



Giaconda

LIMITED

Highlights:

Meetings with regulatory agencies – FDA and MHRA (USA & UK)

Further analysis of Myoconda MAP therapy for Crohn's Disease

First Scientific Advisory Board meeting – Prof. Nicholas Talley joins

Phase II data on Heliconda (resistant *Helicobacter pylori* eradication)

Welcome to Giaconda's first newsletter as a public company. It has been a busy and exciting six months for us since we listed on the Australian Stock Exchange on 28 September 2005.

GIACONDA LTD

(ASX: GIA)

BOARD OF DIRECTORS

*Chris Bilkey
(Chairman)*

*Richard Woods
(Non-Executive Director)*

*Prof. Tony Moon
(Non-Executive Director)*

*Trevor Moore
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*Patrick McLean
(Executive Director)*

*Prof. Thomas Borody
(Executive Director)*

*Tal Dauth
(Company Secretary)*

SCIENTIFIC ADVISORY BOARD

*Prof. Richard Hunt M.D.
Prof. Francis Mégraud M.D.
Prof. Sidney Phillips M.D.
Prof. Nicholas Talley M.D.*

MANAGEMENT

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Chief Executive Officer*

*Prof. Thomas Borody –
Chief Medical Officer*

*Rosa Surace –
Chief Operating Officer*

*Kirrilli Parker –
Corporate Administrative
Officer & Assistant Company
Secretary*

In December, with the support of a BioBusiness Program Grant from the NSW Government, Giaconda made presentations to the FDA (US Food and Drug Administration) and the MHRA (UK's Medicines and Healthcare Products Regulatory Agency) on its lead product Myoconda for Crohn's Disease. The purpose of these meetings was to establish the best clinical development path for Myoconda to obtain an IND in the USA and to guide our development efforts for registration in Europe. An IND (Investigational New Drug) filing is an integral part of registering a new product in the US markets. Our presentations were well received and we gained excellent guidance concerning our plans for Myoconda.

In January we reported that a further clinical analysis of Myoconda in 53 patients had been presented at the Australian Gastroenterology Week meeting in Brisbane. The analysis was undertaken by Professor Tom Borody, Giaconda's Chief Medical Officer and Director of the Centre for Digestive Diseases. The results of the retrospective analysis of 53 patients treated with the Myoconda® combination for a minimum of six months demonstrated some of the highest efficacy levels ever shown in the treatment of Crohn's Disease.

65% of the patients showed complete remission and over 95% showed marked improvement (defined as a reduction in Crohn's Disease Activity Index – CDAI – of 70 or more points and/or a significant reduction in inflammation in the mucosa of the colon). One patient has been in remission for nine and a half years. These data demonstrated that the treatment of *Mycobacterium avium* ssp. *paratuberculosis* (MAP) infection in Crohn's disease can aid in patient's recovery. To date, there has been no effective treatment for a large number of Crohn's patients and these results with Myoconda are extremely encouraging.

In December Giaconda convened its first Scientific Advisory Board meeting and added Professor Nick Talley to its roster of international members. Professor Richard Hunt was also appointed Chairman of the Scientific Advisory Board. Our Scientific Advisory Board represents some of the most prestigious names in gastroenterology from around the world and their contributions to the Company provide Giaconda with unmatched clinical expertise in the areas of gastroenterology. In addition to reviewing the company's scientific platform and the recent meetings with the FDA and the MHRA the Board toured the new facilities for Prof. Borody's Centre for Digestive Diseases.

DISEASE FACTS:

It is estimated that in Europe and the USA over 500,000 people suffer from Crohn's disease.

Crohn's Disease is frequently misdiagnosed as Irritable Bowel Syndrome or not diagnosed at all, particularly in young children.

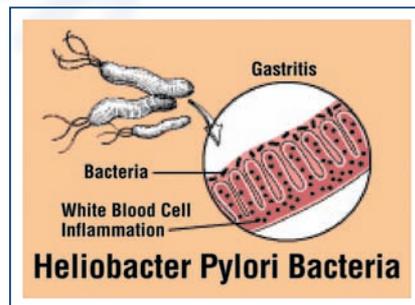
Nobel Prize confirms Giaconda's direction

In October Professor Barry Marshall and Doctor Robin Warren were awarded the Nobel Prize for Medicine. The award was given for their discovery of the bacteria *Helicobacter pylori* in patients with peptic ulcers and gastritis. Prior to this discovery, it was thought that gastritis and peptic ulcers were caused by stress. It is now widely recognized that that these conditions can be successfully treated with antibiotics in many cases.

Professor Marshall and Doctor Warren and Giaconda's Professor Tom Borody worked to devise treatments for *Helicobacter* which led to the early development by Borody of "Triple Therapy" and later to Giaconda's product Heliconda to treat resistant strains of *Helicobacter pylori*. The Nobel Prize award represents official recognition that these illnesses are based on infection and are treatable. Giaconda believes that this recognition will give added impetus to pharmaceutical companies to bring Heliconda to the market faster.

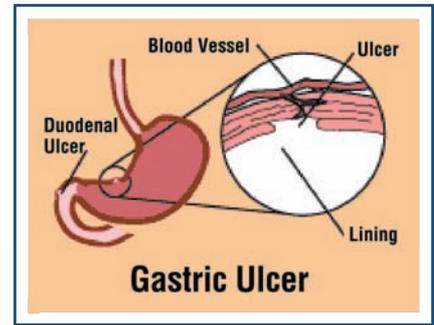
About *Helicobacter pylori*

Helicobacter pylori (*H. pylori*) is known to be the major contributing cause of chronic gastritis, peptic ulcer disease, gastric cancer and mucosa associated lymphoid tissue (MALT) lymphoma. Around 50% of the world population is believed to be infected with *H. pylori*.



It is estimated that in clinical practice, eradication failure after primary treatment outside clinical trials is between 20-40%. *H. pylori* eradication is the key to curing most peptic ulcer disease. Its eradication may also aid in the prevention of gastric cancer. In the last few years, *H. pylori* has been found to be increasingly difficult to eradicate using known, marketed antibiotic agents. This is particularly so using regimens containing metronidazole or clarithromycin due to the progressive development of *H. pylori* resistance to these antibiotics.

In Australia the proportion of *H. pylori* infections resistant to clarithromycin is increasing, from 3-5% in 1996 to 11-17% currently.



Resistance appears to be developing faster in countries where clarithromycin is being used frequently, particularly in the US and in Europe.

The recommended current primary treatment regime is triple therapy, consisting of a proton pump inhibitor (PPI) and two antimicrobial agents; clarithromycin and amoxicillin.

Clarithromycin resistance is not common in the general population, but can subsequently occur in up to 67% of strains isolated from patients who failed eradication therapy.

Giaconda's Phase II clinical study results with Heliconda in patients with drug resistant *Helicobacter pylori* were published in the February 2006 issue of *Alimentary Pharmacology and Therapeutics*

In the study, Heliconda achieved eradication in 90.8% of 130 patients who had failed one or more *Helicobacter pylori* eradication attempts using standard triple antibiotic therapy. The presence of clarithromycin or metronidazole resistant strains had no significant impact on the eradication rates.

In light of the increasing resistance to antibiotics used in the present standard of care therapy, this study proves that Heliconda can be an important addition to the armamentarium of the physician who actively treats *H. pylori*. It reduces the concern about resistant strains of *H. pylori* and this is especially important for the Primary Care Physician who does not normally test for resistance. To date there have been no reported strains of rifabutin resistant *H. pylori* so it has been substantiated that Heliconda can be safely be used as rescue therapy. It may even be used as first line therapy in patients with a history of frequent antibiotic use with less concern about the resistance issue.

This newsletter will be available via email in the future and on the Giaconda website
www.giacondalimited.com

If you would like to receive future newsletters via email please contact Kirrilli Parker on
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