

Biota Holdings Limited

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For Immediate Release

Melbourne, Australia — 22 November 2010

2010 AGM Addresses

A copy of the Chairman's Address and CEO's Address is attached in respect of the Company's Annual General Meeting to be held at 10.00am today.

A recording of the presentation will be available on the Biota website in approximately 24 hours.

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.

In addition, Biota and Daiichi Sankyo co-own a range of second generation influenza anti-virals, of which the lead product lnavir[®], is approved for marketing in Japan.

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

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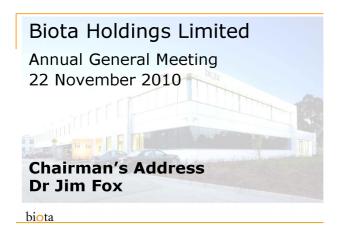
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CHAIRMAN'S ADDRESS

Ladies and gentlemen, this past year has been a successful year for Biota, financially and scientifically, although it has been a very difficult business environment for many other companies globally.

This year we reported a profit after tax of \$16.2 million, on the back of a record year of Relenza royalties. We returned \$20 million to shareholders and expanded our activities through the acquisition of the antibacterial assets of Prolysis and MaxThera. In addition, we increased our cash balances to almost \$105 million and since October, LANI (Inavir) is on sale in Japan earning royalties.

All up it was a strong year for the company!

The share price moved around considerably throughout the year. On the back of expectations of significant ongoing royalties from Relenza as a result of swine flu, the share price raced off to \$3.47 in October, settled around \$2.00 thereafter and dropped significantly after April of this year as Relenza royalties fell and concerns around the global financial crisis re-emerged. The share price is now around \$1.00.

Excluding cash, the market only values the ongoing business at approximately \$95 million or 53 cents per share. This \$95 million valuation therefore represents the market assessment of:

- All future Relenza royalties;
- All future Inavir (LANI) royalties; and
- The commercial value of all our other programs.

We are very aware of the current market valuation and we are very focused on ways to see the business properly valued.

I have been with the Company in this role for just over 18 months and I have now had time to reflect on where the business is going. I think we have an opportunity, driven by LANI to re-think the strategic direction of the business. To this end, we have been working on a number of initiatives to see if we can do more with what we have got, including working with Greenhill Caliburn. This work had led to me personally looking at the market for a company like Biota internationally.

The CEO and I recently spent just under 3 weeks in the USA and the UK meeting with big pharma including our existing partners, investment banks and a couple of similar businesses. As a first timer fronting the company in this environment, I can say that the company and its programs are held in high regard but the "Down Under" distance is a significant barrier unless we get out there and stir the pot and maybe change things.

Overlaying all of this is LANI. LANI has been through the clinical trials required by the Japanese regulators and is now on sale in Japan. So to a meaningful extent, LANI as a product has been technically de-risked, despite the fact in the Rest of World, including in the US, regulators require substantial additional testing, including Phase III clinical trials, before providing approval for sale in those markets.

One key feature of LANI and which is important commercially yet frequently missed or overlooked, is that approvals for such drugs include the inhaler device. So notwithstanding the patent life of the active ingredient, the patent life of the inhaler is equally important. So LANI has a long road to run commercially, namely another 17 years. This "de-risked" product may very well represent a significant potential game changer for Biota.

Senior management at Biota have for some time now been working extremely hard on developing a detailed proposal with an overseas agency which, if successful, would deliver the funding required to complete the approvals process to allow the product to be marketed in, amongst other countries, the USA. This funding would be at no cost to shareholders. Many aspects of this proposal require the Company to be bound by confidentiality requirements so I can say little more right now, but we seem to be reaching the end of the process. It is impossible to predict the timing of any decision but a reasonable estimate is in the 3-6 month bracket.

In addition, we are looking at the feasibility of taking LANI through the work and clinical trials needed to get it to the market directly, with or without the funding mentioned above. This may require access to the US capital markets or M&A activity.

There are a number of options on our table, including the outcome of our normal licensing approach which may arise from ongoing work with three of the large pharma companies currently still interested. Suffice to say that the companies involved are aware of the potential of Biota securing significant funding so are hanging back a little until the outcome is clear. At the same time, the delay in resolving LANI in the Rest of the World has worked for us to the extent that alternative options to our traditional licensing may now emerge. We will keep you advised as best we can within the usual business and confidentiality constraints, when we have commercial progress to report.

The last area I wish to address today is Governance and in particular our remuneration practices.

Biota is a knowledge based company, and our success is based on our people. We have a remuneration structure that is overviewed by the Remuneration & Nominations Committee led by Paul Bell. The Annual Report sets out our policy in full detail.

To date the policy that has worked well for the Company and is intended to:

- Provide employees with a fair market rate base salary, delivered by paying at the median of independent salary survey data; and
- Provide an <u>opportunity</u> for each employee to earn more, for performance. This component of an employee's remuneration is strictly performance related and comprises a near term cash component and a longer term equity component. It is "at risk" and is not paid unless the performance targets are achieved. In the case of the CEO and the executive team, equity rewards are directly aligned with shareholder value through share price growth targets.

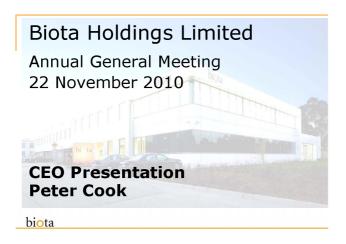
In F2010, the CEO and executive team had their base salary frozen and directors' fees were frozen also.

Our delay in delivering commercial targets on some of our programs and a lower share price at 30 June 2010, have both contributed to significantly lower bonus payments in F2010.

I believe our system to align the remuneration of key executives to the returns available to shareholders works and is in line with current best practice.

I will now ask Peter Cook, our CEO to present to you on the Company and its prospects.

CEO PRESENTATION



Introduction

Good morning Ladies and Gentlemen

May I take the opportunity to welcome you all here and thank you for your continued interest in and support of Biota.

My presentation this morning will provide an additional level of information to that provided by the Chairman and will cover four main topics:

Presentation content

- A summary of what has been accomplished in the reporting year
 fiscal 2010
- A brief update on our financials for the first quarter of F2011
- A short review of our projects, and to the extent possible
- A view of the near term prospects

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- A summary of what has been accomplished in the reporting year
 fiscal 2010;
- A brief update on our financials for the first quarter of F2011;
- A short review of our projects, and to the extent possible; and
- A view of the near term prosects.

The Results for the Reporting Year

These have already been summarised in the Chairman and CEO section of the Annual Report, but let's quickly run through the significant number of achievements:

The significant achievements

- Record royalties of \$67.3m from Relenza as a consequence of the swine flu pandemic
- Laninamivir's New Drug Application lodged with the Japanese Health Authorities in February 2010, with marketing approval granted in September 2010 and launch of Inavir by Dailchi Sankyo in October
 It is worth noting that this has been achieved remarkably quickly and has resulted in the product launch in Japan at least one full flu season ahead of plan
- The broadening and strengthening of the company's pipeline by the successful acquisition and integration of the assets of Prolysis (UK) and MaxThera (USA)
- Cash position strengthened: \$104.9m as at 30 June 2010
- A capital return of \$20m to shareholders

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- Record royalties of \$67.3 million from zanamivir (Relenza) as a consequence of the swine flu pandemic;
- Our long acting neuraminidase inhibitor's (LANI or laninamivir) New Drug Application lodged with the Japanese Health Authorities in February 2010, with marketing approval granted in September 2010 and the launch of laninamivir or Inavir as it has been branded by Daiichi Sankyo, in October. It is worth noting that this has been achieved remarkably quickly and has resulted in the product launch in Japan at least one full flu season ahead of plan;
- The broadening and strengthening of the of the company's pipeline by the successful acquisition and integration of the assets of Prolysis (UK) and MaxThera (USA);
- Cash position strengthened: \$104.9 million at 30 June 2010; and
- A capital return of \$20 million to shareholders.

Financial Results

	FY09	FY10
Revenue	5 m	\$m
Royalties	45.0	63.7
Collaboration income	12.6	1.4
NIH grant	2.8	3.8
Settlement	20.0	-
Other	2.9	2.5
	83.3	71.4
Expenses		
Medicinal chemistry and research	13.3	21.7
Amortistion of antibacterial progran	-	8.8
Product and clinical development	11.3	11.2
Business development	1.0	1.0
Sub royalty	4.3	4.1
Corporate	4.3	4.3
GSK litigation	7.2	-
	41.5	51.1
Profit before tax	41.8	20.2
Profit after tax	38.2	16.2

As can be seen from the accompanying Income Statement, we achieved a profit after tax of \$16.2 million, a solid outcome recognising that the 2009 comparator year included a one off \$20 million settlement from the GSK litigation and considering the \$8.8 million of investment amortisation expensed this year from the MaxThera and Prolysis asset acquisitions.

R&D costs increased to \$21.7 million due to the growth in the company's project pipeline. Product development, business development and corporate costs were essentially flat year on year.

Our cash position increased to \$104.9 million from \$86.4 million, recognising the figure is after the return of \$20 million to shareholders and the purchase of the assets of MaxThera and Prolysis.

Q1 F2011 Financial Results

Profit and Loss	Q1 2010	Q1 2011
Revenue	\$m	\$m
Royalties	24.1	2.1
Collaboration income	1.3	-
NIH grant	1.6	0.5
Other	0.7	1.3
	27.7	3.9
Expenses		
Medicinal chemistry and research	3.7	5.1
Amortisation of antibacterial programs	-	2.7
Product and clinical development	3.5	2.9
Business development	0.3	0.2
Sub royalty	1.0	0.2
Corporate	1.1	1.2
	9.6	12.3
Profit/(Loss) before tax	18.1	(8.4)
Cash at 30 September	77.3	89.5

The accompanying Income Statement provides the summary results for the first quarter of the 2011 financial year, three months up to 30 September 2010.

Revenue is some \$23.8 million lower than last year, due to the high sales of Relenza recorded at the peak of the swine flu outbreak in this quarter in F2010. Expenses, while 30% higher than last year, reflect the increased commitments made to the HRV clinical program and are well within the increased level of pre-clinical expenditure we expected as we moved to our strategic goal of 2 to 3 royalty generating products in the market as soon as possible.

It is also pleasing to note that, despite the first quarter being summer in the northern hemisphere and which also coincided with the WHO declaration of the end of the swine flu pandemic, \$2.1 million of royalties have still been achieved.

Let's move on to a brief review and update of our key projects. Again, considerable detail has been provided in the Annual Report on this topic and I won't go to this level of detail in this forum. I will only touch here on those aspects where an update is relevant or where there are near term commercial matters to report.

Operations

We have a good year financially, as I have just outlined. We have also had a good year scientifically.

In addition to Relenza, we now have 3 additional and game changing products, each well enough down their development paths for us to discuss with some degree of confidence:

- LANI on sale in Japan and with the ROW in play;
- HRV which has just commenced a major clinical trial in the US; and
- RSV for which we have a novel candidate, which is attracting commercial interest.

The complete development of any one of these is an extremely expensive business and each of them, independently, could be a significant game changing undertaking for Biota. Not surprisingly, we are therefore working closely with our advisors, Greenhill Caliburn locally, to look at the best way of advancing our portfolio to the benefit of shareholders.

My following comments therefore cover the programs, in technical and commercial terms.

Let's begin with Relenza.

Relenza

Relenza • 4 years of patent life in major western markets, 9 years in Japan (equal largest market with US) • Production capacity increased 6 fold • New presentations under development • Relenza Rotahaler • Relenza IV

The 2009 H1N1 pandemic peaked around December but the virus has continued to circulate globally. It is now one of the causes of seasonal influenza and has been included in the annual trivalent vaccine. The unpredictability of influenza, such as the recent avian flu case identified as recently as last week in Hong Kong, is what makes influenza such an ever present threat. The influenza itself is most unpredictable and that makes the market difficult to forecast.

However, the year has demonstrated what high revenues and profits can be generated, even in a relatively short and mild period of concern, such as the 09H1N1 outbreak.

The "official conclusion" of the swine flu pandemic, as signalled by the WHO's move to a post pandemic phase in August 2010 does not mean that the threat of influenza has actually gone away, merely that the threat posed by this strain of influenza has diminished. The value of Relenza remains, with more than four years of patent protection in the major western countries and for nine years in the world's equal largest market, Japan.

During the pandemic, GSK increased their manufacturing capacity of their approved product over 6 fold. This increased capacity should be to the product's advantage in the future and ensure that peak demands can be met when the need arises. GSK has also been active in offering additional dose presentations of Relenza.

The current approved product is sold in the Diskhaler device. GSK have also developed a Rotahaler presentation of Relenza, which offers Relenza at a slightly lower price point, but more importantly, uses a simple two part inhaler and a standard capsule to carry the active ingredient. The use of a standard capsule and a simpler inhaler has the potential to offer a significantly higher production volume in the future.

Also, GSK have developed an intravenous form of Relenza. This is currently an unapproved product but was made available by GSK during the swine flu pandemic for acute care cases where other attempts at management had failed. A few of these cases were reported in the world's leading medical journals including The Lancet and one of which related to a patient under care at Melbourne's Austin Hospital. In all cases, patients responded quickly and successfully. Hopefully, at some stage in the near future, the product will be available for commercial supply.

LANI

Key products/projects

LANI

- Japan Inavir
 - Approved for sale
 - Price premium of 30% over Relenza & Tamiflu
 - Patent life 2027



- Rest of World
 - De-risked, but CMC, Phase II & Phase III clinical studies required
 - Discussions continue with 3 large pharmaceutical companies
 - Non-dilutive funding to complete the work programs for registration
 - Commercial USA funding to complete work project for registration

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The Company's share price declined significantly during April 2009, which aligned with both the abatement of the swine flu pandemic and a concurrent concern, expressed by certain shareholders, regarding prospects for LANI. This appeared to be the point at which the market determined share price ceased to reflect a fair and rational value for the assets of the Company. There could well be other external factors influencing our share price from the GFC to competitive pressure offered by alternative investment opportunities including those from resources and energy stocks.

However, the directors believe that the current share price and market capitalisation of Biota does not reflect much more than a conservative view of the likely royalties from Relenza over the remaining years of its royalty life and the cash on hand. Clearly this seriously undervalues the Company. The current share price therefore appears to ascribe no, or very limited, value to LANI.

This is despite the recent events that have seen Inavir's:

- Approval for sale in Japan, one of the world's two largest markets (North America being the other);
- Price premium achieved over both Relenza and Tamiflu in Japan, from launch; and
- Long patent life, which includes its novel disposable inhaler as part of its intellectual property, until 2027.

Given that LANI is the Company's product closest to full global commercialisation (it is of course already on sale in Japan for the treatment of influenza), the release of shareholder value is therefore intimately associated with securing near term value from LANI for the rest of the world (ROW). The launch in Japan has significantly de-risked the program from a ROW perspective, even though western regulators will require additional work before any ROW launch.

On top of ongoing licensing discussions and negotiations with three large pharma companies, a number of other inter-related steps are underway to provide options for value release from LANI (and the company's portfolio at large):

- 1. As noted by the Chairman, the Company is at detailed proposal stage with an overseas agency regarding the provision of funding that, if successful, would substantially complete the chemistry, manufacturing and clinical programs required for registration in major western markets. Many aspects of the proposal requires the company to be bound by confidentiality, but the pharma companies are aware of this potential funding and clearly their commercial interest is influenced on its outcome. Agency timing is impossible to predict but 3 6 months would seem a reasonable estimate;
- 2. At the same time, given the USA appetite for programs such as LANI, management is also exploring USA-based funding possibilities for the same body of work. The USA is being targeted as it is a large capital market and more familiar with funding and valuing late stage clinical assets; and
- 3. On top of the foregoing actions, management and the Board are working with Greenhill Caliburn locally, to broadly look at the most appropriate way to achieve the release of shareholder value, both onshore and offshore

These steps may take up to a year to play out completely and are highly interrelated.

In summary, the Company has four live and active options for the commercialisation of LANI in the Rest of the World:

- 1. Licensing to a suitable partner, in its current form;
- Secure non-dilutive external funding and complete the CMC and clinical programs necessary for registration in ROW. Licensing may be considered with such funding secured or after its programs are completed;
- 3. Secure commercial funding and licence on marketing approval; or
- 4. Consider restructuring the Company in some way to facilitate a significant re-rating of the Company and/or its assets.
- 5. Any combination of appropriate aspects of the above.

As appropriate and where-ever possible and with a clear intent not to jeopardise commercial negotiations, shareholders will be kept fully informed.

In the meantime, Biota will benefit from the early launch of Inavir in the Japanese market, which will produce royalties in this financial year, well ahead of plan. Additionally, the launch in Japan will assist each of the options outlined above and provide a factual reference for progress on the (finally) selected alternative for prospects of LANI in the ROW.

RSV

RSV New scaffold compound identified Confirming market interest Initial interest appears strong

All shareholders would be aware that BTA9881 was licensed to MedImmune/ AstraZeneca in late 2005 and was returned to Biota in 2009. I cannot stress highly enough to shareholders that the return of a product from a licensee does not necessarily mean that the program's assets are valueless and that the program should be scrapped. While it may be true of one compound, it is not usually true of an entire program. BTA9881 had been the lead compound in our RSV program, but since its return, we have made considerable progress with a new compound which offers an improved pharmacokinetic profile and addresses the limitations evident in the original lead compound.

We made it clear at the time of the return that in Biota's judgement, the concerns held by AZ were compound specific. We felt other unrelated compounds, but compounds already part of our program, would probably not have the liabilities AZ felt existed with BTA9881.

I was pleased to note in the Annual Report that, as we had forecast and well ahead of plan, recent experimental work has confirmed that one of our new scaffold compounds has none of the liabilities which caused AZ's concerns.

We are therefore in the process of confirming market interest in an early stage licence with prospective partners. Initial interest appears strong.

HRV

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HRV Proof-of-concept demonstrated in health subjects Commenced Phase IIb in patients with chronic asthma in September 2010 Study involves 400 patients in 60 centres 500 patients screened for admission, 100 assigned to one of the treatment groups Cost \$25.0m Duration ~2 seasons (2 years)

Proof-of-concept in humans of our lead compound BTA798 was successfully demonstrated about 15 months ago and was shown to reduce the incidence and severity of an induced HRV infection in healthy subjects. One of the major markets for BTA798 will be in patients with an underlying chronic lung disease, such as asthma.

The last of the programs I wished to comment at today's AGM is HRV.

The compound is not intended for use in the common cold which is generally in otherwise healthy individuals, a mild and self limiting infection.

It became obvious during licensing discussions and assuming that were we successful, the best commercial outcome for Biota would be to complete a Phase IIb study in patients with chronic asthma. Such a study would provide clinical data on the population base of commercial interest and who had a naturally acquired HRV infection. All these aspects were impossible to cover in the Phase IIa proof-of-concept study. The Phase IIb study therefore provides a significant value adding extension to the overall clinical profile of the product.

That study is now underway in the current winter HRV season in the USA. We are aiming to enrol up to 400 patients in 60 centres and if possible we would like to see this achieved in only one season. Our progress to date has been good with 500 potential candidates screened for admission to the study and approximately 100 assigned to one of the treatment groups.

However, we are dependent on the severity of the outbreak of HRV this year and if lower than usual we may require two years and a budget of \$25 million, to complete the study.

Outlook

Outlook

- Benefit from launch of Inavir in Japan
- Relenza has a reasonable patent life long enough for another real or perceived influenza threat to occur
- LANI ROW to progress
- RSV to move to expressions of commercial interest over next 6-12 months
- Progress with the HRV Phase IIb study
 Novel, attractive and potentially valuable market

 $\ensuremath{\mathsf{F2011}}$ a year of investment in development and where significant outcomes should be achieved

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- 1. The Company will benefit appreciably from the successful introduction of Inavir in Japan. The value of a second royalty generating product will start to be apparent by the end of the financial year, or perhaps even sooner;
- Relenza still has a four year patent life to run in the major western markets and nine years in Japan. While the stockpile market is expected to remain subdued on the near term due to the absence of any immediate influenza threat, seasonal sales will continue to contribute a valuable royalty stream until the next threat or perceived threat reactivates the stockpile market;
- 3. The Company has set itself an aggressive target to extract shareholder value from LANI ROW over the next twelve months. A number of alternatives are already in hand and others continue to be worked on;
- 4. Our RSV program has achieved a critical internal milestone and will be commercialised to extract maximum value for shareholders, while recognising risk. Again a time frame of six to twelve months should be seen as appropriate; and
- 5. The HRV Phase IIb clinical trial is quite an advanced study for an early licensing company such as Biota to be undertaking. However, a combination of the attractiveness of the market, our understanding of the product and our available resources make this product an appropriate vehicle with which to grow the Company's total asset value.

F2011 therefore has been planned as an investment year in technical development and one during which considerable energy will be committed to maximising individual project and overall shareholder value.

Thank you again to those shareholders who have attended today and to those that have joined us on line.

Thank you Mr Chairman.