Biotech Daily

Friday September 12, 2008

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECHS DOWN:**
SUNSHINE HEART UP 57%, POLARTECHNICS DOWN 16%

*** VIRAX ROYALTY HIT BY ROCHE, TRANSGENE PHASE III TRIAL DELAY**

*** AGENIX LOSES ANOTHER TRICK: EX-DIRECTOR IN 'IMPROPRIETY' CASE**

*** FDA APPROVES SUNSHINE HEART TRIAL**

*** LABTECH EARNS $1.75m BIOMÉRIEUX PAYMENT**

*** BIO-MELBOURNE YUM CHAS ON CHINA**

*** GIACONDA GIVES WHITE KNIGHT INVESTOR EXTENSION**

MARKET REPORT

The Australian stock market recovered 1.8 percent on Friday September 12, 2008 with the All Ordinaries up 85.6 points to 4,957.1 points.

Nine of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and 10 were untraded.

Sunshine Heart was best up four cents or 57.14 percent to 11 cents with 433,517 shares traded, followed by Prana up four cents or 8.42 percent to 51.5 cents and Clinuvel up 6.12 percent to 26cents.

Labtech and Pharmaxis climbed more than five percent; Optiscan was up 4.65 percent; Circadian, Cochlear and Resmed were up more than three percent; with Mesoblast up 1.59 percent.

Polartechnics led the falls, down two cents or 16.0 percent to 10.5 cents on modest volumes, followed by Alchemia down 15.63 percent to 27 cents.

Acrux and Starpharma lost more than seven percent; Phylogica was down 6.59 percent; Arana and Avexa fell more than four percent; Novogen and Progen were down more than three percent; Chemgenex and Neuren shed more than two percent; with Biota, Universal Biosensors and Viralytics down more than one percent.

VIRAX

Virax says Transgene and Roche have announced an extension to the clinical development plan for TG4001/R3484.

Virax said TG4001/R3484 was a human papilloma virus (HPV)-targeted vaccine for the treatment of pre-cancerous lesions of the cervix.

The company said TG4001/R3484 was developed by Transgene using Virax's Co-X-Gene technology.

Virax is entitled to royalty and milestone payments under its agreement with Transgene, who subsequently licenced the product to Roche for treatment of HPV-related pathologies.

Roche has exclusive worldwide marketing rights for TG4001/R3484 and is funding all costs associated with the development of the vaccine and is leading clinical studies.

In a media release to the ASX shortly after the close of the market, Virax said that Transgene and Roche had decided to modify the trial program by initiating a further phase II study of the therapeutic vaccine.

The trial will be conducted prior to the phase III trial previously scheduled for the end of 2008.

Virax said the additional phase II trial would "provide valuable additional clinical data to optimize the profile definition of the product and allow for the study of new treatment modalities".

The company said the approach was expected "to significantly increase the prospects of the product's future success".

Regulatory clearance for the conduct of the phase III trial was announced in June 2007.

Virax's chief executive officer Dr Larry Ward said the decision was "in everybody's long term interests".

"By reducing the risk of the program the overall value of the product is enhanced and the likelihood of eventual success in the pivotal phase III studies is increased," Dr Ward said.

"I remain convinced that the combination of Roche's excellence in clinical development of oncology products and Transgene's undoubted expertise in the utilization of live viral vectors as therapeutic vaccines means that TG4001/R3484's development is in very safe hands," he said.

Virax has previously announced a strategy of seeking a corporate transaction with another vaccine or related technology company to broaden its development program pipeline with respect to risk and reward.

In addition the company said it had taken cost-cutting measures to facilitate ongoing operations, protection of the Transgene sub-licence and progression of the South African trial of VIR201 using non-dilutive external funding.

The extension of the TG4001/R3484 trial program will delay the timing of the launch of the product onto the market and therefore has consequences for the timing of potential milestone and royalty payments to Virax," Dr Ward said.

He said the board was "actively considering various options" in relation to corporate transactions or any future fundraisings.

"This recent announcement with respect to TG4001/R3484 will no doubt only give added momentum to the decision making progress," Dr Ward said.

"We are conscious of the need to keep stakeholders informed of progress in relation to the strategy and are committed to providing a further update prior to this year's AGM to be held by November 30, 2008," Dr Ward said.

Virax was untraded at 3.5 cents.

AGENIX

Agenix says that a former unnamed director is involved in legal proceedings in the Supreme Court of Victoria relating to allegations of impropriety.

The previously undocumented proceedings were described by the company in a release to the ASX shortly before the market closed for the weekend as "concerning allegations of impropriety against a former director".

"It is alleged that a series of improper transactions occurred between Agenix Limited and the trustee company of the former director's family trust," Agenix said.

"The legal proceedings have been stayed because the trustee company has been placed into a creditor's voluntary liquidation," the company said.

"The court has now extended orders to freeze assets of the former director and his wife including certain trusts, real estate and bank accounts notwithstanding that the defendants have filed debtor's petitions with Insolvency Trustee Service Australia," Agenix said.

"The transactions are presently the subject of continuing investigations," Agenix said.

Agenix chairman Nick Weston said Agenix had "instigated appropriate action to protect the company and shareholders' interests.

The matter is properly in the hands of the legal system to assess the facts and decide upon outcomes," Mr Weston said.

Agenix is also involved in proceedings in China relating to its almost-completed acquisition of a Shanghai pharmaceutical company (see Biotech Daily July 24, and 28, 2008).

Agenix is in a suspension of following its failure to submit a preliminary final report, due to "control issues" relating to its Shanghai acquisitions (see Biotech Daily August 29, 2008).

Agenix last traded at 1.7 cents.

SUNSHINE HEART

The US Food and Drug Administration has given Sunshine Heart conditional approval to begin its first US clinical trial for its C-Pulse heart assist therapy.

Sunshine Heart said it would begin to enroll up to 20 patients suffering from moderate heart failure in its US-based clinical trials to evaluate the safety and effectiveness of the C-Pulse aorta-cuff heart assist device.

The company said the FDA approval conditions were "acceptable" and would "result in minor changes to the clinical protocol, patient record keeping and device labeling".

Sunshine Heart expects patient enrollment to begin by the end of 2008 at six US medical institutions.

Ohio State University's professor of Internal Medicine Prof William Abraham and the Northwestern University Medical Center's professor of Surgery Dr Patrick McCarthy will be co-lead national principal investigators.

Each patient will be monitored for six months to record the effect of the C-Pulse device.

After completion of this clinical trial, the company said it planned to seek Conformitée Européenne (CE) Mark approval for C-Pulse to enable the device to be marketed in the European Union and other countries accepting CE Mark.

Sunshine Heart said it would also apply to the FDA for approval to undertake a larger US clinical study as a precursor to gaining approval to market the device in the US.

Sunshine Heart chairman Malcolm McComas said the approval was "a very significant event for the company".

"The trials we are about to start will be important next steps in demonstrating the application of our device in the large market of heart failure sufferers," Mr McComas said.

Sunshine Heart climbed four cents or 57.14 percent to 11 cents with 433,517 shares traded.

LABTECH SYSTEMS

Labtech says a key milestone has triggered a further €1 million ($A1.75 million) payment from its partner, Biomérieux.

The 2007 licence agreement with Biomérieux for the commercialization of Labtech's Microstreak technology, contains several milestones.

Labtech said this payment would take it to €4 million of the agreement of the potential €7 million plus royalties.

The company said the latest milestone was achieved when it sent the first pilot production units to Europe in preparation for the full commercial launch by Biomérieux.

Labtech said it had been working to develop efficient, effective, high-speed robotic systems to perform the routine diagnostic task of agar plate streaking.

Labtech said it had conceived the technology and the units and consumables will be manufactured, marketed and distributed by Biomérieux.

The launch of the system, known as Previ Isola, is planned for the end of 2008.

As well as an upfront payment and several milestones, the deal contains a minimum royalty component that will come into effect on January 1, 2009.

Labtech chief executive officer Lusia Guthrie said the payment was the second milestone payment from Biomérieux.

"We expect commercial sales of the Previ Isola system to commence before the end of 2008," Ms Guthrie said.

Labtech was up one cent or 5.88 percent to 18 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network will examine China's biotechnology and pharmaceutical sector at its October 7, 2008, Bio-Breakfast.

Bio-Melbourne Network chief executive officer Michelle Gallaher says there are "great opportunities for Australian biotech companies to consider the advantages of research and clinical collaborations with China".

The Network said that with a gross domestic product (GDP) of $US3,450 billion in 2007, China was the third largest economy in the world, behind the US and Japan.

The industry organization said that since economic liberalization in 1978, the country's GDP had grown an average 9.9 percent a year and China was the world's ninth largest market for pharmaceuticals.

Many global pharmaceutical companies have established manufacturing, as well as research and development centres in China, including Glaxosmithkline, which has established a research and development centre in Tianjin and Roche.

Astrazeneca, Bayer, Eli Lilly, and Hoffman-La Roche have also set up Chinese research and development or clinical trial centres.

Glaxosmithkline Australasia's head of research and development alliances Dr Ashley Bates will talk about biotechnology developments in China, explain his company's views on the global power shift in the pharmaceutical industry and comment on the opportunities for Australian biotech companies.

AT-Bio chief executive officer, Jim Murray, will present a case study of setting up a joint venture company in China. AT-Bio is a joint venture between Melbourne's Atholl Pty Ltd and the Tianjin Institute for Pharmaceutical Research focused on drug development.

The Bio-Breakfast will be at the Supper Room, Melbourne Town Hall, Swanston St, Melbourne. Registration begins at 7.15am with presentations at 8am.

For more information contact: Nicole Pitcher via email: npitcher@biomelbourne.org or tel: +613 9650 8800 or visit www.biomelbourne.org.

GIACONDA

Giaconda has granted Australian Medical Therapy Investments a further extension to complete its proposal to subscribe for shares in Giaconda.

Australian Medical Therapy Investments has until October 30, 2008 to satisfy Giaconda that it has the required financial capacity to complete the subscription.

In July Giaconda said it hoped to raise up to $40 million through the issue of 100,000,000 shares to Australian Medical Therapy Investments (see Biotech Daily; July 18, 2008) but the deal has been entangled in the divorce proceedings of chief scientist, director and major shareholder Dr Tom Borody.

Today's announcement is the second extension granted to Australian Medical Therapy Investments and its managing director Colin Goldrick, formerly Giaconda's lawyer (see Biotech Daily; August 15, 2008).

Giaconda fell half a cent or 3.33 percent to 14.5 cents.