Biotech Daily

Thursday September 27, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: NEUREN UP 4%, ALLIED HEALTH DOWN 8%**

*** CSL, KAROLINSKA: CSL2H10 BLOCKS TYPE 2 DIABETES IN RODENTS**

*** GERMANY EXTENDS PHARMAXIS PATENTS TO 2020**

*** SIRTEX PAYS FULLY-FRANKED 10c DIVIDEND**

*** BLUECHIIP EARNS $920k R&D TAX CREDIT**

*** ISONEA 3-FOR-5 RIGHTS ISSUE FOR $4m**

*** PROGEN: MEDIGEN ENROLS 1st CHINA PI-88 LIVER CANCER PATIENT**

*** CATHRX TO DELIST BEFORE RAISING $5m**

*** CRYOSITE PREPARES FOR CELL CARE BOARD SPILL AGM**

*** NUSEP: DIRECTORS LEND $494k; CHASE $1.4m DEBT**

*** BIODIEM TAKES CAPITAL RAISING HALT TO SUSPENSION**

*** ALL HEALTHLINX OVPLEX SALE EGM VOTES PASS - 19% DISSENT**

MARKET REPORT

The Australian stock market was up 0.52 percent on Thursday September 27, 2012 with the S&P ASX 200 up 22.6 points to 4,384.2 points. Eight of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and five were untraded.

Neuren was the best, up 0.1 cents or 3.85 percent to 2.7 cents, with 810,406 shares traded, followed by Patrys and Sirtex up by more than three percent, with Alchemia, Cochlear, CSL, Living Cell, Pharmaxis and Viralytics up more than one percent and Mesoblast up 0.4 percent.

Allied Health led the falls, down 0.2 cents or 7.7 percent to 2.4 cents with 5.2 million shares traded. Prana lost 6.7 percent; Ellex and Optiscan were down five percent or more; Genetic Technologies fell 4.35 percent; Phosphagenics was down 3.85 percent; Acrux and Uscom shed more than two percent; with Anteo, Bionomics, Biota, Clinuvel, Reva, Resmed, Starpharma, Tissue Therapies and Universal Biosensors down more than one percent.

CSL

CSL says drug candidate CSL2H10 has prevented the development of type 2 diabetes and reverse its progression in mice and rats.

CSL said that 2H10 was acquired with Zenyth Therapeutics, formerly the Victorian State Government-funded Amrad Corp, in 2006.

The company said that 2H10 blocked signaling by the vascular endothelial growth factor-B (VEGF-B) protein, preventing fat from accumulating in muscle and heart tissue, allowing the cells in those tissues to respond to insulin, restoring blood glucose to normal levels.

CSL said this was "an entirely new approach to the treatment of type 2 diabetes" and resulted from an international collaboration led by Sweden's Karolinska Institute's Prof Ulf Eriksson with scientists from CSL, the University of Melbourne and the Ludwig Institute for Cancer Research.

CSL's head of research and former chief executive officer of Zenyth Dr Andrew Nash said the laboratory studies' results "are very promising for the millions of people around the world who are affected by type 2 diabetes".

"This disease is reaching epidemic proportions and is a significant public health burden," Dr Nash said.

"We are very hopeful that the antibody-based drug that we have developed and tested together with Prof Eriksson will ultimately lead to a new treatment option for people with diabetes," Dr Nash said.

CSL said that type 2 diabetes was normally preceded by insulin resistance, most often caused by obesity, with cells no longer responding sufficiently to insulin, leading to elevated levels of blood sugar.

Dr Nash said insulin resistance was related to fat storage in the 'wrong' places, such as the muscles and heart, although how the relationship worked wais not fully understood.

CSL said that Prof Eriksson's research group discovered the VEGF-B protein affected the transport and storage of fat in body tissue and published their study in Nature in 2010 and the latest study showed that VEGF-B signaling was blocked by CSL2H10 in diabetic mice and rats.

The article entitled 'Targeting VEGF-B as a novel treatment for insulin resistance and type 2 diabetes' was published in the Nature and an abstract is available at: http://www.nature.com/nature/journal/vaop/ncurrent/full/nature11464.html.

CSL said that four related studies were reported in the Nature paper.

The company said that in one study, mice bred to spontaneously develop diabetes were treated with CSL2H10 and subsequently developed neither insulin resistance, nor diabetes.

CSL said the researchers crossed the diabetic mouse model with one that lacked the ability to produce VEGF-B and found the at-risk offspring were protected from developing diabetes.

In two other studies, the scientists investigated the effects of CSL2H10 on mice and rats that had developed obesity and type 2 diabetes as a consequence of a fat-rich diet and again the treatment was able to prevent development and progression of the disease.

"It's a great feeling to have published these new results," said Prof Eriksson.

"We discovered VEGF-B back in 1995, and since then the VEGF-B project has been a lengthy sojourn in the wilderness, but now we're making one important discovery after the other," Prof Eriksson said.

CSL said that on the basis of the findings, it was considering options for progressing the development of CSL2H10, including testing the therapy in people with type 2 diabetes as well as in those who are at-risk of developing the disease.

CSL was up 82 cents or 1.8 percent to $46.00 with 1.5 million shares traded.

PHARMAXIS

Pharmaxis says the German Patent Office has extended the European patent for both Aridol and Bronchitol by five years to 2020.

Pharmaxis said the patent extension was through the grant of a supplementary protection certificate and extends the Aridol and Bronchitol patent from February 24, 2015 to February 23, 2020.

The company said supplementary protection certificate effectively compensated companies for lost patent protection caused by the necessary duration of development.

Pharmaxis said that Germany was the first European Union member state to rule on the application and it was expected other EU member states would conclude their individual determinations in due course.

Pharmaxis chief executive officer Dr Alan Robertson said the company was pleased that a full five years of additional market protection had been granted by the German Patent Office and, “for Bronchitol in particular, this protection extends beyond cystic fibrosis into other clinical indications”.

Pharmaxis was up 1.5 cents or 1.4 percent to $1.10.

SIRTEX MEDICAL

Sirtex says it has declared a final fully franked dividend of 10 cents a share, with a record date of October 12, and payment on October 26, 2012.

Sirtex chief executive officer Gilman Wong said the dividend was “a 43 percent increase on last year’s dividend reflecting the 49 percent increase in net profit after tax achieved in financial year 2012”.

“Sirtex’s healthy cash position and reliable operating cash flow permits the increase in the dividend paid to shareholders and to continue to invest in the company’s 2020Vision and future growth,” Mr Wong said.

Sirtex was up 28 cents or three percent to $9.50 with 160,265 shares traded.

BLUECHIIP

Bluechiip says it has received a Federal Government research and development tax credit of $919,843.

Bluechiip chief executive officer Brett Schwarz told Biotech Daily that the funds would be used for current commitments and working capital.

Bluechiip was untraded at 25 cents.

ISONEA

Isonea expects to raise $4 million through a fully underwritten three-for-five renounceable rights issue at five cents a share.

Isonea said the funds raised would be used to develop the Airsonea and Sonosentry devices and rollout the Asthmasense telephone applications.

The company said the issue was fully underwritten by Patersons Securities “whose sub-underwriting commitments were strongly oversubscribed”.

Isonea said the record date for the issue is October 8, 2012.

Isonea was up 0.7 cents or 13.0 percent to 6.1 cents with 1.8 million shares traded.

PROGEN PHARMACEUTICALS

Progen says Medigen Biotechnology Corp has enroled its first China-based patient in its 500-patient phase III trial of PI-88 for hepto-cellular carcinoma or liver cancer.
Progen halted its phase III trial of the drug in 2008, citing an absence of partners and slow patient recruitment (BD: Mar 11, Jul 23, 2008).
Today, Progen said there were 23 active sites, with nine in Taiwan, 11 in South Korea, and three in China.
The company said that Medigen had enroled more than 100 patients in Taiwan and more than 50 patients in South Korea.
Progen said that the Taiwan Food and Drug Administration told Medigen that PI-88 qualified under the cross-strait pharmaceuticals research and development scheme in which Taiwan and China simultaneously examine investigative new drug applications and new drug applications and mutually recognize data from clinical trials conducted in either country.
The company said the scheme reduced repetition of clinical trials and advanced PI-88's potential use in the Chinese market.
Progen said that the trial was designed to confirm the efficacy and safety of PI-88 in the adjuvant treatment of hepto-cellular carcinoma after surgical resection and was a randomised, placebo-controlled, multinational trial, with disease-free survival as the primary endpoint.
Progen said it was entitled to milestone payments based upon the achievement of various stages of clinical development and royalties on sales following marketing approval.
The company said that, to date, Medigen had achieved two milestones and had paid $US1 million to Progen.
Progen said it was contracted to supply the clinical trial material to Medigen through its contract manufacturing subsidiary Pharmasynth.
Progen fell 3.5 cents or 12.1 percent to 25.5 cents.

CATHRX

Cathrx says because of a share price fall, it will not wait to complete a $5 million capital raising and intends to delist from the ASX (BD: May 9, 2012).
Cathrx said it had hoped to complete a fully underwritten renounceable rights issue at one cent a share to raise about $5 million, but recent trades brought the market price to 0.4 cents, well below the proposed issue price.
The company said that ASX Listing Rules provide that a proposed rights issue can not be carried out at a price higher than the then current average market price, so it could not proceed with the rights issue at one cent and a rights issue at 0.4 cents would not reflect the inherent value in the company and would be overly dilutive for shareholders.
Cathrx said it had previously told shareholders of its intention to delist after the capital raising and proposes to apply to the ASX and seek any necessary shareholder approvals to be delisted.
The company said it recently received a Federal Government research and development tax credit of about $2.2 million which would provide sufficient working capital for the capital raising to be deferred until after delisting and once delisted, it expected to undertake a capital raising at the originally intended issue price of one cent a share.
Cathrx designs reprocessable cardiac catheter solutions but failed to gain sales or a partnering deal (BD: Sep 29, 2011, Mar 8, 2012).
Cathrx was unchanged at 0.4 cents.

CRYOSITE

Cryosite is preparing for a potential board spill at its annual general meeting in October with an expected second vote of more that 25 percent against the remuneration report.
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill, and at the later meeting and if passed by more than 50 percent of votes, the directors must stand for reelection at a subsequent meeting within 90 days.
Last year, Cryosite shareholders defeated the remuneration report and the re-election of director Theo Onisforou (BD: Nov 8, 2011).
Cryosite said at that time that the poll of votes showed 3,851,880 proxy votes in favor of the reelection of Mr Onisforou with 9,299,881 proxy votes against and the remuneration report was supported by 2,269,701 proxy votes, with 9,423,809 votes against.
The company then appointed Mr Onisforou as a director to fill a casual vacancy.
Today, the notice of meeting said the four resolutions to be considered at the meeting were the remuneration report, the re-election of directors Andrew Kroger and Graeme Moore and 'Spilling the board of directors'.
Cryosite's annual report said that Cell Care Australia held 10,240,498 shares (21.97%) and Andrew Kroger held 9,314,276 shares (19.97%) at June 30, 2012.
The meeting will be held at Cryosite, 13a Ferndell Street, South Granville, Sydney, on October 31, 2012 at 10am (AEDT).
Cryosite was untraded at 28.5 cents.

NUSEP

Nusep says it has arranged a $494,000 working capital advance from its chairman John Manusu and parties related to director Andrew Goodall.
Nusep said that Mr Manusu's $260,000 and the $234,000 from Mr Goodall's related parties would assist the expansion of its consumables business and the commercialization of its Prime technology.
The company said the facility was provided on normal commercial terms with an interest rate of 12 percent per annum and due for payment in December 2012.
Nusep said it had a commercial arrangement with DCS Healthcare Pte Ltd for the settlement of the $1.8m debt outstanding at December 31, 2011 and the debt had been reduced by $509,227 by June 30, 2012, leaving a balance of $1,384,177, which had been fully impaired in the June 30, 2012 financial statements.
The company said it worked with DCS Healthcare directors and arranged for Thee Woon Goh to reclaim the shares and transfer these into his personal name so Nusep could obtain a full recourse position against an individual as DCS Healthcare was a company without additional chargeable assets.
Nusep said that a commercial debt agreement was executed in September 2012 with Mr Goh which included a formal lien over the related shares and it expected full recovery of the $1,384,177 debt and if not settled, would commence recovery proceedings.
Nusep was untraded at 5.7 cents.

BIODIEM

Biodiem has requested a voluntary suspension to follow the trading halt it requested on September 25, pending capital raising initiatives (BD: Sep 25, 2012).
Biodiem last traded at 6.2 cents.

HEALTHLINX

Healthlinx shareholders have passed all extraordinary general meeting resolutions but faced up to 18.6 percent opposition from directed proxy votes.

The vote on the sale of its major assets to the US-based Mane Cancer Diagnostics primarily in exchange for shares in Mane was supported by 93,998,772 proxy votes (85.5%) and opposed by 15,885,637 proxy votes (14.5%).

Healthlinx said the resolution for authority to accept further payments under a convertible note issued to La Jolla Cove Investors was supported by 87,945,425 proxy votes (81.4%) and opposed by 20,150,388 (18.6%) proxy votes.

The resolution approving a change in nature and scale was passed more easily.

In its last Appendix 3B, Healthlinx said it had 481,896,454 shares on offer, implying the greatest dissent comprised 4.2 percent of all shares on offer.

Healthlinx was untraded at 0.3 cents.