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2011 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.

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 antivirals, of which the lead product Inavir®, is approved for marketing in Japan. Biota holds a contract from the US Office of Biomedical Advanced Research and Development Authority (BARDA) for the advanced development of laninamivir in the USA.

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CHAIRMAN'S ADDRESS

Ladies and gentlemen

While the headlines for the 2011 financial year will focus on the financial results, in my view this was a year that marks the creation of an opportunity that could well transform the Biota business model to one which can deliver significantly higher value than the royalty only version we have historically pursued:

- Firstly "Inavir" (or LANI as we referred to it in the past), our second generation flu drug was launched in Japan in October 2010 and achieved sales of A$75 million in its first winter season. Our Japanese partner, Daiichi Sankyo, have indicated publicly that they hope to capture one-third of the Japanese market in the current year. If this eventuates, sales of the order of A$110 million would be achieved and would represent a very encouraging result in Inavir's second year in Japan.

- Secondly, Biota was successful in securing a very significant contract from BARDA USA to deliver Inavir into the US market. The contract is for up to US$231 million to commission, scale-up and validate existing US manufacturing capability for LANI and to undertake all the support work to allow us to submit a new drug application, including all clinical studies. We note that while the Japanese New Drug Application (NDA) is not recognised by the US Food and Drug Administration (FDA), it does give us confidence that the USA program should again show LANI to be safe and effective. This contract has the potential to enable Biota to supply and market its own product for the first time – a real game changing opportunity for Biota and one that should significantly benefit the Company in the years ahead. Under Peter Cook's leadership, Jane Ryan and her team are to be congratulated on this amazing win. It is Jane also who now has the responsibility of program delivery.

As you are well aware, our Relenza royalties were relatively low this year. This was not unexpected given the significant royalties that arose from the swine flu pandemic and the rapid build of national stockpiles around the world that occurred in that period that are now being worked off. Owing to the volatility of revenue streams and our commitment to continuing to develop our product range, it is important that we monitor our cash balances while we work through the US Inavir opportunity. We will manage our Research and Development (R&D) spend in this context and ensure that we deliver the US Inavir program as a priority.

Clearly over at least the last six (6) months, the world's financial markets have again become very volatile. Credit in terms of both capital and debt has tightened significantly and smaller biotech stocks have come under pressure as capital has moved to so called safer harbours. Comparator Biotech companies that we follow in the USA have experienced share price reductions similar to our own. While we take no comfort from this, it does focus us on pursuing a strategy that will best position us to capitalise on market upturns as and when they occur. The timing of these international events again underscores the significance and value to our Company of the BARDA contract.

I outlined at our last AGM of the Board's intention to explore how best we position our Company to improve recognition of the underlying value that we believe exists. In March this year, we appointed Piper Jaffray as a lead financial advisor to the Company. Piper Jaffray are a significant US based investment bank experienced in working with healthcare companies of our size in exactly this kind of project.

Management, the Board and Piper Jaffray have been working intensively over the last eight (8) months on this task. While the turbulence in the financial markets over the summer months in the USA has cost us three (3) months or so while companies and advisors there confronted the new reality of pricing and capital credit, our work is back in motion.

At a high level, our work involves:

- Reviewing the costs, risks and benefits of separately listing on NASDAQ, whether as Biota USA or through an existing cashbox company; and

- Reviewing and working with select and like-minded US listed companies with suitable programs in pursuit of a possible combination that could deliver a larger scale, listed business with a USA base and direct exposure to the USA pharmaceutical and capital markets.

The Board is committed to the process, although it is too early to predict precisely how this might work out, or whether we get anywhere at all. The underlying logic starts from the BARDA contract which is intended for the potential supply and delivery of LANI to the USA market. It stands to reason that to get the maximum outcome from this program our future should involve a direct presence and exposure in the US. It is, after all, the largest capital healthcare market in the world by a considerable margin.

When a specific path forward has been identified and agreed by your Board, a proposal will be put to shareholders for their consideration. Assuming we can see a viable USA pathway, our working timetable is to have a proposal to shareholders by the end of the financial year.

I would like to thank the management team for their efforts this year and in this work. There is a lot of work in data gathering, interacting with various companies and our advisors that is intensive and comes on top of their regular day jobs.

I will now ask Peter Cook, our CEO to present to you.

CEO PRESENTATION

Introduction

Good morning ladies and gentlemen.

May I add my welcome to that of the Chairman and express my appreciation for your continued interest in and support of Biota.

My presentation will provide some additional level of information to that provided by the Chairman and will cover three (3) main topics:

- A summary of what was accomplished in the reporting year – F2011;
- A short summary of our key operational projects, and to the extent possible;
- Our view on the current commercial environment and our near term prospects.

I intend to be briefer than I have at past AGMs, because I want you to hear directly from Jane Ryan on the BARDA contract. There is no doubt that our success with BARDA has been the most significant event for the Company in my years with Biota – if not in its entire history. We have publicly described it as a "game changing event" – and one which "has the capacity to substantially shift the Company's earnings and value in the medium term". We will use today's forum as an opportunity to explain further the significance of this program.

Jane Ryan has been instrumental in delivering the contract with BARDA and I thought it best that that you hear directly from Jane regarding BARDA, Biota's program with BARDA, its progress and the competitive position of the product we expect to deliver.

Key accomplishments for the reporting year

These have already been summarised in the Chairman and CEO section of the Annual Report, but let's run through the key items again:

- On 31 March 2011 the United States Biomedical Advanced Research and Development Authority (BARDA) awarded a US$231 million contract to Biota, with the potential to lead to the filing of a US New Drug Application (NDA) for our second generation neuraminidase inhibitor, laninamivir;
- Laninamivir's Japanese New Drug Application was approved in September 2010 and the product was launched as Inavir by our partners Daiichi Sankyo, into the 2010/2011 influenza season in their domestic market;
- Inavir generated royalties to Biota of A$2.9 million in its launch season;

- A Phase IIb clinical trial to treat naturally acquired rhinovirus infection in asthmatics commenced at multiple sites in the USA. The expected two (2) year study enrolled 232 subjects in the first rhinovirus season, suggesting that the targeted enrolment of 300 subjects should be comfortably achieved within the trial costs and timeframe. There is an update to this later in my presentation;
- The United States National Institutes of Health (NIH) awarded a US$2.9 million grant for the *C. difficile* (CDI) antibacterial program, one of the programs from the Prolysis asset acquisition approximately two (2) years ago in 2009; and
- A new lead candidate for respiratory syncytial virus infection (RSV, bronchiolitis) has been identified.

Let me move on to the major operational matters for the year.

Operations

Zanamivir

Biota licensed zanamivir – the world's first in class neuraminidase inhibitor and influenza antiviral – to Glaxo (now GlaxoSmithKline) in 1990. This compound was marketed as Relenza in 1999. GSK holds exclusive rights to manufacture, market and sell zanamivir globally.

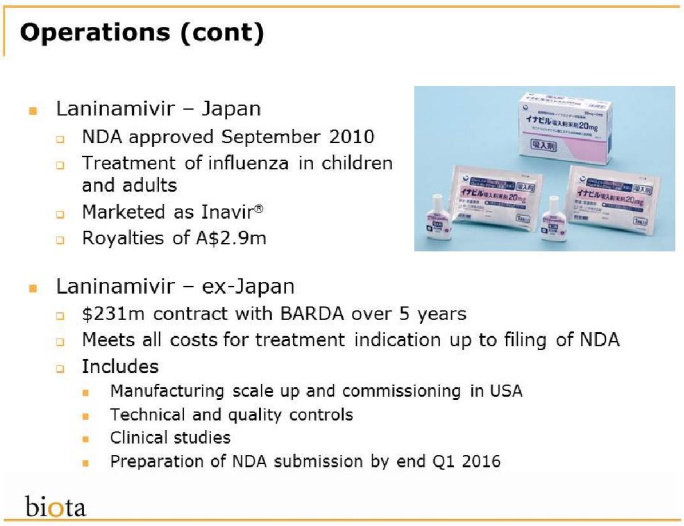
Royalties from Relenza this year were $6.6 million. Royalties were expected to be low relative to the last two financial years, which included record sales during a WHO declared pandemic of 2009H1N1, or "swine flu". Similar levels of royalties were not expected this year. Global stockpiles of neuraminidase inhibitors were high at the conclusion of the swine flu outbreak and demand was therefore expected to remain subdued in F2011.

Future royalties from Relenza are likely to be influenced by:

- Public health concerns regarding the level of preparedness for future influenza outbreaks;
- Replenishment of aging stockpiles, some of which will need to be replaced from F2012; and
- Implementation of the declared policy to re-balance a number of national stockpiles to comprise an equal quantity of Relenza and Tamiflu, given concerns about resistance to Tamiflu.

Relenza royalties are expected to continue to provide an important revenue stream for a number of years, given that key patents do not expire until December 2014 in the USA, May 2015 in the UK and other key European (EU) markets and July 2019 in Japan.

I should also emphasize that influenza outbreaks are highly variable in terms of frequency, severity and morbidity. Despite the lifesaving nature of Relenza and its many clinical advantages, the market will continue to be volatile, unpredictable and difficult to forecast.



Laninamivir in Japan

In September 2010 the New Drug Application for laninamivir was approved for the treatment of influenza in both children and adults in Japan. Our partners Daiichi Sankyo launched their brand Inavir in the 2010/2011 influenza season and achieved a premium price over both Tamiflu and Relenza.

The first season generated royalties for Biota of A$2.9 million and achieved some 25% market share.

It remains Daiichi Sankyo's intention to expand Inavir's indications to include prophylaxis most likely within this influenza season although enrolments may prove difficult. It should be recognised however that treatment is the much larger market.

Laninamivir outside Japan

Management has focused intensely on the development of laninamivir for western markets, particularly regarding funding. During the year, we have secured the US$231 million funding needed to generate the requisite manufacturing, technical support, clinical studies and provide all the additional data necessary for a US New Drug Application, expected to be lodged with the FDA in Q1 2016. The funding is to be provided by way of a contract with US BARDA, which is part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the US Department of Health and Human Services (HHS).

This contract is most likely to have a profound effect on your Company over time.

The BARDA contract has come about because the US HHS took a view that US health objectives would be best served for laninamivir to be available to the US market and from a US production base. On this basis, the Department decided to meet the costs of securing the product's registration for sale. These costs are quite high, in this case, of the order of a quarter of a billion dollars and would otherwise, need to be met commercially. Subject to administrative and technical hurdles being met – the funding is secure – it has been fully appropriated by Congress and would require significant bills to reverse this appropriation – at no charge to shareholders and with no dilutive impact on your ownership of the asset.

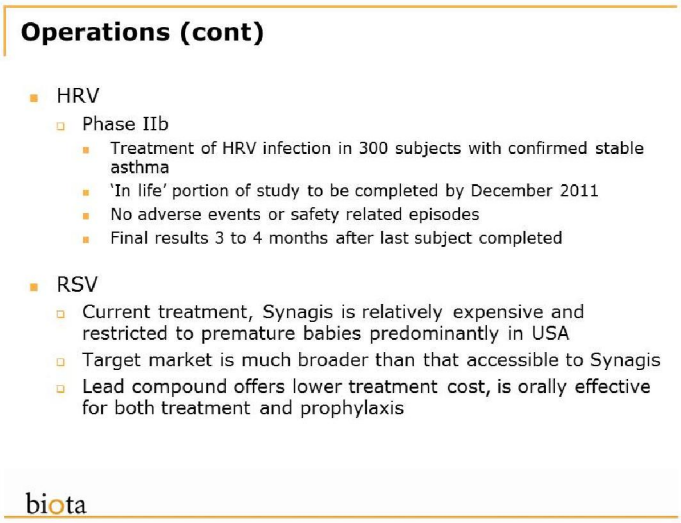
Inavir's marketing approval in Japan does give us confidence that the US program should again show laninamivir to be a safe and effective product.

On the satisfactory completion of the contract and with the NDA approved, Biota will have the ability to supply and market the most advanced antiviral available for the treatment of influenza – in a global market worth over $4.0 billion in C2009. And unlike a drug we've licensed to a third party, like Relenza, we will retain full control of laninamivir. This will create an opportunity for us to significantly increase earnings; there are huge financial benefits of being in a position to directly market laninamivir which will provide a major shift in revenues, margins and profits for Biota in future years.

Late stage development of this type for companies such as Biota is difficult to achieve, usually because of the inability to secure the levels of funding needed, even for one product. This is particularly so within the Australian market.

It is a credit to Jane Ryan and her immediate BARDA team as well as the extended executive that Biota has managed to position itself to achieve this late stage opportunity.

As I indicated earlier I have asked Jane Ryan to provide you with some greater insights into the contract, BARDA and laninamivir. I will introduce her in a few moments time to do exactly that. Before I do I'd like to report on Biota's other major programs.



HRV

Human rhinovirus (HRV) is frequently associated with the infection we call the common cold, a mild and self-limiting disease in otherwise healthy individuals. However, there is a mounting body of medical opinion that links rhinovirus infection to exacerbations in patients with underlying lung disease, such as asthma and COPD (chronic obstructive pulmonary disease), which then requires significant medical intervention to reinstate control of the underlying disease.

The market for our HRV antiviral BTA798 will be within these already high cost treatment groups that currently have no therapy, other than symptomatic treatment, for an infection that creates considerable difficulty for them to clear. In these groups, rhinovirus infection is not trivial or self-limiting and incurs a significant cost to the broad community.

As I am sure you are aware in July 2010 we commenced our Phase IIb clinical study of this compound in subjects with confirmed and stable asthma. I am pleased to announce that the last subject has been admitted to the study and will complete their clinicals before the end of December 2011. It will take us a number of months after that to interpret the study's many facets and report its conclusions – but we have completed the experimental phase on time – itself a worthwhile milestone.

RSV

Respiratory syncytial virus (RSV) infects the lung and is typically a disease of early childhood and commonly referred to as bronchiolitis. Infants with inadequately developed lung mucosal tissue, such as premature infants, are particularly at risk and have been the target market of AstraZeneca's – MedImmune's expensive lead product, Synagis, which sells well over US$1.0 billion annually treating the narrow, premature baby market.

Unfortunately, many others in the community also suffer from severe RSV infection, suggesting that there is a large unmet market need which is valued in excess of Synagis's total market.

Biota's lead RSV compound, is a lower cost, orally effective small molecule antiviral, targeted at these additional markets and is now completing the last of its Preclinical stages of development. We are pleased with the characteristics of our lead product, given its stage of development.

While we will actively promote the product to potential licensees at the appropriate stage, just as we will continue to seek ways to continue to advance the program without total reliance on shareholder funds.

Outlook

I have spoken about the drivers and the outlook for Relenza royalties earlier and which were summarised on Slide 14. In my now almost six (6) years with Biota, there have been three (3) peaks of activity in the neuraminidase market, SARS, the threat of avian flu (H5N1) and of course, swine flu. On that basis we should expect another of those like events between now and our major patent expiry date – although it is not assured.

Some of the projects in our portfolio are naturally some distance from ultimate commercialisation. These relatively early stage "research" projects such as Gyrase, CDI, HCV-NN or even RSV, are therefore of much less overall significance and value today, than a project such as laninamivir. We have been able to extract value from these early stage programs in the past and we will continue in that expectation.

However, we do need to recognise that the large pharmaceutical companies will tend to delay in-licensing activities over the next few years, particularly these earlier stage programs. Certainly there will be a limited number of inevitable "must have" programs but most likely, our traditional customers will focus on "late stage" or "ready to market" products; at least until their patent cliff issues reduce from around 2016. In short, the early licensing model Biota has used to date will prove to be harder to execute against. However, our innovative developments, such as RSV, where there is no other small molecule antiviral as well advanced and with such superior technical attributes and particularly our secure funding for laninamivir, balance this concern.

With laninamivir there is now a period of increased certainty.

We have Inavir launched in Japan, one of the world's largest markets and about to go into its second season. Daiichi Sankyo will make every effort to build on their 25% market penetration achieved in the first season.

Additionally, we are in position to emerge in five (5) years with a product approved for sale and a supply chain fully commissioned for one of the world's largest markets. The quarter of a billion dollars needed to do this is to be met by the BARDA contract and this will create a massively advantageous outcome. We will retain full control of the supply and marketing of the drug including its revenues and profits.

I'm pleased to finish on that very optimistic note and conclude my address this year, save for one other task – to introduce Dr Jane Ryan, Biota's Vice President of Product Development & Strategic Marketing – to talk to you about the BARDA program, our progress since the award of the contract at the end of March and the attributes and competitive position of laninamivir.

Dr Ryan has been with Biota for 14 years and assumed her current position six (6) years ago. Jane has built a highly respected team of specialist professionals whose responsibilities are principally in the manufacturing, clinical studies and regulatory affairs aspects of our programs. Jane has an eye for the less usual approaches and the "off the radar" opportunities, so it is not surprising that Jane has been the key instigator, as well as the successful deliverer, of the BARDA contract for the Company. Not only was this creative in its concept, but also required a monumental amount of perseverance to be achieved – two other attributes that we have come to rely on in Jane.