Biotech Daily

Wednesday September 22, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: MEDICAL DEVELOPMENTS UP 18.5%;**
- PRESCIENT DOWN 5.2%

*** VICTORIA, MONASH UNI 1st CARDIOVASCULAR CENTRE**

*** RHYTHM RECRUITS COLOSTAT TRIAL**

*** LUMOS: US FDA 'DEPRIORITIZES' COVIDX EMERGENCY USE**

*** IMUGENE: JAPAN PATENT FOR HER-VAXX IMMUNOTHERAPY**

*** BOD, WOOLCOCK TRIAL S3 MARIJUANA FOR INSOMNIA**

*** EMYRIA: PRELIMINARY ANALYSIS OF 1st MDMA ANALOGUE**

*** HARBOUR TAKES 10% OF VOLPARA**

*** DORSAVI CHAIR GREG TWEEDLY TO RETIRE AT AGM**

*** CLARITY JOINS CORAR**

MARKET REPORT

The Australian stock market was up 0.32 percent on Wednesday September 22, 2021, with the ASX200 up 23.1 points to 7,296.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and two were untraded.

Medical Developments was the best, up 78 cents or 18.5 percent to $4.99, with 4.3 million shares traded. Actinogen climbed 8.25 percent; Clinuvel and Oncosil improved more than four percent; Cynata, Immutep, Imugene and LBT were up more than three percent; Volpara rose 2.65 percent; Kazia, Neuren, Opthea and Polynovo were up more than one percent; with Avita, CSL, Resmed and Universal Biosensors up by less than one percent.

Prescient led the falls, down 1.5 cents or 5.2 percent to 27.5 cents, with 4.3 million shares traded, followed by Osprey down 5.1 percent to 74 cents, with 12,999 shares traded. Cyclopharm, Pro Medicus and Telix shed more than two percent; Genetic Signatures, Nova Eye, Orthocell, Proteomics and Starpharma were down more than one percent; with Cochlear, Mesoblast, Nanosonics, Next Science and Paradigm down by less than one percent.

VICTORIA GOVERNMENT, MONASH UNIVERSITY

The Victoria Government says it will help establish the Health Innovation Centre, the first Australian centre for cardiovascular research at Monash University in Clayton.
In a media release from Victoria's Minister for Higher Education, Gayle Tierney said the Government contributed $17.5 million of the $17.7 million for the Centre which would be "a key developer of clinical products and therapies, cardiac technology and models of care".
The Government said the Centre would feature "research spaces, flexible office areas, collaboration spaces for industry and manufacturers and cutting-edge equipment including audio visual technology to help develop and commercialize products".
The media release said the centre would put the invention of heart health products in the "hands of patients, healthcare professionals and companies by fostering collaboration and attracting investment".
The Government said Monash University inventors and entrepreneurs would "spin out companies to drive jobs and growth in Victoria".
The media release said research from the Heart Foundation showed that cardiovascular disease accounted for a "quarter of deaths, disproportionately affected Indigenous people and cost the Australian economy $5 billion more each year than any other disease".
The Government said with the facility was expected to open in early 2022.

RHYTHM BIOSCIENCES

Rhythm says it has recruited 815 of an intended 1,000 patients for its Colostat colorectal cancer blood test clinical trial.
In 2019, Rhythm said it had recruited the first of 1,000 patients in a prospective trial of its Colostat blood test for colorectal cancer detection and the multi-centre study would comparing the diagnostic effectiveness of Colostat relative to colonoscopy and faecal immunochemical tests (BD: Feb 20, Mar 18, 2019).
The company said at that time that it expected to complete the trial by October 2019.
Today, Rhythm chief executive officer Glenn Gilbert said that "in the context of market conditions made extremely difficult by Covid-19, I am proud of the achievement by the entire Rhythm team, our trial sites, [contract research organization], operations and laboratory partners".
"This milestone should not be understated, considering the recruitment phase is typically the most resource, logistically challenging and cost intensive component of completing a clinical trial," Mr Gilbert said.
Rhythm said the trial was a prospective, cross-sectional study with the primary endpoint of evaluating the diagnostic performance of the Colostat in-vitro diagnostic relative to colonoscopy.
The company said the secondary endpoints included assessing Colostat's ability to detect advanced adenomas and a comparison of Colostat's performance to the current market standard faecal immunochemical test (FIT).
Rhythm said that the process to close the trial sites, test collected blood samples and finalize the patient database along with other routine work had begun.
Rhythm said it would continue to work with its contract research organisation Accelagen and its analytical testing partner Sonic Clinical Trials to progress the next stages in finalizing the trial before the final clinical study report, which it expected to complete by July 2022.
Last month, the company said it had submitted its initial documentation for Australian Therapeutic Goods Administration approval for Colostat (BD: Aug 19, 2021).
Rhythm was up 14 cents or 11.9 percent to $1.32.

LUMOS DIAGNOSTICS

Lumos says the US Food and Drug Administration has “deprioritized” its emergency use application for the Covidx Sars-Cov-2 rapid antigen test.
Lumos said the FDA had “ceased review” of the emergency use application for the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) test “at this time”.
The company said it was “in active dialogue with the FDA” and was preparing additional data to support the application.
The company said the Covidx test had Conformité Européenne (CE) mark approval and was available in Europe, and was undergoing regulatory review in other markets.
Lumos said it was completing development of its Viradx point of care test “which simultaneously tests for Covid-19 and influenza and has the potential to satisfy an even greater public health need”.
Lumos chief executive officer Rob Sambursky said the company was “clearly disappointed with the delay” but appreciated the effort the FDA put into reviewing the application.
“We believe Covidx has an important role in the rapid identification of patients potentially infected with Covid-19 and Lumos will continue to work with the FDA to secure regulatory clearance for Covidx,” Mr Sambursky said.
Lumos fell 13 cents or 12.0 percent to 95.5 cents with 1.7 million shares traded.

IMUGENE

Imugene says the Japan Patent Office has granted a patent relating to its HER-Vaxx immunotherapy, currently in development for HER2 gastric cancer.
Imugene said the patent, titled ‘A Vaccine Composition and Uses Thereof’ protected its immunotherapy method of composition and method of use until 2036.
The company said the patent was invented by the Medical University of Vienna’s Prof Ursula Wiedermann.
Imugene was up 1.5 cents or 3.3 percent to 47 cents with 53.6 million shares traded.

BOD AUSTRALIA

Bod says Sydney’s Woolcock Institute of Medical Research will conduct a 200-patient, phase IIb, marijuana-based schedule 3 cannabidiol trial for patients with insomnia.
Bod said the double-blind, randomized, placebo-controlled trial would investigate the effect of the 50mg and 100mg daily oral cannabinoid product, compared to placebo in 18 to 65-year-olds with insomnia symptoms over a period of eight weeks.
The company said the study’s primary objective was investigating the effect of cannabidiol on insomnia severity index scores, with a secondary objective to determine objective sleep indices, including wake after sleep onset, as well as anxiety and stress levels.
Bod said the Australian market for schedule 3 cannabinoid products was about $250 million and the unregulated market was worth about $3.5 billion “demonstrating the potential penetration for Schedule 3 medicines”.
The company said that following approval, it would progress product sales to Australian pharmacies through Swisse Wellness and the Health and Happiness Group.
Last year, Zelira said a 23-patient, phase Ib/IIa trial of marijuana-derived ZLT-101 showed safety and statistical significance for reduction of chronic insomnia, with an average 26 percent reduction in the insomnia severity index (ISI) for the low dose (0.5ml of 11.5mg cannabinoids) and high dose (1.0ml of 11.5mg cannabinoids) ZLT-101 groups compared to placebo, with the high dose achieving a 36 percent reduction (BD: Apr 7, 2020).
Bod was up three cents or 11.5 percent to 29 cents.

EMYRIA

Emyria says it has completed a preliminary analysis of the first batch of 3,4-methylene-dioxy meth-amphetamine (MDMA) analogue for neurological disorders.
Last month, Emyria said it would work with the University of Western Australia on MDMA, also known as 'ecstasy' compounds (BD; Aug 5, 2021).
Today, the company said the compounds developed by Dr Matt Piggott demonstrated "excellent purity and stability at room temperature" and the first batch of compounds were being prepared for neurological screening and drug candidate selection and analysis.
Emyria managing-director Dr Michael Winlo said the company was "delighted to confirm that the first batch of MDMA-analogues evaluated show excellent purity and stability".
"This is an important first step in our drug development program, which can now progress to comprehensive neurological receptor screening," Dr Winlo said.
Emyria fell half a cent or 2.3 percent to 21.5 cents with one million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Harbour Asset Management says it has increased it substantial shareholding in Volpara from 19,677,115 shares (9.006%) to 25,207,679 shares (10.029%).
The Wellington, New Zealand-based Harbour Asset Management said it bought and sold shares between April 27, 2020, and September 21, 2021 with the single largest purchase 2,307,693 shares for $3,000,001 or $1.30 a share.
Harbour said it bought a total of 8,577,037 shares for $11,089,126 or an average of $1.29 a share, and sold 2,109,144 shares for $2,904,037 or an average of $1.377 a share.
Volpara was up three cents or 2.65 percent to $1.16.

DORSAVI

Dorsavi says chair Greg Tweedly will retire at the close of company's annual general meeting on November 26, 2021.
Dorsavi said Mr Tweedly joined the board in October 2013 and replaced Herb Elliot as chair in November 2017.
The company said it would begin the search for "at least one new independent non-executive director".
Dorsavi fell 0.1 cents or 4.55 percent to 2.1 cents.

CLARITY PHARMACEUTICALS

Clarity said it has joined the Washington, DC-based Council on Radionuclides and Radiopharmaceuticals (Corar) and been appointed to its board.
Clarity said Corar currently had 16 member companies that "manufactured and distributed radio-pharmaceuticals, radio-nuclides and sealed sources primarily used in medicine and life science research in the US" and monitored and advocated for manufacturing, transportation, safety, security and government reimbursement.
Clarity fell 3.5 cents or 2.7 percent to $1.27.