biota

Annual Report 2002

Biota's blueprint to rebuild value

Biota was the first Australian biotech company to successfully take a therapeutic drug all the way from discovery through to the marketplace, and see it launched in over 50 countries. Despite this impressive achievement, we have faced challenges in recent years, and seen a fall in value for our shareholders.

Biota is now dedicated to rebuilding shareholder value.

Biota Holdings Limited ABN 28 006 479 081

Over the last twelve months, we have taken a number of steps to strengthen our position and rebuild long-term value in the Company:

- The appointment of a new Chief Executive Officer
- Bringing forward a second generation influenza product, FLUNET™, and identifying potential development partners
- Establishing a state-of-the-art nucleoside research and development facility in Carlsbad, California, giving us an exciting new platform for drug discovery
- Securing a $6.5 million funded research and development collaboration with GlaxoSmithKline for the discovery of new treatments for hepatitis C
- Aiming our R&D at programs likely to deliver short-term value by improving existing drugs
- Basing our business development activities and resources in the US, where they have the greatest access to pharmaceutical partnership deals

Financial Summary

	2002 $'000	2001 $'000	2000 $'000
Revenue			
Royalties	1,169	2,428	6,180
Diagnostic sales revenues and profit share	6,080	5,745	1,728
Licensing fees	–	–	4,973
Research grant	195	2,380	139
Interest	1,601	2,352	2,239
Total Revenues	**9,045**	**12,905**	**15,259**
Operating Expenses			
Royalties	158	348	881
Cost of goods sold	2,543	2,281	99
Research and development:			
– Australian operations	7,864	9,046	10,451
– US operations (Biota Inc)	4,874	343	–
Selling and administration costs:			
– Australian operations	1,435	1,351	1,309
– US operations (Biota Inc)	1,440	254	–
Borrowing cost expenses	69	–	–
Total Expenses	**18,383**	**13,623**	**12,740**
Operating (Loss)/Profit	**(9,338)**	**(718)**	**2,519**
Income tax attributable to operating loss	**–**	**–**	**–**
Operating (Loss)/Profit after income tax	**(9,338)**	**(718)**	**2,519**
Net (Loss) attributable to outside equity interest	**(764)**	**59**	**–**
(Loss)/Profit attributable to the members of Biota Holdings Limited	**(8,574)**	**(659)**	**2,519**

CHAIRMAN'S LETTER TO SHAREHOLDERS

One year ago, in my first Letter to Shareholders, I emphasised that the Company had to move beyond the disappointing market performance of Relenza™, Biota's first generation influenza product, and look to other opportunities in our portfolio.

In the first half of the year, we completed a strategic review of the group's operations and announced a number of key initiatives along with milestones to be achieved during calendar 2002.

I am pleased to report that we have made very good progress and are on track to achieve these milestones.

The appointment of a new Chief Executive Officer

Peter Molloy's appointment brings vigour and an impressive depth of commercial experience to Biota. Peter has more than 20 years experience in the international pharmaceutical and biotech arenas – in Australia, Asia, and importantly, the United States. Because the US is such an important market for partnering and value generation, the Board felt it essential to have Peter based there, to lead our group's business development and partnering activities and support the crucial development of Biota Inc in his capacity as Chairman of that entity.

Secure a collaborative partner and undertake fundraising in the US for Biota Inc

The progress at Biota Inc in the past year has been outstanding, culminating in the recent closing of a funded R&D collaboration with GlaxoSmithKline focused on hepatitis C. This is Biota Inc's first pharmaceutical deal and will bring in valuable funding to the unit, over the next two years and beyond. It is also testimony to the value of Biota's investment in N•MAX technology, and an important value point in Biota Inc's pursuit of outside equity funding. In what is clearly a difficult fundraising market, management has attracted the interest of a number of investment groups, and we expect to receive and consider one or more concrete proposals within the next few months.

To secure a commercial collaboration for FLUNET and our other respiratory programs

The Company is pursuing collaborative partnerships for both its influenza and rhinovirus (common cold) programs. The generally low incidence of influenza around the globe over the last two years has not assisted our cause; nor has the recent rejection by the FDA of an alternative rhinovirus treatment. Despite this, FLUNET has attracted considerable interest from prospective pharmaceutical partners, and we expect to be able to announce a major new collaboration before the end of 2002, which would fund the development of FLUNET into clinical trials.

To expand our MUCO™ technology into chronic diseases

MUCO (Multivalent Coupling) technology is the name we now use to describe the technology that underpins FLUNET. Over the last twelve months, our Melbourne-based scientific team has been pursuing applications of the MUCO technology beyond influenza. For example, in the antibiotic field, where resistance has become a serious issue for medical authorities, we have initiated a program to develop a long acting antibiotic. Another early MUCO program is aimed at inflammation disorders.

Results for year

The group loss for the year was $8.6 million, of which establishment and operating costs of Biota Inc contributed $6.4 million. Biota Inc anticipates a similar loss in the current financial year. The Biota Inc expenses are consistent with planned development, and in line with our commitment to fund the US entity, following our acquisition of NuMAX Pharmaceuticals in 2001. We are very pleased with the developments at Biota Inc over the last year, and now have a fully-operational nucleoside research laboratory, and a top-flight scientific team in Carlsbad California, led by Dr Dan Cook, the NuMAX founder and now Biota Inc's chief scientist.

We expect to slow down the rate of net annual cash outgoings for the group through further collaborative partnerships, raising additional equity funds through our US entity, and securing non-dilutive grant funding where possible.

Despite the loss for the year, the group is in a relatively sound financial position with cash resources of $30.1 million, equivalent to $0.40 per Biota share. These reserves place us in a good position relative to many other biotech companies in the current environment.

In closing, I would like to express our gratitude to Dr. Hugh Niall, who retired as CEO in July 2002. Over the last seven years, Hugh has led the organisation through a time of extraordinary change and challenge. Nevertheless, Hugh's departure leaves us with excellent research teams in Australia and the US, a sound cash position, and exciting prospects. I am pleased to advise that Hugh will continue to have a consulting relationship with Biota in scientific matters.

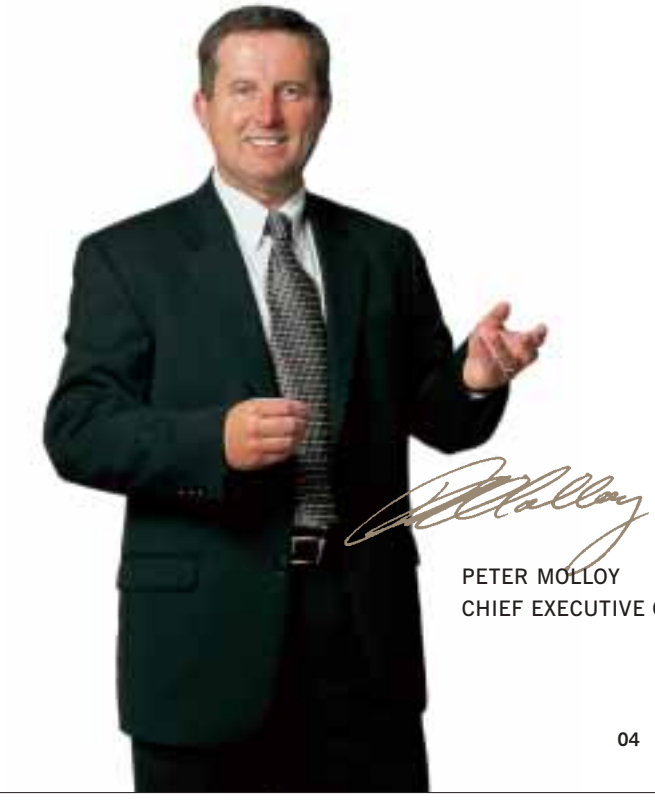
"Biota is in a relatively sound financial position with cash resources of $30 million."

JOHN GRANT
CHAIRMAN

Building value

In the current market climate, we need to plan carefully to preserve and build value. We also need to recognise and leverage our formidable strengths as we pursue opportunities for value capture.

Biota's mission is to become an internationally renowned, Australian biotech company, delivering positive returns for its investors. As we look forward, and while there are still challenges ahead, the prospects for Biota's fulfilling this mission are improving, and the goals we achieve over the next twelve months will be important mileposts on the path forward.



PETER MOLLOY
CHIEF EXECUTIVE OFFICER

Beyond Relenza

Biota's first product, Relenza, has not been successful in the marketplace. GlaxoSmithKline (GSK) launched Relenza in 1999, and sales in its first year reached $87 million worldwide. The following year, they fell to $34 million, and this year, are expected to amount to only $17 million. Biota's royalties on Relenza are based on a percentage of sales value, so the impact on our revenues over the last three years has been considerable, and in 2001/02, our royalty income from Relenza dropped to around $1.2 million.

We continue to discuss with GSK ways to revive Relenza, but need to face the reality that despite evidence of the product's effectiveness, Relenza is unlikely to be a significant contributor to Biota's royalty revenues in the near term.

Against this background, and in the current market climate, we need to plan carefully to preserve and build value. Our current plan for doing so has the following key elements:

1. Our investment and presence in the US is paying off, as evidenced by the progress of Biota Inc over the last year and the deal with GSK to develop a drug to treat hepatitis C infection. We intend to build on that success, pursue other partnering deals, and look for other profitable ways to capture value including external funding.
2. We will focus our R&D strategy, both in Australia and the US, on technologies that offer the potential for early partnering and value capture. Our key technology platforms – N•MAX in the US and MUCO and Structure Based Drug Design in Australia – offer this potential.
3. We aim to secure one or more partners to fund the development of our second-generation influenza drug, FLUNET. If our other respiratory programs progress to candidate drug selection, we will also look for partners for those.
4. We must find ways to extract more value from Relenza, and are currently in discussions with GSK about possible strategies for doing so.

We may add other elements during the year ahead, based on outcomes of partnering activities or based on opportunities that arise. Realistically, none of these strategies is likely to deliver enough in fees, milestones, or other revenues to make Biota profitable in the next year, so we should expect to continue to apply our cash reserves to fund operations. Fortunately, these reserves are substantial, and compared with many other biotech companies in the current climate we are in good shape.

Biota's Strategic Strengths

Clearly, our cash position is an important strength, because it gives us the stamina to support our plans for building and capturing value.

A second strength is our focus on viral diseases. In the last two decades, we have seen the emergence of HIV, hepatitis C and a host of other new viruses. Increasingly, researchers are finding associations between viruses and a number of important diseases, including cancer. Despite the belief by many that viruses are

likely to be a major threat to human health in the 21st century, few biotech companies are focused in this field. Biota is one of the few and is well placed to meet the therapeutic challenge and market opportunity that viral diseases represent.

Biota also has the inherent value of strategic technology options: we have three distinct technology platforms, each offering multiple opportunities for innovation and value capture over the next few years. We are not a one-product or single technology company; this represents real value and makes us particularly attractive as we go forward to find new investors or collaborative partners.

Fourthly, Biota is one of the few Australian biotech companies to successfully project itself into the all-important US marketplace for pharmaceutical deal-making and fundraising. Our US base gives us the option of accessing the US funding market, if we need it. More importantly, it places us firmly on the radar of US pharmaceutical companies looking for new products and technologies, as evidenced by our recent deal with GSK for hepatitis C.

Finally, in both its US and Australian R&D operations, the Company now has a top team of scientists focused on creating value that can be turned into pharmaceutical deals. In the US, Dr Dan Cook, has succeeded in attracting an elite team of scientists, making us the premier commercial nucleoside/nucleotide research lab in the world. In Australia, Dr Simon Tucker was recently promoted to head up all the local Biota research activities and is supported by Dr Jane Ryan, who coordinates all R&D project activity and provides a vital interface with the business development and deal-making function in the US.

Armed with these strengths, Biota finds itself in the biotech market at a time of transition and great opportunity. Despite the vagaries of the stock market in recent times, the fundamentals in the biotech sector are stronger than ever. Each year for the past decade, sales of new therapeutics emerging from biotech pipelines have shown impressive growth, and last year grew by a further 22% to US$39 billion. With the industry generally well funded after a spate of IPOs in 1999 and 2000, and biotech pipelines looking healthier than ever, the prospects for long-term prosperity in the industry are excellent.

FLUNET

Biota has already achieved what every biotech start-up company hopes for, but few realise – successfully developing a new prescription drug and seeing it launched around the world. Unfortunately, and despite their technical merit, not all new products succeed.

Despite its disappointing sales performance, Relenza along with our FLU OIA® diagnostic assay have helped break the ground for Biota in the influenza market, and helped pave the way for our second-generation influenza product, FLUNET.

FLUNET promises to be an important advance in influenza prevention and treatment, and is the first candidate to emerge from Biota's patented Multivalent Coupling (MUCO) technology, which is described

more fully by Dr Simon Tucker later in this report. If successfully developed, FLUNET offers the promise of once-a-week administration, making the product much more convenient for patients and doctors, and overcoming one of the disadvantages of existing influenza antivirals, including Relenza.

The prospects for long-term prosperity in the industry are excellent.

In the past year, we have discussed the licensing of FLUNET with a number of prospective partners who might fund the development program in exchange for certain marketing rights. These discussions are now advanced with one partner and we hope to make an announcement before the end of 2002 about a new global development partnership for Biota.

Beyond Influenza

Biota is more than an influenza company. In Australia, we have a number of R&D projects emerging from our MUCO technology platform and our Structure Based Drug Design know-how. These programs extend our interests to respiratory viruses other than influenza, including RSV (Respiratory Syncytial Virus), a significant cause of lower respiratory infection in the young, and HRV (Human Rhinovirus), the cause of the common cold. Both will reach key decision points over the next twelve months, and either yield a candidate drug for clinical development and licensing, or result in termination of the project.

During the year, we identified applications for the MUCO technology outside the viral respiratory disease arena, including inflammation and bacterial diseases. These may yield commercially relevant programs in the next twelve months.

Overall, Biota's Australian research and development programs are now aimed at improving existing approved drugs, where possible, and delivering early partnering opportunities for Biota.

Building Value in the US

Like any drug discovery company, Biota's principal 'market' is the demand from global pharmaceutical companies for new drugs to fill their depleting product pipelines. The value of this market can be measured by the annual value of pharmaceutical-biotechnology deals, estimated at more than US$5 billion. Most of this deal-making happens in the US, and being able to credibly project itself into the US is essential for any Australian company seeking to gain access to the global partnership marketplace.

Two years ago, Biota made the decision to set up a US base and in 2001 acquired a start-up company in the San Diego area, called NuMAX Pharmaceuticals Inc, along with its N•MAX drug discovery technology. The company was renamed Biota Inc, with Biota Holdings agreeing to provide US$8 million in funding for the unit over the ensuing two years. Since early 2001, Biota Inc has more than fulfilled our expectations.

Dan Cook has succeeded in attracting a first class team of scientists, and along with Sterling Johnson, Biota Inc's CEO, has readied and equipped our facility in Carlsbad, California, which is now fully functional and already working to discover new drugs.

Biota Inc will initially focus on discovering and improving nucleoside drugs – a class of drugs widely used as antivirals and anti-cancer agents. Approximately 50 nucleoside drugs have been marketed over the years, with total current annual sales of around US$15 billion.

Despite their effectiveness, many nucleoside drugs are limited by their side effects. As well as providing a platform for discovering new therapeutics, N•MAX technology offers the potential to rapidly develop new versions of several existing nucleoside drugs, but with less potential for side effects. Clearly, this should be quite attractive to pharmaceutical companies engaged in these disease areas or with a commitment in the nucleoside field.

We recently announced one important partnership between Biota Inc and GSK aimed at developing new drugs against hepatitis C. This partnership will provide vital short-term funding for Biota Inc and valuable credibility for the technology and the US company.

This deal with GSK, however, will not meet Biota Inc's entire funding needs in the medium term and over the last six months, we have been investigating independent funding for Biota Inc in the form of private equity finance. In reviewing any funding proposals that might be offered, we will seek to ensure that our investment and potential value in Biota Inc are not eroded. We are also pursuing new funded collaborations and opportunities for non-dilutive grant funding.

While N•MAX technology represents an important focus for our business development activity, we are also actively engaged in partnering for FLUNET and other Biota technology. Over the past twelve months from our US base, the Biota name has been introduced to more than 100 companies worldwide. These efforts are now paying off as we engage prospective partners for all facets of the Biota technology.

Biota's mission is to become an internationally renowned, Australian biotech company, delivering positive returns for its investors.

Our Mission is to Deliver Value

Biota's mission is to become an internationally renowned, Australian biotech company, delivering positive returns for its investors. As we look forward, and while there are still challenges ahead, the prospects for Biota's fulfilling this mission are improving, and the goals we achieve over the next twelve months will be important mileposts on the path forward.

Biota Drug Discovery Technologies

Novel drug discovery technology, aimed at developing new and improved forms of nucleoside drugs, targeting viral and bacterial diseases, and cancer.

Novel drug discovery technology, based on multivalent coupling and aimed at developing higher potency, long acting drugs, which target viral and bacterial diseases, and inflammation.

A classical drug discovery technology, which bred Relenza‘; based on designing drugs to bind specific biological targets. New applications include rhinovirus and RSV.

Multivalent Coupling (MUCO) Technology

Biological interactions, such as those between drugs and cell surface receptors, frequently involve multiple points of contact. For example, hormones and their receptors are known to bind to each other at several sites on their respective molecular surfaces. In the case of therapeutic drugs, if we could achieve such 'multivalency' between the drug and its receptors, it could lead to greater strength and specificity of the drug interaction. Specificity is important because it could reduce the risk of unwanted side effects, while the stronger the drug-receptor interaction, the lower the dose required to achieve the desired therapeutic effect. Over the years, researchers around the world have attempted to design new drugs that might mimic the multivalency we see in nature.

Building on our extensive experience with zanamivir (Relenza), Biota scientists succeeded in developing such a compound for the treatment or prevention of influenza. We discovered that when we linked two zanamivir molecules together with certain types of chemical linkers, some of the resulting compounds were 100 times more potent than the zanamivir molecule alone. Moreover, these compounds exhibited a remarkable increase in residence time in the respiratory tract, leading to the prospect of once-weekly dosing. We call these compounds our FLUNET products, and have decided to call the underlying technology our MUCO *(Multivalent Coupling)* technology, and have filed a series of patents to protect it.

While our first MUCO development program will be aimed at an improved influenza treatment,

"While our first MUCO development program will be aimed at an improved influenza treatment, FLUNET, we are now applying MUCO technology to several diseases."

DR SIMON P TUCKER
DIRECTOR, RESEARCH

FLUNET, we are now applying the MUCO technology to several diseases. For example, we have an early stage project aimed at bacterial respiratory diseases and another aimed at inflammatory diseases. In exploring applications for the MUCO technology, our strategy is to focus on improving established drugs wherever possible, to potentially accelerate the subsequent development program and make candidate drugs attractive for early partnering with major pharmaceutical companies.

FLUNET

While the MUCO technology promises to be a technology platform that could be applied to a number of therapeutic drugs and diseases, our most advanced project is aimed at developing a second-generation influenza antiviral, with significant advantages over Relenza and other influenza antivirals. This program is called FLUNET.

We have three FLUNET candidate drugs, and all are zanamivir dimers – two molecules of zanamivir joined by a proprietary coupler molecule. The potential benefits of FLUNET are substantial: FLUNET candidate drugs tested so far are approximately 100 times more effective *in vitro* at eliminating the influenza virus than Relenza. This means that a much lower dose of drug might be needed. The other major advantage is dosage frequency. Like Relenza, FLUNET would be an inhaled product, but whereas Relenza needs to be administered twice daily for five days, FLUNET has the potential for once-a-week administration. We are also investigating new inhalation devices for FLUNET, which could prove to be much easier to use than the device currently employed for Relenza.

We are currently in the final stages of candidate drug selection for a FLUNET product, which if successful in preclinical assessment over the next year, will be brought forward into clinical development. If FLUNET does progress through clinical development, the process will take several years, and will be costly. Over the last six months, therefore, we have discussed the licensing of FLUNET with several prospective partners who might fund the development program in exchange for certain marketing rights. These discussions are now well advanced with one partner.

Common Cold

As we all know, the common cold is the leading cause of visits to the doctor, and a major contributor to work and school absenteeism. In some cases, it can lead to serious, life threatening disease for people who suffer asthma, cystic fibrosis or chronic obstructive pulmonary disease.

Inspired by our efforts with influenza, Biota's scientists have been looking at ways to defeat the human rhinovirus (HRV) responsible for the common cold, and develop an orally available, antiviral treatment, which might stop the virus from spreading through the respiratory tract.

One of the challenges was that there are many variations of the virus. Therefore, in order to design an effective therapeutic, broad-spectrum antiviral activity was essential. Our approach was to design molecules that bound the capsid protein on the surface of virus – a protein common to all variations of the rhinovirus and responsible for its attachment and spread through the respiratory tract.

In collaboration with researchers at University of Virginia and the Institute for Antiviral Research in Utah, we have been able to develop several lead compounds with potent, broad-spectrum activity against the rhinovirus *in vitro*. Biota has filed three patent applications covering its discoveries.

During 2002, we worked at optimising these lead compounds for possible selection as candidate drugs. We expect to make the next key decisions about this program before the end of calendar 2002.

Respiratory Syncytial Virus

RSV is a respiratory virus, and is the major cause of infant bronchitis and a frequent cause of pneumonia. Severe cases can even lead to hospitalisation or death. Premature babies and those with cardiac or pulmonary complications are particularly at risk. RSV is also highly contagious, and young children may be infectious for one to three weeks after symptoms have

subsided. Consequently, any effective antiviral treatment should decrease the viral load in the infected person and thus reduce the risk of spreading the infection.

Biota's RSV program aims to develop an orally active, antiviral drug for treatment and prevention of RSV. RSV grows and spreads in the lung of the infected person. The virus uses a protein called the F protein (fusion protein) to enter and spread through lung tissue. Biota scientists were the first develop a model of the F protein, and this protein is now the target of our RSV discovery program.

Using our proprietary information on the expression and processing of the F protein, we developed proprietary assays for testing RSV antiviral activity. These were used to screen prospective antiviral compounds that we developed and to better understand the types of compounds that might work as RSV inhibitors.

We also applied techniques such as structure-based-design and computer modelling, similar to those used to design Relenza.

Over the last 12 months, the screening, molecular modelling and medicinal chemistry activities have lead to identification of several active compounds, which inhibit RSV *in vitro* and could ultimately lead to candidate drugs. More rigorous tests are now being applied to determine which of these will meet the requirements necessary for further development, and we expect to make these determinations in early 2003.

"Inspired by our efforts with Relenza, Biota's scientists have been looking at ways to defeat the common cold."

DR JANE RYAN
DIRECTOR, PROJECT MANAGEMENT/
BUSINESS DEVELOPMENT

Building a US Springboard

Biota Inc was established in the US in early 2001, and moved to its current facility in Carlsbad, California in August of that year. Over the last twelve months, we have achieved a great deal:

– Completed the first phase of the planned R&D staff build-up, and at June 30, 2002 employed 16 scientists, 11 with PhD or MD degrees.
– Set up and equipped our state-of-the-art chemistry and biology labs.
– Filed eight provisional patents on the company's proprietary N•MAX technology.

Dr Dan Cook, the Chief Scientist at Biota Inc and a world-leading nucleoside scientist, has succeeded in attracting an elite team of biochemists, biologists and pharmacologists from leading biotech companies and universities.

With the people and facilities we have in place, we believe that Biota Inc is now the premier commercial nucleoside/nucleotide research lab in the world.

GSK and Hepatitis C

The most notable event of the last year has been the recent signing of the Collaboration and License Agreement with GlaxoSmithKline (GSK) aimed at developing new treatments for hepatitis C. Hepatitis C infection is an important and growing market, which is expected to eventually surpass the HIV market in sales value.

Under the collaboration with GSK, we will apply our proprietary N•MAX nucleotide technology to identify new compounds, which will be screened by GSK as drug candidates for treatment of hepatitis C infection. Over the next two years,

(LEFT) STERLING JOHNSON
CHIEF EXECUTIVE OFFICER, BIOTA INC
VICE PRESIDENT, GLOBAL BUSINESS DEVELOPMENT, BIOTA HOLDINGS LIMITED

(RIGHT) DR P DAN COOK
CHIEF SCIENTIFIC OFFICER, BIOTA INC.

Biota Inc will receive minimum payments from GSK amounting to US$3.5 million (A$6.5 million), along with significant milestone payments if any compound is taken through development. Compounds reaching the market would also generate royalties for Biota Inc.

This is our first pharmaceutical deal for Biota Inc and affirms Biota's belief and investment in Biota Inc. Importantly, it will also provide significant funding toward the running of the US company over the next two years.

N•MAX Technology

Nucleoside drugs are widely used in the treatment of viral diseases and cancer, and account for an estimated US$15 billion in worldwide annual sales. N•MAX technology is a drug discovery technology from which a whole new raft of nucleoside drugs could be developed, not only aimed at viral diseases and cancer, but also at bacterial and fungal diseases.

A major limitation of many nucleoside drugs is their toxicity. This is largely due to the fact that they cannot be effectively delivered into the body in their active, or 'nucleotide' form. Once inside the cell, the nucleoside drug is converted to the active nucleotide form, but the process can lead to toxic by-products. N•MAX technology permits the development of metabolically stable nucleotides, allowing the drug to be delivered into cells as the therapeutically active form. This could lead to a whole new class of nucleoside/nucleotide drugs with improved tolerability, and could open up new therapeutic areas, including bacterial infections and fungal diseases.

One short-term opportunity for N•MAX technology is to rapidly develop new versions of several existing nucleoside drugs, which have large sales, but toxicity problems. Over the next twelve months, we will be actively pursuing this opportunity with a view to generating a second pharmaceutical partnership.

Fundraising in the US

Biota Inc was established with a commitment of US$8 million in funds from Biota Holdings, and now supplemented with funds from the GSK deal. We have several strategies for future external funding, including other pharmaceutical collaborations and government grants.

We have also been investigating the use of private equity finance, and will continue to review such opportunities.

Business Development

After our success with the GSK hepatitis C deal, we are keenly pursuing other collaboration opportunities with pharmaceutical companies in the US, Europe and Japan. With our network of industry relationships and our base in Carlsbad, we are well placed to prospect and follow-up on all opportunities, and are well supported by expert consultants based in Europe and Japan.

Corporate Directory

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Ian D Gust
Barbara J Gibson
Thomas W Quirk

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