



Biotech Daily

Wednesday June 3, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: GENETIC SIGNATURES UP 10%; IMPEDIMED DOWN 10%**
- * **CLARITY: 67CU-SARTATE FDA 'RARE DISEASE' FOR NEUROBLASTOMA**
- * **IMPEDIMED: BIS 'SIGNIFICANT LYMPHOEDEMA DETECTION'**
- * **NUHEARA: \$2m IN IQBUDS MAX PRE-ORDERS**
- * **MEDLAB RECEIVES 1st NANABIS FROM TASMANIAN ALKALOIDS**
- * **CRESO: DHS TO DISTRIBUTE CANNAQIX MARIJUANA IN BRAZIL**
- * **IMPRESSION DROPS MOUTHGUARDS FOR MARIJUANA**
- * **CANN GLOBAL 2nd 'RESEARCH INITIATIVES' EXTENSION SUSPENSION**
- * **REGAL FUNDS REDUCE TO 6% OF MEDICAL DEVELOPMENTS**
- * **REGAL FUNDS REDUCE TO 10.7% OF OPTHEA**
- * **PERENNIAL TAKES 6.4% OF ATOMO**
- * **PARADIGM: DR JEANNIE JOUGHIN COO, DR MICHAEL IMPERIALE SAFETY**
- * **MAYNE APPOINTS TONI NESCI HEAD OF CONTRACT SERVICES**

MARKET REPORT

The Australian stock market was up 1.83 percent on Wednesday June 3, 2020, with the ASX200 up 106.5 points to 5,941.6 points. Twenty of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and one was untraded.

Genetic Signatures was the best, up 22 cents or 10.4 percent to \$2.33, with 752,028 shares traded. Resonance rose 8.1 percent; Osprey improved 7.7 percent; Patrys was up 6.7 percent; Avita, Compumedics and Universal Biosensors were up more than four percent; Pharmaxis was up 3.45 percent; Next Science, Opthea, Optiscan, Polynovo and Proteomics rose more than two percent; Cochlear, Cyclopharm and Prescient were up more than one percent; with Medical Developments, Mesoblast, Nanosonics, Paradigm and Volpara up by less than one percent.

Impedimed led the falls, down 0.8 cents or 9.6 percent to 7.5 cents with 11.7 million shares traded. Amplia lost 7.1 percent; Kazia and LBT were down more than six percent; Alterity and Immutep fell more than five percent; Neuren and Pro Medicus shed two percent or more; Antisense, Ellex, Resmed, Telix and Uscom were down more than one percent; with Clinuvel, CSL and Starpharma down by less than one percent.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has granted it rare paediatric disease designation (RPDD) for ⁶⁷Cu-Sartate for neuroblastoma.

Clarity said neuroblastoma was the most common type of cancer in the first year of life and accounted for 15 percent of paediatric cancer mortality.

The company said the rare paediatric disease designation program was intended to facilitate development of new drugs and biologics for the prevention and treatment of rare paediatric diseases.

Clarity said that on FDA marketing approval, it might receive a priority review voucher to obtain FDA review of a new drug application in an expedited six-month period.

The company said voucher could be sold or transferred, and to date have been sold for between \$US67.5 million (\$A97.3 million) and \$US350 million (\$A504.4 million).

In April, Clarity said ⁶⁷Cu-Sartate had FDA orphan designation for neuroblastoma, and last year the FDA approved a 34-patient phase I/IIa trial (BD: Oct 3, 2019, Apr 22, 2020).

Clarity is a public unlisted company.

IMPEDIMED

Impedimed says bioimpedance spectroscopy detection of subclinical lymphoedema is statistically significantly associated with patient symptoms.

Impedimed said that a two-year trial trajectory analysis showed that bioimpedance spectroscopy (BIS) was associated with patient symptoms “whereas tape measure detection of lymphoedema was not”.

The company said the paper, titled ‘L-Dex, arm volume, and symptom trajectories 24 months after breast cancer surgery’, was published in Cancer Medicine and the full manuscript is at: <https://onlinelibrary.wiley.com/doi/full/10.1002/cam4.3188>.

Last year, Impedimed said a 508-patient trial showed its BIS test for post cancer lymphoedema was superior to the standard tape measure assessment in a one-year post surgery analysis (BD: May 3, 2019).

Today, the company said the same 508 patients were measured using its Sozo device L-Dex measurement technology compared to limb circumference using tape measure, the current method for detection, for the 24-month analysis.

Impedimed said the study found that a “statically significant convergence of symptom cluster scores with L-Dex unit change support BIS as beneficial in early identification of subclinical lymphoedema”.

The manuscript said the symptom trajectory groups, which were either decreasing, stable or increasing for each biomarker, were “statistically significantly associated with distribution of L-Dex change trajectories but not with the percent difference change in arm volume trajectories”.

Impedimed said the study was on-track and expected to be completed in the new year.

Impedimed fell 0.8 cents or 9.6 percent to 7.5 cents with 11.7 million shares traded.

NUHEARA

Nuheara says it has received 4,600 pre-orders for its Iqbuds Max hearing and sound filtering earbuds for more than \$2 million over the past five months.

Nuheara chief executive officer Justin Miller said sales included 85 percent from non-Australian customers, predominantly in Europe, and North America.

The company said it would begin the logistics phase to deliver the completed product.

Nuheara fell 0.1 cents or 5.6 percent to 1.7 cents with 11.3 million shares traded.

MEDLAB CLINICAL, TASMANIAN ALKALOIDS

Medlab says it has received the first three batches of its marijuana-based Nanabis from Tasmanian Alkaloids, with all backorders fulfilled.

In January, Medlab said it had a three-year agreement with Tasmanian Alkaloids to manufacture Nanabis (BD: Jan 29, 2020).

Today, the company said there was a 26 percent increase in Nanabis revenue in the March quarter, with more than 2,000 bottles prescribed.

Medlab chief executive officer Dr Sean Hall said partnering with Tasmanian Alkaloids “allows Medlab to increase production capacities drastically over the short term and therefore to meet increased demand”.

Medlab was up one cent or 4.9 percent to 21.5 cents.

Tasmanian Alkaloids is a private company

CRESO PHARMA

Creso says DHS Business International will distribute its Cannaqix marijuana in the Brazilian retail market.

Creso said it would target the DHS network in Latin and North America in Sao Paulo, Rio de Janeiro and Parana, initially targeting working and aging populations.

The company said it would work with DHS to make the products available this year.

Creso fell 0.4 cents or 6.7 percent to 5.6 cents with 7.4 million shares traded.

IMPRESSION HEALTHCARE

Impression says it will discontinue sales of sport mouthguards by June 30, 2020 to focus on marijuana sales and development.

Last week, Impression said that an extraordinary general meeting would vote to change its name to Incannex Healthcare (BD: May 26, 2020).

Today, the company said sales of sport mouthguards had “severely diminished due to the cancellation of sport seasons resulting from Covid-19 restrictions” and it did not expect recovery in mouthguard sales in the medium term to justify continued financial commitment.

Impression said it expected to change its ASX global industry classification standard (GICS) from healthcare equipment and services to pharmaceuticals, biotechnology and life sciences, but it would retain its ASX code.

Impression chief executive officer Joel Latham said “this move allows us to really focus on the part of the business which will drive value for our shareholders”.

“The opportunities in the medicinal cannabis sector are significant and IHL has assembled a world class team in this space, with four clinical assets undergoing assessment,” Mr Latham said. “In the current climate, continuing with oral devices would consume vital management time and take capital away from Incannex, which is an outcome we do not want for our shareholders.”

Impression was up 0.3 cents or 5.9 percent to 5.4 cents with 2.3 million shares traded.

CANN GLOBAL

Cann Global has requested a second extension to a voluntary suspension, following a trading halt for an announcement on “research initiatives” (BD: May 18, 20, 25, 2020).

Cann Global said it expected the announcement to be made by June 5, 2020.

Cann Global last traded at 0.7 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Regal Funds says it has reduced its substantial shareholding in Medical Developments from 4,668,764 shares (7.12%) to 3,973,464 shares (6.05%).

The Sydney-based Regal Funds said that between March 13 and 27, 2020 it bought 128,195 shares for between \$4.24 and \$5.75 a share and between March 16 and May 29, it sold 823,495 shares for between \$3.95 and \$8.31 a share.

Medical Developments was up seven cents or 0.9 percent to \$8.05 with 169,983 shares traded.

OPTHEA

Regal Funds Management says it has reduced its substantial shareholding in Opthea from 31,579,466 shares (11.73%) to 28,726,324 shares (10.67%).

The Sydney-based Regal Funds said that between April 21 and May 11, 2020 it bought 210,315 shares for between \$2.28 and \$3.01 a share and between April 15 and May 29, it sold 3,063,457 shares for between \$2.23 and \$3.04 a share.

Opthea was up seven cents or 2.1 percent to \$3.40 with 587,486 shares traded.

ATOMO DIAGNOSTICS

Perennial Value Management says it has increased its substantial shareholding in Atomo from 29,884,787 shares (5.33%) to 36,020,169 shares (6.42%).

The Sydney-based Perennial said that on May 6, 2020 it sold 254,148 shares for \$113,020 or 44.47 cents a share.

Perennial said that it bought shares between May 25 and 29, 2020, with the single largest purchase 1,169,813 shares for \$385,889 or 32.99 cents a share.

Atomo was unchanged at 31.5 cents with 2.4 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has appointed Dr Jeannie Joughin as chief operating officer and Dr Michael Imperiale as head of safety.

Paradigm said Dr Joughin had more than 20 years' experience in pharmaceutical companies, including senior executive roles with Enable Injections and CSL Behring. The company said Dr Joughin was a director of the public unlisted Paranta Biosciences and held a Bachelor of Science and a Doctor of Philosophy from Melbourne's Monash University.

Paradigm said Dr Imperiale had more than 25 years' experience in drug development, beginning his career at Germany's Boehringer-Ingelheim and later worked for Nektar Therapeutics leading its immune-oncology and pain programs.

The company said that Dr Imperiale was the medical lead at Biomarin and head of clinical research at Talon Therapeutics, where he developed Marquibo for acute lymphocytic leukaemia.

Paradigm said Dr Imperiale held a Bachelor of Arts from Pennsylvania's Villanova University and a Doctor of Medicine from the Philadelphia, Pennsylvania-based Hahnemann University School of Medicine.

Paradigm was up three cents or 0.9 percent to \$3.21 with 1.7 million shares traded.

MAYNE PHARMA

Mayne Pharma says it has appointed Toni Nesci as head of its Salisbury, South Australia-based contract services division and launched a new website.

Mayne Pharma said Ms Nesci had more than 20 years' experience in the pharmaceutical industry and had held a variety of roles at Pfizer and Hospira.

A Mayne Pharma spokesperson told Biotech Daily that the contract services division manufactured for third party clients to good manufacturing practice and US Food and Drug Administration standards.

The spokesperson said that the facility manufactured oral, topical and modified release drugs.

The website is available at www.maynecontractservices.com.

Mayne Pharma was up one cent or 2.3 percent to 44.5 cents with 9.5 million shares traded.