

# Giaconda Milestones

Since the last newsletter, the team at Giaconda has been extremely busy and has made significant progress on a number of fronts.

In May, the CEO, Patrick McLean undertook a licensing tour in the USA and Europe. The tour went very well and discussions are ongoing with several firms. In terms of commercialisation, several new partners have been secured. In August Giaconda received a second Letter of Intent from Orphan Australia for Myoconda® commercialisation in Australia and Asia and this was followed in September by a third Letter of Intent with Tramedico International BV for the licensing and commercialisation of Myoconda® in the Netherlands, Belgium and Luxembourg. These letters of intent will be converted to full contracts prior to the next clinical trial.

The Company's Board and Management have also seen some change since the last newsletter. Ms Kirrilli Parker was promoted to Chief Administrative Officer and appointed Company Secretary, effective as of 1st July and Richard Woods was appointed Chairman of the Board on 22 August upon Christopher Bilkey's resignation to pursue other projects.

In September Giaconda announced its preliminary year end results to the market. The annual report details the year's events and is now available at [www.giacondalimited.com](http://www.giacondalimited.com). At the end of October the Company held its Annual General Meeting in Sydney.

In preparation for the next clinical trial with Myoconda®, Giaconda announced in October a Letter of Intent with Ind Swift

Laboratories for the supply of Clarithromycin, one of the key ingredients of Myoconda®. In addition, the CDD presented data involving Picoconda® at the Australian Gastroenterology Week in Adelaide and the therapeutic role of Myoconda®

in fistulising Crohn's Disease at the American College of Gastroenterology meeting in Las Vegas. These meetings provide Giaconda with great opportunities to showcase the work conducted at the CDD that involved Giaconda's products.



Dr. Peter de Graff, Tramedico's Managing Director, meets Prof. Borody during his visit to CDD

## Histopath leads the way in Parasitology

Parasitology testing is difficult and requires special expertise.

Histopath is an independent Specialist Pathology Practice, one of the few practices

in Sydney still owned by pathologists. Established in 1998, the practice has a special interest in gastroenterology testing and dermatopathology.

Parasitology testing requires a special collection kit provided free by Histopath. The kit includes instructions to ensure correct handling of the specimen. Examination of the specimen is performed by expert parasitologists. This combination enables us to achieve detection rates higher than most laboratories.

For kits, request pads or information call us on (02) 9764 4300.



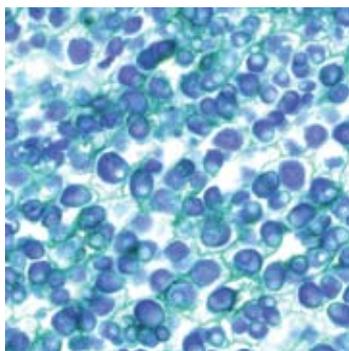
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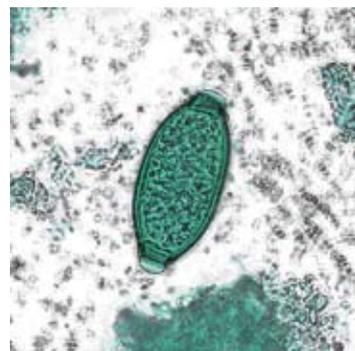
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For more information visit: [www.cdd.com.au](http://www.cdd.com.au)

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Cells



Trichuris Trichiura

# THE Inside Story



## What's eating you now?

Treatments available for bowel parasites and resistant *Helicobacter* infections

## Research Update

PSK, a new adjuvant in the treatment of cancer!

## Clinical Trials

Department of Research and Innovation

## Giaconda Milestones

## Histopath

Leads the way in Parasitology

## The A-Team at CDD

The Centre for Digestive Diseases was opened in Five Dock in 1984, initially with a staff of 4. In 1985, it moved to 144 Great North Road with a staff of 10 performing up to 2,000 procedures per year. By the year 2000, the staff had grown to 30 plus 3 Sedationists and 4 Gastroenterologists performing up to 5,000 procedures per year.

Today after its third move to 229 Great North Road, it is a fully integrated Day Endoscopy Centre accredited under the worldwide ISO9001 standards and licensed by the NSW Health Department. With Prof. Borody, Drs Wettstein and Benstock, the Centre continues to maintain a family oriented atmosphere consistent with delivering excellent care in gastroenterology while consistently doing research to improve patient care in the future.

# What's eating you now?

Although many doctors still treat patients for presumed presence of *Giardia*, it is becoming evident that the more commonly found parasites found in the gastrointestinal tract are *Dientamoeba fragilis* and *Blastocystis hominis* – both now known to be pathogenic.

In other words causing disease. These are poorly recognised in medical circles due to the fact that they are hard to diagnose. Correct collection of stools is required. Using a fixative and expertise in staining with iron hematoxylin, as well as being able to find these under the microscope are crucial elements in diagnosis, especially of *D. fragilis*.

Many patients continue being treated for Irritable Bowel Syndrome with gas, diarrhoea, abdominal cramping and urgency when they could be cured by eradicating *D. fragilis*.

At the Centre for Digestive Diseases, patient stool testing is carried out by Histopath Pathology. Expert parasitologists are able to identify such parasites as illustrated in the attached photographs. As parasites can be a problem to identify, specific stool kits can be

These parasites require combination therapies including Secnidazole, Furazolidone and Nitazoxanide which is now available from an independent in-house pharmacy at the CDD.

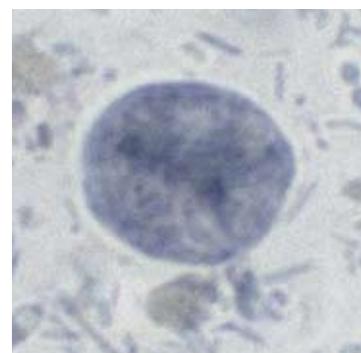
obtained from Histopath for analysis. Another crucial and important issue is that they should never be treated with Flagyl or Tetracycline alone. These parasites require combination therapies including Secnidazole,

Furazolidone and Nitazoxanide which are now available from an independent in-house pharmacy at the CDD. Please speak to our Nursing Team for further information.

Resistant *Helicobacter pylori* can also be a problem for patients. Quite frequently patients are treated two or more times with the same medication with little chance of success. They often present with ongoing, chronic symptoms such as epigastric pain, burping or burning and require culture to identify how we can treat this resistant *H. pylori*. So if any patient has difficulty eradicating *H. pylori*, they should contact the Centre for an appointment. There are a number of protocols available using Lactoferrin, Pronase, Nitazoxanide, Furazolidone and the Rifabutin based rescue therapies for patients with this infection.



Blastocystis hominis



Dientamoeba fragilis

## DRI Department of Research and

In mid-October Dr Ramrakha and the Department of Research and Innovation presented a poster at the Australian Gastroenterology Week Conference in Adelaide. This poster presented results of a clinical trial completed in 2005, which investigated the effectiveness and patient tolerability of new bowel cleansing preparations (PicoPrep™ capsules alone and an electrolyte solution with PicoPrep™ capsules) compared with the currently marketed PicoPrep™ and Glycoprep™ powdered sachets. The results showed that the electrolyte solution with PicoPrep™ capsules was just as, if not more, effective in cleansing the

bowel compared to the other preparations, whilst the PicoPrep™ capsules alone were best tolerated by patients. An abstract summarising these results was published in the October 2006 edition of the peer reviewed Journal of Gastroenterology and Hepatology.

A number of patent applications for new intellectual property, or IP, are currently under examination for approval in the USA and a number of European countries. These patents are for new therapies for the treatment of a number of gastrointestinal conditions.

### NEWS BREAK: NEW COMPOUNDING PHARMACY OP

- We now have an onsite Compounding Pharmacy to supply our patients with t
- See our updated website for information on "Clinical Trials - What are they an

# Research Update from Professor Thomas Borody MD, FRACP, FACP, FACG:

**Clinical trials show that the addition of PSK to standard cancer therapy increases patient survival rates by more than five years.**

PSK, a new adjuvant in the treatment of cancer has been released in Australia. Polysaccharide-K (PSK) is a unique immunotherapeutic agent extracted from the mycelia of the *Coriolus versicolor*, an edible mushroom belonging to the Basidiomycetes family. It is a proteoglycan shown to have an anti-tumour capacity, which helps activate key humoral and cellular components of the host's immune system. PSK has been prescribed in Japan for decades as an integral part of cancer therapy.

The international clinical study results of PSK were presented to members of the Medical Oncology Group of Australia and the Faculty of Radiation Oncology (MOGA/FRO) annual scientific conference recently. It is the first time the MOGA conference executive has included a complementary medical product in the abstract presentation section of the conference and it received a

# PSK

very positive response from attendees.

Professor Thomas Borody (MD PhD FRACP FACP FACG), of Sydney's Centre for Digestive Diseases, revealed the results of a meta-analysis of clinical trials into the effect of the PSK mushroom extract as adjuvant treatment with standard chemotherapy or radiotherapy treatments. The trials included in the meta-analysis had been published in *The Lancet* and the *British Journal of Cancer*, among others.

Taken orally, PSK has proven to be effective in patients with cancers of the colon, rectum, stomach, oesophagus, lung and breast, along with chemotherapy and/or radiotherapy. Significant long term increases in overall survival and disease-free survival rates have been

reported in patients given PSK, with no significant side effects noted.

"The findings make PSK ideally suited for use in cancer treatment regimens in combination therapy with either surgery, chemotherapy and/or radiotherapy," Prof. Borody said. A PSK website for health professionals provides abstracts of the clinical trials and copies of Professor Borody's presentation. Visit [www.pskmushroom.info](http://www.pskmushroom.info)



PSK is now available in Australia in packs of 90 x 500mg capsules through their website

## Innovation

It is hoped that once these are approved, clinical trials will be performed to develop these patents so that the products can be registered for marketing for the benefit of patients.

Current and upcoming clinical trials being conducted at the Centre include investigations into a new breath test detection system for *Helicobacter pylori* infection that can be checked during a normal clinical consultation and a test kit for the detection of *Helicobacter pylori* during a gastroscopy; oxygen delivery system during endoscopy; therapy for toxin positive *Clostridium difficile* and a new combination therapy for Hepatitis C Virus (genotype 1) infection.

**If you are interested in more information on any clinical trials being conducted at the Centre, please contact the Research Department on (02) 9713-4011 prompt #3.**

## EN & WEBSITE UPDATED!

**the medication required for our specialised treatments.**

and why do we need them?" [www.cdd.com.au/html/expertise/research.html](http://www.cdd.com.au/html/expertise/research.html)

## your team

The medical team is lead by Prof. Thomas Borody and includes a number of full-time and part-time medical practitioners.

Among them are:

- Emeritus Prof. Robert Clancy, Professor of Pathology in the Faculty of Medicine and Health Sciences at the University of Newcastle, is a Clinical Academic at the Hunter Immunology Unit of John Hunter Hospital
- Dr Andrew Finckh, Staff Specialist at St Vincent's Hospital, holds degrees in Bachelor of Arts from Macquarie University and Medicine from the University of Sydney. He holds the position of Emergency Registrar at Liverpool Hospital
- Dr Sanjay Ramrakha is a graduate in Medicine from the University of NSW in 1986 and a Fellow of the Royal Australian College of General Practitioners
- Dr John Saxon is a graduate from the University of NSW in 1985 and has been the Senior Sedationist at CDD since 1995, with some 10,000 patients to date
- Dr Antony Wettstein is a graduate with Honours from the University of NSW. He is a Fellow of the Royal Australian Society of Physicians
- Dr Simon Benstock is a graduate in Medicine from the University of NSW. He is a Fellow of the Royal Australian Society of Physicians
- Dr Ori Ashman is a Registered Psychologist in NSW and holds dual Master's and PhD degrees in Human Development. His clinical focus is on patient management and health promotion. Ori is a firm believer that chronically ill patients with Digestive Disorders such as IBD, IBS, Colitis and Crohn's respond well to adjuvant psychological support in conjunction with pharmacological GI treatment. His quality of service is supported by his commitment to the ethical standards of the Australian Psychological Society



Dr Ori Ashman