



Biotech Daily

Wednesday March 22, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: DIMERIX, PROTEOMICS UP 9.5%;
- ATOMO DOWN 6%**
- * **MELBOURNE UNI: 2nd ENTREPRENEUR PROGRAM OPENS**
- * **MESOBLAST: FDA INSPECTS REMESTEMCEL-L MANUFACTURER**
- * **REDHILL TALICIA HELICOBACTER PYLORI WARRANTY**
- * **RACE REQUESTS 'BOARD CHANGE' TRADING HALT**
- * **REGAL REDUCES TO 5.3% OF PHARMAXIS**

MARKET REPORT

The Australian stock market was up 0.87 percent on Wednesday March 22, 2023, with the ASX200 up 60.2 points to 7,015.6 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and three were untraded. All three Big Caps were up.

Dimerix and Proteomics were the equal best, both up 9.52 percent to 11.5 cents and 80.52 cents, respectively, with 585,190 shares and 158,563 shares traded, respectively.

Emvision climbed 9.2 percent; Compumedics was up 7.4 percent; Mesoblast improved five percent; Actinogen and Cyclopharm were up more than four percent; Starpharma was up 3.2 percent; Avita, Next Science, Pharmaxis, Polynovo, Resmed and Volpara rose more than two percent; Nanosonics, Nova Eye, Pro Medicus and Telix were up one percent or more; with Cochlear and CSL up by less than one percent.

Atomo led the falls, down 0.3 cents or 6.4 percent to 4.4 cents, with 328,941 shares traded.

Patrys fell four percent; Genetic Signatures, Medical Developments and Resonance retreated two percent or more; Antisense, Clinuvel, Immutep and Orthocell were down more than one percent; with Neuren down by 0.9 percent.

UNIVERSITY OF MELBOURNE, FEDERAL GOVERNMENT, MTP CONNECT

The University of Melbourne says applications have opened for the second intake of the Australian Clinical Entrepreneur Program (AUSCEP) pilot program.

The University said the program aimed to support the medical technologies, biotechnologies and pharmaceutical sectors, clinicians and health services by providing “commercial knowledge, expertise, a supportive and safe network and permission to innovate”.

The University of Melbourne said it was administering the program in partnership with the University of Western Australia and was supported by the Federally-funded MTP Connect’s Research Exchange and Development within Industry (REDI) initiative.

In 2021, MTP Connect said that the REDI Clinical Entrepreneur Program was based on the United Kingdom’s Clinical Entrepreneur Program and would help equip healthcare professionals with the skills to translate and commercialize ideas and innovations into products and “effect cultural change within the healthcare system by encouraging entrepreneurialism” (BD: Nov 19, 2021).

Today, the University said the pilot program had 55 fully-funded places available, and would run across two consecutive cohorts.

The University said that the program included eight online workshops over 12-months as well as other seminars, mentorship and networking.

The University of Melbourne said that AUSCEP would initially be delivered in Western Australia, Victoria and New South Wales and intended to be rolled out nationally.

The University said that eligible applicants “must have an innovative idea that solves an unmet need which will be used as a test case and developed during the course”.

The University said the program would help participants with commercializing innovations that solved key system challenges, with skills to translate ideas into solutions with impact, drive development, help effect cultural change within the health system and retain talented staff.

The University said a virtual information session would be held on March 28, 2023 at 7.30pm (AEST), with registration available at: <https://lu.ma/2pgfeiw6>.

Application close on April 16, 2023.

For more information, go to: www.auscep.com.au.

To apply, go to: <https://airtable.com/shruKYwDmskDA72Wa>.

MESOBLAST

Mesoblast says the US Food and Drug Administration will inspect its Singapore manufacturer of remestemcel-L for children with acute graft versus host disease.

Earlier this month, the company said the resubmission of its biological license application for remestemcel-L had been accepted by the FDA, which set a US Prescription Drug User Fee Act goal date of August 2, 2023 (BD: Mar 8, 2023).

Today, Mesoblast said the inspection of its manufacturing facility at Singapore’s Lonza Biosciences was part of the FDA’s ongoing review of its resubmitted application for remestemcel-L.

The company did not specify the date of inspection.

Mesoblast chief executive officer Prof Silviu Itescu said the company was “pleased that the pre-licence inspection of our manufacturing operations has been scheduled”.

“We look forward to continuing to work closely with FDA during the review period with the aim to make remestemcel-L available as a therapy for children suffering from severe-refractory acute graft versus host disease,” Prof Itescu said.

Mesoblast was up 4.5 cents or five percent to 94 cents with 2.1 million shares traded.

REDHILL BIOPHARMA

Redhill says it will begin a reimbursement warranty program for non-responsive patients prescribed its antibiotic Talicia (formerly RHB-105) for Helicobacter pylori.

Redhill said the program was “believed to be the first of its kind offered for a widespread community (non-hospital) treated condition, lowering the bar for patient access” to its combination amoxicillin, rifabutin and omeprazole for Helicobacter pylori.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

Today, the company said eradication of Helicobacter pylori was increasingly difficult due to high antibiotic resistance to commonly used standard combination therapies, especially clarithromycin.

Redhill said a 2021 study of clarithromycin-based triple therapy for Helicobacter pylori showed a declining eradication rate of 68.5 percent, and a 32 percent eradication rate in patients with resistant Helicobacter pylori organisms.

Redhill said its pivotal phase III study showed a 90.3 percent eradication rate in the Talicia arm compared to 64.7 percent in the active comparator arm and there was “minimal zero resistance to the antibiotic rifabutin, a key component of Talicia”.

On the Nasdaq, was Redhill up 0.02 US cents or 0.14 percent to 14.03 US cents (20.96 Australian cents) with 2.6 million shares traded.

RACE ONCOLOGY

Race says it has requested a trading halt pending an announcement in “relation to a board change”.

Trading will resume March 24, 2023, or on an earlier announcement.

Race last traded at \$1.995.

PHARMAXIS

Regal Funds says it has reduced its substantial shareholding in Pharmaxis from 47,336,848 shares (6.58%) to 38,159,163 shares (5.30%)

The Sydney-based Regal Funds said between February 10 and March 17, 2023 it sold 9,177,685 shares in 12 transactions with the single largest sale on March 17 of 2,033,965 shares on March 17 for \$93,969 or 4.6 cents a share.

Pharmaxis was up 0.1 cents or 2.3 percent to 4.5 cents.