Current Agreements

Dealdoc

Licensing, development and marketing agreement for Relenza

Glaxo Wellcome
GSK
Biota

Sep 04 2000

Licensing, development and marketing agreement for Relenza

Companies:	Glaxo Wellcome GSK Biota
Announcement date:	Sep 04 2000
Deal value, US$m:	15.56 : sum of royalty payments

- Details
- Financials
- Termsheet
- Press Release
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- Contract

Details

Announcement date:	Sep 04 2000
Industry sectors:	Bigpharma Bigbiotech Pharmaceutical
Therapy areas:	Infectives » Viral » Influenza
Technology types:	Drug delivery Small molecules
Deal components:	Development Licensing Marketing
Stages of development:	Marketed
Geographic focus:	Worldwide

Financials

Deal value, US$m:	15.56 : sum of royalty payments n/d : royalty payments of $12 million
Royalty rates, %:	n/d : royalty payments of $1.46 million n/d : royalty payments of $2.1 million

Termsheet

4 Septemeber 2000

Biota Holdings has signed a Heads of Agreement granting Glaxo Wellcome rights to develop and market worldwide, a new influenza drug based on inhibition of the viral neuraminidase.

Biota has discovered and will work with Glaxo Wellcome to develop drug candidates with properties that will result in increased convenience in dosing regimen for both patient and doctor.

Press Release

Biota Signs Agreement to Develop New Influenza Drug

4 September 2000

Melbourne, Australia – September 4, 2000 - Biota Holdings Limited (ASX:BTA) today announced that it has signed a Heads of Agreement granting Glaxo Wellcome rights to develop and market worldwide, a new influenza drug based on inhibition of the viral neuraminidase.

Biota has discovered and will, subject to final agreement being reached, work with Glaxo Wellcome to develop drug candidates with properties that will result in increased convenience in dosing regimen for both patient and doctor.

Biota also said that Glaxo Wellcome had recently completed a clinical study of Relenza, Biota's first generation flu drug, in over 500 high-risk influenza patients, including those with asthma and chronic lung disease. The study, which will be published shortly, demonstrated significant clinical benefit to the patients with no drug-related side effects. This result provides further support for the efficacy and safety of the direct delivery approach used with Relenza.

Chief Executive Officer of Biota, Dr Hugh Niall said, "Biota has developed a considerable level of expertise in the area and has already spent a number of years on this particular project. The work with Glaxo Wellcome is already underway. I don't want to underestimate the challenges ahead, but we can look forward to the development of a new drug that is expected to dominate the anti-viral market for influenza and importantly, deliver a royalty stream out to 2020."

The new generation neuraminidase inhibitors, are, like Relenza, delivered directly to the site of infection in the lungs. They will therefore still have the key advantages to patients of Relenza. These are: low effective dose, almost instant onset of action, minimal systemic absorption resulting in negligible systemic side effects, high anti-viral activity, comprehensive strain coverage and minimal propensity to resistance.

This new research and development collaboration between Biota and Glaxo Wellcome will build on the successful partnership established with Relenza. It aims to exploit Biota's expertise and leadership in the area of anti-virals for respiratory infections, and Glaxo Wellcome's expertise and leadership in developing and marketing drugs for delivery directly to the lungs.

The agreement will provide for the two companies to work closely together and to fund their own research and development costs to the point of selecting a lead compound for clinical development. Beyond that point Glaxo Wellcome will fund the program through to the market. Biota will receive development milestones at various stages of the project and royalties to be paid over the life of the relevant patents.

Biota is an Australian listed company (BTA), based in Melbourne and engaged in the research and development of new human pharmaceuticals for the treatment of viral respiratory diseases. The Company's ADRs (BTAHY) trade in the US on the pink sheets at a ratio of three shares to each ADR.

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24 July 2001

BIOTA REGAINS RIGHTS TO SECOND GENERATION INFLUENZA DRUG PROGRAM

Melbourne, Australia - 24 July 2001 - Biota Holdings Limited (ASX:BTA) announced today that it has regained all rights to its second-generation influenza program which is currently in late stage pre-clinical lead selection following a two year collaboration with GlaxoSmithKline.

As part of the transfer of rights back to Biota, GlaxoSmithKline has agreed to complete a series of ongoing pre-clinical studies aimed at identifying the most promising lead candidate for clinical development. Biota is now in a position to take such a lead candidate into clinical trials for prevention and treatment of influenza, either alone or with a new partner.

The decision to transfer the rights of the second-generation program to Biota resulted from a global portfolio review following the recent merger to form GlaxoSmithKline. A strategic long-term decision was made to allocate resources into areas other than antiviral influenza treatments.

Biota and GlaxoSmithKline's current worldwide marketing and sales agreement for Relenza (zanamivir for inhalation), Biota's novel influenza drug, is unchanged. Preparations to market the product during the forthcoming influenza season in the Northern Hemisphere are underway by GlaxoSmithKline.

The Chief Executive of GlaxoSmithKline, Dr.J.P. Garnier said, "We value our relationship with Biota and our marketing plans for use of Relenza this coming flu season are well underway. The second -generation product, whilst it is promising, now no longer fits with our strategy, as we have immediate needs to resource other programs. "

Biota and GlaxoSmithKline scientists have been working closely on the second- generation project for some time. Both parties are very pleased with the progress of the project that has met or exceeded expectations. A number of long-acting and highly potent compounds have been identified that have the potential for further development as products for influenza prevention and treatment.

Biota's Chief Executive Officer, Dr Hugh Niall said, "The excellent progress the second- generation project has made, coupled with regaining of the rights, means that Biota is well positioned to optimise the value of its investment in the area. Resources at Biota's US-based company, Biota Inc., provide additional means for moving the project rapidly into development, and, at the appropriate time, to work more closely with an international partner(s)."

Biota Holdings Limited is an Australian listed company (ASX:BTA) based in Melbourne and engaged in the research and development of new human pharmaceuticals for the treatment of respiratory infections. The Company's ADRs (BTAHY) trade in the United States on the pink sheets at a ratio of three shares to each ADR. US-based Biota Inc. is a member of the Biota group of companies.

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29 September 2006

Biota Holdings Limited Welcomes GlaxoSmithKline License Grant For The Manufacture And Supply Of Zanamivir In China And Other Countries

Biota Holdings Limited (ASX: BTA) today welcomed the announcement that GlaxoSmithKline (GSK) has granted its first sub-license to manufacture and supply zanamivir. The sub-license is to Simcere Pharmaceutical Group (Simcere) of China, and permits the manufacture and supply of zanamivir in China, Indonesia, Thailand, Vietnam and other developing countries. Zanamivir is the active ingredient in Relenza, the anti-influenza drug developed by GSK under licence from Biota.

Biota CEO Mr Peter Cook said "When GSK requested Biota's approval for this agreement with Simcere, it was readily given in recognition of the critical public health need. We hope to see GSK further increase supply to ensure that the world is able to gain better access to zanamivir, one of the world's only two effective antiviral drugs in the event of an avian flu pandemic."

The agreement enables Simcere to manufacture and sell zanamivir in China, Indonesia, Thailand, Vietnam and all United Nations classified Least Developed Countries. GSK's competitor, Roche, has already put in place a number of arrangements with developing countries for the manufacture and use of the rival anti-influenza drug Tamiflu, ranging from licensing such as the Simcere deal, to sub-contract manufacturing agreements with more than 16 third parties in 10 different countries. Biota will be entitled to receive royalties on sales by Simcere, under the sub-license.

About Biota Biota is a leading antiviral drug development company based in Melbourne, with key expertise in respiratory diseases, particularly influenza. Biota developed the first-in-class neuraminidase inhibitor, zanamivir, and subsequently marketed by GlaxoSmithKline (GSK) as Relenza. Relenza is currently being stockpiled by a number of national governments for defense against avian influenza. Biota receives royalties from sales of Relenza.

Recent Biota research breakthroughs have included a series of candidate drugs aimed at RSV (Respiratory Syncytial Virus, bronchiolitis), subsequently licensed to MedImmune Inc. Biota has Phase I clinical trials underway with HRV (human rhinovirus) and is also engaged in early stage research targeting hepatitis C virus infection. In addition, Biota has key partnerships with Sankyo; for the development of second generation influenza antivirals (called LANI or Long Acting Neuraminidase Inhibitors) and with Thermo Electron (Inverness Medical); Biota developed the FLU OIA® influenza diagnostics, currently marketed in the US.

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8 February 2008

Relenza Q2 Royalty $12.0 million

Biota Holdings Limited (ASX:BTA) today announced that it had received written notification from GlaxoSmithKline (GSK) that Relenza sales for the three months to 31 December 2007 were A$171.4 million or GBP75 million. Biota estimates indicative royalties to be $12.0 million for the three months to 31 December 2007.

This will bring cumulative royalties in the six months to 31 December 2007 to $16.5 million, up from $12.7 million for the comparable period last year.

Biota CEO, Peter Cook commented "This confirms the sustainability of the global stockpiling market on an ongoing basis. The increase in GSK's sales of Relenza stand in contrast to the decline in Tamiflu sales, as reported by Roche. We expect that GSK will sell its installed capacity over the year".

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 a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease, licensed to MedImmune Inc. and novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim. 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 antivirals. Inverness Medical markets Biota's co-developed OIA FLU influenza diagnostics.

Relenza Royalty for December 2008 quarter

Melbourne, Australia — 6 February 2009

Biota Holdings Limited (ASX:BTA) today announced that it had received written notification from GlaxoSmithKline (GSK) that Relenza sales were $20.8 million and indicative royalties were $1.46 million, for the three months ended 31 December 2008.

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 RelenzaTM.

Biota research breakthroughs have included a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease, licensed to AstraZeneca and novel nucleoside analogues designed to treat hepatitis C virus (HCV) infections, licensed to Boehringer Ingelheim. 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 antivirals. Inverness Medical markets Biota's co-developed OIA FLU influenza diagnostics.

Relenza™ is a registered trademark of the GlaxoSmithKline group of companies.

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22 October 2010

Relenza September Quarter Royalty

Biota Holdings Limited (ASX:BTA) today advised that it had received written notification from GlaxoSmithKline (GSK) that, for the three months ended 30 September 2010, Relenza sales were $29.6 million and indicative royalties were $2.1 million. GSK advised that the figures were calculated on an Australian dollar exchange rate of 1.6399 A$ to the UK pound.

Actual payment will be calculated on the exchange rate of 30 April 2011.

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 include a series of candidate drugs aimed at treatment of respiratory syncytial virus (RSV) disease and Hepatitis C (HCV) virus infections. Biota has clinical trials underway with its lead compound for human rhinovirus (HRV) infection in patients with compromised respiration or immune systems.

Filing Data

Not available.

Contract

Not available.