with GSK that created a suitable opportunity for us to acquire the IP rights held by CSIRO and VCP, and we did that under terms all parties found favourable. For them, it was about turning the variable sub-royalty payment stream they enjoyed into a fixed figure. As research organisations that need to understand the resources available to invest in their ongoing projects, they found that outcome favourable.

For us, the acquisition of the IP is a simplification. We'll now retain the full Relenza royalty of 7 percent, and up to 10 percent in some markets, from all sales. Also, we won't have the ongoing costs relating to the sub-royalty payments, which rose in 2007 to \$4.9 million from \$0.7 million and we can manage the IP as we see appropriate.

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In 2007, litigation expenses increased to \$10.4 million from \$4.4 million, with Biota's legal action against GSK scheduled to begin trial in April 2008. Under the action, Biota is claiming damages for GSK's failure to use best endeavours in the development and marketing of Relenza. What's the expected level of litigation costs this year and to what extent does this assume the case proceeds as scheduled?

CEO Peter Cook

There are a number of unknowns in the litigation. Particularly, there's the potential for delay. We're confident of our case and we're looking forward to our day in court as soon as possible. On the other hand, GSK may see that it's in its own interests for there to be delay and for this to become part of its tactics.

With that qualification, we're prepared to provide guidance that, on current timetables and known activities, we'll expend in the order of \$15 million on the litigation this year. Clearly costs will be higher if there are delays, but if there are delays, they're likely to be of short duration and have a minimal impact overall.

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Under the litigation you've claimed damages of \$564 million to \$704 million. How have you arrived at this value range?

CEO Peter Cook

The range is based on some well established principles of how pharmaceutical markets grow on the introduction of new drugs that have a known therapeutic advantage over existing drugs.

An independent expert has calculated the total royalties that should have been paid to us from the launch date through to the end of the patent life had GSK used its best endeavours to support the drug.

The reason for the range in our damages claim is that there are two assumptions in the analysis. The lower figure assumes GSK persisted with its inferior, current inhaler. The higher figure assumes the use of a new and improved inhaler.

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Sales revenue for 2007 included research and partnering income totalling \$13.0 million, up from \$5.2 million, reflecting contributions from major licensing deals with MedImmune and BI. The BI research collaboration and licensing agreement, which you announced in November, relates to Biota's nucleoside analogues to treat hepatitis C (HCV). Can you comment on the progress in this project to date?

CEO Peter Cook

Although our partnered programs are the property of our licensees, and they rightly identify what can be said, we can assist our shareholders on our progress. We usually identify specific milestones in our licence agreements that will be publicly announced by both parties, and we've had one of those with the MedImmune deal, under which we received a \$3 million milestone payment in July. There's been no such milestone delivered yet under the BI deal, nor do we expect one in fiscal 2008. However, I can add that we're pleased with our collaboration arrangements with BI, and we're working well with the BI team on the project.

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In August Biota received the first instalment of US\$2.4 million of a US National Institutes of Health award of up to US\$8.5 million for the development of the FLUNET long-acting neuraminidase inhibitors (LANI). What's the progress in developing the FLUNET compounds and when might they be expected to enter clinical trials?

CEO Peter Cook

It's important to remember where FLUNET fits into our overall strategy. It's part of our LANI program, whose lead product is CS8958 which is in Phase I clinical trials in the UK. It's completed Phase I in Japan, and our co-owner Daiichi-Sankyo has indicated it will commence Phase II in Japan during fiscal 2008.

Under the program, the FLUNET compounds are backup compounds to CS 8958. At this stage, we're progressing them through the pre-clinical stage. They are a number of years off clinic. With the grants provided by the US National Institute of Health we hope to complete the pre-clinical work over the next two to three years.

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You announced in March the successful completion of the Phase Ib trial of your Human Rhinovirus (HRV) drug BTA798. Does it remain your intention to take the drug into Phase II trials rather than immediately seeking a licensing deal? When are the Phase II trials likely to start and what processes have to be completed before then?

CEO Peter Cook

We've said throughout that we wouldn't license the HRV compound until the completion of the Phase IIa study, which would be a clear demonstration of efficacy.

Normally in a Phase II trial you treat a limited number of people who are suffering from the disease to get some indicative measure of efficacy. In a Phase IIa challenge study, you induce the disease, which we're able to do ethically in the case of rhinovirus because it's a relatively minor ailment in otherwise healthy individuals.

Challenge studies are different from normal studies, and some additional steps are required. You not only have to supply the drug to GMP standards and make certain the patients are all adequately informed, you also have to develop a standardised and reproducible viral strain so you can give a known amount of disease to the patients. As a result, for studies of this type there are extra regulatory requirements, so they're fairly long in the planning, but relatively short in the execution.

We have plans to get the Phase IIa process for HRV underway in the US or UK this fiscal year, and, depending on lead times and any regulatory issues, we'd expect to complete the study in the second or third quarter of next calendar year.

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As at the end of June 2007, Biota had no debt and cash in hand of \$62.2 million, up from \$41.9 million six months earlier. What's the optimum level of cash Biota needs to hold on its balance sheet?

CEO Peter Cook

Our observation is that biotech companies generally need a number of years of cash cover for two general reasons, and these apply equally to us.

Firstly, you can spend relatively large amounts fairly quickly at specific points in projects, clinical trials being a good example. Our Phase IIa HRV study will cost upwards of \$15 million. Most of that will be spent in preparing for the trial, and will be spent in advance.

Secondly, biotech companies can't always raise money cost effectively when they need it. Many biotechs struggle with second or third round financing. In our case we have the strategic option to provide for our development needs now, rather than to call on shareholders when we need to in the future, which is going to be more expensive from everybody's point of view.

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With three drugs in the clinic currently, do you see the need to replenish Biota's development pipeline? In which areas are your most prospective opportunities?

CEO Peter Cook

We're delighted to have three drugs in the clinic. A maturing pipeline provides significant potential value accretion points for shareholders. You need to remember though that our projects are only at or near Phase I. They're not in late clinic. As such, we shouldn't get too far ahead of ourselves.

Our approach is to aim partly at growth and partly at risk-minimising our overall portfolio for the benefit of our shareholders. Over time we'll increase the number of projects we're working on, and we'll continue to maintain a balanced portfolio, with compounds that are in the market, projects/compounds that are licensed and we're working on in collaboration with partners, and with some of our programs also funded by shareholders' money.

In terms of opportunities, we'll stick to our knitting. Our skills are in microbiology, in medicinal chemistry, and in the clinical development of anti-infectives. Underpinning that we have highly developed project management systems. We see plenty of commercial opportunities and attractive targets within the anti-infective space to which we believe we can apply our commercial and technical capability.

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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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