



Biotech Daily

Monday June 23, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ACRUX UP 11%, UNIVERSAL BIOSENSORS DOWN 9%**
- * **LIVING CELL RESUMES PHASE I/II NTCELL PARKINSON'S TRIAL**
- * **USCOM MANUFACTURES 1st BP+ UNITS IN SYDNEY**
- * **PHARMAUST SCREENS CANCER PATIENTS IN PHASE I/II PPL-1 TRIAL**
- * **SIMAVITA COMPLETES \$3m PART 1 OF CAPITAL RAISING**
- * **CIRCADIAN WINS \$245k 1st QUEENSLAND BIOPHARMACEUTICALS GRANT**
- * **ACUVAX TO RAISE \$600,000**
- * **COURT ORDERS CBIO OFFICERS TO PAY INVION \$1.3m**
- * **ISONEA CLOSE TO US APPROVAL FOR SONOSENTRY (WHEEZEOMETER)**
- * **VIRAX APPOINTS GROUND ZERO FOR GGTI-2418 US IND**
- * **BIONOMICS REQUESTS 'COMMERCIAL TRANSACTION' TRADING HALT**
- * **STEVEN KRITZLER BELOW 5% IN NANOSONICS**
- * **SAFETY MEDICAL SWAPS BRAZILIAN GOLD MINE FOR 3D PRINTING**
- * **NEUREN APPOINTS DR CLIVE BLOWER TO PRODUCT DEVELOPMENT**

MARKET REPORT

The Australian stock market climbed 0.62 percent on Monday June 23, 2014 with the S&P ASX 200 up 33.8 points to 5,453.3 points. Nine of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and two were untraded.

Acrux was the best, up 11 cents or 10.95 percent to \$1.115 with 3.4 million shares traded. Analytica, Circadian and Mesoblast climbed more than four percent; Ellex, Medical Developments and Phosphagenics were up more than three percent; Benitec was up 1.3 percent; with Cochlear, CSL and Starpharma up less than one percent.

Universal Biosensors led the falls, down two cents or 9.3 percent to 19.5 cents with 704,819 shares traded. Patrys lost 9.1 percent; Avita and Optiscan fell more than eight percent; Uscom and Prana shed more than six percent; GI Dynamics lost 5.5 percent; Atcor and Psivida fell more than four percent; Nanosonics was down 3.1 percent; Anteo, Impedimed, Neuren and Prima shed more than two percent; with Alchemia, Clinuvel, Osprey, Pharmaxis, Resmed and Tissue Therapies down more than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says it has New Zealand regulatory approval to resume recruitment of the remaining three patients in its phase I/IIa clinical trial of NTCell for Parkinson's disease.

The trial of the encapsulated pig brain choroid plexus cells was paused in December last year following the withdrawal from publication of a rat study (BD: Dec 19, 2013).

The first patient was implanted in September 2013 and in November the independent data safety monitoring board approved three more patients (BD: Sep 20, Nov 25, 2013).

Living Cell acting chief executive and NTCell program director Dr Ken Taylor said the trial was "an initial step in progressing NTCell to commercialization as the first disease modifying treatment for Parkinson's disease".

The company said that existing treatments addressed the symptoms rather than attempting to regenerate the affected brain cells.

"We also intend to further investigate the potential of our patented cell therapy as a treatment for other neurodegenerative disorders," Dr Taylor said.

Living Cell said that pre-clinical studies which confirmed that NTCell initiated nerve growth supported the development of NTCell as a potential treatment for other neurological diseases such as Huntington's, motor neuron and Alzheimer's diseases.

Living Cell was unchanged at 5.3 cents.

USCOM

Uscom says it has manufactured the first of 180 Uscom BP+ central blood pressure and pulse pressure wave analysis units at its head office in Circular Quay, Sydney.

Uscom said that the first production run of 180 BP+ units was the final step in the acquisition and integration of Pulsecor assets announced in 2013 and the first step in the sales and marketing of the Uscom BP+ (BD: Jun 18, 2013).

The company said the acquisition involved the transfer of ownership of all Pulsecor assets, application for and granting of regulatory approvals, development of manufacturing specifications and processes and assembly of components into the first device.

Uscom said that the BP+ had both Conformité Européenne (CE) mark and US Food and Drug Administration 510K status.

Uscom executive chairman Dr Rob Phillips said the production was "a significant milestone for Uscom and a success story for the Australian medical device industry".

"Uscom now owns and manufactures within Australia two practice-leading, non-invasive cardiovascular technologies being exported and sold into global markets," Mr Phillips said
Uscom fell 1.5 cents or 6.1 percent to 23 cents.

PHARMAUST

Pharmaust says the screening of patients for recruitment and treatment has begun for its Royal Adelaide Hospital phase I/II trial of PPL-1 for cancer (BD: Apr 15, May 19, 2014).

Pharmaust said the principal investigator was Prof Michael Brown, IDT's CMax was managing clinical services, with analytical services by CPR Pharma Services,

Pharmaust executive chairman Dr Roger Aston said that as PPL-1 had "potential value in diverse cancers, recruitment will include selection of patients suffering from the major cancers including lung, pancreas, oesophageal, gastric, colorectal, ovarian, breast, prostate, liver, sarcoma, lymphoma, and melanoma [and] consequently, we are hoping the first patients will be enrolled shortly".

Pharmaust was unchanged at one cent with 6.4 million shares traded.

SIMAVITA

Simavita says it has raised the first \$3,099,003 tranche of its \$9.6 million capital raising at 45 cents a share and Chess depositary interest (BD: Jun 19, 2014)

Today, Simavita said that the funds would accelerate the roll-out of its incontinence management systems in the US and Europe, accelerate its internet cloud compatible product Generation 5 product as well as the home-based product, appoint distributors to roll-out the Generation 4 product in Europe, acquire and develop complimentary intellectual property and for general working capital purposes.

Simavita fell three cents or 6.1 percent to 46 cents with 1.1 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian says that wholly-owned subsidiary Opthea has been awarded \$245,150 grant from Queensland's Biopharmaceuticals Australia to manufacture OPT-302.

Circadian said the State Government's Biopharmaceutical Development Fund grant was announced by the Queensland Science Minister Ian Walker at the BIO 2014 convention in San Diego California.

The company said that OPT-302 was being developed for the treatment of wet age-related macular degeneration.

Circadian said that Biopharmaceuticals Australia intended to foster Queensland's and Australia's biopharmaceutical industry sector by providing assistance to companies and institutes to offset the costs of biopharmaceutical manufacturing at the Patheon Biologics (formerly DSM Biologics) facility in Brisbane.

Circadian said that Opthea would the funding would go to the initial scale-up manufacturing of OPT-302.

Biopharmaceuticals Australia chief executive officer Dr David Hughes said the Fund "looks to reduce the risk of projects, like Opthea's, being delayed due to the significant costs associated with manufacturing bio-drugs".

Circadian chief executive officer Dr Megan Baldwin said the company was pleased to be the first beneficiary of the initiative.

"The grant provides significant, non-dilutive funding to validate the manufacture of OPT-302 at scale," Dr Baldwin said. "We remain on track to commence clinical studies in the first half of 2015."

Circadian said that OPT-302 was a soluble receptor that blocked vascular endothelial growth factor C and D and inhibited the hallmarks of wet age-related macular degeneration in preclinical models, including blood vessel growth and vessel leakage.

The company said that wet age-related macular degeneration was the leading cause of blindness for people over the age of 50 years in the US and Europe.

Circadian was up one cent or 4.55 percent to 23 cents.

ACUVAX

Acuvax says it expects to raise \$600,000 through the placement to sophisticated and professional investors of 1,200,000,000 shares at 0.05 cents a share.

Acuvax said that intended to place 340,000,000 shares under its 15 percent capacity to raise \$170,000 and would call a shareholder meeting by August 2014 to seek approval to place up to 860,000,000 shares to raise a further \$430,000.

The company said the funds would be used for the current business, provide funding to allow the company to seek re-quotations on the ASX; and investigate opportunities.

Acuvax was suspended and last traded at 0.1 cents.

INVION (FORMERLY CBIO)

Invion says that a Supreme Court of Queensland subsequent judgment orders former officers to repay the company \$1,306,283, including interest (BD: Jun 4, 2014).

Invion said that the defendants were ordered to pay Invion's costs, including reserved costs, on an indemnity basis.

Queensland Supreme Court documents named former executive chairman Stephen Jones, former chief executive officer Jason Yates, former chief financial officer James Greig and former company secretary Benjamin Graham as the defendants in the matter.

The company said that the proceedings related to the resignations in October 2011 of the officers and payments made to the officers, which Invion alleged were in breach of the defendants' fiduciary duties to the company and contravened the statutory duties imposed by sections 180, 181 and 182 of the Commonwealth Corporations Act 2001.

Invion fell 0.7 cents or 8.6 percent to 7.4 cents with one million shares traded.

ISONEA

Isona says that following a request for a supervisory review by the US Food and Drug Administration it will make label-related changes to its Sonosentry device.

Isona said the Sonosentry was designed to replace the Wheezeometer portable acoustic device for measuring and recording wheeze rate.

The company said that the Sonosentry device used a sensor head, acoustic respiratory algorithms and a liquid crystal display (LCD) screen and was suitable for marketing in markets and market segments where smart phone penetration, or use, was relatively low. Isona chairman Leon L'Huillier said "the new board that assumed office in February 2014 is pleased with this outcome as FDA approval was one of its near term objectives outlined to shareholders in the director's report announced to ASX on 28th February 2014."

Isona was up one cent or 3.9 percent to 26.5 cents with 2.9 million shares traded.

VIRAX HOLDINGS

Virax says it has appointed Ground Zero Pharmaceuticals for its US investigational new drug application for cancer drug candidate GGTI-2418 (BD: Mar 17, 2014).

Virax said that the Irvine, California-based Ground Zero provided strategic and tactical guidance with a particular emphasis on investigational new drug (IND) application submissions to the US Food and Drug Administration.

The company said that GGTI-2418 was a novel, first in-class peptidio-mimetic inhibitor with the ability to block the cancer growth enzyme geranylgeranyltransferase type 1 (GGTI) and also blocked the in cancer cells, which acted as oncogenic survival pathways. Virax managing director Dr Robert Crombie said the appointment paved the way for the drug candidate to move toward further clinical trials.

"The IND review and allowance process is an integral part of the development of a new drug candidate and we are eager to get this process underway and understand the expectations we need to fulfill moving forward," Dr Crombie said.

Virax said it would be required to provide manufacturing data, a clinical protocol, an investigator's brochure to guide the principal investigator, animal pharmacology and toxicology data, clinical safety and efficacy data to date and a clinical development plan.

The company said that Ground Zero would produce an FDA regulatory pathway report, which would be considered before a new clinical study could be conducted.

Virax was unchanged at 0.7 cents with 4.6 million shares traded.

BIONOMICS

Bionomics has requested a trading halt “pending an announcement ... regarding a significant commercial transaction”.

Trading will resume on June 25, 2014 or on an earlier announcement.

Bionomics last traded at 43.5 cents.

NANOSONICS

The Sydney-based Steven Kritzler says he has reduced his substantial holding in Nanosonics from 13,651,439 shares (5.19%) to 10,651,439 shares (4.04%).

Mr Kritzler said he sold 3,000,000 shares for \$2,400,000 or 80 cents a share.

Nanosonics fell 2.5 cents or 3.1 percent to 78.5 cents.

SAFETY MEDICAL PRODUCTS

Safety Medical says it has a heads of agreement to acquire 3D Medical commercializing and integrating 3D printing and holographic projection technology.

Safety Medical said the application of the two technologies to medicine had “the potential to revolutionize patient treatment and care, by providing healthcare professionals with more meaningful information and greater insight into the complexities of patient anatomy”.

The company said the acquisition was “a very positive step” for the company and offered potential for significant increase in shareholder value over the medium to long term.

In 2012, Safety Medical said it would allow its syringe patents to lapse and would go gold mining in Brazil (BD: Jun 15, 2012).

Safety Medical was up 0.2 cents or 100 percent to 0.4 cents with 86.7 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has appointed Acrux’s Dr Clive Blower as product development and technical affairs, vice-president, effective from August 25, 2014.

Neuren said that Dr Blower was currently Acrux’s chief operating officer and had been a member of that company’s senior management team for seven years.

Neuren said that Dr Blower was directly responsible for the chemistry, manufacturing and controls aspects of the development of Axiron through to submission of a marketing application to the US Food and Drug Administration, as well as the establishment of commercial product supply.

The company said that Dr Blower had more than 20 years experience in all stages of drug development, from concept through to commercialization.

Dr Blower’s LinkedIn page said that he previously was Hospira’s injectables development manager, a senior executive at Mayne Pharma and Faulding Pharmaceuticals for 18 years and held a Bachelor of Science and Doctorate of Philosophy in chemistry from Monash University.

Neuren said the appointment supported its strategy “to optimize the technical attributes, manufacturing process and commercial product supply of its lead drug NNZ-2566 as it progresses towards the final stages of development”.

Neuren fell 0.2 cents or 2.4 percent to eight cents with 2.2 millions shares traded.

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