Biotech Daily

Monday February 17, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: COMPUMEDICS UP 27%; IMPEDIMED DOWN 9%**

*** FDA APPROVES COMPUMEDICS ORION LIFESPAN MEG**

*** MEMPHASYS: 'FELIX VALIDATION ON-TRACK FOR CLINICAL TRIAL'**

*** NUHEARA H1 REVENUE DOWN 4% TO $1.4m, LOSS UP 43% TO $5.7m**

*** PYC, MURDOCH UNI, LIONS EYE $1.2m NHMRC GRANT**

*** ZELIRA RAISES $54k, TOTAL $4.6m; RESULTS TRADING HALT**

*** ACTINOGEN RECEIVES EXTRA $650k R&D TAX INCENTIVE; TOTAL $5m**

*** CRESO MILESTONE: TO PAY MERNOVA $900k, 8.3m SHARES VEST**

*** MGC PLACEMENT, SHARE PLAN FOR $4m**

*** CANN GLOBAL TO RAISE $419k IN PLACEMENT**

*** HERAMED DETAILS MAYO MONITOR STUDY**

*** KEMPER SHAW BELOW 5% IN IMAGION**

*** RACE APPOINTS DR MARINELLA MESSINA CLINICAL PROGRAM HEAD**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Monday February 17, 2020, with the ASX200 down 5.1 points to 7,125.1 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Compumedics was the best, up 18.5 cents or 26.6 percent to 88 cents, with 2.6 million shares traded. Optiscan climbed 6.45 percent; Actinogen, Avita, Ellex, Imugene, LBT and Orthocell were up more than three percent; Cyclopharm, Immutep and Polynovo rose more than two percent; Amplia, Antisense, Neuren and Proteomics were up by more than one percent; with Cochlear, CSL and Resmed up by less than one percent.

Impedimed led the falls, down one cent or 8.7 percent to 10.5 cents with 944,557 shares traded. Pro Medicus lost 6.5 percent; Osprey was down 5.9 percent; Mesoblast, Next Science and Mesoblast fell more than four percent; Volpara was down 3.1 percent; Kazia, Nanosonics, Oncosil, Pharmaxis and Uscom shed two percent or more; Clinuvel, Cynata and Paradigm were down more than one percent; with Medical Developments down 0.45 percent.

COMPUMEDICS

Compumedics says the US Food and Drug Administration has cleared its Orion Lifespan magneto-encephalography (MEG) single Dewar system for brain mapping.

Compumedics said that MEG was a neuro-imaging technique for mapping brain activity by recording magnetic fields produced by electrical currents occurring naturally in the brain.

The company said that the FDA 510(k) clearance would allow "for routine clinical use of the single MEG device, primarily for epilepsy and pre-surgical brain function mapping".

Compumedics said that sites using the Orion Lifespan could "bill both private and public insurance plans for MEG examinations".

A Compumedics spokesperson told Biotech Daily that the company's Dewar system was a module for measuring the receptivity of brain function.

The company said the FDA approval allowed it to sell the Orion Lifespan in the US, which "typically sell for around $US3 million to $US4 million ($A4.5 million to $A6.0 million), depending on specification".

Compumedics chief executive officer Dr David Burton said the company was "pleased to have achieved this important milestone for the Orion Lifespan MEG".

"Much like MRI technology in the late 1980s which transitioned from research to clinical application, we expect MEG to follow a similar trajectory," Dr Burton said.

"In addition to the technical accomplishments achieved by the company and our partners at the Korea Research Institute of Standards and Science, it represents a foundation for the commercialization of our MEG technology," Dr Burton said."

"This market clearance will allow us to transition from product development to full commercialization," Dr Burton said.

Compumedics said that the FDA approval followed the milestone installation and first phase commissioning of the Orion Lifespan MEG at the Phoenix, Arizona-based Barrow Neurological Institute (BD: May 9, 2019).

The company said that the Orion Lifespan MEG would allow for a unique dual-helmet sensing system, with one side optimized for adult MEG recordings and the other for paediatrics, which would be installed at the Barrow Neurological Institute in coming months, with its FDA application to follow.

Compumedics climbed 18.5 cents or 26.6 percent to 88 cents, with 2.6 million shares traded.

MEMPHASYS

Memphasys says it expects to complete the verification and validation process of its Felix sperm separation device by "mid-2020", with a clinical trial to begin by October.

Earlier this month, Memphasys said that "key opinion leaders" had provided positive feedback of the Felix device, and the company had signed a key opinion leader agreement with a New Zealand-based in-vitro fertilization clinic (BD: Feb 5, 2020).

Today, the company said that the devices being used in the verification and validation process were from the same batch as the devices provided to the key opinion leaders.

Memphasys said the proposed clinical trial would test the safety and efficacy of the Felix device for Australia, the US and Europe.

The company said that it "believed commercial sales can occur on completion of the verification and initial validation phase" in Japan, India, New Zealand and Canada.

Memphasys executive chair Alison Coutts the company was "well advanced with the [verification and validation] process".

Memphasys was unchanged at 6.3 cents with 1.3 million shares traded.

NUHEARA

Nuheara says revenue for the six months to December 31, 2018 was down 3.75 percent to $1,365,966 with net loss after tax up 42.8 percent to $5,726,307.
Nuheara said it had “one-off costs during the period associated with the transition of all manufacturing from China to contract facility in Malaysia and investment in the development of new technology hardware platform”.
Nuheara chief executive officer Justin Miller said the six months had shown “that our improved retail models were scalable”.
“Significantly, increased market awareness and sales growth was achieved with our legacy products,” Mr Miller said.
Mr Miller said that with the Iqbuds Max launched, the company had “a solid foundation for growth in the second half” of the financial year.
The company said diluted loss per share was up 34.1 percent from 0.41 cents in the previous year to 0.55 cents in the six months to December 31, 2018, with net tangible assets constant down 50 percent to 0.3 cents and cash and cash equivalents of $3,541,540 at December 31, 2019, compared to of $8,080,492 at December 31, 2018.
Nuheara fell 0.1 cents or 3.45 percent to 2.8 cents.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says its collaboration with Murdoch University and the Lions Eye Institute has received a $1.2 million grant from the National Health and Medical Research Council.
PYC said that the grant was to identify new treatments for a range of blinding retinal diseases.
The company said the funds would be used to research the simulation of patient retinal cells through the use of patient skin cells and clustered regularly interspaced short palindromic repeats-activation (Crispra).
PYC said that its subsidiary, Vision Pharma Pty Ltd would use the patient skin cell and Crispra approach to accelerate the development of its retinal pipeline beyond its lead program, retinitis pigmentosa.
PYC chief executive officer, Doug Huey said that “the independent peer review and competitive nature of the NHMRC grant process is testament to the quality of work being done in this field by the collaborative group driving Vision Pharma, and we look forward to adding further treatments to our development pipeline with the aid of this funding”.
PYC was up 0.1 cents or 1.6 percent to 6.4 cents with 6.85 million shares traded.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says it will raise an additional $54,259 from foreign investors in its placement at five cents a share, for a total of $4,642,759; and has requested trial results trading halt.
Earlier this month, Zelira said it had commitments to raise $4,588,500 in a fully-subscribed placement to sophisticated investors at five cents a share (BD: Feb 5, 2020).
Today, in a separate announcement, the company said it had requested a trading halt “pending an announcement by the company in relation to interim results of its insomnia clinical trial”.
Zelira said trading will resume on February 19, 2020 or on an earlier announcement.
Zelira last traded at 5.8 cents.

ACTINOGEN MEDICAL

Actinogen says it has received an additional $653,508 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Actinogen said the rebate related to research and development expenditure for the year to June 30, 2019.
Actinogen chief executive officer Dr Bill Ketelbey told Biotech Daily that the company received an initial rebate of $$4,580,736 and had received a total payment of $5,234,244.
Actinogen was up 0.1 cents or 3.3 percent to 3.1 cents.

CRESO PHARMA

Creso says it will pay a milestone payment of $C800,000 ($A898,431) to Mernova vendors after achieving its second Mernova Medical acquisition milestone.
In 2018, Creso said it had completed the acquisition of the Halifax, Nova Scotia-based medical marijuana producer Mernova Medicinal for $C200,000 ($A201,312) and 8,300,000 Creso Canada shares (BD: Jul 27, 2017; Feb 19, 2018).
In the acquisition announcement in 2017, the company said that the second milestone involved the granting of a sales licence to Mernova under the Access to Cannabis for Medical Purposes Regulations law.
Today, Creso said that 4,150,000 Creso Canada shares would vest as part of the second milestone payment.
The company said it was “pleased with the progress of Mernova and its growing facility” and looked forward to further sales once it secured European good manufacturing practice (GMP) certification”.
Creso said that if the GMP certification was secured, it would “be one of very few [European] GMP certified producers in Canada, allowing it to export and sell to Europe, including … Germany and Switzerland”.
Creso was unchanged at 12 cents with 1.1 million shares traded.

MGC PHARMACEUTICALS

MGC says it will raise $1 million in a placement at 3.2 cents a share to a strategic investor, and hopes to raise up to $3 million in a share plan at 2.7 cents a share.
MGC said that every two shares in the share plan would come with one free attaching option, excisable at 4.5 cents by August 31, 2021.
The company said that the placement share price was the closing price on February 12 and the share plan price was a 15 percent discount to the 5-day volume weighted average price to February 12, 2020.
The company said that existing eligible shareholders at the record date of February 14 would be able to buy up to $30,000 worth of new shares in the share plan, which would open on February 19 and close on March 4, 2020.
MGC fell 0.4 cents or 12.9 percent to 2.7 cents with 10.9 million shares traded.

CANN GLOBAL

Cann Global says it will raise $418,880 in a placement of shares at 1.2 cents each to institutional and sophisticated investors.
Cann said the placement would be led by the New York-based Sea Otter Global.
The company said the funds would be used to progress its projects and working capital.
Cann Global fell 0.1 cents or 7.1 percent to 1.3 cents with 11.5 million shares traded.

HERAMED

Heramed has provided details of its 50-patient Herabeat Plus foetal and maternal heartrate monitor trial with the Rochester, Minnesota-based Mayo Clinic.
Last week, Heramed announced the trial to evaluate the use, accuracy and value of using the monitor at home but did not provide any protocol details (BD: Feb 10, 2020).
Today, Heramed said the randomized, open-label trial would initially recruit 50 low-risk pregnancy patients for eight weeks of monitoring.
The company said that after the eight-week period, patients would complete an “ease of use survey, then crossover to the alternate study product”.
Heramed said the study would be completed by March 1, 2021.
Heramed was unchanged at 16.5 cents.

IMAGION BIOSYSTEMS

The Sydney-based Kemper Shaw says he was ceased his substantial holding in Imagion.
Mr Shaw said that in three transactions between February 10 and 13, 2020 he sold 17,000,000 shares for $637,288 or an average of 3.75 cents a share.
Last year, Mr Shaw said he held 31,789,818 shares or 6.25 percent (BD: Dec 3, 2019).
Biotech Daily calculated that Mr Shaw held 14,789,818 shares or 2.89 percent of the company.
Imagion was unchanged at 2.9 cents with 6.7 million shares traded.

RACE ONCOLOGY

Race says it has appointed Dr Marinella Messina as its Australian clinical program director, effective from March 16, 2020.
Race said that Dr Messina had 10 years’ experience in managing clinical trials from phase I to IV and had worked with pharmaceuticals companies and research investigators during that time.
The company said Dr Messina had previously worked for Datapharm and Noxopharm.
Race said Dr Messina held a Bachelor of Science and Doctor of Philosophy from the University of Sydney.
Race was unchanged at 34.5 cents with 1.8 million shares traded.