Biotech Daily

Tuesday May 31, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: LIVING CELL UP 8%, VIRALYTICS DOWN 8%**

*** NANOSONICS: 'TROPHON MEETS SCOTLAND NHS GUIDELINES'**

*** ALLAN GRAY TAKES MORE PROFIT TO 6.5% OF NANOSONICS**

*** BARDA $3.4m FOR POLYNOVO NEXT STEP IN BTM FOR BURNS TRIAL**

*** AVITA STARTS REGENERCELL DIABETIC FOOT ULCER TRIAL**

*** IMMURON RIGHTS OFFER FOR $6m**

*** TASMANIA UNI LICENCES EMTIN FOR ALZHEIMER'S TO ALZHYME**

*** FEDERAL $1.4m GRANT FOR ATOMO DENGUE, CHIKUNGUNYA TEST**

*** VOLPARA REVENUE UP 31% TO $2.3m, LOSS UP 95% TO $4.2m**

MARKET REPORT

The Australian stock market fell 0.54 percent on Tuesday May 31, 2016 with the ASX200 down 29.4 points to 5,378.6 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, 12 traded unchanged and one was untraded.

Living Cell was best, up 0.4 cents or 7.8 percent to 5.5 cents with 118,000 shares traded.

Compumedics climbed five percent; Admedus and Polynovo were up more than four percent; Factor Therapeutics was up three percent; Acrux and Ellex rose more than two percent; Medical Developments, Mesoblast, Psivida and Universal Biosensors were up more than one percent; with Cochlear, Pro Medicus and Reva up less than one percent.

Viralytics led the falls, down 7.5 cents or 7.9 percent to 87.5 cents, with 329,974 shares traded, followed by Atcor down 7.1 percent to 13 cents with 421,159 shares traded.

Anteo and Avita fell more than four percent; Bionomics, IDT and Pharmaxis were down more than three percent; Clinuvel, Prana, Prima and Uscom shed more than two percent; Impedimed and Nanosonics were down more than one percent; with CSL, Resmed and Sirtex down by less than one percent.

NANOSONICS

Nanosonics says its Trophon EPR ultra-sound probe disinfectant system meet all criteria in new Scotland National Health Service guidelines.

Nanosonics said that the new guidance followed a survey carried out by Health Facilities Scotland on current decontamination practices and concluded that “there is an ongoing risk to patient safety with regard to decontamination of semi-invasive ultrasound probes”.

The company said that the guidelines required high level disinfection after all semi-critical ultrasound procedures and specified a range of criteria for disinfection system purchase, including efficacy, safety of use, probe compatibility, process validation and costs.

“The Trophon EPR meets the full range of criteria outlined in the guidelines,” Nanosonics said.

Nanosonics chief financial officer McGregor Grant told Biotech Daily that previously Scotland did not have any guidelines for decontamination of ultrasound probes and the new guidelines included the use of ultraviolet light, hydrogen peroxide and manual wipes.

The Trophon EPR uses nebulized hydrogen peroxide as its cleansing product.

The company said that the ultrasound probe decontamination guidelines, highlighted the risks of cross-contamination associated with the use of ultrasound probes and supported the requirement for high level disinfection of semi-invasive ultrasound probes for trans-vaginal and trans-rectal probes, as well as non-invasive probes used on broken skin.

Nanosonics said that there was “a wealth of peer reviewed, published evidence demonstrating the efficacy of the automated Trophon system including, most importantly, a recently published paper showing that Trophon is the only [high level disinfection] system to kill high-risk, cancer causing human papillomavirus”.

The company said that other systems could not make that claim as they had not been tested on real, natural, infectious human papillomavirus.

Nanosonics said that the Trophon system protected operators with its fully-closed design and disinfectant cartridges that remained sealed until they were inside the device.

The company said that in addition to system process validation, an independent chemical indicator delivers further validation that decontamination cycles were successful.

Nanosonics said that the Trophon system was also validated with more than 1,000 probes from all major and many minor probe manufacturers and “no other [high level disinfection] system has undergone such extensive validation with probe manufacturers”.

The company said that Trophon was a cost-effective high level disinfection product.

Nanosonics chief executive officer Michael Kavanagh said the company was “pleased with the growing global trend where increasing numbers of guidelines stipulate the requirement for [high level disinfection] of ultrasound probes”.

“[High level disinfection] is crucial to mitigate the risks of cross infection and improve safety for both patients and healthcare staff,” Mr Kavanagh said.

Nanosonics 5.7 percent to $2.59 before closing down four cents or 1.6 percent at $2.41 with 4.9 million shares traded.

NANOSONICS

Allan Gray Australia has reduced its substantial holding in Nanosonics from 21,358,410 (7.35%) to 19,290,763 shares (6.52%).

Allan Gray said the 2,067,647 shares were sold between April 12 and May 27, 2016 for $4,729,317 or an average price of $2.29 a share.

Last month Allan Gray sold 2,933,635 shares for $5,971,521 or an average price of $2.04 a share (BD: Apr 14, 2016).

Allan Gray last bought Nanosonics shares at about 40 cents (BD: Aug 11, 2014).

POLYNOVO

Polynovo says the US Government has exercised one of two options to conduct a toxicology study in pigs on its biodegradable temporising matrix (BTM) skin repair.
Polynovo said the US Biomedical Advanced Research and Development Authority (BARDA) would pay $US2,446,000 ($A3,376,960) for the study which would map the rate that the polymer bio-reabsorbed until it was fully removed from the body, with the data supporting a pre-market application to the US Food and Drug Administration.
Polynovo said that BARDA described the biodegradable temporising matrix as “a novel device for treatment of burn injuries … specifically designed and optimized for the purpose of burn care [and] the purpose of this program is to further investigate, develop and commercialize the BTM device”.
The company said the development plan would culminate in a large multi-centre, clinical trial, to support a pre-market application submission for the BTM leading to a full scale production facility capable of supplying the US with BTM to meet a mass-casualty event.
Polynovo was up 1.25 cents or 4.8 percent to 27.5 cents with one million shares traded.

AVITA MEDICAL

Avita says the first of 24 patients has been enrolled in its UK safety and efficacy trial of Regenercell spray-on-skin for diabetic foot ulcers.
Avita said that following positive study outcomes for Regenercell for venous leg ulcers the new research opened up “a significant new indication area” (BD: Mar 9, 2016).
The company said that the diabetic foot ulcer study was being conducted at Manchester Royal Infirmary, with London’s King’s College and Northwick Park hospitals to join shortly.
Avita said that diabetic foot ulcers were a common and growing complication of diabetes and often led to amputation among the UK’s four million diabetics.
The company said that the treatment would be evaluated as an adjunct to standard care treatments, such as debridement, cleansing, dressings and offloading, with patients to be followed over a 26-week evaluation period, with the key outcome measures incidence of healing and rate of wound closure, as well as patient and physician satisfaction.
Avita said the study followed “successful patient outcomes”, indicating that the regenerative approach could be effective for treating diabetic foot ulcers and earlier work at an Italian wound clinic achieved complete wound closure for three of four diabetic foot ulcers within 50 days of treatment, with similar outcomes in patients treated in the UK.
Avita fell half a cent or 4.55 percent to 10.5 cents.

IMMURON

Immuron says it hopes to raise up to $6 million through a three-for-10 rights issue at 25 cents a share.
Immuron said that each new share would come with an attaching option, exercisable at 55 cents each within three years from the date of issue, pending shareholder approval.
The company said the capital raising was not under-written but it had commitments for $3 million from directors, major shareholders,and shortfall applicants.
Immuron said the money would fund the company to interim results from the phase II non-alcoholic steato-hepatitis trial, when 30 patients had completed the trial, which was expected by end of the year, with 25 patients having completed treatment to date.
Immuron said that record date would be June 3, the offer would open on June 9 and close on June 20, 2016.
Immuron fell six cents or 18.2 percent to 27 cents.

THE UNIVERSITY OF TASMANIA, ALZHYME PTY LTD

The University of Tasmania says that it has licenced emtin peptides for Alzheimer's disease to the Perth, West Australian-based Alzhyme Pty Ltd.

The University of Tasmania said that emtin peptides were derived from the naturally-occurring metallothionein protein which metabolizes and regulates metals in mammals and plays "a critical role in the regeneration of neural cells in the human brain".

The University said that emtin peptides had "the ability to offer protection from some of the toxic processes associated with Alzheimer's disease".

The University said that the emtin licence, represented the transfer of technology 10 years in the making, led by the School of Medicine's Prof Adrian West.

"This and related work demonstrates that emtins have significant potential to reduce the neurochemical processes associated with Alzheimer's disease and to promote regenerative growth of damaged neurons," Prof West said.

"The hope is that emtins form the basis of a new class of therapeutic compounds that are able to promote recovery from a range of neurological conditions including Alzheimer's," Prof West said.

The University's business development and technology transfer director Dr Darren Cundy said the licence would provide access to expertize and support for a comprehensive trial, in return for upfront and milestone payments.

"This class of molecule is particularly interesting as we believe it may be useful in treating a range of neurodegenerative conditions," Dr Cundy said.

Alzhyme chief executive officer Matt Liddelow said that his company invested "in a number of disease management options that will ultimately arrest the progression of this debilitating disease".

"In addition to its potential as a treatment for Alzheimer's disease and based on its neuro-regenerative capability, the emtin peptides also offer huge potential to be developed as therapeutic treatments for a number of other neurodegenerative conditions which also lack effective treatment options," Mr Liddelow said.

Alzhyme is a private company.

ATOMO DIAGNOSTICS

Atomo says it has been awarded $1.38 million from the Federal Government's Tropical Medicine Commercialisation program for tests for dengue and chikungunya viruses.

The Sydney-based Atomo's chief executive officer John Kelly said the funds would "help us deliver a much needed, easy-to-use solution for the rapid diagnosis of diseases which impact hundreds of millions of people".

The company said that half the world's population lived in areas at risk of infection from the two mosquito-transmitted viruses, which were leading causes of illness and death in the tropics and subtropics, and with no vaccines to prevent infection, early detection and treatment was critical to limit the risk of complications and death.

The company said that its all-in-one integrated rapid diagnostic tests were recognized "for their excellent usability and performance".

Atomo said that its first product Atomorapid HIV was best-in-show at the 2014 New York Medical Design Excellence Awards (BD: Jun 17, 2014).

The company said that the funds, provide through the Department of Foreign Affairs and Trade, was an "important milestone", along with an $8.3 million loan from the Global Health Investment Fund to support scale-up of its tests.

An Atomo media relations representative told Biotech Daily that the Auckland, New Zealand-based Lang Walker Group owned 27 percent of the public unlisted company.

VOLPARA HEALTH TECHNOLOGIES

Volpara says that revenue for the year to March 31, 2016, was up 30.8 percent to $NZ2,518,000 ($2,337,000) with net loss after tax up 94.5 percent to $NZ4,495,000 ($A4,171,900).

Volpara said that the preliminary final report and annual report were for the period prior to raising $10 million to list on the ASX (BD: Apr 27, 2016).

Volpara chief executive officer Dr Ralph Highnam told Biotech Daily that “90 percent of the revenue came from US sales of our breast density assessment software”.

The company said that net tangible asset backing per share increased from negative $NZ1.09 to negative $NZ1.33, with diluted loss per share up 881.8 percent from 0.11 NZ cents to 1.08 NZ cents.

The company said that it had cash and cash equivalents of $NZ277,000 at March 31, 2016 compared to $NZ3,719,000 at March 31, 2015.

Volpara was unchanged at 45 cents.