



Biotech Daily

Thursday February 20, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: DIMERIX UP 17%; USCOM DOWN 16%**
- * **AROA LAUNCHES MYRIAD FOR SOFT TISSUE REPAIR IN US**
- * **IMPEDIMED H1 REVENUE UP 58% TO \$2.8m, LOSS UP 7% TO \$12.9m**
- * **MESOBLAST: GVHD STUDY TAKES REMESTEMCEL-L TO PIVOTAL TRIAL**
- * **EMVISION, UQ WIN \$360k FELLOWSHIPS**
- * **LIFE SCIENCES QUEENSLAND, INDIA'S ABLE COLLABORATE**
- * **RESAPP: TGA APPROVES RESAPPDX-EU VERSION 2**
- * **EXOPHARM: 'CEVARIS WORKS FOR BLADDER DYSFUNCTION, EX-VIVO'**
- * **RACE APPOINTS PROF JAAP-JAN BOELEN ADVISOR**
- * **BIO-MELBOURNE DEVICES, DIAGNOSTICS LAB**

MARKET REPORT

The Australian stock market was up 0.25 percent on Thursday February 20, 2020, with the ASX200 up 17.9 points to 7,162.5 points.

Eleven of the Biotech Daily Top 40 stocks were up, 23 fell and six traded unchanged.

Dimerix was the best on no news, up 2.5 cents or 17.2 percent to 17 cents with 1.6 million shares traded. Osprey and Starpharma climbed more than five percent; Impedimed improved 4.8 percent; LBT was up 3.45 percent; Genetic Signatures, Medical Developments and Universal Biosensors rose more than two percent; with Cynata, Neuren, Next Science and Resmed up by more than one percent.

Uscom led the falls for the second day in a row, down five cents or 15.9 percent to 26.5 cents with 2.5 million shares traded. Immutep lost 10.1 percent; Optiscan and Paradigm shed more than six percent; Avita, Compumedics and Patrys fell more than five percent; Cochlear, Kazia and Oncosil were down more than three percent; Amplia, Antisense, Clinuvel, Imugene, Opthea, Orthocell, Pro Medicus, Resonance and Telix shed two percent or more; Mesoblast, Polynovo and Prescient were down more than one percent; with CSL, Nanosonics and Volpara down by less than one percent.

AROA BIOSURGERY

The Auckland, New Zealand based Aroa says it has launched its Myriad soft tissue repair and reconstruction product in the US.

Aroa founder and chief executive Dr Brian Ward said the product name, Myriad, reflected the potential uses for the product in soft tissue repair and reconstruction.

“As the name implies, our latest extracellular matrix product has a myriad of uses,” Dr Ward said.

“Myriad is a graft designed for the operating room and can be used for a wide range of plastic and reconstructive surgical procedures where soft tissue needs to be repaired or reinforced, including plastic surgery, limb salvage, burns, and trauma,” Dr Ward said.

“It may also assist healing in patients with impaired or compromised healing due to factors at the wound site or within their body such as compromised blood circulation,” Dr Ward said.

The company said that Myriad contained more than 150 protein sheep-derived components, “including structural, adhesion and signalling proteins that naturally exist in tissue and are known to aid the healing process”.

Aroa said its first product, Endoform Natural dermal template, was an extracellular matrix containing natural intact collagen scaffold, secondary molecules important for healing, it supported healing in acute and chronic wounds and was available as a collagen dressing. An Aroa spokesman told Biotech Daily that the company was established by Dr Ward in 2007 to use the prion-free status of the isolated New Zealand sheep flock to develop ovine-based tissue repair devices.

The spokesman said Aroa products were classified as medical devices by regulatory authorities and it had US Food and Drug Administration approvals for six products beginning with Endoform Natural in 2010, which was approved in the European Union in 2017, Canada in 2018 and Brazil, Thailand and Jordan and Costa Rica in 2019.

The spokesman said that Aroa had International Organization for Standardization quality certification ISO 13485: 2016.

He said that the company employed about 120 people at its head office in Auckland, with a further 25 located in a marketing joint venture in the US, it had revenue of about \$NZ24 million (\$A23 million) in the year to March 31, 2019 and had recorded its maiden profit.

“The release of Myriad in the United States marks the next step of growth for Aroa and our commitment to providing leading solutions that are accessible for both clinicians and their patients,” Dr Ward said.

Aroa head of technology Dr Barnaby May said that Myriad used the company’s core Endoform extracellular matrix (ECM) technology platform with engineered elements to promote the formation of blood vessels and rapid ingrowth of cells.

“The biological structure of Myriad is designed for rapid cell infiltration and blood vessel formation, to enable the patient’s cells to kick start the tissue building process,” Dr May said.

“Residual natural vascular channels present in the Endoform ECM technology facilitate a process we’ve termed angio-conduction,” Dr May said.

“These channels provide the architecture to support migrating endothelial cells to establish new vasculature and a robust blood supply,” Dr May said.

Aroa said that Myriad was available in a range of formats and required no special handling.

The company said that the product was rehydrated prior to use and conformed to the tissue defect during both routine and more challenging procedures.

Aroa said it would make Myriad available in a range of countries, pending approvals.

Aroa is a private company.

IMPEDIMED

Impedimed says revenue for the six months to December 31, 2019 was up 57.5 percent to \$2,837,000 with net loss after tax up 6.6 percent to \$12,941,000.

Impedimed said legacy revenue from its L-Dex lymphoedema test technology was down 29.1 percent to \$687,000, Sozo bio-impedance spectroscopy revenue was up 164.8 percent to \$2,126,000 and other revenue was down 17.2 percent to \$24,000.

The company said diluted loss per share was constant at 3.0 cents a share, net tangible assets per share fell 66.7 percent to 2.0 cents and it had cash and cash equivalents of \$12,971,000 at December 31, 2019 compared to \$22,638,000 at December 31, 2018. Impedimed was up half a cent or 4.8 percent to 11 cents with 1.9 million shares traded.

MESOBLAST

Mesoblast says remestemcel-L has shown “clinically meaningful outcomes” in three chronic graft versus host disease patients, taking the product to a pivotal trial.

Mesoblast said the outcomes from an investigator-initiated, expanded access protocol study were achieved in 28 days, after two infusions of its allogeneic cell therapy candidate remestemcel-L in two children and one adult.

The company said that it would expand the study into a pivotal trial of remestemcel-L for chronic graft versus host disease.

Mesoblast said chronic graft versus host disease occurred in 30 to 70 percent of allogeneic bone marrow transplant recipients, primarily during treatment for blood cancers and amounted to more than 30,000 patients worldwide each year.

The company said that in both chronic and acute graft versus host disease, the donated bone marrow stem cells viewed the recipient’s body as foreign and attacked the body, causing significant morbidity and mortality, usually manifesting within 100 days for acute graft versus host disease (GvHD) and later than 100 days for chronic GvHD.

Mesoblast said chronic GVHD occurred in more than 14,000 patients in the US costing about \$US300,000 (\$A451,264) per patient per year.

Duke University lead investigator Dr Joanne Kurtzberg said she was “delighted” with the initial outcomes using remestemcel-L as first-line therapy in steroid-refractory GvHD.

Mesoblast fell four cents or 1.4 percent to \$2.74 with 1.8 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says that in collaboration with the University of Queensland and Metro South Hospital and Health Service, it has won grants worth \$360,000 over three years.

Emvision said the Advance Queensland Industry Research fellowships would be used for its portable brain scanner system and would add capacity and allow accelerated approaches to image reconstruction.

Emvision director and co-founder Scott Kirkland told Biotech Daily that the fellowships were won by Dr Ali Zamani and Dr Lei Guo, employed by the University of Queensland under the fellowships to work on its brain scanner program.

Emvision chief executive officer Dr Ron Weinberger said the company was “thrilled with the State Government’s recognition and support of our transformational brain scanner development program”.

“These highly competitive fellowship wins will help offset the cost to [Emvision] for key team members and coincide with the company’s ongoing recruitment of key roles in its product development team,” Dr Weinberger said.

Emvision was unchanged at 90 cents.

LIFE SCIENCES QUEENSLAND

Life Sciences Queensland says it has a strategic partnership with India's Association of Biotechnology Led Enterprises.

Life Sciences Queensland said both organisations would promote and develop the bioscience sectors in Australia and India over the next five years and would focus on biotechnology, pharmaceuticals, clinical trials, start-ups and the international bioeconomy. The industry organization said the collaboration would provide access to India's \$US12 billion (\$A18.1 billion) biotechnology sector.

Life Sciences Queensland company said it would include Queensland organizations in regular meetings with Indian industry stakeholders, reciprocal delegate exchanges and a start-up exchange program to accelerate Queensland organizations' growth.

The organization said the partnership would also allow Indian companies to explore research and industry collaborations in Queensland.

Life Sciences Queensland chief executive officer Clare Blain said the partnership would "create increased opportunities for our organizations to use our existing networks, resources and expertise, and share agendas to form new collaborations and help diversify and strengthen the biosciences industry on an international scale".

Association of Biotechnology Led Enterprises chair Dr Kiran Mazumdar-Shaw said the partnership was "the way forward in collaboration between innovative companies in Queensland and India, to co-create many exciting products and solutions in biotechnology that will tackle the challenging healthcare needs of our communities".

"While [a memorandum of understanding] is the first step, the real task is to make it a reality quickly with meaningful collaborative projects from both sides," Dr Mazumdar-Shaw said.

RESAPP HEALTH

Resapp says its Resappdx-EU version 2 smartphone application has been approved by the Australian Therapeutic Goods Administration as a class IIa medical device.

Resapp said it was an extension of an existing approval and would allow its Resappdx-EU device to test both children and adults for lower respiratory tract disease, pneumonia, asthma exacerbation and chronic obstructive pulmonary disease exacerbation.

The company said acute respiratory tract infections were the most common acute illnesses in primary care, with diagnosis complex and subjective, combining clinical judgement with auscultation with a stethoscope, imaging, blood and sputum tests.

Resapp chief executive officer Dr Tony Keating said the company was "pleased that our lead product, Resappdx-EU is now approved for use on both adults and children in Australia and Europe".

Resapp was in a trading halt for a capital raise and last traded at 24 cents.

EXOPHARM

Exopharm says that its Cevaris exosome product has been shown to work in an ex-vivo model of bladder dysfunction.

Yesterday, Exopharm said ex-vivo models of erectile dysfunction showed that its Cevaris treatment provided "statistically significant improvement in muscle contraction and release" (BD: Feb 19, 2020).

Today, the company said testing was done by France's Plevipharm and provided a basis for further pre-clinical testing and potential clinical trials in urinary bladder control.

Exopharm was up 1.5 cents or 5.1 percent to 31 cents.

RACE ONCOLOGY

Race says it has appointed paediatric haematology oncologist Prof Jaap-Jan Boelens to its clinical advisory board.

Race said Prof Boelens had more than 20 years' experience in immunology, oncology and paediatrics and was currently the chair and chief of the New York-based Memorial Sloan Kettering Cancer Centre's Paediatric Stem Cell Transplantation and Cellular Therapies Service.

The company said Prof Boelens held a Doctor of Medicine from the University Medical Centre Utrecht and a Doctor of Philosophy from the Netherlands-based University of Amsterdam Academic Medical Centre.

Race was up 1.5 cents or 4.2 percent to 37.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will hold its eight annual Devices + Diagnostics Lab with the theme 'Manufacturing, Markets and Minefields' on March 5, 2020.

The Network said the full-day event would involve presentations and panel conversations from industry experts concluding with a plenary session led by sector leaders.

The Bio-Melbourne Network said that topics for the workshop included 'Industry 4.0', driving innovation, manufacturing in Victoria, the keys to success, obstacles to market and making sense of manufacturing mayhem.

The Network said the event was sponsored by the Victoria Government, Commonwealth Scientific and Industrial Research Organisation, Davies Collison Cave, Medtronic Australasia, Seerpharma and the Federal Department of Industry, Science, Energy and Resources - Business Entrepreneurs' Program.

The Network said the workshop would be held at International Chamber House, Level 5, 121 Exhibition Street, Melbourne with registrations from 8:30am, official event opening at 8:45am and sessions from 9am until 5pm, followed by post-event networking, with more information about the program and registration available at:

<https://biomelbourne.org/event/8th-annual-devices-diagnostics-lab/>.