Biotech Daily

Wednesday July 29, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: POLYNOVO UP 11%, ANALYTICA DOWN 12.5%**

*** SIEMENS FDA 510(K) TRIGGERS $1.4m FOR UNIVERSAL BIOSENSORS**

*** FDA APPROVES USCOM TARGET THOR SPIROMETER**

*** NSW GRANTS MEDLAB CANNABIS RESEARCH LICENCE**

*** LIVING CELL RESPONDS TO ASX AWARE QUERY**

*** NEUREN WINS EMA ORPHAN FOR TROFINETIDE FOR RETT, FRAGILE X**

*** BIOTECH DAILY APPENDIX 4C QUARTERLY REPORTS POLICY**

*** AVITA HAS ONE QUARTER CASH, $20m RAISING**

*** UBS AG 'RETURNS', BUYS, SELLS BELOW 5% OF SIRTEX, AGAIN**

*** GI DYNAMICS REQUESTS ENDO TRIAL TRADING HALT**

*** GORDAGEN APPOINTS GREGORY MACOSKO US-BASED DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.71 percent on Wednesday July 29, 2015 with the ASX200 up 39.5 points to 5,624.2 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and two were untraded. All three Big Caps were up.

Polynovo was the best, up 1.1 cents or 11.1 percent to 11 cents with 145,409 shares traded. Biotron climbed 8.25 percent; Anteo and Oncosil were up more than four percent; Actinogen, Prana and Universal Biosensors were up more than three percent; Impedimed, Osprey and Reva rose more than two percent; with Avita, Clinuvel, CSL, Neuren and Resmed were up more than one percent.

Analytica led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with 446,667 shares traded. Antisense lost 8.6 percent; Ellex and Genetic Technologies shed more than six percent; IDT and Tissue Therapies fell more than five percent; Benitec and Bionomics fell more than four percent; Acrux, Prima and Uscom were down more than three percent; Admedus, Living Cell and Starpharma shed more than two percent; with Viralytics down 1.3 percent.

UNIVERSAL BIOSENSORS

Universal Biosensors says that Siemens Healthcare lodging a 510(k) submission to the US Food and Drug Administration triggers a $US1 million ($A1.36 million) payment.
Universal Biosensors said that the milestone would be the fourth of six under its collaboration agreement for the Xprecia Stride coagulation system point-of-care test, with the Munich, Germany-based Siemens Healthcare Diagnostics.
The company said that the Xprecia Stride was a prothrombin time, international normalized ratio (PT-INR) testing system that incorporated its electro-chemical sensing technology, for “high performance and ease-of-use in a handheld format” to monitor the application of the anti-coagulant therapy, warfarin.
Universal Biosensors said that the Siemens submission followed the launch of the Xprecia Stride coagulation system (BD: May 14, 2015).
Universal Biosensors chief executive officer Paul Wright said it was “another important milestone for both Universal Biosensors and Siemens”.
“We are confident that the Xprecia Stride coagulation system will be well-received in the US point-of-care market, which represents almost half of current worldwide demand for PT-INR testing,” Mr Wright said.
Universal Biosensors said that up to 10 million patients globally were taking warfarin for the treatment of blood clots in the veins or heart conditions which increased the likelihood of a potentially life-threatening clot forming and required frequent testing to assess the clotting tendency of their blood.
The company said that the PT-INR test allowed physicians to adjust patient doses for diet and lifestyle changes.
Universal Biosensors was up one cent or three percent to 34 cents.

USCOM

Uscom says the US Food and Drug Administration has approved Spirothor digital ultrasonic spirometers as equivalent to predicated class II diagnostic spirometers.
Uscom said that it had an agreement to purchase Thor operations and intellectual property, subject to completion of satisfactory due diligence.
Last week, Uscom said it had placed $1.55 million with a further $400,000 expected from a share purchase plan to acquire Hungary’s Thor Laboratories (BD: Jul 20, 2015).
Today, the company said that Thor manufactured a range of high accuracy digital ultrasonic spirometers for the specialized measurement and monitoring of lung function and lung therapy, with particular application in asthma and chronic obstructive pulmonary disease (COPD) and emerging applications in sleep medicine.
Uscom said that Thor was a cash flow positive medical device manufacturer with current annual revenues of about $500,000 and its devices already had Conformité Européenne (CE mark) and Australian Therapeutic Goods Administration approvals.
Uscom executive chairman Prof Rob Phillips said that “products are profit and the FDA approval of the Thor ultrasonic spirometers provides great commercial opportunity for Uscom to expand into the US market”.
“One person dies from COPD every four minutes in the US and asthma continues to increase world-wide as air quality deteriorates,” Prof Phillips said. “There are a number of different technologies applied to spirometry, but digital Doppler ultrasound is considered the most accurate and the Thor products are class leading.”
“This acquisition and FDA approval, now allows us to deliver practice leading devices into the lucrative US cardiac, vascular and pulmonary markets,” Prof Phillips said.
Uscom fell half a cent or 3.2 percent to 15 cents.

MEDLAB CLINICAL

Medlab says that the New South Wales Government has granted a research licence for the use of medical cannabis.

Medlab said that it operated a certified biologics laboratory facility in Sydney and its research on cannabis would be for therapeutic purposes, including development of an alternative method of administration of cannabis, for example buccal, or through the mouth gums or cheeks, delivery.

The company said its research would broadly encompass pain management as well as other medical conditions for varying age groups and it intended to use its Nanocelle small particle delivery platform for therapeutic cannabis applications.

Medlab was up one cent or 5.4 percent to 19.5 cents with 1.3 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell has told the ASX that it made a decision on the afternoon of Friday June 12, 2015 to announce its NTCell for Parkinson's disease results the following Monday.

The ASX 'Aware Query' asked: "When did the company first become aware of the information?"

Living Cell said: "At 4:20pm New Zealand time on Friday June 12, the company's disclosure committee … determined that there was sufficient certainty regarding the NTCell clinical study results to permit an ASX announcement to be released on Monday June 15".

An ASX spokesman told Biotech Daily that the word "aware" as used in an ASX Aware Query did not mean when the company first became aware of the information, but when it deemed it was aware of the information "such that it needs to be disclosed".

The company said on June 15 that its four-patient phase I/IIa study of NTCell for Parkinson's disease met its primary endpoint of safety, and "improved clinical features of Parkinson's disease" (BD: Jun 15, 2015).

The ASX Aware Query did not cite changes to the company's share price, but the Living Cell share price and volume chart shows an increase in closing share price at low volumes from 6.1 cents on June 11 to 6.6 cents on June 12 and then a spike with stronger volumes to a high of 8.2 cents and a close of 7.4 cents on June 15, 2015, with 11.1 million shares traded.

The ASX asked Living Cell whether it considered the information in the announcement to be information that a reasonable person would expect to have a material effect on the price or value of its securities, to which the company said "Yes".

The ASX asked: "If the answer to question 1 is 'yes' and the company first became aware of the information before the relevant date, did the company make any announcement prior to the relevant date which disclosed the information?"

Living Cell said it "did not make any announcement prior to June 15 which disclosed the information".

"The information was not released to the market at an earlier time as the company planned to release the announcement to ASX on June 15, so that this would occur after trade in the company's [American depository receipts] had ceased on [the US Over-The-Counter Quality Exchange] on June 12, so as not to pre-empt trade on ASX, and prior to the release of the results to the Congress of Parkinson's Disease Movement Disorders in California," Living Cell said. "At the time, the company did not consider that it was obliged to release the information any earlier."

The company said it was in compliance with the Listing Rules.

Living Cell fell 0.1 cents or 2.1 percent to 4.6 cents.

NEUREN PHARMACEUTICALS

Neuren says the European Medicines Agency has recommended that orphan designation be granted for trofinetide (NNZ-2566) for Rett and Fragile X syndrome.

In 2013, the US Food and Drug Administration granted orphan drug designation for NNZ-2566 for Fragile X syndrome and earlier this year granted orphan drug designation for trofinetide for Rett syndrome (BD: Oct 30, 2013; Feb 16, 2015).

Today, Neuren said it expected the European Commission would provide formal confirmation of the designations in August 2015.

The company said that orphan designation in the EU enabled sponsors to benefit from incentives, including 10 years of market exclusivity once the medicine is on the market, and during the exclusivity period, the EMA and the EU member states would not accept another application for a marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product.

Neuren said that it recently attended “a highly productive meeting with the FDA to discuss the remaining development requirements for trofinetide in Rett syndrome”.

The company said that the meeting “provided meaningful guidance for Neuren in all areas of the development program” including guidance on efficacy endpoints for pivotal clinical trials, the requirements for phase III trials and the testing of trofinetide in subjects younger than age 16.

Neuren said the FDA committed to reach agreement quickly on the primary efficacy endpoint for a pivotal trial for Rett syndrome, with Neuren to propose a subset of items from the clinician completed motor behavior assessment (MBA), which was used in its phase II trial and had been used to assess more than 1,100 children, adolescents and adults in the US National Institutes of Health-sponsored Rett Natural History Study.

Neuren said that generally, two phase III clinical trials were required to support approval of a new drug application in the US, but for rare diseases it might be acceptable to design a single phase III trial to collect sufficient evidence of safety and efficacy and the FDA agreed that Neuren would submit a design proposal to the FDA for a single phase III trial.

Neuren said it “received encouragement to conduct a brief paediatric tolerability clinical trial in which higher doses of trofinetide will be tested in subjects below the age of 16” which would enable it to confirm the optimum doses for the phase III trial, as well as generating information on the treatment of children and younger adolescents.

The company said its phase II trial tested adults and adolescents aged 16 years and older (BD Nov 12, 2014).

Neuren said it was well-funded, with cash reserves at June 30 2015 of $17.7 million and the board would consider all options for progressing the phase III development as quickly and efficiently as possible.

Neuren chief science officer Larry Glass said that trofinetide had “demonstrated an excellent safety and tolerability profile, with evidence of a pattern of clinical benefit across the broad phenotype of Rett syndrome, which is consistent with its normalising effects on brain biology”.

Neuren said it had completed enrolment of 72 subjects in its US phase II trial of trofinetide for adults and adolescents with Fragile X syndrome, with the last patient due to complete the trial at the end of September and top-line results in December 2015.

Neuren executive chairman Dr Richard Treagus said that following the FDA meeting “we now have a pathway towards a new drug application for Rett syndrome … [and] have secured the important commercial incentive of orphan designation in the European Union for both indications”.

Neuren was up 0.1 cents or 1.1 percent to 8.9 cents.

BIOTECH DAILY APPENDIX 4C REPORTS

Biotech Daily reports all the significant announcements to the ASX.
Biotechnology companies bleeding money is not news, unless the company involved has less than two quarters of cash.
When companies clearly explain that they have equity draw-down facilities or loans or are about to have a capital raising, Biotech Daily will not report their Appendix 4C statement.
Where there is no explanation or it is not clear and the company has less than six months of cash reserves, it will be reported, as will maiden revenues or profits.
Companies reporting after the close of business will be reported in the following edition.

David Langsam, Editor

AVITA MEDICAL

Avita says its net operating cash burn for the three months to June 30, 2015 was $2,356,000 with cash at the end of the quarter of $2,967,000.
Last week, in a notice of general meeting Avita said that shareholders would vote to raise $20 million to list on either the Nasdaq of the New York Stock Exchange in 2016 and support a new US commercialization direction (BD: Jul 23, 2015).
Avita was up 0.1 cents or 1.1 percent to 9.1 cents.

SIRTEX MEDICAL

The Singapore-based UBS AG and related bodies corporate say they have again reduced their shareholding in Sirtex to below the five percent substantial level.
Yesterday UBS said it had increased to 2,875,242 shares or 5.03 percent with more than 160 separate trades, including single share trades, bought, sold, borrowed and returned and held for various custodians with the “power to control disposal over shares pursuant to stock borrowing and lending activities” (BD: Jul 28, 2015).
Today, UBS said that in 35 trades on July 24 it reduced its overall holding below the five percent threshold, saying it sold and bought shares as well as “returned” stock and collateral, with about half the trades for one to six shares at a time.
In March, UBS AG became substantial in Sirtex with 3,028,395 shares (5.36%), but a week later said it had reduced below five percent (BD: Mar 20, 27, 2015)
Sirtex was up 19 cents or 0.6 percent to $30.90 with 136,262 shares traded.

GORDAGEN PHARMACEUTICALS

Gordagen says it has appointed the US-based Gregory Macosko as a director, effective from August 1, 2015.
Gordagen said that Mr Macosko had “a long, established career in the financial industry and experience serving as a board member for companies in the biotechnology and sports nutrition space”.
The company said that Mr Macosko was currently a director of Montrose Advisors and was also a business advisor to the directors of California’s Bioxiness Pharmaceuticals, Gordagen said that Mr Macosko was previously a director of the Colorado-based Musclepharm sports nutrition company.
The company said Mr Macosko held a Bachelor of Arts from the Michigan’s Albion College and held a Masters of Business Administration from New York’s Columbia University.
Gordagen said that with Mr Macocko’s appointment the board consisted of five directors of which three were non-executive and independent.
Gordagen is a private company.

GI DYNAMICS

GI Dynamics has requested a trading halt “pending the release of an announcement regarding [its] Endo trial”.
Trading will resume on July 31, 2015 or on an earlier announcement.
GI Dynamics last traded at 13.5 cents.