Biotech Daily

Tuesday February 20, 2018

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: PRO MEDICUS UP 8%**
- COMPUMEDICS DOWN 13%

*** UNIVERSAL BIOTECH, SERVIER $141k INNOVATION PRIZE**

*** LA TROBE, MONASH: 'AMNIOTIC SAC CELLS REDUCE STROKE DAMAGE'**

*** MRCF $7m FOR CINCERA COMPOUNDS FOR INFLAMMATION, FIBROSIS**

*** RESONANCE MRI-TEST FOR NASH**

*** MEDICAL DEVELOPMENTS, CSIRO: 'BETTER, CHEAPER LIDOCAINE'**

*** ACRUX H1 REVENUE DOWN 81% TO $2.7m, PROFIT TO $8.7m LOSS**

*** REGENEUS H1 REVENUE DOWN 96% TO $353k, PROFIT TO $3m LOSS**

*** CLINUVEL: NEW IDENTITY, WEBSITE, VALUES**

*** DIRECTOR MICHAEL STORK INCREASES, DILUTED TO 11% IN PATRYS**

MARKET REPORT

The Australian stock market slipped 0.01 percent on Tuesday February 20, 2018 with the ASX200 down 0.7 points to 5,940.9 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, four traded unchanged and six were untraded.

Pro Medicus was the best, up 61 cents or 8.1 percent to $8.10 with 98,895 shares traded.

Admedus, Immutep (Prima) and Osprey climbed more than four percent; Psivida, Telix and Uscom were up more than three percent; Medical Developments rose 2.1 percent; Optiscan and Pharmaxis were up more than one percent; with Cochlear, CSL and Nanosonics up by less than one percent.

Yesterday's 12 percent best, Compumedics led the falls, down 5.5 cents or 13.1 percent to 36.5 cents with 63,631 shares traded.

Genetic Signatures lost 8.3 percent; Impedimed was down 6.1 percent; Factor Therapeutics and LBT fell more than five percent; Opthea was down 4.55 percent; Acrux, Oncosil and Polynovo were down more than three percent; Actinogen shed two percent; Avita, Bionomics, Neuren, Starpharma and Volpara were down one percent or more; with Airxpanders, Clinuvel, Mesoblast and Resmed down by less than one percent.

UNIVERSAL BIOTECH, SERVIER

Paris-based healthcare innovation consultancy Universal Biotech says the Servier co-funded EUR90,000 ($A141,139) Innovation Prize is open for applications.
Universal Biotech said the prize was intended "to promote the most innovative projects in … healthcare to help increase their visibility among potential partners and investors".
The company said that participating in the prize provided applicants with feedback and advice from its jury members from the private and public healthcare sector.
Universal Biotech said there were three prizes worth EUR30,000 each, for biotechnology including innovative drugs, molecules and vaccines; medical technology for innovative diagnostic and medical devices and digital technology, including applications, platforms and connected devices.
The company said that the competition was open to start-ups which were less than eight years old and academic research groups currently developing an innovative project from discovery to pre-market stage.
Universal Biotech said that applicants should submit projects online by April 30, 2018, with prizes to be awarded in Paris in October.
For more information go to: https://www.universal-biotech-prize.com/.

LA TROBE UNIVERSITY, MONASH UNIVERSITY

La Trobe University says that injecting human amniotic cells discarded after birth into stroke patients can significantly reduce brain injury and aid recovery.
La Trobe University said that stroke was one of Australia's biggest killers and a leading cause of disability.
The University said that stroke was treatable but treatments were time critical and a limited number of Australians had access, with some treatments for ischemic stroke caused by a clot could only be delivered within the first few hours of a stroke.
La Trobe said that its Prof Chris Sobey and researchers from Monash University and Monash Health found that when human amnion epithelial cells, the cells lining the human amniotic sac during pregnancy and discarded after birth, were injected after a stroke the impact was less severe and recovery was significantly improved.
"If we administered human amnion epithelial cells 90 minutes after stroke the cells quickly homed-in on the affected area of the brain, greatly reducing inflammation and nerve cell death," Professor Sobey said.
"But what is particularly exciting about these new findings is that when the amniotic cells were administered as late as one or three days after stroke there was accelerated healing and long term functional recovery was still greatly improved," Prof Sobey said.
The research article, entitled 'Acute or Delayed Systemic Administration of Human Amnion Epithelial Cells Improves Outcomes in Experimental Stroke' was published in Stroke and the abstract is available at: https://www.ncbi.nlm.nih.gov/pubmed/29382802.
Prof Sobey said human amnion epithelial cells were particularly effective in cell therapy and were abundant, discarded after birth and did not require any treatment before use.
"They already contain natural immune-suppressants which means the patient's body won't reject them and they don't form tumors, both [of which are] issues with other forms of cell therapy," Prof Sobey said.
La Trobe University said that a Monash Health team led by neurology director Prof Henry Ma would begin a first-in-human trial in acute stroke patients to assess its feasibility and safety profile.
"The trial will be a great opportunity to translate this exciting research finding into clinical practice which may benefit stroke patients in the future," Dr Ma said.

CINCERA THERAPEUTICS

Cincera says the Medical Research Commercialisation Fund has committed $7 million “to develop new therapies to target conditions relating to an unhealthy Western diet”.
Cincera said that the funds would come from the Brandon Capital-managed Medical Research Commercialisation Fund 3 and the development program would target “serious and highly prevalent diseases associated with obesity” with an initial focus on treatments for non-alcoholic steatohepatitis (NASH), or fatty liver disease.
The company said that Western diets were high in saturated fats and processed carbohydrates, which could alter the abundance, in both quantity and quality, of fats in the body leading to inflammation and tissue fibrosis, or scarring, compromising function and eventual organ failure.
Cincera said it hoped to treat diseases like NASH by reducing specific toxic fats in the body, using research from Adelaide’s Centre for Cancer Biology, which was an alliance between the University of South Australia and Adelaide’s SA Pathology, Monash University’s Institute of Pharmaceutical Sciences in Melbourne.
The company said that its chief executive officer was the Monash Institute’s Prof Bernard Flynn, with Brandon Capital investment manager Dr Michael Bettess a director.
Dr Bettess told Biotech Daily that the a number of small molecule compounds targeting inflammation and fibrosis were being assessed for pre-clinical studies.
“Through the rapid assembly of initial research compounds we were able to identify the most important enzymatic targets that contribute to inflammatory and fibrotic disease and then develop drug-like lead compounds to specifically intercept these new targets,” Prof Flynn said.
The Centre for Cancer Biology’s Prof Stuart Pitson said that the collaboration had drug candidates that were “potent and broad-acting anti-inflammatory and anti-fibrotic agents that show strong potential to become new treatments”.
“There are many aspects of the disease that could be improved by these drugs from treating liver or kidney dysfunction through to possible treatments for certain cancers,” Prof Pitson said.
Dr Bettess said it was “important to lead and maintain a healthy lifestyle as diseases like NASH are often associated with poor dietary choices and therefore largely preventable”.
“However, for the many people who do suffer from this serious disorder a drug-based treatment is really their only option and needed urgently,” Dr Bettess said.
Cincera is private company.

RESONANCE HEALTH

Resonance says it has a new magnetic resonance imaging-based assessment tool for the screening of non-alcoholic steatohepatitis, or fatty liver, patients.
Resonance said that the tool had been developed to help clinicians identify those patients with non-alcoholic steatohepatitis (NASH).
The company said that NASH was “a serious manifestation” of non-alcoholic fatty liver disease with about 25 million people in the US having undiagnosed NASH, and of these, about five million were expected to develop cirrhosis and/or be diagnosed with hepatocellular carcinoma.
Resonance said that it expected the initial uptake would come from pharmaceutical companies engaged in the development of drugs to treat NASH.
The company said it would launch its test at the NASH Engage Global conference in London on February 26 to 27, 2018.
Resonance was up 0.4 cents or 18.2 percent to 2.6 cents with 1.6 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL
COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Medical Developments says it has completed a small-scale production run of the local anaesthetic lidocaine using its platform manufacturing technology.

Medical Developments chief executive officer John Sharman told Biotech Daily that the method of production was “different to the usual batch manufacture of drugs” but was unable to disclose the process, which was developed in partnership with the Commonwealth Scientific and Industrial Research Organisation.

The company said that lidocaine had worldwide sales of about $3.4 billion and was used for cardiac arrhythmia as well as a local anaesthetic for minor surgery and dentistry.

Medical Developments said the platform manufacturing technology was the same as that company used for the manufacture of its Penthrox inhaled methoxyflurane analgesic.

The company said it expected the technology to include significant cost reductions, improved consistency in terms of quality and yield, better scalability and improved safety, than that currently used to manufacture the drug.

Mr Sharman said that “having completed the small-scale production run for lidocaine, we are now thinking about manufacturing partners to fully exploit the technology”.

“This is an encouraging result for our development program and ahead of our expectations,” Mr Sharman said. “Together with the CSIRO we are continuing to work on other drug products which we believe would benefit from our technology.”

CSIRO biomedical manufacturing director Dr Paul Savage said his organization was “very excited to see that this cutting-edge manufacturing technology can be adapted to new drug molecules of great commercial significance”.

“This partnership with [Medical Developments] is critical to the CSIRO in finding a commercial pathway to market for this innovation,” Dr Savage said.

Medical Developments was up 15 cents or 2.1 percent to $7.39.

ACRUX

Acrux says that revenue for the six months to December 31, 2017 fell 80.9 percent to $2,743,000 taking last year’s net profit after tax $6,322,000 to a $8,694,000 loss.

Acrux said the fall in revenue related to a decline in Axiron sales by partner Eli Lilly due to generic competition and the termination of the Axiron licencing agreement.

The company said that the Lenzetto estradiol spray for menopause symptoms, also known as Evamist and Ellavie, was being launched in specific European Union countries by licencee Gedeon Richter but sales fell 30.8 percent from $740,000 in the previous period to $512,000 for the six months to December 31, 2017 (BD: Jan 28, 2016).

Acrux said the expenses totalled $13.1 million compared to the previous period’s $5.28 million, including a non-cash, pre-tax loss of $5.65 million in relation to the impairment of Axiron capitalized development costs and operational expenditure of $7.43 million.

The company said that the previous period’s diluted earnings per share of 0.04 cents turned to a diluted loss per share of 0.05 cents at December 31, 2017.

The company’s most recent Appendix 3B new issue announcement said the company had 166,521,711 shares on offer, implying that with a loss of $8,694,000, the loss per share was 5.2 cents not the 0.05 cents stated in the half year report, and compared with earnings per share of 3.8 cents for the six months to December 31, 2016.

The company said that net tangible asset backing per share was up 10.5 percent to 21 cents and it held cash and cash equivalents of $32,363,000 at December 31, 2017 compared to $31,718,000 at December 31, 2016.

Acrux fell half a cent or three percent to 16 cents.

REGENEUS

Regeneus says that revenue for the six months to December 31, 2017, fell 95.7 percent to $353,503, turning the previous net profit after tax to a $2,713,768 loss.
Last year, Regeneus said it received $US5.5 million ($A7.3 million) from the Tokyo, Japan-based AGC Asahi Glass as an upfront payment for the rights to manufacture Progenza and expected a further $US11 million in development and approval milestone payments and would be entitled to a share of upfront licence fees, milestone payments and royalties from sub-licencing the development and commercialization of Progenza for osteoarthritis and other indications in Japan (BD: Jan 22, 23, 2017).
Today, the company said that receipts from customers fell 46.2 percent to $339,015 for the six months to December 31, 2017 compared to the previous corresponding period.
Regeneus said diluted loss per share for the six months to December 31, 2017 was 1.3 cents compared to a diluted earnings per share of 1.7 cents for the six months to December 31, 2016, with net tangible assets per share down 36.6 percent to 2.6 cents, with cash and cash equivalents of $3,371,946 at December 31, 2017, compared to $395,558 at December 31, 2016.
Regeneus was unchanged at 12 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has “a new group identity and website … [reflecting] its values and evolution”.
Clinuvel said the move was parallel to its focus on research and development on complimentary product lines with a theme on “the interaction of human skin with its environments” to deliver innovative pharmaceutical products for complex problems.
The company said its value system was a reflection of how it sought to operate, under five headings: people and environment; approach; respect and appreciation; knowledge building and sharing; and technology.
Clinuvel chief executive officer Dr Philippe Wolgen said that “in a challenging business climate and changing landscape of our sector, we experience how pharmaceutical companies are making daily headlines for the wrong reasons”.
“We strongly believe that Clinuvel needs to differentiate itself by a value system guiding our conduct and setting a standard for decision makers and users of our products to fully understand our rationale and modus operandi,” Dr Wolgen said.
“We have established ourselves as the leaders and experts in an emerging field of photo-medicine and now seek to expand our research delivering life-long care and novel products for patients and users,” Dr Wolgen said.
“Our first product Scenesse offers an innovative solution to [erythropoietic protoporphyria] patients in a specialised setting, and now we are close to launching the first of our complimentary skin and body care products to strengthen our offering,” Dr Wolgen said.
Clinuvel said it had re-launched its website www.clinuvel.com and adopted Diana, goddess of the hunt, representing “precision, tenacity, compassion, and as the guardian of the moon protects the wellbeing of children” with the motto ‘Per diligentiam sinceritatemque progredimur et populum servimus,’ meaning ‘Through diligence and integrity we advance and serve the people’.
Clinuvel fell three cents or 0.35 percent to $8.50.

PATRYS

Patrys director Michael Stork says his Stork Holdings has increased and been diluted from 95,731,764 shares (12.28%) to 98,773,814 shares (10.60%).

The Ontario, Canada-based Mr Stork said the dilution was through the company's issues of shares on February 16, 2018, following the rights issue at 1.7 cents a share which raised $2.4 million (BD: Feb 14, 2018).

Patrys was up 0.1 cents or 4.8 percent to 2.2 cents with 3.8 million shares traded.