Biotech Daily

Wednesday January 22, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 13.5%; IMPEDIMED DOWN 21%**

*** POLYNOVO: 1st GERMAN NOVOSORB PATIENT; 1st POLYMEDICS ORDER**

*** SIENNA: SOUTH KOREA HTERT CANCER TEST VALIDATION STUDY**

*** IMPEDIMED H1 RECEIPTS UP 17% TO $2.7m**

*** LBT RECEIVES $1.1m R&D TAX INCENTIVE**

*** REDHILL ENDS DONNATAL, ENTERAGAM DEAL FOR TALICIA, AEMCOLO**

*** ADMEDUS STARTS 1st HUMAN ADAPT AORTIC VALVE TRIAL**

*** NEUROSCIENTIFIC US PATENT FOR EMTIN TECHNOLOGY**

*** ANATARA: GARP PRECLINICAL STUDIES**

*** THC: TGA GRANTS SOUTHPORT FACILITY GMP LICENCE**

*** CRESO RENEWS EVERBLU CORPORATE ADVICE MANDATES**

MARKET REPORT

The Australian stock market was up 0.94 percent on Wednesday January 22, 2020, with the ASX200 up 66.4 points to 7,132.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and two were untraded. All three Big Caps were up.

Actinogen was the best, up half a cent or 13.5 percent to 4.2 cents, with 15.8 million shares traded. Polynovo climbed 11.0 percent; Mesoblast was up 10.2 percent; Opthea and Resonance improved four percent or more; Osprey and Paradigm were up more than three percent; Pro Medicus, Resmed, Universal Biosensors and Volpara rose two percent or more; Clinuvel, Cochlear, CSL and Nanosonics were up one percent or more; with Compumedics, Ellex, Kazia, Next Science and Starpharma up by less than one percent.

Impedimed led the falls, down 3.5 cents or 20.6 percent to 13.5 cents with 14.0 million shares traded. Amplia lost 10 percent; Patrys fell 4.8 percent; Dimerix, Genetic Signatures, Pharmaxis and Prescient were down more than three percent; Oncosil, Optiscan and Telix shed more than two percent; Antisense, Avita and Cynata were down more than one percent; with Medical Developments and Neuren down by less than one percent.

POLYNOVO

Polynovo says the first German burns patient has been treated with Novosorb biodegradable temporising matrix (BTM) and Polymedics has made its first order.
Polynovo said that the Stuttgart, Germany-based Polymedics Innovations was its distributor for Germany, Austria, Switzerland and Luxembourg (BD: Apr 29, 2019).
The company said the first patient in Germany was treated on Sunday in Germany and there were “a number of surgeons planning on using BTM this week and the coming fortnight”.
Polynovo said that at a conference in Austria last week “numerous surgeons made clear their intention to use the product in the near future”.
“That is now happening,” the company said.
Polynovo chief executive officer Paul Brennan said that Polymedics “facilitated an impressive launch and demonstrated their excellent and established relationships with surgeons and hospitals in Germany, Austria and Switzerland”.
“The enthusiasm and engagement of surgeons for Novosorb BTM is very exciting and likely to bring further product sales in the near term,” Mr Brennan said.
Polynovo chairman David Williams said that the company was “off and running in Europe”.
“When we announced our EU approval in mid-December we said we expected near term sales,” Mr Williams said.
“We have achieved that now and better still we have the first patients being treated,” Mr Williams said.
Polynovo was up 28 cents or 11.0 percent to $2.83 with 9.9 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says it has begun a clinical study in South Korea of its human telomerase reverse transcriptase (hTERT) in-vitro diagnostic for bladder cancer.
Sienna said the study was a collaboration between its exclusive South Korea distributor Mirax and Soul National University Hospital to provide further validation of the clinical utility of the test, investigating patients with symptoms linked to bladder cancer, or being monitored for bladder cancer.
The company said the study would further validate the clinical validity of the hTERT test and would enable local pathologists and urologists to access data from a Korean population sample.
Sienna chief executive officer Carl Stubbings told Biotech Daily that “Each region may have differing profiles of bladder cancer and therefore we need a local study to show the test demonstrates the same utility as in existing regions”.
Sienna was up 0.1 cents or 2.5 percent to 4.1 cents.

IMPEDIMED

Impedimed says receipts from customers for the six months to December 31, 2019 were up 17.4 percent to $2,694,000.
Impedimed said it was on track to achieve its financial year 2020 low to midrange guidance of $7.0 million to $8.5 million in revenue.
In its Appendix 4C, the company said it had cash and cash equivalents of $12,971,000 and expected a cash burn for the coming six months of $6,700,000.
Impedimed fell 3.5 cents or 20.6 percent to 13.5 cents with 14.0 million shares traded.

LBT INNOVATIONS

LBT says it has received $1,110,362 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
LBT said the rebate related to research and development expenditure for the year to June 30, 2019.
LBT was unchanged at 16 cents.

REDHILL BIOPHARMA

Redhill says it will focus on its existing products and discontinue promotion and commercialization of legacy gastrointestinal products Donnatal and Enteragam.
In 2017, Redhill said it had begun promoting Advanz Pharma Corp's Donnatal and Entera Health Entergam in the US (BD: Jun 14, 2017).
Today the company said the termination of the agreement would allow it to "focus on its lead commercial products, Talicia, formerly Heliconda or RHB-105, and Aemcolo and create capacity for additional products."
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
The combination antibiotics were developed by Prof Tom Borody who has continued as a scientific consultant to Redhill.
In November, the company said the US Food and Drug Administration had approved Talicia delayed-release capsules, for Helicobacter pylori infection (BD: Nov 5, 2019).
On the Nasdaq, Redhill fell 12 US cents or 1.96 percent to $US6.01 ($A8.78) with 173,462 shares traded.

ADMEDUS

Admedus says it will begin a 15-patient, first in-human trial of its Adapt single-piece, three-dimensional, transcatheter replacement aortic valve in Belgium.
Last year, Admedus said a sheep study of its aortic valve suggested it could be implanted safely and had potential benefits (BD: Feb 19, 2019).
Today, the company said the single arm, single-site trial at the Leuven University Hospitals would assess 15 adults with aortic valve insufficiency or stenosis, including a 26-week follow up period, for evidence of safety and performance.
Admedus said that the patients would be followed for six months with results expected by October 2021.
The company posted the trial protocols on https://clinicaltrials.com which said the primary outcomes were the mean pressure gradient across the valve, the derived effective orifice area range and the rate of thromboembolism, valve thrombosis, paravalvular leak, major haemorrhage, and endocarditis, with a further 14 secondary outcomes.
Admedus was up half a cent or 4.35 percent to 12 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has an additional US patent for its Emtin technology for Alzheimer's disease and glaucoma-induced optic nerve damage.
The US Patent and Trademark Office said the patent was titled 'Metallothionein-derived peptide fragments' and was filed on December 13, 2016.
Neuroscientific was up 2.5 cents or 15.15 percent to 19 cents.

ANATARA LIFESCIENCES

Anatara says pre-clinical studies on its gastrointestinal reprogramming (Garp) dietary supplement have paved the way for a human trial expected to begin by July 2020.
Anatara said the pineapple-stem, bromelain-based dietary supplement addressed the dysbiosis or microbial imbalance of the microbiome by inhibiting pro-inflammatory bacteria in healthy gut cells by more than 95 percent ($p = 0.002$).
The company said the supplement reduced gut inflammation by 85 percent by reducing production of pro-inflammatory proteins ($p < 0.001$) and reduced combined disease characteristics of colon inflammation and disrupted bowel habits by 2.5-fold when compared to a placebo ($p = 0.012$).
Anatara said it also promoted mucosal healing by increasing both mucin 2 oliogomeric mucus gel-forming (MUC 2) and mucin 6 oliogomeric mucus gel-forming (MUC 6) genes, by a factor of five to seven-fold ($p < 0.001$).
The company said the supplement was being developed for irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD).
Anatara was up half a cent or 1.5 percent to 34 cents.

THC GLOBAL

THC says the Australian Therapeutic Goods Administration has granted its Southport facility on the Queensland Gold Coast a licence to manufacture therapeutic goods.
Yesterday, THC requested a trading halt pending an announcement regarding “the receipt of a licence to manufacture therapeutic goods from the Australian Therapeutic Goods Administration” (BD: Jan 20, 2020).
Today, the company said it had all the licences required to begin the commercial manufacture of medical marijuana.
THC fell two cents or 4.65 percent to 41 cents with one million shares traded.

CRESO PHARMA

Creso says it has renewed mandates with Everblu for corporate advice replacing mandates agreed in July 2017.
Creso said that it would issue Everblu 2,000,000 shares and 8,000,000 options, exercisable at 20 cents each within three years, pending shareholder approval.
The company said that director Adam Blumenthal was the chairman of Everblu.
Creso fell half a cent or 2.7 percent to 18 cents with 3.3 million shares traded.