Biotech Daily

Monday March 27, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMPEDIMED UP 112%; DIMERIX DOWN 11.5%**

*** IMPEDIMED: US NCCN GUIDELINES BACK SOZO FOR LYMPHOEDEMA**

*** ANTERIS MEETS FDA REQUIREMENTS FOR DURAVR THV MANUFACTURE**

*** PROTEOMICS STUDY: ENDOMETRIOSIS BLOOD TEST 90% ACCURATE**

*** IMAGION: FDA OKs MAGSENSE BREAST CANCER TRIAL 'KEY ELEMENTS'**

*** OSTEOPORE: TAIWAN APPROVES OSTEOMESH FOR FACE SURGERY**

*** RADIOPHARM, GENESISCARE PARTNER FOR RADIO-PHARMACEUTICALS**

*** GENETIC TECHNOLOGIES: GENETYPE PERFORMS 9 RISK TESTS**

*** RACE RECEIVES $1.5m FEDERAL R&D TAX INCENTIVE**

*** MATHEW REGAN REPLACES ARTRYA CEO JOHN BARRINGTON**

*** DANNY ENGLISH REPLACES PRO MEDICUS CO SEC CLAYTON HATCH**

MARKET REPORT

The Australian stock market was up 0.1 percent on Monday March 27, 2023, with the ASX200 up 6.8 points to 6,962.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and two were untraded. All three Big Caps rose.

Impedimed was the best, up 6.6 cents or 111.9 percent to 12.5 cents with 60.9 million shares traded. Proteomics climbed 12.0 percent; Alcidion was up 8.3 percent; Medical Developments improved 7.9 percent; Micro-X and Universal Biosensors were up more than four percent; Avita and Nanosonics were up more than three percent; Polynovo rose two percent; Actinogen, Cochlear, Emvision, Mesoblast, Orthocell, Paradigm and Resmed were up more than one percent; with CSL, Neuren and Pro Medicus up by less than one percent.

Dimerix led the falls, down 1.5 cents or 11.5 percent to 11.5 cents, with 1.1 million shares traded. Immutep lost 5.45 percent; Patrys and Pharmaxis fell more than four percent; Cynata, Imugene and Opthea were down more than three percent; Atomo and Next Science shed more than two percent; Nova Eye and Starpharma were down more than one percent; with Clinuvel and Cyclopharm down by less than one percent.

IMPEDIMED

Impedimed says that the US National Comprehensive Cancer Network clinical practice guidelines in oncology include bioimpedance spectroscopy for the first time.
Impedimed said that the guidelines "specifically name bioimpedance spectroscopy as an objective measurement tool to identify early signs of lymphoedema … and recommended] regular screening for all cancer survivors at risk of lymphoedema".
The company said that the inclusion of bioimpedance spectroscopy in the guidelines would help establish bioimpedance spectroscopy as the standard-of-care and accelerate adoption by private payors and providers.
Impedimed said the updated guidelines recommended that cancer survivors at risk of lymphoedema be screened at regular intervals to identify early signs of lymphoedema via symptom assessment, clinical exam, and, if available, bioimpedance spectroscopy.
Impedimed said it had the only US Food and Drug Administration-cleared bioimpedance spectroscopy technology for the assessment of lymphoedema.
The company said its Sozo digital health platform was "broadly accepted and recognized for effective and accurate screening of lymphoedema".
Impedimed managing-director Richard Valencia said the recommendation in the NCCN Guidelines was "a major validating moment for the company".
"The authors of the NCCN Guidelines are world leaders in global cancer care driven by sound clinical evidence and patients' best interests," Mr Valencia said.
"Their recommendations are highly influential for clinicians, patients, policymakers, and insurance companies," Mr Valencia said.
"We will take the information in these updated NCCN Guidelines and immediately integrate it into our reimbursement strategy to expand coverage of Sozo testing for lymphoedema," Mr Valencia said.
"Our near-term focus remains leveraging our strong clinical evidence, market position, and now these guidelines to drive growth and adoption of our solution for breast cancer-related lymphoedema," Mr Valencia said. "Longer-term, these guidelines also support an opportunity to expand into other cancer types, broaden our footprint in oncology, and benefit even more patients."
Impedimed climbed 6.6 cents or 111.9 percent to 12.5 cents with 60.9 million shares traded.

ANTERIS TECHNOLOGIES

Anteris says the US Food and Drug Administration has approved the manufacture of its Duravr transcatheter heart valve at its expanded production facility in Minnesota.
Anteris said it had met regulatory requirements for the manufacture at the Maple Grove, Minnesota factory, which would allow it to expand in-house production capabilities that would "lead to significant cost savings".
The company said the Duravr devices produced would be available to interventional cardiologists treating patients with severe aortic stenosis, as part of the company's early feasibility study and pivotal studies.
Anteris said the expanded Maple Grove facility complemented tissue-engineering capabilities in Perth, where the company's Adapt anti-calcification technology was manufactured, while expanding overall production capacity.
Anteris chief executive officer Wayne Paterson said the start of valve production at the US Maple Grove facility "introduces great efficiencies and reduces manufacturing costs and is within easy reach of the world's largest TAVR centres and cardiovascular market."
Anteris was up 20 cents or 1.1 percent to $18.70.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says a 901-sample study showed that its blood test for endometriosis achieved both 90 percent sensitivity and specificity.

Proteomics said the test, developed in collaboration with the Melbourne's Royal Women's Hospital and the University of Melbourne, used blood bio-markers to screen for endometriosis, a disease which occurs in one in nine women and requires an invasive laparoscopy and surgical procedure to diagnose.

The company said that it compared samples from 494 women who had been diagnosed with endometriosis through a laparoscopy, with two control groups including 153 healthy individuals and 254 patients with pelvic pain but surgically diagnosed absence of endometriosis.

The Royal Women's Hospital director of research Prof Peter Rogers said that a "non-invasive test for endometriosis could save women "years of suffering".

"Endometriosis symptoms often start when women are teenagers," Prof Rogers said.

"But because it's so hard to diagnose, girls can struggle with unexplained pain throughout their lives," Prof Rogers said.

"We're hoping to prevent this with a simple, accessible blood test that can be ordered by a family [general practitioner]," Prof Rogers said.

Proteomics was up 9.5 cents or 12.0 percent to 88.5 cents.

IMAGION BIOSYSTEMS

Imagion says the US Food and Drug Administration has agreed with "key elements" of its proposed phase II trial of its Magsense HER-2 breast cancer imaging agent.

Imagion said it planned to proceed with a multi-site, phase II, US clinical trial that would investigate optimal dosages and imaging parameters before it committed to a phase III pivotal study.

The company said it expected to file an investigational new drug (IND) application with the FDA by September 1, 2023 at the earliest, allowing it to expand US trials.

Imagion said that, following the FDA feedback, it would collect additional clinical and non-clinical data to support the phase II study, manufacture additional Magsense material and establish the initial clinical investigators and sites for the study.

Imagion executive chair Bob Proulx said that "receiving this early feedback from the FDA was very important as we prepare for the IND filing later this year, yet another major milestone for our imaging technology and pipeline development".

"The FDA feedback provides clarity for our actions in the coming months, including our plans to use our new facility for part of the manufacturing process," Mr Proulx said.

Imagion fell 0.1 cents or 5.6 percent to 1.7 cents with 2.6 million shares traded.

OSTEOPORE

Osteopore says Taiwan has approved the use of its Osteomesh facial reconstruction implants for cranio-facial (head and face) tissue regeneration.

Osteopore said it had previously secured Taiwanese regulatory approval for Osteomesh for eye area reconstruction.

The company said that in addition to addressing functional issues, surgical treatment of the nasal bone area provided "aesthetic relief" for patients.

Osteopore said a survey from 2021 showed nasal surgery, included in the category of "craniofacial" reconstruction, was the fourth most common aesthetic procedure in Taiwan.

Osteopore was unchanged at 8.4 cents.

RADIOPHARM THERANOSTICS

Radiopharm says it has a two-year strategic research collaboration with Genesiscare to develop novel radio-pharmaceuticals for “some complex, hard-to-treat cancers”.
Radiopharm said that the partnership would conduct phase I trials in Australia to study the safety and tolerability of the new radio-pharmaceuticals.
The company said radio-pharmaceuticals delivered small doses of radiation to specific cells for either therapeutic or diagnostic purposes, with the majority of clinically used radiopharmaceuticals targeting prostate cancer and neuroendocrine tumors.
Radiopharm said Genesiscare’s contract research organization and imaging research organization would start three phase I trials using Radiopharm’s radio-pharmaceutical nanobodies.
The company said one trial would use the proprietary nanobody from its nano-monoclonal antibodies platform to target non-small cell lung cancer, the second would study its protein tyrosine phosphatases-? for brain tumors, and the final trial would involve its prostate specific antigen targeting antibody for prostate cancer.
Radiopharm was up 1.5 cents or 9.4 percent to 17.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it has begun the phase two roll-out of its Genetype Multi-Test, providing risk assessments on nine diseases from a single saliva sample.
Genetic Technologies said it had included melanoma, pancreatic cancer and atrial fibrillation to the existing six indications, which include breast cancer, colorectal cancer, prostate cancer, ovarian cancer, coronary artery disease and type 2 diabetes.
The company said that the expanded panel was “available population-wide for all ethnicities to doctors and their patients in the US”.
Genetic Technologies said the Multi-Test provided “a stratification assessment of a person’s risk profile for six cancers, two cardiovascular diseases and a metabolic disease - for a total of seven diseases for men and eight for women”.
The company said that the Multi-Test was available to adults of all ethnicities, starting at the age of 30 years.
Genetic Technologies said that “as with the other diseases included in Multi-Test, being able to stratify people at risk enables enhanced surveillance, early detection and early intervention which can lead to significantly improved patient outcomes”.
Genetic Technologies chief executive officer Simon Morriss said the company “continues to deliver on our commitment to being a world leader in delivering personalized risk assessments to enable preventative healthcare for a range of serious diseases”.
Genetic Technologies was unchanged at 0.3 cents with 2.2 million shares traded.

RACE ONCOLOGY

Race says it has received $1,476,425 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.
Race said the rebate related to research and development expenditure for the year to June 30, 2022.
The company said it had submitted an overseas finding claim to the Australian Taxation Office that could provide an additional refund for research and development expenditure undertaking in the year to June 30, 2022.
Race fell eight cents or 4.4 percent to $1.75.

ARTRYA

Artrya says Mathew Regan will replace co-founder John Barrington as chief executive officer, effective from today.

Artrya said that Mr Barrington and the board agreed the company would benefit from a "fresh leadership approach to ensure Artrya's ongoing success as it pursues regulatory approvals in the United States, and business opportunities in the jurisdictions in which it has approval".

The company said Mr Regan had worked for companies including Imdex and Quintis Sandalwood, and had experience in supply chain management, logistics, finance and trading.

Mr Barrington said he "had some recent health issues, so I intend to spend some time in the immediate future focussed on that".

Artrya was up four cents or 16.7 percent to 28 cents.

PRO MEDICUS

Pro Medicus says Danny English will replace Clayton Hatch as company secretary, effective from March 27, 2023.

Pro Medicus said Ms English had worked with the company for many years and was currently its financial controller.

The company said Mr Hatch would remain as its chief financial officer and "expressed its gratitude for Mr Hatch's commitment and dedication during his 13-year tenure as company secretary.

Pro Medicus was up 18 cents or 0.3 percent to $65.17 with 127,918 shares traded.