



# Biotech Daily

Thursday May 31, 2012

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH UP: BIONOMICS UP 16%, CELLMID DOWN 15%**
- \* **NOVOGEN, MARSHALL EDWARDS DOSE 1<sup>st</sup> ME-344 CANCER COHORT**
- \* **PFIZER PAYS PHYLOGICA UNDISCLOSED RESEARCH MILESTONE**
- \* **GI DYNAMICS, GORE CLOSER TO PATENT OWNERSHIP TRIAL**
- \* **PRIMA INTRODUCES CEO-DESIGNATE MATTHEW LEHMAN**
- \* **IMMURON EGM VOTES PASS EASILY - 6% OPPOSE DIRECTOR SHARES**
- \* **BIO-MELBOURNE ENGAGING WITH JAPAN BRIEFING**

## MARKET REPORT

The Australian stock market fell 0.44 percent on Thursday May 31, 2012 with the S&P ASX 200 down 17.9 points to 4,076.3 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and six were untraded.

Bionomics was the best on no news, up five cents or 16.1 percent to 36 cents with 59,052 shares traded, followed by Circadian up 14.3 percent to 48 cents with 62,726 shares traded.

Pharmaxis climbed 9.5 percent; Patrys was up 8.7 percent; Mesoblast and Prana were up more than three percent; Optiscan, Phosphagenics, Tissue Therapies and Universal Biosensors rose two percent or more; Cochlear, CSL, Heartware and Viralytics were up more than one percent; with Biota, QRX and Starpharma up by less than one percent.

Yesterday's best, Cellmid, led the falls, down 0.3 cents or 15 percent to 1.7 cents with 10.1 million shares traded.

Antisense, Genetic Technologies and Living Cell lost more than five percent; Allied Health fell 4.2 percent; Bioniche and Sunshine Heart were down more than three percent; Alchemia, Anteo and Reva shed more than two percent; Acrux and Nanosonics were down one percent or more; with Sirtex down 0.7 percent.

## NOVOGEN

Novogen 63.5 percent subsidiary Marshall Edwards says the first cohort of patients has been dosed in its phase I clinical trial of ME-344 for refractory solid tumors.

Novogen said the US Food and Drug Administration-approved dose escalation trial expected to enrol up to 24 patients in up to five cohorts with final safety and pharmacokinetic data on the company's lead mitochondrial inhibitor drug candidate expected by July 2013.

Marshall Edwards chief medical officer Dr Robert Mass said the first cohort in the ME-344 trial was "well underway just a month after our investigational new drug application was approved by the FDA".

"ME-344 is a novel compound that showed compelling anti-tumor activity in preclinical studies," Dr Mass said.

"Now we look forward to gathering valuable clinical data in the months ahead, all of which will help to optimize the design of our phase II efficacy studies," Dr Mass said.

Novogen said the phase I clinical trial was evaluating the safety and tolerability of intravenous ME-344 in escalating dose cohorts of 1.2mg/kg, 2.5mg/kg, 5mg/kg, 10mg/kg and 20 mg/kg.

The company said the trial was designed to characterize the pharmacokinetic profile of ME-344 and describe any preliminary clinical anti-tumor activity observed.

Novogen said that patients were administered intravenous infusions of ME-344 once weekly for three weeks and, after safety assessment, could continue weekly dosing if a clinical benefit was determined.

The company said the open-label trial was being conducted in collaboration with the Sarah Cannon Research Institute at Florida Cancer Specialists in Sarasota, the University of Oklahoma and Tennessee Oncology in Nashville.

Novogen said that Marshall Edwards' lead mitochondrial inhibitor ME-344 was an active metabolite of NV-128, the company's first-generation compound.

The company said that preclinical data presented at the 2011 American Association for Cancer Research meeting and published in the journal Molecular Cancer Therapeutics demonstrated the ability of NV-128 to induce mitochondrial instability, ultimately leading to cell death in otherwise chemotherapy-resistant ovarian cancer stem cells.

Novogen said that ME-344 had demonstrated superior anti-tumor activity against a broad range of human cancer cell lines compared to NV-128, including breast, colorectal and ovarian cancers.

Novogen was up 0.1 cents or 1.1 percent to 9.1 cents.

## PHYLOGICA

Phylogica says Pfizer will pay an undisclosed milestone payment under their collaboration and licence agreement to discover novel peptide-based vaccines.

Phylogica said the milestone followed the completion of the first stage of the collaboration, announced in December 2010 (BD: Dec 12, 2011).

Phylogica chief executive officer Dr Paul Watt said the company was "excited to have reached this research milestone in our collaboration with Pfizer".

"Our Phylomer platform has unique capabilities to identify candidate antigens and we have identified multiple novel Phylomers that meet the criteria required for further evaluation by Pfizer," Dr Watt said.

"We look forward to the outcome of Pfizer's ongoing evaluation of these Phylomers and hopefully advancing a candidate towards development," Dr Watt said.

Phylogica was unchanged at 4.8 cents.

## GI DYNAMICS

The US District Court for the District of Arizona has reduced GI Dynamics counterclaims against Gore & Associates with a final pretrial conference scheduled for July 2012

GI Dynamics has previously said that Gore, the supplier of the material used to manufacture its products including the Endobarrier gastrointestinal liner, began proceedings against GI Dynamics in 2010, claiming that it was the co-owner of all of the company's then-issued patents and applications as well as claiming that it was the co-inventor of several GI Dynamics' issued patents and seeking a declaration that its supply agreement with GI was void (BD: Aug 15, 2011).

GI Dynamics lodged a response to the Gore claims as well as counterclaims against Gore.

Today, GI Dynamics said the District Court summary judgment ruling determined that all but one of the trade secret claims GI Dynamics was pursuing could proceed to trial and "certain ancillary counterclaims made by the company ... against Gore were struck out".

GI Dynamics said that other counterclaims remained and would be decided at trial.

GI Dynamics said it opposed a November 10, 2011 Gore-filed a motion for summary judgment on all the GI Dynamics counterclaims except those seeking declarations that Gore was not a co-inventor or co-owner.

GI Dynamics said that on May 30, 2012 the District Court ruled that: all but one of the trade secret claims that GI Dynamics was actively pursuing could proceed to trial; GI Dynamics' breach of confidence and unjust enrichment claims were preempted by GI Dynamics' trade secrets claim and as such, if GI Dynamics continued to pursue the trade secrets claim, it could not also pursue its claims against Gore relating to breach of confidence and unjust enrichment; and that GI Dynamics's misrepresentation claim was preempted by the trade secrets claims, but only insofar as the misrepresentation claim related to the misappropriation of confidential information.

GI Dynamics said the Court denied Gore's motion for summary judgment on GI Dynamics' claims for breach of contract and GI Dynamics' claim under Massachusetts General Laws Chapter 93A, which seeks damages and attorneys' fees for unfair and deceptive trade practices.

GI Dynamics chief executive officer Stuart Randle said the company was "pleased with these rulings and look forward to presenting our claims to a jury".

GI Dynamics was unchanged at 90 cents.

## PRIMA BIOMED

Prima says it will hold a shareholder briefing with chief executive officer-designate Matthew Lehman in Sydney on June 15, 2012.

Prima said the briefing would include out-going chief executive officer Martin Rogers, chair Lucy Turnbull and deputy chair Albert Wong and provide an opportunity for Mr Lehman to meet shareholders and deliver an update on the company's activities.

Last week, Prima announced that chief operating officer Mr Lehman would replace Mr Rogers as chief executive officer from September 1 2012 (BD: May24, 2012).

The company said the shareholder briefing would be held at the Radisson Blu Hotel, 27 O'Connell Street, Sydney on June 15, 2012 at 9:30am (AEST).

Prima said shareholders outside Sydney would be able to access the briefing through a webcast and dial-in facility and dial-in details would be provided prior to the meeting.

Prima was unchanged at 15 cents with 5.3 million shares traded.

## IMMURON

Immuron shareholders passed six of seven extraordinary general meeting resolutions overwhelmingly, but 6.2 percent of votes opposed directors buying share plan shares. The resolution to allow directors to participate in the two cents a share plan was passed with 91,388,940 proxy votes (93.8%) in favor and 5,996,769 proxy votes (6.2%) against. All other resolutions relating to a placement, the company's share plan and the election of Dr Stewart Washer as a director were passed overwhelmingly. Immuron has more than 372 million shares on offer, implying the opposition came from holders of about 1.6 percent of the company's shares. Immuron fell 0.1 cents or 5.6 percent to 1.7 cents with 1.5 million shares traded.

## BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its June 7 Bio-Briefing will discuss Australian biotechnology engagement with Japan. The Network said that the briefing entitled 'Japan: Key insights for Australian Bio-success' would host Angas MG deputy chief executive officer and director Masanori Murayama discussing strategies for successful biotechnology deals. The Bio-Melbourne Network said that Angas MG was one of the first Japanese biotechnology companies to go to an initial public offer in Japan and had completed a number of international deals with pharmaceutical companies. The Network said that Japan External Trade Organisation managing director Takashi Tsuchiya would discuss the current Japanese economic climate and marketing trends in the pharmaceutical industry. Bio-Melbourne Network chief executive officer Michelle Gallaher said that Japan "has always been a key market for Australian biotech companies as it has the world's second largest pharmaceutical market". "Given the current Japanese financial environment it is unclear whether Japan should be considered a front of mind destination for Melbourne biotech companies now" Ms Gallaher said. The Network said that the managing director of V2V, Katsumi Maruyama, would cover the opportunities for Australian businesses, as well as possible market entry strategies and lead times. The June 7, 2012 Bio-Briefing will be held at Melbourne Town Hall, Swanston Street, Melbourne. Registration is from 3:45pm, with presentations from 4pm followed by networking drinks. For more information and to book go to: <http://www.biomelbourne.org/events/view/236>.