Biotech Daily

Thursday October 7, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 14%; ALTERITY DOWN 6.25%**

*** ELLUME RECALLS SARS-COV-2 HOME TESTS ON FALSE POSITIVES**

*** MAYNE: US FDA 2nd NUVARING REJECTION**

*** NATIONAL FACILITY, LA TROBE UNI DEVELOP NANOMSLIDE**

*** MEDI-CAL TO REIMBURSE REDHILL TALICIA (SYDNEY'S HELICONDA)**

*** ADALTA: BTB $760k MOVED TO INHALED AD-214**

*** NOVA EYE 5-YEAR ITRACK RESULTS**

*** CARDIEX: CONNEQT, FENDA MANUFACTURING AGREEMENT**

*** EMYRIA JOINS PALANTIR FOUNDRY BUILDERS PROGRAM**

*** IMPEDIMED AGM: M-D RIGHTS, OPTIONS; CHAIR SCOTT WARD GOES**

*** MGC: AMC ORDERS $4m OF CIMETRA**

*** AUSTRALIAN ETHICAL DILUTED TO 4.9% OF IMMUTEP**

*** PETER MEURS, SKIPTAN TAKE 13.8% OF DIMERIX**

*** HONSUE CHO TAKES 26% OF INVION**

MARKET REPORT

The Australian stock market was up 0.7 percent on Thursday October 7, 2021, with the ASX200 up 50.2 points to 7,256.7 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 11 fell and eight traded unchanged. All three Big Caps were up.

Optiscan was the best, up three cents or 14.3 percent to 24 cents, with 686,338 shares traded. Antisense climbed 10 percent; Imugene and LBT improved more than nine percent; Uscom rose 7.7 percent; Telix was up 5.1 percent; Clinuvel, Impedimed, Polynovo, Prescient and Pro Medicus were up more than four percent; Amplia, Cochlear, Oncosil and Volpara rose more than two percent; Dimerix, Immutep, Mesoblast, Nanosonics, Next Science, Orthocell and Osprey were up one percent or more; with CSL and Resmed up by less than one percent.

Alterity led the falls, down 0.2 cents or 6.25 percent to three cents, with 949,295 shares traded, followed by Nova Eye down 6.2 percent to 38 cents, with 80,320 shares traded. Kazia and Resonance shed more than two percent; Genetic Signatures and Neuren lost one percent or more; with Avita, Cyclopharm, Opthea, Starpharma and Universal Biosensors down by less than one percent.

ELLUME

Ellume says it has recalled a “specific product lots of [Sars-Cov-2] tests” after they reported false-positive test result rates higher than was observed in clinical testing.
Ellume chief executive officer Dr Sean Parsons said that “upon determining that a portion of our test kits were reporting higher than expected false-positive test results, we worked quickly with the Food and Drug Administration to voluntarily recall the problematic test kits and correct the issue”.
“In this case, we noted that some tests from specific lot numbers may provide an incorrect positive result at a higher rate than was observed in clinical testing,” Dr Parsons said.
“Following a thorough investigation, we isolated the cause and confirmed that this incidence of false positives is limited to specific lots,” Dr Parsons said.
In February, Ellume said the US Government would provide $US231.8 million ($A302.8 million) to produce its severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) home tests (BD: Feb 2, 2021).
Today, Ellume said that certain affected Covid-19 test kits were also supplied to the US Department of Defense to be further distributed to community health programs as part of the National Strategy for the Covid-19 Response and Pandemic Preparedness Plan.
The company said that customers who attempted to use the affected tests would be notified in the application that the test had been recalled and affected tests disabled.
Ellume said that customers who purchased recalled tests with affected lot numbers and who previously tested positive were being contacted by the company.
The company said that the reliability of negative results was unaffected by the issue.
Ellume is a public unlisted company.

MAYNE PHARMA GROUP

Mayne says the US Food and Drug Administration has rejected its response to a complete response letter for its generic version of the Nuvaring intra-vaginal contraceptive ring.
In 2018, Mayne said the FDA accepted its abbreviated new drug application for generic Nuvaring intra-vaginal hormonal contraceptive device combined etonogestrel and ethinyl estradiol delivered over a three-week period (BD: Mar 20, 2018).
Last year, in a media release titled ‘Mayne Pharma provides update on women’s health pipeline’, the company said the FDA rejected applications for its Nuvaring contraceptive and an unnamed product believed to be a contraceptive pill (BD: Oct 7, 2020).
Today, a Mayne spokesperson told Biotech Daily that the Nuvaring application was refiled with Mithra Pharmaceuticals in March 2021.
Today, Mayne said it had received a complete response letter from the FDA for Nuvaring and was “working closely with its development partner, Mithra Pharmaceuticals and the FDA to address the questions raised in the [complete response letter]”.
On its website, Mithra said it was working with Mayne and the FDA “to address the few remaining questions raised in the [complete response letter] before year-end”.
Mayne Pharma said it would receive a new target action date from the FDA following the submission of a response to the complete response letter.
Mayne chief executive officer Scott Richards said the team was “confident that we can address the few remaining outstanding questions raised by the FDA in a timely manner”.
“Pleasingly, the FDA had no questions around Mithra’s facility, the drug product manufacturing process, drug substance or bioequivalence,” Mr Richards said.
“The market opportunity continues to be attractive with two independent generics approved and an addressable market of $US670 million,” Mr Richards said.
Mayne was unchanged at 31.5 cents with 5.35 million shares traded.

AUSTRALIAN NATIONAL FABRICATION FACILITY, LA TROBE UNIVERSITY

The Australian National Fabrication Facility says it has helped La Trobe University develop a microscope slide that “may forever change how we identify cancer cells”.
The Facility said that the Nanomslide was invented by La Trobe University researchers Prof Brian Abbey and Dr Eugeniu Balaur, and with the Peter MacCallum Cancer Centre’s Prof Belinda Parker developed the technology as a tool for detecting cancer cells.
The ANFF said that the slide incorporated layers of finely printed metals on the surface of the glass to manipulate the interaction of light with cells.
“The result is massively enhanced contrast when viewing tissue under the microscope,” the Facility said.
The ANFF said that researchers described the difference as going from black and white television to color.
“For the first time I saw cancer cells just popping up at me,” Prof Parker said.
“All we did was take a section of breast cancer tissue, put it on a glass slide and look at it under a conventional light microscope,” Prof Parker said. “And we could easily distinguish cancer cells from the surrounding normal tissue.”.
“The slide also distinguishes cancer from other non-cancerous abnormalities in the breast, which has great promise for early cancer diagnosis,” Prof Parker said.
Prof Abbey said the technology aimed to make finding cancer cells “much easier and quicker for the pathologist by identifying abnormal cancer cells from a field of thousands”.
“We developed the slide using specialist machines at the Melbourne Centre for Nanofabrication, part of the Australian National Fabrication Facility,” Prof Abbey said.
“Until recently, we lacked a key piece of equipment, meaning that we had to post our slides to Europe for additional processing,” Prof Abbey said.
ANFF said that with La Trobe University it had invested $500,000 to bring the Eulitha Phabler 100C to Australia, providing the La Trobe team with the tool needed to scale up prototyping, provide proof-of-concept, and develop the product for market.
The research article, titled ‘Colorimetric histology using plasmonically active microscope slides’ was published in the journal Nature, with an abstract available at: https://www.nature.com/articles/s41586-021-03835-2.

REDHILL BIOPHARMA

Redhill says Medi-Cal has added Talicia for Helicobacter pylori to its contract drug list, with no prior authorization required, effective from October 1, 2021.
Redhill said that Medi-Cal was California's Medicaid Health Care program covering two million patients.
In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).
Redhill previously told Biotech Daily that it further developed Heliconda and in 2019 it was approved by the US Food and Drug Administration (BD: Nov 5, 2019).
Today, Redhill said that Talicia was a fixed-dose, oral capsule combination of two antibiotics (amoxicillin and rifabutin) and a proton pump inhibitor (PPI) (omeprazole).
Redhill chief commercial officer Rick Scruggs said that Medi-Cal’s addition of Talicia with no prior authorization required was “an important step in Talicia’s continuing growth”.
“There is growing recognition of the need to employ effective, first-line therapy against Helicobacter pylori infections that does not rely on clarithromycin and that patients can tolerate well and adhere to over 14 days of therapy,” Mr Scruggs said.
On the Nasdaq, Redhill fell one US cent or 0.21 percent to $US4.69 ($A6.44) with 711,549 shares traded.

ADALTA

Adalta says it will reallocate $760,000 in matched funding from the Biomedical Translation Bridge program to develop an inhaled version AD-214 for fibrosis.
Adalta said it received $1 million in matched funding from the Medical Research Future Fund program, through MTP Connect in December 2019, to evaluate AD-214.
In July, the company said that results from a phase I trial "led Adalta to shift the focus of its idiopathic pulmonary fibrosis clinical program from intravenous administration to an inhaled formulation" (BD: Jul 19, 2021).
Today, Adalta said that with MTP Connect the agreement had been amended to transfer $760,000 originally allocated to other workstreams to support the development of inhaled and improved intravenous formulations of AD-214 idiopathic pulmonary fibrosis.
Adalta said the development of an inhaled formulation was "intended to prepare AD-214 for inhalation toxicology studies" to begin by the end of 2022.
Adalta fell 0.1 cents or 1.1 percent to 8.9 cents.

NOVA EYE MEDICAL

Nova Eye says a five-year Itrack canaloplasty follow-up shows significant reduction in intraocular pressure compared to baseline and a decrease in medication burden.
Nova Eye said the results showed that performing canaloplasty with the Itrack was a safe procedure associated with a low risk of complications.
The company said the data would be presented at the European Society of Cataract and Refractive Surgeons meeting from October 8 to 11, 2021.
Nova Eye said Prof Norbert Koerber and colleagues evaluated the long-term effectiveness of Itrack canaloplasty in reducing intraocular pressure and glaucoma medications in patients with uncontrolled or controlled open-angle glaucoma (OAG) in the study.
Nova Eye said 14 of the 27 patients showed reduction in intraocular pressure after 60 months, with the Itrack canolaplasty also effective in in reducing glaucoma medication dependence.
Nova Eye fell 2.5 cents or 6.2 percent to 38 cents.

CARDIEX

Cardiex says its subsidiary Conneqt Inc has a manufacturing agreement with Shenzen, China-based Fenda Technology for its Conneqt Band for heart health.
In June, Cardiex said it had an agreement with Lifeq to develop an "artificial intelligence powered" wearable Conneqt Band to provide biometric data (BD: June 22, 2021).
Today, the company said Lifeq would contribute to the design and development work of the Conneqt Band with Fenda and Conneqt.
Cardiex said that Conneqt would be responsible for the costs of manufacturing and development, own the intellectual property and be responsible for promotion, marketing, sales and distribution of Conneqt products, with Fenda responsible for manufacturing.
The company said it was expanding its footprint in China and had hired Gordon Lau to accelerate development efforts with Fenda.
Cardiex managing-director Craig Cooper said the work with Fenda had "been in process since April this year and we are well advanced on finalizing our design and technical specifications for the Conneqt Band".
"Our product development and manufacturing contract with Fenda is a key step toward the commercialization of our Conneqt Band," Mr Cooper said.
Cardiex was up 0.2 cents or three percent to 6.8 cents with 6.6 million shares traded.

EMYRIA

Emyria says it has been invited to participate in the second cohort of Palantir Technologies' Foundry Builders Program for real world evidence data processing.
Emryria said Palantir was a "world leader in data platforms for major organizations and institutions with complex and sensitive data environments including the [US Food and Drug Administration], National Institutes of Health and Sanofi".
The company said under Foundry for Builders, Palantir Technologies provided a software platform to emerging companies.
Emyria said the platform created a central operating system for data and supported the growth of companies while "powering data-driven decision-making".
Emyria said it would have access to "the full Palantir Foundry stack" enhancing its data infrastructure, security, integration and analysis capabilities, and Foundry would form the "backbone of Emyria's proprietary real-world evidence asset".
Emyria managing-director Dr Michael WInlo said real world evidence was being "increasingly used by major global drug regulators, like the FDA, to evaluate the safety and efficacy of new treatments".
"By using Palantir Foundry, we can generate dose-response insights and clinical decision support tools using advanced statistical and machine learning algorithms," Dr Winlo said.
"We are also able to capture all relevant intellectual property related to our research while securely protecting patient privacy," Dr Winlo said.
Emyria was up half a cent or 2.4 percent to 21 cents.

IMPEDIMED

Impedimed says investors will vote to issue 7,400,000 rights and 6,159,000 options to managing-director Richard Carreon, with chair Scott Ward retiring at the meeting.
Impedimed said Mr Ward had been director of the company since July 2013 and chair since November 2017 and would be replaced by Donald Williams effective from the conclusion of the annual general meeting.
Impedimed said Mr Carreon's 7.4 million performance rights would vest based on contracted revenue pipeline growth over three hears to $25.4 million for 50 percent of the rights, $33.9 million for 100 percent of the rights and $49.5 million for 200 percent of the rights, as well as total shareholder return over three years targeting 100 percent share price increase to 21 cents.
Impedimed said the 6,159,000 options would be exercisable at the five-day volume weighted average market price (VWAP) at the close of trading prior to the date of grant, for up to seven years from the date of grant, vesting on share price targets of 17 cents to 21 cents.
The company said the targets were based on expansion of its Sozo digital health platform in one or more of its key strategic areas of focus, which include oncology, heart failure and renal failure.
Impedimed said shareholders would vote on the remuneration report, the re-election of directors Amit Patel and Donald Williams, the approval of the 10 percent placement capacity, approval to issue securities under the Impedimed employee incentive plan, the amendments to the constitution and the renewal of proportional takeover provision.
The meeting will be held virtually on November 10, 2021, at 9am (AEDT).
Impedimed was up half a cent or 4.2 percent to 12.5 cents with 4.4 million shares traded.

MGC PHARMACEUTICALS

MGC says the Tampa, Florida-based AMC Holdings has ordered $US3 million ($A4.1 million) of its Cimetra.
In August, MGC said it had supply and distribution deal with AMC Holdings, with minimum orders of $US24 million ($A32.9 million) for its marijuana, and artemisinin and curcumin products over three years (BD: Aug 27, 2021).
Today, the company said AMC was in the process of securing approval for receiving Cimetra for distribution within the US, which was expected take about six weeks.
MGC said payment had been secured with a $US375,000 deposit received and a $US625,000 letter of credit.
MGC was up 0.1 cents or 1.7 percent to 5.9 cents with 12.0 million shares traded.

IMMUTEP

The Sydney-based Australian Ethical says its 41,583,333 share-holding in Immutep has been diluted from 5.56 percent to 4.89 percent.
Australian Ethical said it was diluted due to the issue of 88,970,717 shares on July 30, 2021 as a result of a placement on June 21, 2021.
In July, Immutep said its share plan raised $7.2 million at 52 cents a share and with the June $60 million placement, raised a total of $67.2 million (BD: Jun 21, Jul 21, 2021).
Immutep was up half a cent or one percent to 52 cents with 1.9 million shares traded.

DIMERIX

Peter Meurs and Skiptan Pty Ltd say they have increased their shareholding in Dimerix from 26,529,309 shares (10.68%) to 44,179,309 shares (13.77%).
Mr Meurs said all 17,650,000 shares were bought in Dimerix's recent placement and share plan at 20 cents a share.
On Friday, Dimerix said its share plan at 20 cents a share raised $4 million taking its total raised with the placement to $24 million (BD Aug 16, Oct 1, 2021).
Dimerix was up half a cent or 1.7 percent to 30 cents with 1.9 million shares traded.

INVION

Honsue Cho and associates say they have increased their shareholding in Invion from 1,146,031,359 shares (20.70%) to 1,467,459,930 shares (26.01%).
Mr Cho said he acquired 321,428,571 shares in a private placement at 14 cents share following extraordinary general meeting approval on September 23, 2021.
Invion was unchanged at 1.3 cents with 1.7 million shares traded.