Biotech Daily

Monday May 24, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PATRYS UP 36%; GENETIC TECHNO DOWN 17%**

*** PATRYS READIES FOR PHASE I PAT-SM6 MELANOMA TRIAL**

*** CALZADA TAKES 12% OF AVEXA; $23m CONTROL FIGHT LOOMING**

*** GENERA SIGNS R&D DEAL WITH UNNAMED 'TOP 10' TEST COMPANY**

*** NOVOGEN'S PHENOXODIOL SHOWS PROMISE FOR PROSTATE CANCER**

*** MERCK SERONO EXTENDS BIONOMICS MS DEAL**

*** DR MERVYN JACOBSON 2011 TRIAL; TAMARA NEWING, DPP TALKS**

*** SUNSHINE HEART IMPLANTS 8th AORTA CUFF PUMP PATIENT**

*** GIACONDA TELLS ASX: SALE WILL FUND ACTIVITIES**

MARKET REPORT

The Australian stock market recovered 2.09 percent on Monday May 24, 2010 with the S&P ASX 200 up 90.0 points to 4395.4 points.

Twenty-one of the Biotech Daily Top 40 stocks were up, nine fell, six traded unchanged and four were untraded. All three Big Caps fell.

Patrys was best, up 3.2 cents or 36.4 percent to 12 cents with 346,224 shares traded, followed by Living Cell up 16 percent to 29 cents on small volumes, Phosphagenics up 12.9 percent to 17.5 cents with 2.7 million shares traded and Prana up 10 percent.

Bionomics climbed 8.9 percent; Biota, Clinuvel and Viralytics were up more than four percent; Avexa, Cellestis, Circadian and Nanosonics were up more than three percent; Acrux, Tissue Therapies and Universal Biosensors rose more than two percent; with Impedimed, Novogen, Sirtex and Starpharma up more than one percent.

Uscom led the falls, down 5.5 cents or 12.1 percent to 40 cents with 20,000 shares traded, followed by Benitec down 7.5 percent to 3.7 cents with 174,928 shares traded.

Cathrx lost 6.25 percent; Chemgenex, Heartware and Psivida fell more than three percent; Mesoblast shed 2.2 percent; with Cochlear, CSL and Resmed down more than one percent.

PATRYS

Patrys says it is 30 to 60 days from dosing the first patient in a phase I safety and tolerability trial of PAT-SM6 for melanoma, with efficacy as a secondary endpoint.

Patrys said an application for approval to commence a human clinical trial for its lead compound PAT-SM6 had been lodged with Australian authorities.

The company said PAT-SM6 product produced for the trial passed all typical quality release standards set by appropriate regulatory agencies and the tests were conducted by certified and independent third party firms.

Patrys said the primary endpoints for the first human clinical trial for PAT-SM6 were related to safety and tolerability.

The company said the first patient data was expected by August 2010 and the trial was expected to take twelve months during which time PAT-SM6 would also be assessed for its ability to effectively target melanoma tumors.

Patrys said PAT-SM6 had potential applications across a number of cancers, but melanoma was selected for several reasons.

The company said strong data had been generated showing that PAT-SM6 was effective at killing melanoma cancer cells and binding to 100 percent of all melanoma patient tumors screened.

Patrys said that based on consultation with independent clinicians and third party reports, melanoma was attractive, because PAT-SM6 targeted GRP78, a protein on the surface of cancer cells that correlates strongly with the aggressiveness of the disease and shorter survival times for patients, suggesting GRP78's potential therapeutic relevance.

The company said two-thirds of Australians would be diagnosed with skin cancer before the age of 70 years, the highest rate in the world so it was a major medical need and commercial opportunity, as well as supporting patient recruitment for the PAT-SM6 trial which would be conducted in Australia.

Patrys said Australia trends were reflected worldwide with the number of melanoma cases increasing faster than any other cancer, with estimates suggesting a doubling of melanoma incidence every 10-20 years.

Patrys has filed patent applications to cover the PAT-SM6 antibody molecule and its disease target GRP78.

Patrys chief executive officer Dan Devine said the start of the trial was “an exciting milestone for the company and the patients we aim to treat as it marks the imminent commencement of the clinical development of a very promising product in PAT-SM6”.

“Patrys, with the support of our shareholders, has dedicated considerable time and effort to reach a point where we can systematically offer a novel and promising new method for treating cancer - natural human antibody based therapeutics,” Mr Devine said.

“The advancement of lead product PAT-SM6 to this stage signals we have reached that objective,” Mr Devine said.

“Longer-term, we now have a robust technology platform that can be applied to treat many cancers through the advancement of several lead products into the clinic in a timely manner,” Mr Devine said.

Patrys said PAT-SM6 was the second product from its pipeline evaluated in a human clinical trial, with PAT-SC1, a natural human antibody evaluated in a gastric cancer human clinical trial, shown to provide treated patients with a survival rate that was significantly higher than untreated patients.

The company said a larger trial for PAT-SC1 was expected to begin in 2011.

Patrys was up 3.2 cents or 36.4 percent to 12 cents.

AVEXA, CALZADA

Calzada has become a substantial shareholder in Avexa with a holding of 102,352,939 shares or 12.07 percent.

Calzada said the shares cost $2,983,104 or an average price of 2.9 cents per share.

Calzada chairman David Franklyn told Biotech Daily that his company bought “a single line of 5.6 percent of Avexa” and the balance was bought on-market.

Last week, Orbis Investment Management ceased its substantial shareholding in Avexa selling 47,660,761 shares for $1,472,718 or an average price of 3.1 cents per share, losing $5,968,500 through its investment in Avexa (BD: May 21, 2010).

Mr Franklyn emerged as the chairman of Calzada, then known as Metabolic, through the intervention of the Melbourne-based Entrust Funds Management of which he is managing director (BD: Apr 7, 20, 2009).

Entrust was also one of the major investors in Progen when it closed its PI-88 trial leaving the company with about $70 million in cash.

Avexa said it had about $23 million remaining from capital raised for the development of apricitabine (ATC) for HIV.

Avexa’s share price fell after it closed the ATC program, having failed to licence the drug.

The company will hold an extraordinary general meeting following a call for the removal of Avexa’s chairman Nathan Drona and the appointment of Bruce Hewett and Steven Crowley as directors (BD: May 10, 2010).

Biotech Daily has had a brief conversation with Mr Hewett confirming that he was the principal consultant of Melbourne’s Rx Connect and has not been able to make contact with Mr Crowley.

Biotech Daily believes the shareholders associated with Mr Crowley and Mr Hewett are unrelated to the Calzada interests.

Last week Avexa disclosed that the call for a meeting to remove Mr Drona included “a resolution that any board member appointed between May 6, 2010 and the date of the general meeting be removed” and the newly appointed Uri Ratner would be subject of such a resolution (BD: May 20, 2010).

The Avexa media release announcing Mr Ratner’s appointment as a director said that “in his former capacity as a portfolio manager at a major US based fund, Mr Ratner represented Avexa’s largest shareholder”.

Avexa’s media relations company Buchan Consulting subsequently told Biotech Daily that Mr Ratner was with the US-based Passport Capital which acquired 9.14 percent of Avexa on March 30, 2006.

At that time there were larger shareholders, Circadian-related company Fibre Optics with 12.09 percent and Zenyth had 16.72 percent reducing to 10.65 percent on May 19, 2006.

By the September 29, 2006 annual report Fibre Optics held 12.09 percent, Zenyth had 10.65 percent and Passport held 7.27 percent.

By the time of publication of the 2007 annual report, Passport was no longer substantial, but the absence of substantial shareholder notices disclosing its reductions and without a ceasing substantial shareholder notice from Passport, it is uncertain for how long Passport might have been “Avexa’s largest shareholder”.

Biotech Daily asked the ASX for assistance in the matter, but the ASX said that “without the relevant notices being lodged, it is not possible to reconcile and confirm this, nor is it possible to dispute it”.

The ASX also said the lodgement of substantial shareholder notices was a matter for the Australian Securities and Investments Commission (ASIC)

Avexa was up 0.1 cents or 3.45 percent to three cents with 8.8 million shares traded.

Calzada was up 0.1 cents or 3.6 percent to 2.9 cents.

GENERA BIOSYSTEMS

Genera says it has signed “a major collaboration agreement with one of the world’s leading diagnostic equipment and test manufacturers”.

Genera chief executive officer Dr Allen Bollands told Biotech Daily he could not disclose the identity of the “top 10” company but said the research and development agreement for the Paptype human papillomavirus would not conflict with Genera’s distribution arrangements with Healthscope and Sonic Health.

In a media release to the ASX, Genera said the research and development program was designed to investigate the integration of the Paptype human papillomavirus (HPV) detection and genotyping test with the partner’s instrumentation platform.

Genera said the partner would have the opportunity to negotiate global rights to Paptype for a period following completion of the work.

Genera’s chairman Fernando Careri said the principal commercialization strategy for Paptype was to work through a global partner “so this is a pivotal milestone”.

“Our development partner is a very substantial and highly regarded healthcare company, with global sales and marketing outreach,” Mr Careri said.

“We see this agreement as a strong endorsement of Genera’s technology and are very hopeful of a more substantive follow-on agreement,” Mr Careri said.

The company said the development program’s objective was to optimize the Paptype test to work on the partner’s instrument platform.

Genera said the unnamed partner would meet all costs of the program, which was expected to take six to seven months.

“A successful outcome will pave the way towards a compelling new approach to cervical cancer screening, which will add value to all the major stakeholders - pathology companies, healthcare payers, doctors, and of course the patients,” Dr Bollands said.

“There is a very strong technological alignment between the companies and we’re very hopeful that this agreement will be the start of what will grow to become an enduring and mutually beneficial partnership,” Dr Bollands said.

Genera said the current version of Paptype was approved by the Australian Therapeutic Goods Administration and was registered in Europe.

Genera fell half a cent or 0.8 percent to 59 cents.

NOVOGEN

Novogen says a 24-patient study of phenoxodiol for prostate cancer “showed modest activity with a third of the patients demonstrating stable disease”.

Novogen said the data would be presented at the Annual Meeting of the American Society of Clinical Oncology in Chicago on June 7, 2010.

An abstract of the study entitled ‘A phase II study of oral phenoxodiol in castrate and non-castrate prostate cancer patients with associated cytokine changes’ by the Yale School of Medicine’s Dr Kevin Kelly is at http://abstract.asco.org/AbstView_74_53644.html.

The abstract concluded that larger studies were warranted.

Novogen said phenoxodiol was being developed as a chemo-sensitizing agent in combination with platinum drugs for late stage, chemo-resistant ovarian cancer and as a monotherapy for prostate and cervical cancers.

The company said phenoxodiol was believed to have a unique mechanism of action, binding to cancer cells via a cell membrane oxidase, causing disturbances in expression of proteins necessary for cancer cell survival and responsible for the development of drug resistance.

Novogen was up half a cent or 1.2 percent to 41 cents.

BIONOMICS

Bionomics says Merck Serono has extended their 2008 development and licence agreement on multiple sclerosis and autoimmune diseases for a further 12 months.
Bionomics said Merck Serono would increase its research funding.
The company said Merck Serono was "actively developing potential new treatments for multiple sclerosis and other autoimmune conditions based on compounds from Bionomics Kv1.3 program".
Bionomics said the collaboration combined Bionomics Kv1.3 biology and Merck Serono's expertise in multiple sclerosis pharmacology in a combination hoped to speed up progress in the identification of novel drug candidates.
Bionomics chief executive officer Dr Deborah Rathjen said the collaboration was working well.
"In addition to the close collaboration with Bionomics in Kv1.3 chemistry and biology, our European subsidiary, Neurofit, has forged close links with Merck Serono scientists in delivering our contributions to the development program," Dr Rathjen said.
Bionomics said that under the 2008 agreement, the company received an upfront payment of $US2 million and research funding.
The company said Merck Serono would fund all development activities, including clinical development of drug candidates.
Bionomics said that for each compound successfully developed and commercialized as a result of the partnership, Bionomics might receive milestone payments up to $US47 million and be eligible to receive undisclosed royalties on the net sales of licenced products.
Bionomics said the compounds licenced by Merck Serono targeted the potassium ion channel Kv1.3, an immune system modulator and a target found on human immune cells associated with nerve cell damage in patients with multiple sclerosis.
Inhibitors of Kv1.3 have been shown to inhibit the proliferation of these immune cells, suggesting that they have application in the treatment of multiple sclerosis and potentially other autoimmune conditions, including arthritis.
Bionomics was up 2.5 cents or 8.9 percent to 30.5 cents.

GENETIC TECHNOLOGIES

A trial date of August 1, 2011 has been set for Genetic Technologies' founder Dr Mervyn Jacobson and July 9, 2010 for his daughter Tamara Newing.
Dr Jacobson has been charged with 319 counts of market manipulation and Ms Newing faces 353 charges of market manipulation.
In March 2010, Ms Newing's husband and former Genetic Technologies chief operating officer Geoffrey Newing was sentenced to 22 months gaol with a minimum of six months on five charges of market manipulation (BD: Mar 18, 2010).
Representatives of the Commonwealth Director of Public Prosecutions and lawyers for Dr Jacobson told Biotech Daily that Ms Newing had been bailed to appear in the Melbourne County Court on July 9, 2010.
They said Ms Newing had been in discussions with the office of the Commonwealth Director of Public Prosecutions.
They said representatives of Dr Jacobson would be in court on July 9, 2010 for a directions hearing. Dr Jacobson's bail was extended to July 1, 2011 for a directions hearing prior to the August 1, 2011 County Court trial date.
Lawyers for Dr Jacobson said there had been discussions of moving the case to the Supreme Court of Victoria.

SUNSHINE HEART

Sunshine Heart has implanted its eighth patient in its US Food and Drug Administration approved trial of the C- Pulse heart assist system.

Sunshine Heart said the patient was implanted on May 21, 2010 at the University of Alabama Birmingham Medical Centre, the third patient implanted at the Centre.

Sunshine Heart was unchanged at 3.2 cents.

GIACONDA

Giaconda has told the ASX that the sale of its Myoconda assets to Australian Medical Therapy Investments would allow it to fund its activities.

Giaconda said it expected to sell the assets to AMTI for $928,000 plus five percent royalties on net sales (BD: Mar 19, May 3, 17, 2010).

Giaconda was untraded at 4.6 cents.