Biotech Daily

Wednesday October 2, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRESCIENT UP 15%; ACTINOGEN DOWN 25.5%**

*** INNATE CHRIS COLLINS PLEADS GUILTY, RESIGNS US CONGRESS**

*** AUSBIOTECH MELBOURNE BIOTECH INVEST, CONFERENCE**

*** IMMURON, US DEFENSE $5.5m COLLABORATION**

*** MEDLAB: 1st EXPORT ORDER FOR HEMP/MARIJUANA NANOCBD**

*** HERAMED INTMED BRAZIL HERACARE, HERABEAT COLLABORATION**

*** MAYNE TO PAY MITHRA UP TO $440m FOR US CONTRACEPTIVE DEAL**

*** RESAPP TGA APPROVAL FOR RESAPPDX-EU DIAGNOSTIC**

*** US FDA CHANGES CLINUVEL PDUFA DATE TO OCTOBER 8**

*** MACH7 US PATENT FOR DYNAMIC MEDIA MANAGEMENT SYSTEM**

*** ANTEO BUYS BACK 12.7m UNMARKETABLE SHARES**

*** G MEDICAL IN SUSPENSION: 'PREPARING ASX QUERY RESPONSE'**

*** RON DEWHURST, KROY WEN BELOW 5% IN RHINOMED**

*** FEDERAL GOVERNMENT APPOINTS STEM CELL ADVISORS**

MARKET REPORT

The Australian stock market fell 1.53 percent on Wednesday October 2, 2019, with the ASX200 down 102.9 points to 6,639.9 points. Ten of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and four were untraded. All three Big Caps fell.

Prescient was the best, up 0.8 cents or 14.55 percent to 6.3 cents with 7.8 million shares traded. Immutep climbed 6.1 percent; Compumedics and Ellex were up more than five percent; Clinuvel improved 3.3 percent; Amplia and Universal Biosensors rose more than two percent; with Antisense, Cynata and Oncosil up by more than one percent.

Yesterday's 467 percent best, Actinogen, led the falls, down 1.3 cents or 25.5 percent to 3.8 cents, with 425.1 million shares traded. Impedimed, Kazia and Telix lost more than five percent; Avita, LBT, Optiscan and Starpharma fell more than four percent; Proteomics was down three percent; Cochlear, Nanosonics, Opthea, Orthocell and Resmed shed two percent or more; CSL, Polynovo and Pro Medicus were down more than one percent; with Medical Developments, Neuren, Next Science, Paradigm and Volpara were down by less than one percent.

INNATE IMMUNOTHERAPEUTICS (NOW AMPLIA THERAPEUTICS)

Former Innate director and Republican US House of Representatives member Chris Collins has pleaded guilty to insider trading charges and resigned from the House.
House Speaker Nancy Pelosi's office told Biotech Daily that Mr Collins had formally resigned as a member of Congress.
The US Department of Justice told Biotech Daily that Mr Collins had entered guilty pleas to the charges relating to the sale of Innate Immunotherapies shares during a trading halt and lying to Federal law enforcement agents.
Last year, US authorities charged Mr Collins and relatives with insider trading in relation to Innate shares (BD: Aug 9, 2018).
Innate effectively became a new company acquiring Amplia Therapeutics, with a significant change of technology, directors, staff and shareholders (BD: Apr 26, 2018).
In August 2018, the US Department of Justice said the New York Southern District attorney Geoffrey Berman and the Federal Bureau of Investigation arrested Mr Collins, his son Cameron and the father of Cameron Collins's fiancée Stephen Zarsky in relation to trading shares prior to the release of an announcement relating to the multiple sclerosis trial result (BD: Jun 23, 27, 2017).
On Friday June 23, 2017, Innate called a trading halt and on Tuesday June 27, said that MIS416 failed to meet its primary endpoint, with the share price falling 92.3 percent to 4.9 cents - having peaked at $1.83, on news that Republicans close to US President Donald Trump including Health Secretary Dr Tom Price were shareholders (BD: Jan 22, 2017).
In 2018, the Department of Justice said Christopher and Cameron Collins and Mr Zarsky were charged with "participating in a scheme to commit insider trading" citing 12 counts of conspiracy to commit securities fraud, securities fraud, conspiracy to commit wire fraud, wire fraud and false statements, with penalties ranging from five to 20 years gaol.
Today, the Department of Justice said that Congressman Christopher Collins had pleaded guilty to the insider trading scheme and lying to Federal law enforcement agents.
The Department of Justice said that Mr Collins resigned his seat in Congress on September 30, 2019.
The media release said that the US attorney for the Southern District of New York Geoffrey Berman announced that Mr Collins, who represented the 27th District of New York as a member of the US House of Representatives, pled guilty to participating in a scheme to commit insider trading and to making false statements to Federal law enforcement agents when interviewed about his conduct.
"By virtue of his office, Christopher Collins helped write the laws of this country, but he acted as if the law did not apply to him," Mr Berman said.
"Today, by pleading guilty, Collins acknowledged that while he was a member of Congress, he committed insider trading and then lied to the FBI in an attempt to cover it up," Mr Berman said.
"Today's plea is a reminder that all citizens stand equal before the law in our criminal justice system," Mr Berman said.
The media release said that Mr Collins, 69, pled guilty to one count of conspiracy to commit securities fraud, in violation of Title 18, US Code, Section 371, which carries a maximum penalty of five years in prison, and one count of making false statements to law enforcement officials, in violation of Title 18, US Code, Section 1001, which also carries a maximum penalty of five years in prison.
The Department of Justice said that Mr Collins would be sentenced on January 17, 2020.
The Department said that the charges against Cameron Collins and Stephen Zarsky were "merely accusations, and they are deemed innocent unless and until proven guilty".
Amplia was up 0.2 cents or 2.2 percent to 9.2 cents.

AUSBIOTECH

Ausbiotech says it will hold its Biotech Invest and Partnering 2019 and annual conferences in Melbourne from October 30 to November 1, 2019.
Ausbiotech said the conferences, supported by the Victorian Government, would be held at the Melbourne Convention and Exhibition Centre, with more than 1,000 “industry leaders, investors, researchers and regulatory representatives” expected to attend.
The industry organization said the conferences would “lift the profile of the Australian biotechnology industry, share new and ground-breaking knowledge, connect companies and create access to greater funding sources for companies to develop world-class science into therapies, diagnostics and medical devices”.
Ausbiotech said that about 100 speakers would discuss biotechnology trends and opportunities, policy updates and industry challenges.
The organization said that the conference would feature networking activities, a trade exhibition and a partnering platform to facilitate one-to-one meetings for collaboration and partnership opportunities with other attendees.
Ausbiotech said keynote speakers included science journalist Dr Elizabeth Finkel Texas Medical Centre Innovation Institute director Dr Tom Luby, the Murdoch Children’s Research Institute’s Prof Melissa Little, the University of Queensland’s Prof Maree Smith, Baylor College of Medicine’s Dr Shashikant Kulkarni and Quark Ventures chief executive officer Karimah Es Sabar.
For more information and to register, go to: https://www.ausbiotechinvestment.com.au/ and https://www.ausbiotechnc.org/ .

IMMURON

Immuron says it has $5.5 million collaboration with the US Department of Defense for an oral therapeutic for Campylobacter and entero toxigenic Escherichia coli.
Immuron said it would work with the Silver Spring, Maryland-based Naval Medical Research Center to develop the Camplobacter and entero-toxigenic Escheria coli-specific anti-microbial preventive for travellers’ diarrhoea with its bovine colostrum based technology to target pathogenic bacteria at the gastrointestinal tract site of infection.
The company said one clinical trial would test the product against moderate to severe campylobacteriosis and a second would focus on entero-toxigenic Escheria coli infections.
Immuron chief operating officer Dr Jerry Kanellos told Biotech Daily that the trials would have about 30 healthy volunteers each and were expected to begin in mid-2020.
Immuron rose seven cents or 66.7 percent to 17.5 cents with 18.6 million shares traded.

MEDLAB CLINICAL

Medlab says it has received its first export order of 1,500 units of its Nanocelle-delivered cannabidiol (CBD), marijuana or hemp derivative, Nanocbd for Hong Kong.
Medlab said Nanocbd was a sub-micron oro-buccal spray, contained 16.67mg/mL of cannabidiol as its active ingredient and was its third Nanocelle cannabidiol product.
Medlab said “countries that allow CBD from hemp as opposed to marijuana, specifically the US … are being investigated with potential partners” as well as countries that allowed cannabidiol from hemp as opposed to marijuana.
The company said the deposit had been paid but did not state commercial terms.
Medlab said it was working with potential clients for a US market release and Australian delivery for use under the special access scheme was expected by Christmas 2019.
Medlab was up two cents or 4.65 percent to 45 cents.

HERAMED

Heramed says it has a six-month collaboration with Brazil's Intmed Software to expedite co-development, adaptation, optimization and progress its Heracare products.
Heramed said it would integrate the home and professional versions of its Heracare foetal cardiac monitor into Intmed's existing software and technology suite.
The company said both would refine and optimize Heracare for use and scale-up across Brazil and Intmed would assist in the adoption of the platform.
Heramed said it would enter into a revenue sharing agreement with Intmed for new projects for Heracare and its Herabeat smart foetal heart rate monitor.
The company said it would offer one third of revenue received from a prospect introduced, engaged and managed by Intmed for the Heracare platform and five percent of revenue from a prospect for its Herabeat monitor.
Heramed was unchanged at 16 cents.

MAYNE PHARMA GROUP

Mayne says it has a 20-year deal with Mithra Pharmaceuticals to commercialize a new oral contraceptive combining oestetrol and drospirenone in the US.
Mayne said phase III clinical trials had been completed and it expected to launch the contraceptive by July 2021, subject to US Food and Drug Administration approval for five-year new chemical identity exclusivity and patent protection beyond 2030.
The company said it would pay Mithra up to $US295 million ($A440 million) including $US8.75 million in cash and 4.95 percent of Mayne's shares at closing, along with $US11 million in cash and a further 4.65 percent of Mayne's shares following FDA approval, as well as contingent payments based on cumulative net sales targets.
Mayne said the total of $US295 million would be paid if net sales exceeded $US2.25 billion.
The company said that Mithra's shares were subject to a two-year lock up period and would offer a future seat on its board.
The company said it expected the contraceptive to be earnings before interest, tax, depreciation and amortization (Ebitda) positive in its first full financial year following approval and expected peak net sales potential to exceed $US200 million a year.
Mayne was up 10 cents or 18.9 percent to 63 cents with 53.3 million shares traded.

RESAPP HEALTH

Resapp says it has Australian Therapeutic Goods Administration approval for its Resappdx-EU smartphone diagnostic test for acute paediatric respiratory disease.
Resapp said the algorithm was approved as a class IIa medical device for lower respiratory tract disease, croup, pneumonia, asthma or reactive airway disease and bronchiolitis in infants and children and had been listed on the Australian Register of Therapeutic Goods.
In August and September, the company said it had Conformité Européenne (CE) mark approval for the first and second versions of its Resappdx-EU diagnostic test for adult and paediatric respiratory disease (BD: Aug 23, Sep 26, 2019).
Resapp chief executive officer Dr Tony Keating said, "achieving TGA approval is an important regulatory milestone that allows us to sell Resappdx-EU in Australia, our home market".
Resapp was up 2.75 cents or 11.1 percent to 27.5 cents with 11.2 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says the US Food and Drug Administration has changed its prescription drug user fee act (PDUFA) goal date from October 6 to October 8, 2019 following miscommunication.
In June, Clinuvel said the FDA had extended the date for a decision on Scenesse to October 6, 2019 (BD: Jun 3, 2019).
Today, the company said a review of the Scenesse scientific dossier submission was miscommunicated by the agency as October 6.
Clinuvel was up 82 cents or 3.3 percent to $25.61 with 207,531 shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has been granted a US patent for its management studio, which communicates medical imaging data and solves complex inter-operability issues.
Mach7 said the patent, titled “Dynamic Media Object Management System”, would provide coverage until August 12, 2029.
Mach7 was up four cents or 6.15 percent to 69 cents.

ANTEO DIAGNOSTICS

Anteo says it has bought-back 12,669,911 shares at an average price of 1.37 cents a share in an unmarketable parcel facility for invetsors with parcels worth $500 or less.
Anteo said the number of shareholders had been reduced from about 4,360 to fewer than 2,370, which would reduce the cost of notices, reports and other communications.
The company said CPS Capital managed the sale.
Anteo was unchanged at 1.3 cents with three million shares traded.

G MEDICAL INNOVATIONS HOLDINGS

G Medical says it is “in the process of preparing a response to an ASX query” in response to recent shareholder enquiries.
Last month, G Medical was suspended from the ASX for failure to respond to an ASX query, after it requested a trading halt and voluntary suspension pending “a response to an ASX query” (BD: Sep 6, 10, 17, 2019).
G Medical last traded at 8.1 cents.

RHINOMED

Rhinomed chairman Ron Dewhurst says his company Kroy Wen Pty Ltd has been diluted in the recent placement and he has ceased to be a substantial shareholder.
In January, director Mr Dewhurst said that he held 8,200,000 shares and 4,000,000 options through Kroy Wen.
Last month, the company said it had raised $6 million in a placement at 22 cents a share (BD: Sep 23, 2019).
Rhinomed was up 1.5 cents or 5.6 percent to 28.5 cents.

FEDERAL GOVERNMENT

The Federal Government says it has selected a stem cell therapies expert advisory panel to guide its $150 million stem cell therapies mission.

A media release from Federal Health Minister Greg Hunt said the mission was an opportunity for Australian researchers to use stem cell research to further investigate an area that presented significant opportunities for new chronic and inherited disease medical treatments.

The Government said stem cells had been shown to restore function to damaged tissues, had been used to engineer replacement tissue and organs and boost the body's ability to heal itself, and could be used to better understand what happens to the body during disease and to test new drugs without risk to patients.

The media release said the panel would be co-chaired by the Murdoch Children's Research Institute's Prof Melissa Little and the Australian National University's Prof Mark Kendall.

The Government said members of the panel included Prof Pritinder Kaur, Dr Siok Tey, Prof Simon Koblar, Prof Stephanie Watson, Dr Christine Walker, Dr Dan Grant, Prof Megan Munsie, Prof Peter Rathjen, Prof Maria Kavallaris and Prof Iona Novak.

The media release said first grants under the mission would begin in the coming months.

For more information go to: https://bit.ly/2nF76Qg.