biota

**Biota Holdings Limited**
ACN 006 479 081
10/585 Blackburn Road
Notting Hill VIC 3168
Australia
**T** +61 3 9915 3700
**F** +61 3 9915 3702
**E** info@biota.com.au
**W** www.biota.com.au

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**Biota delivers net profit after tax of $38.2 million**

**Highlights**

- PAT of $38.2 million.
- Relenza royalties of $45 million.
- Strong cash position at $86.7 million.
- Phase IIa of HRV lead compound achieves clinical proof-of-concept.
- Daiichi Sankyo exercises right to market CS-8958 (laninamivir) in Japan.
- RSV licence with AstraZeneca extended for US$3.5 million.
- Litigation against GSK resolved at mediation.

**Events subsequent to 30 June 2009**

- GSK intends to increase Relenza production capacity to 190 million courses by the end of 2009.
- The long-acting neuraminidase inhibitor laninamivir shown to be effective in Phase III clinical trials in Asia.
- RSV program returned to Biota.
- $20 million cash return to shareholders.

Biota Holdings Limited (ASX: BTA) today announced a net profit after tax of $38.2 million (2008: loss of $6.5m). Profit before tax was $41.8 million (2008: loss $9.3m) and includes $12.8 million net from the litigation settlement. Income tax expense at $3.6 million benefited through the recovery of $26.7 million in previously unbooked tax losses.

Total revenues were $83.3 million, up significantly from $45 million in 2008. Total revenues included $45 million of Relenza royalties (2008: $20.5m), $12.6 million of collaboration income from licensing agreements with AstraZeneca and Boehringer Ingelheim (2008:$15.2m), $20 million from the litigation settlement with GSK and grant income of $2.8 million from the US National Institutes of Health for the development of LANI programs (2008: $5.7m). Collaboration income in 2008 included a significant milestone payment of $3.4 million from AstraZeneca.

Costs decreased to $41.5 million (2008: $54.3m) with litigation costs of $7.2 million (2008: $21.8m), following conclusion of the litigation.

Cash at 30 June 2009 increased by $26.5 million to $86.7 million (2008: $60.2m).

**Other Significant Events**

- Mediated conclusion to the GlaxoSmithKline (GSK) litigation in July 2008 resulted in a payment to Biota of $20 million, and the normalisation of commercial relations;
- Increase in Relenza royalties from improved sales volumes. In May, GSK announced their intention to increase production levels to 5 million courses per month. In July 2009, GSK indicated that production capacity of Relenza would further increase to 190 million courses by the end of 2009;
- Biota's long acting neuraminidase inhibitor (second generation influenza anti-viral), laninamivir, reported successful results in its initial Phase II study in Japan and commenced the pivotal Phase III study at a number of centres in Asia. In August 2009, the successful results of the Phase III clinical evaluation of CS-8958 (laninamivir) in Asia were announced. Laninamivir is co-owned with Daiichi Sankyo;
- Daiichi Sankyo has elected to market laninamivir in Japan, which will result in a new royalty flow to Biota on all Japanese sales, once the product is approved;
- Successful results of the Phase IIa clinical evaluation of BTA798 for the treatment of complications of human rhinovirus (HRV) infection in patients with pre-existing asthma and other diseases; and
- The expansion of the licence of the Respiratory Syncytial Virus (RSV) program with AstraZeneca into additional Asian & Pacific territories for an additional US$3.5 million payment. The licence was terminated and the program reverted to Biota in August 2009. Biota will look to re-partner the promising backup compounds.

**Future plans**

Biota intends to move as soon as possible to the stage where it has two or three royalty generating products in the market.

During the recent period, the Board has confirmed its view that the Company's focus should be on building a balanced portfolio of anti-infective programs reasonably distributed across the various stages of discovery and development. Further, that the Company's proven business model of sharing the development risk through early licensing should be maintained and the portfolio be expanded to deliver the objective of multiple, royalty generating, products in market.

The Company is satisfied that there are a sufficient number of project candidates; through research institutes, universities or acquisition of projects or companies that align with our requirements; that it has the necessary core skills to exploit those potential opportunities and an adequate knowledge of customer's and market needs to be able to deliver commercially attractive returns to its shareholders. The expansion of the portfolio will occur progressively and start in the near future.

The current commercial outlook indicates that the financial resources to achieve those plans are also available.

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**Outlook**

The outlook for F2010 is strong:

- GSK has announced substantial forward orders and the intention to triple Relenza production capacity to 190 million courses by the end of 2009;
- A further increase in royalty income is expected. Relenza sales and royalties will continue to be provided on a quarterly market basis – the next being in late October;
- Following the success of the Phase III clinical trial in Asia for laninamivir, Daiichi Sankyo has undertaken to lodge a New Drug Application in Japan by March 2010 and commence prophylaxis studies;
- The Phase III laninamivir results have also seen an increase in commercial interest for markets outside of Japan; and
- The demonstrated proof-of-concept of BTA798 for the treatment of complications for HRV infection, has resulted in expressions of interest from a number of companies.

**Capital Management**

A cash return of $20 million will be made to shareholders in December 2009, subject to receiving shareholder approval if needed, at the forthcoming annual general meeting. The record date is 19 November 2009. This return follows the completion of an on-market share buyback in October 2008 when 6.6 million shares were purchased at a cost of $4.9 million (74 cents per share) and subsequently cancelled.

Commenting on the results today, Biota CEO Peter Cook said:

"*Relenza is now becoming a significant contributor to global influenza pandemic stockpiles and starting to deliver on its potential for shareholders.*

*Our clinical pipeline has achieved important key milestones this year, in particular through success with laninamivir and the human rhinovirus program.*

*Prudent management of cash over the recent period now allows an initial return of $20 million to shareholders and we start the next financial year in a very strong position".*

**About Biota**

Biota is a leading anti-infective drug development company based in Melbourne Australia, with key expertise in respiratory diseases, particularly influenza. Biota developed the first-in-class neuraminidase inhibitor, zanamivir, subsequently marketed by GlaxoSmithKline as Relenza. Biota research breakthroughs have included novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim, and a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease. Biota has clinical trials underway with its lead compound for human rhinovirus (HRV) infection in patients with compromised respiration or immune systems.

In addition, Biota has a key partnership with Daiichi Sankyo for the development of second generation influenza anti-virals.


*Further information available at www.biota.com.au

**Investor / Analyst Enquiries**
**Biota Holdings Limited**
Peter Cook
T: +61 3 9915 3720
Damian Lismore
T: +61 3 9915 3721

**Media Enquiries**
Jo Lynch
Hinton & Associates
T: +61 3 9600 1979
M: +61 411 208 101