Biotech Daily

Monday May 19, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: SUNSHINE HEART UP 13%; CYTOPIA DOWN 10%**

*** FDA CLARIFIES BONE'S OSTEOPOROSIS PIVOTAL PHASE III TRIAL**

*** GERMANY APPROVES PHARMAXIS' ARIDOL TEST**

*** PROGEN DENIES, EG CAPITAL SILENT ON ASIC RAID**

*** NOVOGEN'S PHASE I TRIPHENDIOL TUMOR TRIAL REPORTED BY ASCO**

*** MEDICAL THERAPIES VOTES ON MIDKINE SHARE ISSUE, CEO OPTIONS**

*** KARMELSONIX APPOINTS SCIENTIFIC COMMITTEE**

*** VENTRACOR CEO PETER CROSBY'S CONTRACT EXTENDED**

*** CHRISTOPHER WALKER TAKES 8% OF MEDICAL THERAPIES**

*** QRX, ASX RELEASE 12.5m SHARES FROM ESCROW**

MARKET REPORT

The Australian stock market climbed 0.5 percent on Monday May 19, 2008 with the All Ordinaries up 28.9 points to 6,035.0 points. Eighteen of the Biotech Daily Top 40 stocks were up, 11 fell, seven traded unchanged and four were untraded.

Sunshine Heart was best, up one cent or 13.33 percent to 8.5 cents on very small volumes, followed by Tissue Therapies up 1.5 cents or 11.54 percent to 14.5 cents and Peplin up five cents or 11.36 percent to 49 cents.

Bionomics climbed 8.57 percent; Cellestis and Novogen were up more than six percent; Polartechnics and Psivida were up five percent or more; Alchemia, Antisense and Chemgenex rose more than four percent; Avexa and Optiscan were up more than three percent; Mesoblast and Pharmaxis were up more than two percent; with Agenix, Cochlear and Universal Biosensors up more than one percent.

Cytopia led the falls down three cents or 10.0 percent to 27 cents on small volumes, followed by Living Cell and Starpharma down more than nine percent.

Benitec, Neuren and Prana fell more than four percent; Clinuvel and Phosphagenics lost more than three percent; with Biota and Ventracor down more than one percent.

BONE MEDICAL

Bone says it has received “clarification” from the US Food and Drug Administration for a pivotal trial for approval of its oral calcitonin product, Capsitonin.

Bone said that after reviewing the data from its recent phase II study (see Biotech Daily; August 1, 2007), the FDA confirmed that Capsitonin was eligible for registration via a 505(b)(2) pathway.

The FDA website says a 505(b)(2) application refers to changes to dosage form, strength, route of administration, formulation or change of active ingredient

Bone said the FDA confirmed that demonstration of non-inferiority to a current nasally-administered form should be sufficient to obtain approval.

Bone said it intended to file an investigational new drug application prior to commencing a phase III pivotal study comparing several different dose levels of Capsitonin with a nasal version, administered as a capsule once daily.

The company said Calcitonin had been used “as a safe treatment for osteoporosis for many years as an injection and recently as a nasal form”.

“Both have disadvantages with compliance when treating the elderly for a rest-of-life treatment, Bone said.

Osteoporosis affects one-third of women over the age of 50 years and up to 20 percent of elderly men.

Bone was untraded at 25.5 cents.

PHARMAXIS

Pharmaxis says it has received approval to market Aridol in Germany.

The company said Aridol was indicated for measuring airway hyper-responsiveness and has been approved in 14 European countries under the mutual recognition procedure and necessary national approvals have been received for Denmark, Germany, Ireland, The Netherlands, Portugal, Sweden and the United Kingdom.

Pharmaxis said that 660,000 lung function tests were conducted in German each year, of which 90 percent were conducted by office-based physicians and the rest in hospitals.

Pharmaxis said it would negotiate with insurance companies that cover the office-based physician market before launching with a local distributor.

The company said the Aridol test was “a simple-to-use airways inflammation test” using a dry powder administered to patients’ lungs.

Doctors can use the test to identify airway hyper-responsiveness, which is a hallmark of asthma and medication can be adjusted according to the severity of the disease.

Pharmaxis climbed four cents or 2.58 percent to $1.59.

PROGEN

Progen chief financial officer Linton Burns has told Biotech Daily his company is not the subject of an Australian Securities and Investments Commission probe.

Mr Burns said the investigation relating to EG Capital “does not involve Progen, it involves Progen’s securities”.

“No director or employee of Progen is involved as far as I’m aware,” Mr Burns said.

EG Capital managing director Mark Fordree told Biotech Daily he was under instructions from lawyers not to make any comment on the matter.

Mr Fordree said the visit to his office by ASIC last year was part of “a broader investigation”.

Progen was unchanged at $1.34.

NOVOGEN

Novogen says an article on the safety and pharmacokinetics of its phase I triphendiol trial is available on line.

Novogen said the article entitled 'Phase Ia Safety and Pharmacokinetic Study of Oral NV-196 in Patients with Solid Tumors' was submitted to the American Society of Clinical Oncology meeting and has been published by the society and was available at www.asco.org (abstract 14615).

Novogen said the paper reports on a human clinical study of oral triphendiol "which demonstrated a good safety profile and successful pharmacokinetics".

The trial was conducted by Prof Paul Mainwaring at the Brisbane Mater Adult Hospital.

Novogen said NV-196 was now known as triphendiol and was granted orphan drug status by the US Food and Drug Administration for pancreatic cancer and cholangio-carcinoma in January 2008 and for treatment of stage IIb-IV malignant melanoma in February 2008.

Laboratory testing in vitro and in mice bearing human pancreatic, bile duct or melanoma tumors demonstrated the activity of triphendiol against the cancer cells.

In mice bearing a human pancreatic cancer tumor, triphendiol administration resulted in a mean reduction in tumor volume by 62 percent compared with untreated control animals.

The group director of Novogen's 72 percent US subsidiary Marshall Edwards Prof Alan Husband said the study presented at ASCO was "an important step towards the clinical development of triphendiol".

He said the data indicated that oral triphendiol appeared to be safe and could be delivered effectively in humans.

"We will now be well placed to apply for an investigational new drug approval to continue into phase II studies in the US later this year," Prof Husband said.

Novogen was up 10 cents or 6.06 percent to $1.75.

MEDICAL THERAPIES

Medical Therapies shareholders will vote on a share issue related to an acquisition, directors' options and a capital raising of up to $3 million.

The resolutions to the extraordinary general meeting include issuing up to 19.98 percent of its total share issue to NS Capital and up to 17 percent of the share issue to Cell Signals for the acquisition of its midkine intellectual property assets.

The company also proposes to raise up to $3 million within three months of approval.

A final resolution proposes to issue 5,000,000 options to director and chief executive officer Maria Halasz in line with her employment agreement.

The meeting will be held at Level 6, 40 King Street, Sydney on June 16, 2008 at 2.30pm.

Medical Therapies fell half a cent or 7.14 percent to 6.5 cents.

KARMELSONIX

Karmelsonix says it has appointed asthma experts to its scientific and medical advisory committee.

The company said the committee would be chaired by Hadassah Medical Center and Hebrew University Prof Simon Godfrey and include the University of Denver's Prof Lynn Taussig and Chicago's Northwestern University Prof Lewis J Smith.

The company said the first meeting would be held on May 18, 2008 at the American Thoracic Society International Conference in Toronto.

Karmelsonix climbed 1.5 cents or 13.64 percent to 12.5 cents.

VENTRACOR

Ventracor has extended chief executive officer Peter Crosby's employment agreement for one year, until June 30, 2009.
Mr Crosby was appointed CEO with a two-year contract from July 1, 2006.
Current terms, conditions and remuneration will continue to apply under the extension "and have been independently assessed as market appropriate" Ventracor said.
Mr Crosby was the company's chief operating officer since January 2005 and has more than 25 years' experience in the commercialization of cardiac medical devices.
Ventracor
In 2006 (see Biotech Daily June 28, 2006) Ventracor said Mr Crosby's total fixed remuneration package would be $650,000 a year with an annual incentive to a maximum of 50 percent based on performance hurdles.
Mr Crosby also has access to a long term incentive plan of up to four million performance shares vesting over next three years.
The proportion of Mr Crosby's total potential remuneration which is at risk and subject to performance criteria is 78 percent, Ventracor said.
Ventracor fell half a cent or 1.32 percent to 37.5 cents.

MEDICAL THERAPIES

Christopher Peter Walker has become a substantial shareholder in Medical Therapies with a holding of 5,714,286 shares or 7.71 percent of the company.
Medical Therapies fell half a cent or 7.14 percent to 6.5 cents.

QRX PHARMA

QRX Pharma says 1,721,942 shares will be released from ASX escrow and 10,795,929 shares will be released from voluntary escrow on May 25, 2008.
A further 34,213,203 shares are in voluntary escrow until May 25, 2009, of which 10,461,317 are also in ASX escrow.
The total number of QRX shares including those yet to be released from escrow is 75,000,000 shares.
QRX Pharma was down two cents or 2.22 percent to 88 cents.