Biotech Daily

Wednesday September 24, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ACRUX UP 5%, CLINUVEL DOWN 8%**

*** NEUREN EXPECTS NOVEMBER RETT SYNDROME RESULTS**

*** SIRTEX DECLARES 14c FULLY-FRANKED FINAL DIVIDEND**

*** INVION, 3M COMPLETE INHALED INV102 FEASIBILITY STUDIES**

*** IBSEN, NARULA TAKE 7% OF OPTISCAN**

*** PATRYS TO LOSE M-D DR MARIE ROSKROW**

*** GREG TUNNY REPLACES ISONEA CEO STEPHEN TUNNELL, UPDATE**

*** GENETIC TECH: DAVID CARTER, DR LINDSAY WAKEFIELD DIRECTORS**

*** SHARON PAPWORTH REPLACES ACRUX CFO, CO SEC TONY DI PIETRO**

MARKET REPORT

The Australian stock market fell 0.74 percent on Wednesday September 24, 2014 with the S&P ASX 200 down 39.9 points to 5,375.8 points. Six of the Biotech Daily Top 40 stocks were up, 19 fell, eight traded unchanged and seven were untraded.

Acrux was the best, up 6.5 cents or 5.2 percent to $1.305 with 968,970 shares traded.

Biotron and Tissue Therapies climbed more than four percent; Analytica, Bionomics and Prima rose more than two percent; with Cochlear and CSL up by less than one percent.

Clinuvel led the falls for the second day in a row, down 33 cents or 8.4 percent to $3.58 with 83,099 shares traded.

Oncosil lost 7.7 percent; Universal Biosensors fell 6.1 percent; Medical Developments was down 5.2 percent; Anteo, Patrys and Prana fell four percent or more; Admedus, Benitec, Cellmid, Impedimed and Neuren were down three percent or more; Atcor, GI Dynamics and Osprey shed more than two percent; Resmed and Starpharma lost more than one percent; with Mesoblast, Psivida and Sirtex were down by less than one percent.

NEUREN PHARMACEUTICALS

Neuren says it expects top-line results from its phase II clinical trial of NNZ-2566 for Rett syndrome in November 2014.

Neuren said that 53 patients completed the double-blind, placebo-controlled trial, to evaluate orally administered treatment with NNZ-2566 for up to one month in adolescent and adult females, aged 16 to 45 years).

The company said that the trial was the first multi-site, sponsor-led clinical trial in Rett syndrome, for which there were no approved medicines.

Last year, the US Food and Drug Administration granted fast track designation for the program to develop NNZ-2566 for Rett syndrome (BD: Jun 5, 2013).

Neuren said that Rett syndrome was a severe neurological disorder caused by mutations of the MeCP2 gene on the X-chromosome, with onset in early childhood and often progressive into adolescence and adulthood.

The company said that the primary endpoint was safety and tolerability of two dose levels of NNZ-2556 as compared to placebo but the trial had outcome measures that would provide insight into efficacy and sought to establish whether there was a pattern of clinical benefit evident from treatment with NNZ-2566.

The company said that the efficacy outcomes included rating scales specific to Rett syndrome signs and symptoms such as motor behavior assessment and clinical severity scale completed by the clinician; global assessments keyed to the specific signs and symptoms of Rett syndrome such as clinical global impression of improvement, completed by the clinician; rating scales keyed to specific Rett syndrome signs and symptoms including main three concerns and general rating scales such as aberrant behavior checklist completed by caregivers; and physiological measures including assessments that evaluate breathing abnormalities).

Neuren said that the clinical responses compared to baseline in the four domains would be examined for each subject individually, as well as for each treatment group as a whole.

The company said that the analysis of the results would determine for individuals and for the group whether NNZ-2566 provided a systematic pattern of benefit.

Neuren executive chairman Dr Richard Treagus said the company was “grateful to the patients and families affected by Rett syndrome that have made this ground-breaking clinical trial possible”.

“Neuren is approaching a very important milestone in November, which has the potential to materially increase the value of NNZ-2566,” Dr Treagus said.

“If the trial results establish a clinical benefit in Rett syndrome, we will move quickly to apply to the FDA for orphan drug designation and potentially for breakthrough therapy designation,” Dr Treagus said.

Neuren fell 0.3 cents or 3.5 percent to 8.2 cents with 2.95 million shares traded.

SIRTEX MEDICAL

Sirtex says it has declared a final fully franked dividend of 14 cents per share with a record date of October 8 to be paid on October 22, 2014.

Sirtex chief executive officer Gilman Wong said that the dividend payment was a “17 percent increase on last year’s dividend reflecting Sirtex’s continued improvement both in dose sales and financial performance”.

“The board is confident that Sirtex will continue to have a reliable operating cash flow to support the increase in the dividend to be paid to shareholders while continuing to invest in the company’s 2020Vision and future growth,” Mr Wong said.

Sirtex fell 20 cents or 0.9 percent to $22.00 with 168,557 shares traded.

INVION

Invion says it has completion the first stage feasibility studies with 3M Drug Delivery Systems for the development of inhaled INV102, or nadolol.

Invion said that it had developed and validated analytical methods to a suitable level for the purposes of toxicology and clinical supply; completed presentation of solubility and gross compatibility data; and had a recommendation from 3M for proprietary systems to progress to stage two feasibility studies of pressurized metered dose inhalation product screening.

The company said that its agreement with 3M was assessing the feasibility of inhaled versions of its two respiratory drug assets delivered using 3M's proprietary pressurized metered dose inhalation technology and would enable manufacture for toxicology, and subsequently phase I studies, under an Invion-sponsored investigational new drug application to the US Food and Drug Administration.

Invion said that INV102 was a beta blocker, or beta adrenergic biased ligand, used to treat high blood pressure and migraine, but the company was "repurposing this drug as a target therapy for chronic inflammatory airway diseases".

The company said its two oral INV102 phase II trials were studying the effectiveness of INV102 in assisting smoking cessation of patients with chronic obstructive pulmonary disease; and the effect on INV102 on patients with mild asthma.

Invion said that the 3M agreement was targeted to develop inhaled versions of the drug for cystic fibrosis, asthma and chronic obstructive pulmonary disease.

Invion executive vice-president and chief medical officer Dr Mitchell Glass said the company was "very pleased with progress towards developing an inhaled version of INV102".

Invion was unchanged at 7.9 cents.

OPTISCAN

Ibsen Pty Ltd and Narula Family Settlement No 3 have increased their holding in Optiscan from 6,675,417 shares (5.11%) to 13,334,167 shares (7.19%).

The substantial shareholder notice, signed by Canterbury, Victoria-based director Ian Mann, said the two entities bought and sold shares between August 26, 2011 and September 19, 2014 with the most recent and single largest acquisition 3,500,000 shares for $105,000 or three cents a share

Optiscan was untraded at 3.5 cents.

PATRYS

Patrys says that chief executive officer and managing director Dr Marie Roskrow has resigned, effective from "the end of 2014".

Patrys appointed Dr Roskrow as its chief medical officer in 2010 and promoted her to chief executive officer in 2011 replacing Daniel Devine (BD: May 26, 2011).

Patrys chairman John Read said that it was "with regret that we have today accepted Marie's resignation".

"Under Marie's stewardship the company has made significant progress in meeting its clinical objectives and advancing its novel platform of natural human antibodies for the treatment of cancer," Mr Read said.

Patrys said that Dr Roskrow would continue in the role until the end of 2014 during which time the board would begin a search for a replacement.

Patrys fell 0.1 cents or 4.8 percent to two cents with 4.4 million shares traded.

ISONEA

On the second page of a four page letter to shareholders, Isonea says that chief executive officer Stephen Tunnell has resigned and Greg Tunny has been appointed.

Isonea said that Mr Tunny was a former managing director of the France-based Thales ATM (Australasia) and the former managing director of the Australian Submarine Corporation Pty Ltd.

In February, Isonea replaced its board and management, appointing Leon L'Huillier as chairman with Bruce Mathieson and John Ribot-de-Bresac as directors, and promoted the head of operations Mr Tunnell to managing director (BD: Feb 5, 2014).

Last year, Isonea said chief executive officer Michael Thomas would depart from the company in 2014 and in January said that chairman Dr Stewart Washer had resigned with Ross Haghighat promoted to chairman, director Jerry Korten appointed chief executive officer and Dr Tim Oldham appointed as a director (BD: Nov 13, 2013; Jan 19, 2014).

Today, Isonea said it had a new supplier partnership with information technology firm Two Bulls Holdings and had hired marketing company the Wall Partnership.

Isonea said it had "one overarching step to be in put in place to establish an effective pathway for commercialization and value creation ... [it] needs to more effectively collaborate with leading clinicians, health care professionals and peak asthma bodies that are dedicated to addressing the need for a comprehensive approach to managing asthma".

The company said it had "reduced the excessively high cash burn and achieved more robust internal systems and controls" and consolidated the intellectual property management and oversight to Australia.

Isonea said that the Airsonea devices were "symptom monitors rather than a diagnostic tool".

"Our technology will not predict an asthma attack as suggested previously as part of the company's mission".

Isonea said it was holding productive discussions with a major Australian pharmacy chain for an exclusive arrangement for its pilot and subsequent Australian launch.

Isonea fell half a cent or five percent to 9.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed David Carter and Dr Lindsay Wakefield as non-executive directors.

Genetic Technologies said that Mr Carter was a company director, corporate lawyer and adviser and was currently a director of Thorn Group and the Group's immediate past chair, along with Glutagen Pty Ltd; and Incapital Pty Ltd and was formerly a director of Vencorp, Azure Healthcare and Diabetes Australia Victoria.

The company said that Mr Carter held a Bachelor and Masters of Law from Monash University and a Bachelor of Civil Law from Oxford University.

Genetic Technologies said that Dr Wakefield was the founder of the material handling and lifting equipment company Safetech in 1985 and in 1993 left medicine to become the full-time chief executive officer of the company.

The company said that in 2013, Safetech became Safetech Tieman Solutions Australia's largest manufacturer and supplier of dock equipment, freight hoists and custom lifting products, with Dr Wakefield continuing as managing director.

Genetic Technologies said that Dr Wakefield held Bachelor of Medicine and Bachelor of Surgery degrees from Monash University.

Genetic Technologies was untraded at 2.7 cents.

ACRUX

Acrux says that chief financial officer and company secretary Tony Di Pietro has resigned and will be replaced by Sharon Papworth effective from September 29, 2014.

Acrux climbed 6.5 cents or 5.2 percent to $1.305 with 968,970 shares traded.