Biotech Daily

Wednesday November 21, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LBT UP 5%; NANOSONICS DOWN 6%**

*** ALLEGRA: 'FDA OKAYS SR-HT-GAHNITE SPINAL CAGE PATH'**

*** SIMAVITA RAISES FURTHER $100k, TOTAL $3.075m**

*** DORSAVI RIGHTS OFFER FOR $3.2m**

*** EU ORPHAN STATUS FOR DIMERIX DMX-200 FOR FSGS**

*** UP TO 17% DISSENT AGAINST CLINUVEL CHAIR STAN MCLIESH**

*** MICRO-X AGM PLACEMENT FACILITY FACES 12% DISSENT**

*** VANGUARD TAKES 5% OF COCHLEAR**

*** GENETIC TECHNOLOGIES TO LOSE CFO, CO SEC KEVIN FISCHER**

*** NOXOPHARM APPOINTS JOHN MOORE DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.51 percent on Wednesday November 21, 2018 with the ASX200 down 29.0 points to 5,642.8 points.

Five of the Biotech Daily Top 40 stocks were up, 20 fell, 11 traded unchanged and four were untraded. All three Big Caps were up.

LBT was the best, up half a cent or 5.4 percent to 9.8 cents with 71,500 shares traded.

Dimerix climbed 4.3 percent; Cochlear and Universal Biosensors rose more than two percent; CSL was up 1.7 percent; with Ellex, Mesoblast and Resmed up by less than one percent.

Nanosonics led the falls, down 18 cents or 5.9 percent to $2.87 with 2.4 million shares traded.

Impedimed and Prescient lost five percent or more; Avita, Neuren and Telix fell more than four percent; Osprey was down 3.45 percent; Actinogen, Clinuvel, Genetic Signatures, Immutep, Medical Developments, Orthocell and Polynovo shed more than two percent; Pharmaxis and Volpara were down more than one percent; with Cynata, Paradigm, Pro Medicus and Starpharma down by less than one percent.

ALLEGRA ORTHOPAEDICS (FORMERLY ADVANCED SURGICAL DESIGN AND MANUFACTURE)

Allegra says a November 7 meeting with the US Food and Drug Administration “clarifies our regulatory pathway” for its Sr-HT-gahnite spinal cage device.

In 2014, the then Advanced Surgical said it had licenced the Sr-HT-gahnite composite bio-compatible ceramic material from the University of Sydney for veterinary and orthopaedic indications (BD: Apr 2, 2014).

In 2016, Allegra said that a collaboration with the University of Sydney had developed a ceramic scaffold to assist regenerate bone tissue and degrade as it was replaced by natural bone (BD: Jun 8, 2016).

Allegra said at that time that University of Sydney professor of bio-medical engineering Prof Hala Zreiqat and her team used three-dimensional printing technology to developed the ceramic, composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite (a zinc-aluminium-oxide), and described as Sr-HT-gahnite.

Today, Allegra said that the Sr-HT-gahnite spinal fusion device worked to regenerate bone under spinal load conditions and was resorbed by the body, leaving the body free of foreign materials.

“In addition to being the first degradable structural porous bio-ceramic available in a medical implant, our large animal study has shown the device can achieve spinal fusion, in the absence of added bone grafts, reducing operative time while addressing clinical limitation associated with existing spinal fusion devices [for example] minimal bone integration and contribution to infection,” the company said.

Allegra said that unlike other FDA-approved devices its Sr-HT-gahnite spinal cage design did not need a large central cavity to hold a bone graft, but consisted of a network of three-dimensional-printed pores that allowed bone growth.

The company said that the FDA “indicated that a six to 12 month, large animal study will be sufficient, in order to prove the success of this device without a large central hole”.

Allegra said that the FDA would require “a small human confirmatory study” to ensure the animal results were representative of clinical benefit in the human population, and the US regulator “responded positively” to the human study taking place in Australia.

Allegra chief executive officer Jenny Swain said the meeting was “a significant milestone for Allegra, as it clarifies our regulatory pathway into the US market”.

“This first meeting with the FDA was considered a great success,” Ms Swain said.

“We are excited to start the animal study in line with FDA requirements and move into the human clinical trial,” Ms Swain said.

Ms Swain said the company was planning the clinical trial so it would address FDA, European Union and Australian Therapeutic Goods Administration regulatory requirements.

Allegra was unchanged at 22 cents.

SIMAVITA

Simavita says it has raised a further $100,000 in a placement at three cents a share, taking the total raised to $3,075,000.

In October, Simavita said it had raised $2.975 million through a $1.975 million placement at three cents per Chess depository instrument (CDI) and a $1 million convertible note facility (BD: Oct 4, 2018).

Today, the company said the funds would be used for working capital and commercialization activities in North America and Europe.

Simavita was unchanged at 2.9 cents.

DORSAVI

Dorsavi says it hopes to raise up to $3.2 million in a one-for-three, non-renounceable rights offer at 5.8 cents a share, and offer a top-up facility.
Dorsavi said that two director Dr Michael Panaccio-related Starfish funds would take-up their entitlements of about $200,000 and underwrite up-to $800,000 of the offer.
The company said the funds raised would be used for general working capital purposes.
Dorsavi said the 5.8 cents price was a 13.5 percent discount to the 15-day volume-weighted average price to November 20, 2018.
The company said the directors intended to take-up their entitlements in full and chief executive officer Dr Andrew Ronchi intended to take-up his personal entitlement but not the entitlement of the AR BSM Trust, which he controlled.
Dorsavi said the record date was November 26, the offer would open on November 28 and close on December 14, 2018.
Dorsavi was unchanged at seven cents.

DIMERIX

Dimerix says the European Commission has granted DMX-200 orphan medical product designation for the kidney disease focal segmental glomerulo-sclerosis (FSGS).
Dimerix said that FSGS was a rare disease of the kidney's filtering units, or glomeruli, causing scarring which led to kidney damage and failure.
The company said that the designation meant it had established that "the intention to treat FSGS with [DMX-200] was justified based on preliminary non-clinical data which showed a reduction in the number of podocytes lost and an improvement in proteinuria" and the European Medicines Agency had determined it had "provided sufficient justification for the assumption that [DMX-200] will be of significant benefit to those affected by the condition" and as an alternative to currently marketed products, it had a clinically relevant advantage.
Dimerix said that orphan designation provided regulatory and financial benefits to bring DMX-200 to market faster, including reduced fees during the product development phase, direct access to centralized marketing authorization and 10-year post-approval exclusivity.
The company said it was granted US orphan status in 2015 and it was conducting two phase II trials of DMX-200 for FSGS and for diabetic kidney disease. (BD: Dec 14, 2015).
Dimerix was up 0.4 cents or 4.3 percent to 9.8 cents.

CLINUVEL

Clinuvel's annual general meeting passed all resolutions but with dissent of up to 17 percent against the re-election as a director of chair Stan McLiesh.
Clinuvel said that the resolution was passed with 14,940,992 votes (83.3%) in favor and 2,987,047 votes (16.7%) against.
The company said that director Dr Karen Agersborg faced 13.4 percent dissent with the remuneration report opposed by 7.2 percent of the annual general meeting votes.
The company's most recent Appendix 3B new issue announcement said it had 47,857,986 shares on issue meaning that the opposition to Mr McLiesh amounted to 6.2 percent of the company's shares on issue, sufficient to requisition extraordinary general meetings.
In 2015 and 2017, Clinuvel's annual general meeting voted up to 17 percent against the 37.5 percent increase in the directors' remuneration pool to $550,000 and the performance rights plan, respectively (BD: Nov 24, 2015; Nov 28, 2017).
All resolutions to the 2016 annual general meeting passed easily.
Clinuvel fell 48 cents or 2.9 percent to $16.30.

MICRO-X

All resolutions at the Micro-X annual general meeting were passed, but with up to 11.8 percent opposition to the renewal of the 10 percent placement facility.
Micro-X said that 8,898,260 votes (11.8%) opposed the facility, with 66,277,184 votes (87.8%) in favor and 334,126 votes (0.4%) at the proxy's discretion.
The company said that the remuneration report, the issue of 30,000 convertible notes and the re-election of director Alexander Gosling were passed overwhelmingly.
The most recent Micro-X Appendix 3B new issue announcement said it had 144,350,698 shares meaning that the vote against the placement facility amounted to 6.2 percent of the company's shares on issue, sufficient to requisition extraordinary general meetings.
Micro-X was up three cents or 9.1 percent to 36 cents.

COCHLEAR

The Valley Forge, Pennsylvania-based Vanguard Group says it has become a substantial shareholder in Cochlear with 2,886,647 shares (5.002%).
Vanguard said the shares were acquired by it and the Melbourne-based Vanguard Investments Australia, and they bought and sold the shares in more than 150 trades between July 19 and November 16, 2018 at prices ranging from $161.28 to $219.34 each.
Vanguard said it held the shares as the manager of mutual funds and accounts and the shares were held by JP Morgan Chase Bank, Brown Brothers Harriman, Bank of New York Mellon and State Street Bank and Trust Co.
Cochlear was up $3.92 or 2.5 percent to $162.66 with 355,081 shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says that chief financial officer and company secretary Kevin Fischer has resigned and will assist a transition until the end of December 2018.
Genetic Technologies said that Mr Fischer was appointed chief financial officer on November 2, 2015 and company secretary on January 13, 2016.
The company said it thanked Mr Fischer "for his significant contribution to the company and wishes him all the best for the future".
Genetic Technologies fell 0.1 cents or 10 percent to 0.9 cents with 3.3 million shares traded.

NOXOPHARM

Noxopharm says it has appointed John Moore as a non-executive director, effective from the end of today's annual general meeting.
Noxopharm said that Mr Moore had "experience in the venture and capital markets, with a particular focus on new and emerging technologies, including the healthcare space".
The company said t Mr Moore was currently chair of the clinical trial informatics business Trialogics, as well as education finance technology provider Funderbolt and previously was chief executive officer of several technology companies, as well as a partner and chief executive officer of Edson Moore Healthcare Ventures which acquired a portfolio of 16 drug delivery investments from Elan Pharmaceuticals for $148 million.
Noxopharm fell 2.5 cents or 4.55 percent to 52.5 cents.