



**ANNUAL GENERAL MEETING  
15 OCTOBER 2007  
CEO'S SPEECH**

As Richard has just outlined, Giaconda's approach to drug development is almost unique within the Australian biotechnology space, and it is something we're very proud of. Here I will give an update of the Company's progress within the framework of that strategy.

It has been a busy year in terms of clinical development. Our lead product, Myoconda<sup>®</sup> for Crohn's Disease, has been in some exciting scientific publications. Early Phase III trial data from Pharmacia, published only recently, showed that a low dose formulation of the product can produce a high rate of remission. The remission rate compares very favourably with existing therapies—anti-TNF drugs—which are a multi-billion dollar market.

The US Food and Drug Administration (FDA) issued the Company an IND (investigational new drug approval) for a reformulated version of Myoconda<sup>®</sup> containing an increased dose of antibiotic in an all-in-one capsule.

Evidence suggests that the results published by Pharmacia, positive as they were, can be improved upon, and Phase III clinical trials will begin soon in Europe.

A retrospective analysis by our Chief Medical Officer, Prof. Borody, was also published earlier this year. He found that in some patients, Myoconda<sup>®</sup> could produce long-lasting remission, even leading to complete healing of the damaged intestine. This article prompted a journal editor to suggest that the diagnostic criteria for recovery from Crohn's Disease should be redefined in light of these spectacular results. This reinforces our position that we are redefining the approach to treating this devastating disease.

We know that the condition known as Crohn's Disease cannot be pinned down to a single cause. The bacteria that Myoconda<sup>®</sup> targets, known as MAP, seems to be present in about half of the cases of Crohn's Disease. However, with current technology it is difficult to determine the number accurately. So it is with great anticipation that Giaconda looks to the new, improved diagnostic test for MAP recently developed by the Company's partners in the US. This will let us target only those patients for which Myoconda<sup>®</sup> is suitable, improving the quality of our clinical trial data, and also ensuring maximum benefit for patients. These factors will translate into a quicker and more cost-effective clinical trial process, as well as greater market uptake and penetration, and therefore have an important impact on the bottom line.

The Company has also signed a Heads of Agreement with an FDA approved manufacturing company for the production of Myoconda. Further negotiations are in progress to finalise the details of the commercial supply agreement. The APIs (Active Pharmaceutical Ingredients) for the product have been sourced and the first manufacturing batch was made in April, 2007. A Pilot Pharmacokinetic trial was run using these capsules and was reported in September. On that basis we have selected the optimum formulation of the product that will be used in our next clinical trial.

We also recently announced an extremely important collaboration with PCS, a clinical research organisation in the Czech Republic who will undertake all of the regulatory and clinical development of Myoconda in Europe. The trial is expected to commence by the end

GIACONDA LIMITED

Ground Floor, 44 East Street, Five Dock NSW 2046 Phone: [612] 9370 0069 Fax: [612] 9712 1469  
email: [info@giacondalimited.com](mailto:info@giacondalimited.com) ABN 68 108 088 517 [www.giacondalimited.com](http://www.giacondalimited.com)

of the year.

The past year has also brought significant developments in our other therapeutic areas. Heliconda<sup>®</sup> was granted patent protection in Europe, offering hope to stomach ulcer sufferers with drug-resistant *H. pylori* infection. Likewise Ibaconda<sup>®</sup> had its patent protection extended to Europe for the treatment of irritable bowel syndrome. Phase IIa trial results for Picoconda<sup>®</sup>, showed excellent effectiveness and superior tolerability for pre-colonoscopy bowel cleansing.

In July we commenced the first phase II study of Hepaconda, our product for genotype 1 Hepatitis C. Chronic Hepatitis C infection represents a major cost to the healthcare services of all nations and a significant number of patients do not respond to current therapies. Hepaconda was notably mentioned in a report by Thomson Scientific, "The Ones To Watch" as one of the top 5 most promising drugs entering Phase II testing. We anticipate that we will be able to report the results of the proof of concept trial in early 2008.

Myoconda has been the key focus of our licensing efforts this year. We have secured Letter of Intent agreements with various partners around the world and are in the process of converting these into full licensing agreements.

Our already substantial pipeline will be bolstered by new intellectual property from our research partner, the Centre for Digestive Diseases. Giaconda is currently reviewing the intellectual property portfolio at the Centre for Digestive Diseases for therapies to treat *Clostridium difficile* infection.

I will shortly be handing you over to Professor Borody, our Chief Medical Officer who will tell you more about *Clostridium difficile* and potential treatments for it and give an overview of what we call "The Bloody Epidemic" – the role of anti-MAP treatment, MAP infection and its role in the rising epidemic of Crohn's Disease.

The stock market has not been kind to biotech in recent months. While over the course of the year our share price has not reflected the value we believe is inherent in the Company we have done what we set out to do – that is to deliver on our milestones. A key barrier to investment for many people has been the limited liquidity of our stock, and with the shares that have recently come out of ESCROW we believe this will change. As one industry analyst commented, "Giaconda is Australia's best kept secret in biotechnology".

In summary, as I have presented to numerous investor groups and market analysts, Giaconda is consistently meeting milestones and progressing the portfolio of products we acquired when we launched the company. We have published Phase II studies, increased our patent coverage, developed manufacturing, clinical and regulatory pathways for Myoconda and expanded our licensing commitments. I am personally proud of what we have accomplished and the people that have helped us achieve what we have achieved.

Finally I'd like to direct a few comments to Giaconda's most important people – the patients. I want to promise you that I – we – are working as hard as we can to bring you help. You are why we exist and why we do what we do. We think of you every day.

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