Biotech Daily

Tuesday June 10, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS DOWN: PHYLOGICA UP 12.5%, PORTLAND DOWN 14%**

*** PEPLIN HALTS US IPO, BUYS $7m NEOSIL, PREPARES PHASE III TRIAL**

*** CHEMGENEX BUYS DRUG'S EURO-IP FOR $35m SHARES**

*** DATA COMMITTEE CLEARS NOVOGEN PHASE III OVARIAN CANCER TRIAL**

*** METABOLIC PLEADS SCHULTZ TO ASX QUERY**

*** GENERA STARTS TRADING TOMORROW**

*** PSIVIDA PROVIDES US MOVE SCHEME TIMETABLE**

*** IM MEDICAL REQUESTS CONTRACT TRADING HALT**

*** WILSON HTM REDUCES IN NANOSONICS**

*** ROCKEBY APPOINTS IVAN CHONG DIRECTOR**

MARKET REPORT

The Australian stock market tumbled 2.6 percent on Tuesday June 10, 2008 with the All Ordinaries down 146.9 points to 5,544.3 points.

Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, eight were unchanged and four were untraded.

Phylogica was best, up 12.5 percent to 9.9 cents on modest volumes, followed by Polartechnics up 7.69 percent to 14 cents.

Agenix, Chemgenex and Peplin climbed more than five percent; Circadian and Novogen were up more than four percent; with Benitec and Progen up more than one percent.

Portland led the falls, down 14.29 percent to three cents, followed by Phosphagenics down 8.33 percent to 11 cents and Proteome down 7.14 percent to 13 cents.

Universal Biosensors lost five percent; Genetic Technologies, Living Cell and Psivida fell more than four percent; Cytopia, Heartware and Sirtex were down more than three percent; Acrux, Bionomics, CSL and Optiscan shed more than two percent; with Clinuvel, Resmed and Starpharma down more than one percent.

PEPLIN

Peplin has shelved its plan for a US initial public offering instead acquiring Neosil Inc's $7 million in cash for about 16.4 million Peplin shares.

In a brief notice to the ASX, Peplin said it "had withdrawn its registration statement on Form S-1 and will pursue alternative financing options".

On February 15, 2008 Peplin filed amendment four to its registration statement on Form S-1 with the US Securities and Exchange Commission relating to the proposed initial public offering of shares of its common stock.

Peplin said its current cash, with the net cash it expects to acquire from Neosil "should be sufficient to fund the PEP005-014 phase III and PEP005-015 phase IIb clinical trials".

Peplin said Neosil was a privately-held, dermatology-focused company and the purchase price of $US6.7 million ($A7.0 million) in shares was the amount of net cash held by Neosil at signing.

The boards of both companies have recommended the transaction, which is expected to be completed in the third quarter of 2008, subject to shareholder approval.

Neosil would become a wholly-owned subsidiary of Peplin.

In addition to its net cash, Peplin will also acquire Neosil's intellectual property which comprises early clinical stage development programs for a hair growth stimulation technology and a broad spectrum anti-microbial technology to treat acne.

Peplin intends to use the net cash obtained from the acquisition to continue the development of its lead product candidates PEP005 (ingenol mebutate) gel for actinic keratosis and for basal cell carcinoma.

Peplin said Neosil's technologies in hair loss and acne could enable it to expand its product pipeline in the future, but Peplin does not expect to commence further development of these programs before 2009.

Peplin does not expect to retain any of the Neosil employees and has accounted for the cost of rationalization in the calculation of net cash. Peplin's board of directors and its management are not expected to change as a result of the transaction.

Peplin said it would begin its phase III clinical trial, PEP005-014, in the third quarter of 2008, based on its recent receipt of a special protocol assessment from the US Food and Drug Administration.

The phase III clinical trial is designed to test the safety and efficacy of PEP005 for actinic (solar) keratosis in non-head treatment sites.

Prior to filing a new drug application with the FDA, Peplin intends to complete a series of clinical trials for head, comprising face or scalp and non-head comprising areas on the back of the hand, arm, shoulder and back. It is the first phase III trial in the program.

Peplin plans to file a single new drug application for applications on both head and non-head treatment locations with the FDA in mid 2010, assuming a successful end-of- phase II meeting and the completion of a phase III clinical program.

The non-head phase III trial is a US and Australian multi-center, randomized, double blind, vehicle-controlled trial to evaluate the safety and efficacy of PEP005 (0.05%) compared to vehicle gel in patients with AK lesions on non-head locations.

Peplin expects to enroll 250 patients who would apply the study medication or vehicle gel to a 25 cm^2 treatment area containing four to eight AK lesions. The medication would be applied at home once a day for two consecutive days.

The primary efficacy endpoint for the PEP005-014 clinical trial will be the complete clearance rate of AK lesions and the secondary efficacy endpoint will be the partial clearance rate of AK lesions.

Peplin will evaluate efficacy on the 57th day after treatment.

Peplin was up two cents or 5.0 percent to 42 cents.

CHEMGENEX

Chemgenex will take full control of its lead compound omacetaxine by paying $35 million in shares for Stragen Pharma's intellectual property and commercial rights to the drug.
Omacetaxine mepesuccinate (formerly Ceflatonin) is in the final stages of a phase II/III clinical trial in chronic myeloid leukemia patients with the T315I mutation for whom there are currently no effective drug treatment.
Chemgenex said the new agreement will result in the assignment of Stragen's omacetaxine intellectual property suite to Chemgenex, removing the need for a royalty on manufacturing and significantly reducing the cost of goods.
The agreement removes the need for a European joint venture, allowing Chemgenex to control European development and access all profits from sales of omacetaxine in Europe, including current compassionate use sales of the drug.
The acquisition strengthens Chemgenex's ability to pursue multiple commercialization opportunities for omacetaxine.
Subject to shareholder approval at a general meeting to be held within the next two months, consideration for the acquisition of global rights and European commercialization rights will be through the issue of 37,235,343 new ordinary shares in Chemgenex.
At the 93 cents a share closing price on June 6, 2008 the shares were worth $34.6 million and will comprise 16.6 percent of the expanded capital base.
Chemgenex said Stragen will remain its supplier of omacetaxine "reflecting Stragen's manufacturing expertise and understanding of omacetaxine".
The agreement concludes three year old formal manufacturing and commercialization agreements in which Chemgenex provided expertise in drug development and clinical trial management while Stragen provided a patented manufacturing process, manufacturing and product distribution expertise.
The agreements entailed a royalty as a component of the manufacturing cost and mandated the establishment of a European joint venture for marketing in Europe. The Chemgenex-Stragen 49%-51% profit split of sales will no longer be in effect.
Chemgenex's chief executive officer Dr Greg Collier said Stragen had been "an excellent partner" and had worked to progress omacetaxine to an advanced state.
Stragen president Jean-Luc Tetard said the consolidation of global intellectual property and commercialization rights for omacetaxine would "open a range of new possibilities for Chemgenex to continue to build upon the successes reported over the past year".
Chemgenex was up five cents or 5.38 percent to 98 cents.

NOVOGEN

The US independent data monitoring committee overseeing Novogen's phase III ovarian cancer trial has recommended the study continue.
The multi-centre phase III trial is studying oral phenoxodiol in combination with carboplatin in women with advanced ovarian cancer resistant or refractory to platinum-based drugs, to determine its safety and effectiveness.
The data monitoring committee met in Chicago at the meeting of the American Society of Clinical Oncology and is responsible to ensure that patients recruited to the study are not exposed to unnecessary safety risks, that the study meets its clinical objectives and is run according to the required standards.
Novogen said that following a scheduled review of safety and efficacy data, the committee recommended the study remained open and continue to its accrual target of 340 patients.

The US Food and Drug Administration has approved a reduction from the original target of 470 patients and Novogen said it expected to reach the half-way mark of 95 patients by the end of 2008.
Patients are being recruited at 51 clinical sites in the US, Europe and Australia.
Novogen said the trial had been approved by the FDA under a special protocol assessment, which provided for an interim analysis of the data, which, if statistically significant, can be used to support a request for accelerated marketing approval.
An analysis of interim results will be possible after the targeted patient recruitment to the study is completed and 95 patients have disease progression.
Novogen climbed six cents or 4.48 percent to $1.40.

METABOLIC

Metabolic has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose from 4.1 cents on May 30, 2008 to 7.3 cents on June 6, along with an increase in trading volume.
Metabolic fell 1.5 cents or 22.73 percent to 5.1 cents.

GENERA BIOSYSTEMS

Genera Biosystems has been admitted to the ASX official list and will begin trading under the ticker code of GBI at 11am tomorrow.
Genera has raised $5 million through the issue of 10,000,000 shares at 50 cents a share to develop women's health diagnostic tests (see Biotech Daily April 30, 2008).
The company has been spun-out from the Walter and Eliza Hall Insititute.

PSIVIDA

The Federal Court of Australia has approved Psivida's scheme of arrangement for reincorporation in the US.
Psivida said it would lodge a copy of the order with the Australian Securities and Investments Commission on June 11, 2008, when reincorporation becomes effective.
Psivida's shares will cease trading on the ASX at the close of trading on June 11, 2008.
The record date for determining entitlements to the scheme consideration will be June 18, 2008. Payment of the scheme consideration will be made on June 19, 2008 - the implementation date of the scheme.
Psivida's CHESS depositary interests are expected to commence trading on ASX on a deferred settlement basis on June 12, 2008, with normal trading expected to commence on June 26, 2008.
Psivida common stock is expected to commence trading on Nasdaq on on June 11 or 12 and on the Frankfurt Exchange on a deferred settlement basis on June 12.
Psivida fell half a cent or 4.35 percent to 11 cents.

IM MEDICAL

IM Medical has requested a trading halt pending an announcement regarding the "finalization of contract negotiations".
Trading will resume on June 12, 2008 or on an earlier announcement.
IM Medical last traded at 2.8 cents.

NANOSONICS

Wilson HTM Investment Group has reduced its substantial holding in Nanosonics from 9,526,631 shares (9.26%) to 8,367,681 shares (8.14%).
Nanosonics fell one cent or 4.76 percent to 20 cents.

ROCKEBY

Rockeby Biomed has appointed Ivan Chong Hon Kuan as a non-executive director.
Rockeby said Mr Chong had more than 30 years experience in the advertising industry in Singapore and was the founder of Eureka Advertising in 1978.
Rockeby said Mr Chong was a director of Novena Holdings, an advisor to the Advertising Standards Authority of Singapore and chairman of the Business Practice Committee of the Consumers Association of Singapore.
The company said Mr Chong was “ordinarily resident in Australia for the purposes of meeting the requirements of Section 201A of the Corporations Act”.
Rockeby was unchanged at 0.9 cents.