Biotech Daily

Monday July 28, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CLINUVEL UP 29%, LIVING CELL DOWN 12%**

*** RETROPHIN OFFERS $92-95m FOR $71m CLINUVEL**

*** PROGEN FALLS 76% AS PI-88 FAILS TO MEET LIVER CANCER ENDPOINTS**

*** TISSUE THERAPIES FILES EU ANSWERS - RESPONSE WITHIN 90 DAYS**

*** CYNATA CONTRACTS UNI OF WISCONSIN FOR STEM CELL SHELF LIFE**

*** CHANGES DELAY PHOSPHAGENICS OPIOID TRIALS**

*** PRANA DEREGISTERS $22m SHARES**

*** VALE CLINUVEL DIRECTOR JACK WOOD**

*** MEDICAL DEVELOPMENT DIRECTOR MAURICE VAN RYN RESIGNS**

MARKET REPORT

The Australian stock market slipped 0.11 percent on Monday July 28, 2014 with the S&P ASX 200 down 6.1 points to 5,577.4 points. Fourteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and three were untraded.

Clinuvel was the best, up 49.5 cents or 29.4 percent to $2.18 with 313,734 shares traded, followed by Uscom up 15.9 percent to 25.5 cents with 3,000 shares traded and Neuren up 15.0 percent to 11.5 cents with 15.4 million shares traded.

Tissue Therapies climbed 9.8 percent; Phosphagenics was up 8.2 percent; Antisense and Ellex rose four percent or more; Atcor, Genetic Technologies, Patrys and Pharmaxis were up more than three percent; Analytica and Circadian rose more than two percent; with Acrux, Cochlear and Resmed up by less than one percent.

Living Cell led the falls, down 0.7 cents or 11.7 percent to 5.3 cents with 48,865 shares traded, followed by Universal Biosensors down 10 percent to 18 cents with 141,131 shares traded.

Cellmid and Oncosil lost more than six percent; Avita, Benitec and GI Dynamics fell more than four percent; Admedus, Alchemia, IDT, Osprey, Prana and Viralytics were down more than three percent; Medical Developments and Prima shed more than two percent; Mesoblast and Starpharma were down more than one percent; with CSL and Sirtex down by less than one percent.

CLINUVEL PHARMACEUTICALS

Clinuvel says that the New York-based Retrophin has bid about $95 million to buy the company through a share swap worth about $2.14 a share or $2.17 in cash per share.
The cash per share offer is a 28.8 percent premium to Clinuvel's closing price on Friday, July 25, 2014 of $1.685 and values Clinuvel at $91.99 million.
Retrophin closed on the Nasdaq on Friday July 25, 2014 at $US11.50 ($A12.24) and had a market capitalization of $A312 million.
Clinuvel said that the offer was unsolicited and advised shareholders "to take no action" while it evaluated the proposal which was subject to numerous conditions.
The company said the offer was to acquire all of the shares for either 0.175 Retrophin shares per Clinuvel share, valued at $2.14 a share based on the one month volume weighted average price of Retrophin shares on July 16, 2014, or $2.17 a share in cash through a scheme of arrangement.
Clinuvel said that Retrophin had acquired a stake of about 4.88 percent and the company's directors were "evaluating all aspects of the proposal with a focus on optimizing shareholder value".
Clinuvel said it was "in the final stages of the European Medicines Agency review process for marketing authorization for Scenesse as a treatment for erythropoietic protoporphyria .... in Europe" which was expected to be completed by the end of October 2014.
The company said it was concurrently undertaking a phase II clinical trial in Asia to evaluate the use of Scenesse as a treatment for vitiligo and that Scenesse had been proposed as a therapy in other rare skin diseases, including Hailey-Hailey disease.
Clinuvel said it was "highly confident that it will be in a position to market Scenesse throughout Europe in 2015".
The company said that Greenhill was acting as its financial adviser and Arnold Bloch Leibler as its legal adviser.
Clinuvel climbed 49.5 cents or 29.4 percent to $2.18 with 313,734 shares traded.

PROGEN PHARMACEUTICALS

Progen fell as much as 76 percent on news that an interim analysis of Medigen's phase III trial of PI-88 for liver cancer showed the drug failed to meet its primary endpoint.
Progen said the interim analysis of the first 131 patients or 60 percent of all 218 patients recruited in the trial by Taiwanese licencee Medigen Biotechnology Corp concluded that PI-88 had "a good safety profile and that based on recurrent data from each individual clinical trial centre, PI- 88 did not meet the primary endpoint of disease free survival".
Progen said that the PI-88 phase III Patron clinical trial was a fully-recruited, randomized, placebo-controlled trial being conducted in Taiwan, South Korea, China and Hong Kong to confirm the safety and efficacy of PI-88 in the adjuvant treatment of hepatocellular carcinoma after surgical resection.
The company said that further data analysis by the independent committee would be performed when data from US-based independent medical imaging company Bioclinica was available.
Progen said that in 2010 it licenced the worldwide oncology rights of PI-88 to Medigen to complete product development and commercialization of PI-88.
The company closed its own trial of PI-88 for liver cancer in July 2008, sparking a fight for control over the company's cash reserves and concluding with the drug being licenced to Medigen (BD: Jul 23, 2008; Apr 30, 2010).
Progen fell as much as 91.5 cents or 76.25 percent from $1.20 to a low of 28.5 cents, closing down 90.5 cents or 75.42 percent to 29.5 cents with 1.4 million shares traded.

TISSUE THERAPIES

Tissue Therapies says the British Standards Institute has a further 60 days for questions about its Vitrogro wound treatment and 90 days for a decision.
Tissue Therapies said that it had provided “a comprehensive response” to the European Medicines Agency committee review questions and the Agency was required to provide any further questions and comments to the British Standards Institute as the notified body within 60 days, September 24, 2014, with up to a further 30 days for a decision.
The company said that a positive response from the Agency was the last step in the process for Conformité Européenne (CE) mark to allow the sale of Vitrogro ECM in the European Union.
Tissue Therapies said its response to the Agency’s questions provided detailed answers and was expected to result in a favorable opinion during the second half of 2014.
The company said that its submission provided answers to the 120-day questions received from the Agency reviewers, as part of the maximum 210 calendar day review.
Tissue Therapies said the review stopped while answers were prepared and lodging the response restarted the clock at 120 days with the Agency required to provide any further questions and comments to the notified body by the 180-day point, September 24, 2014.
The company said that the most definitive response would involve the development of additional test methods for stability and release for sale of Vitrogro ECM and that this would take a few months and a detailed project plan for the development of this additional testing was reviewed and agreed at site meetings in Belgium with the company’s key manufacturers, Eurogentec and Catalent during February 2014 and this generated the data for the response to the Agency.
The company said that in parallel with the preparation of the response to the Agency, it had continued health economics analyses in preparation for reimbursement applications as well as sales, marketing, logistics and publication preparation to optimize the launch of Vitrogro ECM in the UK and Europe shortly after CE mark was granted.
Tissue Therapies was up 2.5 cents or 9.8 percent to 28 cents.

CYNATA THERAPEUTICS

Cynata says it has contracted the University of Wisconsin, Madison to develop a novel approach for preserving cell therapy products to enhance their shelf life and convenience.
Cynata originally licenced its stem cell technology from Wisconsin Alumni Research Foundation, the commercialization arm of the university
Today the company said that the development program would be overseen Cynata co-founder and University of Wisconsin, Madison professor of pathology and laboratory medicine Prof Igor Slukvin.
Cynata said that an important component of a commercially successful stem cell therapeutic product was to provide a practical and effective means of preserving the cell product in storage and during transport to the site of eventual use in patients, including the process of reconstituting the product to prepare it for administration.
The company said that the program’s goal was to develop such a process and provide further user advantages to for its Cymerus platform.
Cynata said that any patentable discoveries from the program would augment its existing intellectual property position.
Cynata product development vice-president Dr Kilian Kelly said that preservation of cell therapy products for commercial use “poses a product logistics challenge” and the University of Wisconsin, Madison had an exemplary track record in the field.
Cynata was up two cents or 4.9 percent to 43 cents.

PHOSPHAGENICS

Phosphagenics says it hopes to begin a US phase II trial of TPM-oxymorphone by July 2015 and an Australian phase IIa trial of TPM-oxycodone by the end of 2014.

Last year, Phosphagenics said that its tocopheryl phosphate mixture-oxymorphone patch delivered therapeutic plasma concentrations to all 12 subjects in its multi-dose phase I trial and it would proceed to a phase II trial, in mid-2014, to define the dosage regimes to be used and enhancing its commercial value (BD: Oct 24, 2013).

In July last year, the company said its TPM-oxycodone program would continue with a phase I multiple dose trial due to commence by July 2014 (BD: Jul 26, 2013).

Today, Phosphagenics said that it had conducted two phase I trials with TPM-oxymorphone, including confirmation of transdermal delivery of therapeutic oxymorphone plasma concentrations, a predictor of efficacy.

The company said the TPM-oxymorphone patch was being characterized in two additional studies to support an investigational new drug application to the US Food and Drug Administration.

Phosphagenics said that the first trial was in progress and addressed supplementary pharmacokinetic parameters to those examined in the previous trials and the second trial, which was expected to start in October 2014, would evaluate two standard investigational endpoints for transdermal products: the consistency of the delivery profile among several potential patch application sites such as flank, chest, upper arm and upper back; and the rest period required before a patch can be reapplied to the same application site.

The company said it hoped to start the larger US phase II study of TPM-oxymorphone by July 2015.

Phosphagenics said that the TPM-oxycodone patch was scheduled to re-enter the clinic in an Australian phase IIa study by the end of 2014, with ethics committee approval expected in October 2014.

The company said that the single dose, proof-of-concept trial would investigate the ability of the topical application of the TPM-oxycodone patch to provide pain relief for patients suffering from post-herpetic neuralgia, a peripheral neuropathic pain condition.

Phosphagenics said it expected to complete the trial by July 2015, pending patient recruitment.

The company said that the TPM-oxymorphone patch has been developed for systemic delivery and treatment of moderate to severe chronic pain, while the TPM-oxycodone patch was for localized topical delivery and treatment of peripheral neuropathic pain.

Phosphagenics climbed 0.7 cents or 8.2 percent to 9.2 cents with 1.8 million shares traded.

PRANA BIOTECHNOLOGY

On July 25, 2014 Prana filed a US Securities and Exchange Commission registration form deregistering $US20,864,934 ($A22,218,667) of unused securities (BD: Sep 2, 2013).

Prana chief financial officer Phillip Hains told Biotech Daily that in May 2011 the company registered the capacity to raise $US50 million in the US, which was subsequently increased to $57 million.

The shelf life of the registered facility expired in May 2014, with $US21 million not used.

Mr Hains said that in the period since registration the company raised $US36 million

Prana fell one cent or 3.9 percent to 24.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says that non-executive director Jack Wood has died, suddenly.
Clinuvel said that Mr Wood had an extensive background in international marketing and manufacture of pharmaceutical products, had lived in Germany, England, Australia, the US and Canada and overseen pharmaceutical operations throughout Europe, Asia and North America.
The company said that prior to his role with Clinuvel Mr Wood was CSL's executive vice president, Exogene Corp chief executive officer and Bioresponse Corp senior vice-president and well as Bayer Corp's pharmaceutical division vice-president.
Clinuvel said that Mr Wood was an active member of several civic boards and organizations in Vancouver, Canada where he resided.
Clinuvel chair Stan McLiesh said that Mr Wood "was a remarkable individual and a dear friend and colleague".
"On behalf of our management and team, we offer our sincere condolences to his wife Yan and family," Mr McLiesh said.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that director Maurice van Ryn has resigned, effective from today.
Medical Developments said that Mr van Ryn had been a director for 10 years and it would consider applicants for the vacancy especially "candidates with hands-on experience with respiratory and/or finance" matters.
Medical Developments fell 3.5 cents or 2.9 percent to $1.18.