Biotech Daily

Monday February 10, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: USCOM UP 52%; ANTISENSE DOWN 6%**

*** US COURT: INNATE CHRIS COLLINS 26 MONTHS JAIL; TAKEOVERS PANEL**

*** USCOM: CORONAVIRUS CHINA DEMAND FOR USCOM 1A; ASX HALT**

*** CLINUVEL, FDA TO DISCUSS SCENESSE FOR VITILIGO**

*** UK NICE BRIEFING BACKS OSPREY'S DYEVERT**

*** IMPEDIMED: NCCN GUIDELINES RECOGNIZE LYMPHOEDEMA**

*** RECCE: RECCE-327 'WELL-TOLERATED IN RATS, DOGS'**

*** HERAMED, MAYO TO START HERABEAT STUDY**

*** TOTAL BRAIN RECEIVES $1.3m FEDERAL R&D TAX INCENTIVE**

*** THC TO LAUNCH CANNDEO MARIJUANA**

MARKET REPORT

The Australian stock market fell 0.14 percent on Monday February 10, 2020, with the ASX200 down 10.1 points to 7,012.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and one was untraded. All three Big Caps rose.

Uscom was the best, again, up a further 16.5 cents or 52.4 percent to 48 cents with 12.3 million shares traded. The company is up 284 percent in one week.

Dimerix climbed 11.1 percent; Impedimed was up 6.7 percent; Osprey and Universal Biosensors were up more than five percent; Avita and Immutep improved more than four percent; Clinuvel, Genetic Signatures and Oncosil rose more than two percent; Amplia was up 1.4 percent; with Cochlear, CSL, Cyclopharm, Nanosonics, Pro Medicus, Resmed, Starpharma and Telix up by less than one percent.

Antisense led the falls, down 0.4 cents or 6.15 percent to 6.1 cents with 2.4 million shares traded.

Alterity and Next Science lost more than five percent; Polynovo fell four percent; LBT and Optiscan were down more than three percent; Actinogen, Ellex, Medical Developments, Opthea and Resonance shed more than two percent; Cynata, Mesoblast, Paradigm and Volpara were down more than one percent; with Kazia down 0.85 percent.

INNATE IMMUNOTHERAPIES (NOW AMPLIA THERAPEUTICS)

The US Department of Justice says former Innate director and US congressman Christopher Collins has been jailed for 26 months and fined $US200,000 ($A299,718).

A media release on the US Attorney for the Southern District of New York website said District Judge Vernon Broderick also sentence Mr Collins to one year of supervised release along with the fine and imprisonment "for participating in a scheme to commit insider trading and for making false statements to Federal law enforcement agents".

"… Collins received confidential, non-public information that one of Innate's drugs in development had just failed a clinical trial," US Attorney Geoffrey Berman said.

"Moments later, from the White House lawn, Collins notified his son Cameron, so that he could trade the stock ahead of the public announcement and avoid taking a substantial loss on the stock," Mr Berman said. "He then lied to the FBI."

"Collins's greed and disregard for the law have now led to a criminal conviction," Mr Berman said. "Lawmakers bear the profound privilege and responsibility of writing and passing laws, but equally as important, the absolute obligation of following them."

The media release including case details is available at: https://bit.ly/37d7Ahx.

The announcement was made on Friday January 17, 2020, a Saturday in Australia, just before Biotech Daily returned from holidays. We apologize for the late posting.

In 2015, Sydney investor James Wheeldon complained to the Australian Takeovers Panel that Mr Collins might be associated with family members and other shareholders in contravention of section 606 of the Corporations Act 2001 (BD: Feb 15, 20, 2015).

Six days later, the Panel said that although the combined Collins family holding was more than 20 percent, an association had not been established (BD: Feb 21, 2015).

The Panel said Mr Wheeldon submitted that 18 recipients of shares in placements were either employees of, financial donors to, or otherwise had close ties to Mr Collins and many had businesses in Buffalo, New York, in Mr Collins' congressional district.

But the Panel said "the applicant has not provided sufficient material to justify us making further enquiries as to the alleged association between Mr Collins and these investors".

In an interview with the US Office of Congressional Ethics on June 5, 2017 Mr Collins said he was aware that he was near or over the 20 percent maximum shareholding.

Mr Collins said that at one point he held about 18 percent of Innate and his children, Caitlyn and Cameron held about two percent each.

He said that "most of" his congressional staff held Innate shares, as did friend Dr Tom Price who President Trump appointed as Secretary of Health and Human Services.

Mr Collins said the Australian initial public offer was for a minimum of $10 million and was said to be over-subscribed, requiring a scale-back for investors, but in fact had not raised that minimum (BD: Nov 19, Dec 18, 2013).

"I'm putting in what I'm putting in to keep my ownership at a 15-ish, 16-ish percent range. My kids own one or two percent so maybe after - you can't go over 20 percent in Australia without hitting it with what they call a takeover … I guess you would consider that some kind of effective control so, I made sure it I wasn't there," Mr Collins said in the interview.

Mr Collins said the broker "failed" and was "way under … he was under by 1.3 million dollars. He raised 8.7. He didn't raise 10 million bucks … So, I put in 1.3 million dollars, luckily, I had it in the bank. That's how I ended up at a higher percentage than I wanted."

Tonight, on the ABC Television program Four Corners, questions will be raised about the supervision, or lack of it, by Australian authorities in the Collins matter.

In 2018, Innate acquired Amplia for cancer therapeutics with Mr Collins resigning as a director on May 4 (BD: Mar 28, Apr 6, 2018). His wife Mary continues to hold 6.26 percent.

Biotech Daily editor David Langsam owns Amplia shares.

Amplia was up 0.1 cents or 1.4 percent to 7.2 cents.

USCOM

Uscom says that the outbreak of the 2019-nCoV coronavirus in China has increased the demand for its ultra-sonic cardiac output monitor 1 A (Uscom 1A).
Uscom said it would increase the manufacturing of Uscom 1A by 121 percent on 10-year average outputs to meet the anticipated demand.
The company said the Uscom 1A haemodynamic, or blood flow, monitor was developed to optimize management of infectious diseases, with many Uscom 1A units widely installed in Chinese hospitals, mostly for the management of sepsis.
Uscom said some devices were specifically installed for the monitoring of hospital patients diagnosed with coronavirus.
The company said that the China National Health Commission released the new Fifth Edition of the National Protocol for the Detection and Management of Coronavirus on February 5, 2020 which recommended the haemodynamic monitoring of severe and critically severe cases of coronavirus.
Uscom said that unit orders for the first five weeks of 2020 were up 124 percent compared to the first full two months of 2019, and prior to the China Government announcement.
The company said it was “unable to provide further details or specific numbers due to the rapidly evolving situation in China”.
Uscom chairman Prof Rob Phillips said that coronavirus was “a dangerous epidemic in the world’s most populous country and the Government of China is acting decisively to limit the spread and impact of the disease by providing guidelines, equipment and personnel to most effectively care for the 1.4 billion people of China”.
“This epidemic is forcing our technology from the hands of a small number of infectious disease experts into the hands of physicians dealing day-to-day with tens of thousands of patients with deadly infections,” Prof Phillips said.
Uscom made the announcement at 2.56pm and at 3.23pm the ASX called a pause in trading “pending a further announcement’, which was followed at 4.18pm by a suspension “pending the release of an announcement regarding a clarification of a recent announcement of [Uscom’s] orders”.
Prof Phillips told Biotech Daily that he made the announcement as he believed the increase in orders was material.
Uscom climbed 16.5 cents or 52.4 percent to 48 cents, with 12.3 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has requested a US Food and Drug Administration guidance meeting for a phase IIb trial of Scenesse for vitiligo.
Clinuvel said that vitiligo caused loss of pigmentation, specifically in patients of darker skin complexion, and there were no US pharmaceutical agents approved for vitiligo.
Last year, the company said it had FDA approval for Scenesse, or afamelanotide, for erythropoietic protoporphyria (EPP) to “increase pain free light exposure in adult patients with a history of phototoxic reactions from EPP” (BD: Oct 9, 2019).
Today, Clinuvel said the proposed study “planned to address findings in earlier clinical trials and better understand the effect of [narrowband-ultraviolet-A] combination therapy in re-pigmenting vitiliginous lesions at specific body sites”.
The company said the meeting would provide guidance on the requirements for filing a supplemental new drug application to expand the indications for Scenesse in the US.
Clinuvel said it expected a response from the FDA on the meeting request within three weeks, and if approved, the meeting would be held within 75 days of the request.
Clinuvel was up 51 cents or two percent to $25.59, with 176,573 shares traded.

OSPREY MEDICAL

Osprey says the UK National Institute of Health and Care Excellence has published a Medtech Innovation Briefing supporting its Dyevert technology.

Osprey said that its Dyevert dye reduction and monitoring technologies minimized dye usage and monitored the dose of dye used during angiographic imaging procedures, which helped to decreased the patient's risk for dye-related kidney damage.

The company said that Medtech Innovation Briefings informed hospital personnel and healthcare providers within the National Health Service (NHS) “on new medical devices with the potential to improve patient care and reduce healthcare costs”.

Osprey said that an article published in ‘The Open Pharmacoeconomics & Health Economics Journal’ showed that the “introduction of Dyevert Plus Ez system led to cost savings of GBP3,878 ($A7478) per patient over a lifetime … [with] 100 percent probability of being cost-effective and 100 percent probability of being cost-saving to the UK healthcare system”.

Osprey chief executive officer Mike McCormick said that the Medtech Innovation Briefing was “not a specific NICE recommendation that results in implementation of payment throughout the NHS, [but] we are hopeful of securing such a recommendation in late 2020 to early 2021”.

The company said that Dyevert was commercially available in the UK for GBP350 ($A675) per patient and there were about 50,000 chronic kidney disease patients that undergo coronary angiograms each year in the UK who would benefit from the dye reduction technology.

Osprey was up 0.1 cents or 5.6 percent to 1.9 cents, with 3.7 million shares traded.

IMPEDIMED

Impedimed says the US National Comprehensive Care Network has recognized the need for the early detection and diagnosis lymphoedema.

Impedimed said that last week, the Plymouth Meeting, Pennsylvania-based National Comprehensive Care Network (NCCN) updated its clinical practice guidelines following a meeting on August 15, 2019.

Impedimed chief executive officer Richard Carreon said the NCCN guidelines update “shows that the medical community recognizes the impact of lymphoedema on cancer survivors and the value of programs like Impedimed’s [lymphoedema prevention program] to address it.”

The company said that the updates did not specify a measurement technique but were “consistent with the test, trigger treat protocol outlined in Impedimed’s lymphoedema prevention program”.

Impedimed said the update followed a request from Vanderbilt University and the American Society of Breast Surgeons Foundation “to add language recommending “establishing a surveillance program with [bioimpedance spectroscopy] to detect sub-clinical breast cancer-related lymphoedema and initiate early intervention to reduce the need for complete decongestive physiotherapy”.

The company said that a recommendation for pre-treatment baseline measurements to facilitate the earliest identification of sub-clinical lymphoedema was also requested.

Impedimed said the NCCN updates were consistent with the treatment protocol outlined in its lymphoedema prevention program, which used its Sozo device with bioimpedance spectroscopy technology to measure extracellular fluid (BD: Oct 23, 2019).

Impedimed was up 0.75 cents or 6.7 percent to 12 cents, with 13.3 million shares traded.

RECCE PHARMACEUTICALS

Recce says Recce-327 is well-tolerated in rats and dogs at up-to 4,000mg/kg and had no observed adverse effects at seven days of dosing of 500mg/kg.
Recce said that animal studies showed that Recce-327 indicated efficacy at 50mg/kg to 70mg/kg "suggesting a wide therapeutic dosing window".
The company said four groups of six rats were dosed at 525mg/kg, 1025mg/kg, 2000mg/kg, and 4000mg/kg to identify the maximum 24-hour dose.
Recce said that three groups of 10 rats were dosed at 50mg/kg, 500mg/kg, and 4000mg/kg a day for seven days, which showed that the drug was tolerated for at least seven days at 500mg/kg.
The company said that "some minor indications of a dosing limit were observed in some animals beyond the seven-day continuous intravenous infusion administration at 4000 mg/kg".
Recce said that vancomycin, a commercially successful broad-spectrum antibiotic, indicated efficacy at 50mg/kg when intravenously administered, but was highly toxic at 400mg/kg, with all rats dying in a 2007 study before completion of a course.
The company said that a group of two dogs was given an escalated dose over 24-hours, beginning at 95mg/kg and rising to 4,000mg/kg, and another group of two dogs was administered 4,000mg/kg.
Recce said that the doses were well tolerated.
The company said that three groups of four dogs were dosed at 50mg/kg, 500mg/kg and 4,000mg/kg for seven days and showed that like the seven-day rat study, "there was an indication of dose limit at very high levels".
Recce said that a "seven-day continuous intravenous infusion administration of Recce-327 up to 500mg/kg/day were well tolerated; with no mortalities, clinical signs, changes in body weight, coagulation, clinical chemistry or salient macroscopic abnormalities".
Recce chairman Dr John Prendergast said the in-vivo study showed "the potential of Recce-327 as a first-line-therapy for the treatment of superbug infections".
"This sees us in an encouraging position ahead of our anticipated phase I human clinical studies," Dr Prendergast said.
Recce fell one cent or 2.6 percent to 38 cents.

HERAMED

Heramed says that the Rochester, Minnesota-based Mayo Clinic will begin a study of its Herabeat Plus foetal and maternal heartrate monitor.
Heramed said the study would evaluate the ease of use, accuracy and medical value of using the Herabeat smart foetal heart rate monitor at home.
The company said the study would "recruit low-risk expectant mothers from the obstetrics and gynecology department at Mayo Clinic in Rochester, Minnesota", but did not disclose the number of participants.
Heramed said the study would "be guided by an assessment of device functionality and user acceptability, as well as an evaluation of the impact of the device on expectant mothers' perception of foetal well-being, as measured by standardized surveys".
Herabeat chief executive officer David Groberman said that "the decision to initiate a clinical study by Heramed's [research and development] collaborator is a major milestone and another significant building block in Heramed's US expansion strategy".
Heramed was up half a cent or 2.9 percent to 17.5 cents.

TOTAL BRAIN

Total Brain says it has received $1,337,976 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Total Brain said the rebate related to research and development expenditure for the year to June 30, 2019.
Total Brain was up 2.5 cents or 3.6 percent to 71.5 cents.

THC GLOBAL

THC says it will launch Canndeo brand marijuana-based medicines in Australia and has applied for supply licences in Canada.
Last month, THC said it would sell MGC Pharmaceuticals' marijuana formulations in Australia and New Zealand under its Canndeo brand, with the first purchase for EUR25,000 ($A40,307) (BD: Jan 20, 2020).
Today, the company said it would launch Canndeo medicines in Australia by April 2020, initially offering four products included "a full spectrum [cannabidiol] medicine".
THC said Canndeo would "offer existing clinics and prescribers under the special access schemes a high-quality alternative to the current product available for prescription".
The company said it has submitted licence applications to supply marijuana-based medicine to Canada.
THC said that Canndeo Canada would target more than 369,000 Canadian medical client registrations accessing medicinal cannabis under existing valid authorities.
The company said it had received orders from licenced producers in Canada to supply finished and bulk good manufacturing practice product from its Southport, Gold Coast, Queensland facility "for delivery in the second half of 2020".
THC was up one cent or 2.7 percent to 38 cents.