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Bionomics Limited 31 Dalgleish Street Thebarton, South Australia 5031

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Bionomics Limited's recent AGM speeches highlighted the company's focus on development opportunities within core assets. How has the company's strategy evolved in the last year and what are the key corporate and research and development (R&D) priorities for 2006?

# MD & CEO Deborah Rathjen

Our primary focus is on the development of therapeutic compounds for treating cancer, multiple sclerosis, anxiety and epilepsy. This represents a significant change on the one hand but also a natural progression for the company stemming from the implementation of its strategic plan to 2008. The company has progressed from being a genomics-based company into a drug discovery and development company and is now on the brink of becoming a clinical development company through the progress of its therapeutic development program in cancer.

The acquisition of Iliad Chemicals mid-year complemented our existing development pipeline by providing not only anti-cancer compounds and compounds with the potential for development for the treatment of multiple sclerosis, but also business development opportunities around its proprietary chemistry platform MultiCore<sup>®</sup>.

Our key priority in 2006 is to bring our anti-cancer compound for vascular targeting to the clinic. This will require a selection of the clinical drug candidate in the first quarter of 2006 and the completion of studies, which enable clinical trials to commence.

In our other R&D areas, our objective will be to select lead compounds for our multiple sclerosis, anxiety and epilepsy programs. By 2007 this should lead to the selection of clinical drug candidates and enable these programs to move into clinical development, pending the outcome of R&D.

On the corporate side, our key objective is to commercialise our non-core assets including our validated drug targets, which are prime candidates for antibody therapeutic development. This is a particularly hot area right now and successful commercialisation of these targets will further grow the commercial revenue streams we initiated in the last financial year through further commercialisation of our diagnostic for severe childhood epilepsy and also the commercialisation of a second diagnostic for benign seizures in children.

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Vascular-targeting compounds, created using your proprietary MultiCore<sup>®</sup> technology, will commence clinical trial enabling work in the 2005/06 financial year. How do these compounds work and do they provide advantages over other existing treatments?

# MD & CEO Deborah Rathjen

Our vascular-targeting agents are second generation compounds. They work by 'vascular shutdown', essentially attacking the core of the cancer and starving the cancer from within. Cancers such as breast cancers, lung cancers, colon cancers – really any solid tumour is vulnerable to this kind of attack. The advantage of our approach is the cancers are unable to find pathways around the attack from these compounds, so they're not able to become resistant to the treatment as they may become to other therapeutic approaches.

MultiCore<sup>®</sup> chemistry has enabled us to address the issues in tumour vascular targeting in a very direct way. Our compounds have a much wider therapeutic index that flows through from their increased selectivity and potency. That's a key competitive advantage.

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What will be the objective of the first clinical trial and when do you expect it to commence?

# MD & CEO Deborah Rathjen

Our first clinical trial will commence in the 2006/07 financial year. We're already in discussion with clinical groups with respect to planning clinical trials. The objective will be to demonstrate our compound is safe and that it blocks cancer vessels in patients with advanced solid-tumour cancer through 'vascular shutdown'.

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How large is the potential market for vascular-targeting compounds and what are the commercial opportunities?

# MD & CEO Deborah Rathjen

This is "blockbuster drug" territory. The potential market opportunity is very significant. In breast cancer alone, revenues from current treatments are in excess of US\$4 billion per annum.

Our strategy is to conduct early stage Phase I and II clinical trials prior to seeking a licensing partner for further development and ultimately regulatory approval and marketing of the drug developed by Bionomics. Some of the larger pharmaceutical and biotechnology companies interested in the antiangiogenesis approach to cancer treatment are also watching the vascular targeting area very closely and as such are ideal commercialisation partners. Bionomics knows this area well and has already established lines of communication with these companies as a result of its work in the angiogenesis field.

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The company was recently granted a patent in New Zealand for a series of compounds that have resulted from the application of Bionomics' MultiCore<sup>®</sup> chemistry platform to vascular targeting. This patent was originally licensed to Iliad Chemicals and provides patent coverage out to February 1, 2022. Can you outline the scope and protection provided by this patent?

# MD & CEO Deborah Rathjen

This is a very broad-ranging patent providing "composition of matter" claims over compounds of interest to Bionomics. In addition the granted patent claims also cover the key elements of Bionomics' proprietary MultiCore<sup>®</sup> chemistry platform. This patent family provides an important underpinning of our technology and is likely to be a key factor in the future, in securing the substantial licensing deals we seek.

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How strong is your current patent position and will any further patents will be sought this financial year?

# MD & CEO Deborah Rathjen

The recent patent grant gives us cause for optimism that our patent position is strong and that further applications in this patent family will be granted in key markets including the US and Europe. This is just the beginning of a patent roll-out we hope will ultimately result in worldwide patent protection for this class of compound.

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At your recent AGM you also described your three CNS programs: multiple sclerosis, anxiety and epilepsy which are heading into preclinical status in the 2005/06 year. For each of these three programs can you outline the differentiating factors from other treatments available and what you hope to achieve for all three during the upcoming year?

# MD & CEO Deborah Rathjen

The best way to address this is to look at each program individually.

# **Multiple Sclerosis**

This is a condition with a very high unmet clinical need. No new treatments for Multiple Sclerosis have received FDA regulatory approval for 11 years. Our program has three distinct advantages, all focussed on the ion channel Kv1.3. First is its ability to target very specifically T-cells that attack and destroy the myelin sheath. Second, our compounds are the most selective and potent Kv1.3 channel blockers currently under development. Finally, they are the

only 'small molecule' compounds and the only potentially orally active compounds in development.

#### Anxiety

One of the significant problems associated with current drugs used to treat anxiety is they tend to promote sedation. Our European subsidiary, Neurofit, has recently evaluated for Bionomics anxiolytic compounds that lack sedation which are being further developed.

#### Epilepsy

In epilepsy we're making use of all of our genomics information to get more specific anti-epilepsy drugs. Epilepsy and anxiety share similar issues around the product profile, where you need a drug that suppresses seizures but again lacks sedation.

Each of these programs is at a similar stage of development. We're aiming to identify the most prospective compounds we can take into a pre-clinical development program over the coming financial year.

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What progress do you expect to make in your angiogenesis programs during the 2005/06 year?

# MD & CEO Deborah Rathjen

We're doing two things. We've prepared licensing packages for some areas of the IP portfolio as we see this as a highly prospective commercialisation area for us. In particular BNO69, which we believe has strong prospects of being a very important cancer drug target. Work on this target augments our interests in vascular-targeting agents and we're looking for licensing opportunities which will allow us to fully exploit our IP on BNO69.

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Bionomics' commercial cash inflow has to date generally been sourced from the licensing of non-core assets and increased from \$68,000 to \$1.208 million in the financial year ended June 30, 2005. Can you detail the revenue possibilities from existing and potential licensing agreements over the next year?

# MD & CEO Deborah Rathjen

A key objective is to increase commercial income through existing licensees and through new licenses.

Last financial year we established licensing agreements with Genetic Technologies and Athena Diagnostics to bring the Severe Myoclonic Epilepsy of Infancy (SMEI) test to market. Last week, we signed a licensing agreement with LabCorp for both the SMEI diagnostic test and for the Benign Familial Seizures Panel test. LabCorp is the first licensee of our BFSP test and the third licensee for the SMEI test.

The LabCorp licensing arrangement is a significant deal for which Bionomics will receive upfront payments amd royalties on net sales. LabCorp had annual sales in excess of US\$3.0 billion in 2004 and is the second largest provider of diagnostic services in the US. Through its national network of 33 clinical

laboratories and approximately 1,300 patient service centers, LabCorp provides clinical testing services to more than 220,000 physicians, government agencies, managed care organisations, hospitals, clinical labs, and pharmaceutical companies.

We've approached our licensing agreements strategically and believe we're well placed to pursue future growth opportunities.

Over this financial year we will also be looking to out-license other non-core assets around our validated drug targets.

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At June 30, 2005, Bionomics' cash position was \$9 million. Your net operating out flow in FY05 was \$3.33 million. What impact will your planned programs have on annual cash outflow?

#### MD & CEO Deborah Rathjen

Over the short to medium term it is envisaged that Bionomics net cash outflow will be at similar levels to that of previous years. This has usually been around \$4.0 million. Our cash outflow will be offset by commercialisation revenues and the establishment of additional licenses for our non-core assets and grant funding for our R&D projects. There will be a clear focus on the priority project – the anti-cancer vascular targeting compounds – in allocating the company's resources. As the company progresses into clinical trials there will be an increased need for capital to support clinical development activities.

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Thank you Deborah.

For previous Open Briefings with Bionomics Limited, or to receive future Open Briefings by e-mail, please visit <u>www.corporatefile.com.au</u>.

For more information about Bionomics Limited, please visit www.bionomics.com.au or call Deborah Rathjen on (08) 8354 6101.

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