



Biotech Daily

Monday November 27, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: IMUGENE, MICRO-X UP 8%; PATRYS DOWN 12.5%**
- * **FEDERAL \$392m INDUSTRY GROWTH PROGRAM OPENS**
- * **BOTANIX \$13.5m 'FIRM COMMITMENTS' FOR SOFDRA LAUNCH**
- * **MEDADVISOR FORECAST H1 REVENUE UP 10-15% TO \$70.5m-\$73.5m**
- * **MESOBLAST FILES US ORPHAN, CHILDREN REVASCOR HEART STATUS**
- * **EMVISION RECRUITS 'EMU' BRAIN SCANNER TRIAL**
- * **SUFIAN AHMAD, SIXTY TWO TAKE 6.7% OF EMYRIA**
- * **AUDEARA AGM 12.4% OPPOSE PLACEMENT CAPACITY**
- * **DR MATUA JANSEN BACKS VITURA BOARD-OPPOSED DIRECTORS**
- * **LBT TO LOSE DIRECTOR DAMIAN LISMORE AHEAD AT AGM**
- * **BIO-MELBOURNE 2024 WOMEN IN LEADERSHIP NOMINATIONS OPEN**

MARKET REPORT

The Australian stock market fell 0.76 percent on Monday November 27, 2023, with the ASX200 down 53.2 points to 6,987.6 points. Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, four traded unchanged and two were untraded. All three Big Caps fell.

Imugene and Micro-X were the best, both up 8.3 percent to 9.1 cents and 13 cents, respectively, with 93.0 million shares and 197,429 shares traded, respectively. Prescient and Volpara climbed six percent or more; Alcidion was up 5.5 percent; Actinogen improved 4.55 percent; Dimerix and Mesoblast were up more than three percent; Antisense, Clinuvel, Paradigm and Proteomics rose more than one percent; with Avita and Telix up by less than one percent.

Patrys led the falls, down 0.1 cents or 12.5 percent to 0.7 cents, with 20.3 million shares traded. Cynata lost 8.3 percent; both Impedimed and Next Science shed 7.4 percent; Amplia was down 6.25 percent; 4D Medical and Universal Biosensors fell more than four percent; Cyclopharm, Immutep, Nova Eye, Orthocell and Pharmaxis were down more than three percent; Emvision shed 2.6 percent; Opthea, Pro Medicus, Resmed and SDI were down more than one percent; with Cochlear, CSL, Medical Developments, Nanosonics, Neuren and Polynovo down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it has opened the \$392 million Industry Growth Program “to help start-ups and small businesses commercialize”.

A joint media release from the Minister for Industry and Science Ed Husic and Minister for Small Business Julie Collins said the program included advisory services to provide guidance as well as matched grant funding ranging from \$50,000 to \$5 million to eligible start-ups and innovative small and medium-sized enterprises.

The Government said the program would support projects in the National Reconstruction Fund priority areas – including medical science - and “help expand the pipeline of businesses working to transform and diversify Australia’s economy”.

The Federal Government said the opening of the program coincided with the publication of a report that businesses in Australia often face barriers in scaling-up.

The Government said the report from the Industry Innovation and Science Australia Board recommended that it identify businesses with “the need and risk appetite to innovate and deliver novel products and services”.

The Federal Government said the report detailed ways Australia could take steps to translate its research into commercialization outcomes and grow a diverse economy while at the same time delivering well-paid jobs.

The Government said grant funding would open in “early 2024” and the Industry Innovation and Science Australia report was available at:

<https://www.industry.gov.au/publications/barriers-collaboration-and-commercialisation>.

Mr Husic said “the challenge for our economy long term is to scale-up our businesses and help them create more secure jobs.”

“The Industry Growth Program is designed to commercialize great ideas and know-how, build stronger, Australian businesses and put them on a pathway for potential support by the National Reconstruction Fund,” Mr Husic said.

Industry Innovation and Science Australia chair Andrew Stevens said while Australia outperformed “in the creation of start-ups and small businesses against other [Organization for Economic Cooperation and Development] countries, our industry structure is overly skewed to small businesses with less than 20 employees”.

“It’s hard to compete when you are small,” Mr Stevens said. “The outcome we need right now is the scaling of small businesses into medium sized businesses.”

“This will build sovereign capability and economic complexity in Australia,” he said.

In a media release from Science and Technology Australia welcoming the Industry Growth Program, chief executive officer Misha Schubert said the program was designed “to help propel commercialization and enable more businesses to scale”.

“The new Industry Growth Program will be a powerful spur for more and better [research and development] in Australia and has been designed to help more of our country’s remarkable innovative small businesses to become medium-sized businesses,” Ms Schubert said. “It can turn more great Australian ideas and innovations into the products, services, and jobs of tomorrow - strengthening complexity in our economy and securing tomorrow’s prosperity.”

The Tech Council of Australia also welcomed the launch of the Industry Growth Program. Council chief executive officer Kate Pounder the Program would “provide much-needed support to help translate great ideas into more jobs”.

Australia’s chief scientist Dr Cathy Foley said that Australia had “a scale-up problem, not a start-up problem”.

“Medium-sized businesses, key to innovation, are underrepresented and struggling. By international comparisons, Australia’s industry structure is heavily skewed to micro businesses,” Dr Foley said.

BOTANIX PHARMACEUTICALS

Botanix says it has “firm commitments” to raise \$13.5 million in a placement at 13 cents a share to fund the commercialization of Sofdra for axillary hyperhidrosis.

Botanix said the placement price was a 14.1 percent discount to the 15-day volume weighted average price and the placement was not underwritten.

The company said the funds would be used to prepare the commercialization of Sofdra, or sofipironium bromide gel, for excessive sweating, testing the telemedicine and supply chain and sales strategies, as well as general working capital.

Botanix said it expected to submit the final component required for US Food and Drug Administration approval of Sofdra by April 2024, with approval targeted for “mid-2024”.

Botanix said Euroz Hartleys Ltd was the lead manager and bookrunner to the placement.

Botanix fell half a cent or 3.2 percent to 15 cents with 6.8 million shares traded.

MEDADVISOR

Medadvisor says it expects revenue for the six months to December 31, 2023 to be up 10-to-15 percent on the prior corresponding period to \$70.5 million to \$73.5 million.

Medadvisor said the increased revenue was expected due to improved sales of its prescription adherence programs in the US, with current contracted revenue exceeding 90 percent of anticipated US revenue and between eight and 13 percent on the prior period.

The company said that software as a service fee increases and growth in health programs, Australia and New Zealand revenue was expected to increase by more than 15 percent over the prior period, and it expected to have cash and cash equivalents of \$20 million at December 31, 2023 compared to \$32.7 million at December 31, 2022.

Medadvisor was up two cents or 9.8 percent to 22.5 cents.

MESOBLAST

Mesoblast says it has filed for US orphan drug and rare pediatric disease status for Revascor, or rexlemestrocil-L, for the congenital hypoplastic left heart syndrome.

In 2019, Mesoblast said the US Food and Drug Administration granted orphan drug status to Revascro for bleeding associated with end-stage heart failure (BD: Jun 24, 2019).

Today, Mesoblast said the filing was based on results from a blinded, randomized, controlled, prospective, 19-patient trial of Revascor for children with hypoplastic left heart syndrome conducted in the US.

The company said hypoplastic left heart syndrome was a disease that led to a child’s heart not fully developing and the left ventricle not effectively pumping oxygenated blood.

Mesoblast said without immediate surgical intervention after birth, hypoplastic left heart syndrome had a 25 percent to 40 percent of all newborn cardiac mortality.

The company said Revascor mesenchymal precursor cells had been shown to have “multiple mechanisms-of-action that may be beneficial to children with [hypoplastic left heart syndrome], including neovascularization, anti-fibrosis, anti-apoptosis, immunomodulation, reduction in inflammation, and reversal of endothelial dysfunction”.

Mesoblast said the trial showed Revascor “significantly increased [left ventricular] systolic and diastolic volumes over 12 months compared with control”.

The company said the results built on a randomized, controlled, prospective trial of Revascor in 565 adult patients with heart failure with low ejection fraction which showed a single administration of Revascor into the left ventricle resulted in “significant improvement in left ventricle ejection fraction at 12 months” (BD: Dec 15, 2020, Jan 17, 2021).

Mesoblast was up 1.5 cents or 3.9 percent to 40 cents with 3.8 million shares traded.

EMVISION

Emvision says it has recruited all 150 suspected stroke patients for stage two of its pre-validation trial of its 'Emu' portable, point-of-care brain imaging device.

In May, Emvision said it had begun its up-to 150-patient, stage two, multi-site trial of its portable brain scanner for stroke and stroke mimic patients in emergency departments, at Sydney's Liverpool Hospital, the Royal Melbourne Hospital and Brisbane's Princess Alexandra Hospital (BD: May 29, 2023).

Today, the company said it expected to report results from the trial by April 2024.

Emvision said it was preparing to begin work with the US Food and Drug Administration in "early 2024" to validate the clinical trial phase.

The company said completing this phase was expected to support an FDA submission for the Emu product, and it would activate stage three of the trial as planned, allowing recruitment to continue in the interim at the three trial sites.

Emvision said stage three of the trial would include up-to 30 haemorrhagic patients during the coming months, with samples expected to further de-risk the trial.

Emvision said that the name 'Emu' represented "the excellent vision, speed and agility of [is] point-of-care brain scanner device".

The company said that emus were Australian birds and its Emu shared their "qualities of mobility and precision" with the "em" in Emu echoing the core electro-magnetic technology.

Emvision managing-director Scott Kirkland said reaching the recruitment target represented "a significant milestone for Emvision and reflects the unique qualities of our product".

"Additionally, reaching our target patient recruitment for stage two of the trial is an important step towards our pathway to commercialization and we are encouraged by the clinical response and data to date," Mr Kirkland said.

"We are on track to commence FDA engagement in early 2024 and will continue to collect data in support of the validation phase, further enhanced by stage three of our multi-site trials as planned," Mr Kirkland said.

Emvision fell four cents or 2.6 percent to \$1.52.

EMYRIA

Sufian Ahmad, Sixty Two and BRSB Super Fund say they have increased their substantial holding in Emyria from 16,593,437 shares (5.38%) to 24,459,229 shares (6.67%).

Last year, Emyria said it appointed Perth's Sixty Two Capital as a corporate adviser and would pay it \$120,000 over the next year and issue 6,000,000 performance based options, exercisable at 55 cents each within two years (BD: Jan 16, 2022).

Today, Mr Ahmad said Sixty Two was an entity he controlled and that BRSB Super Fund was his superannuation.

Mr Ahmad said he and the related parties acquired 995,792 shares through a rights issue on October 5, 2023 for \$74,684, or 7.5 cents a share, bought 203,333 shares on market between October 24 and November 21, 2023 for \$12,838, or 6.3 cents a share and on November 11 bought 6,666,667 shares in a placement for \$500,000, or 7.5 cents a share. In September, Emyria said it had "firm bids" for the \$2 million placement, and a month later, said it had raised \$1.18 million of a hoped-for \$3.1 million in a one-for-7.5 rights offer, at 7.5 cents a share (BD: Sep 4, 2023).

Emyria was up 0.2 cents or 2.7 percent to 7.6 cents.

AUDEARA

Audeara says its annual general meeting voted 12.38 percent against the approval of the 10 percent placement capacity.

Audeara said the placement capacity was opposed by 10,269,633 votes (12.38%), with 72,695,357 votes (87.62%) in favor.

The company said that all other resolutions were passed overwhelmingly.

According to its most recent filing, Audeara had 143,660,227 shares on issue, meaning that the 10,269,633 votes against the placement capacity amounted to 7.1 percent of the company, sufficient to requisition extraordinary general meetings.

Audeara fell 0.2 cents or 6.25 percent to three cents.

VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

CDA Health Ltd founder Dr Matua Jansen says he is Vitura's fourth largest shareholder and supports resolutions to elect three directors.

In a shareholder statement from Dr Jansen released to the ASX by Vitura, Dr Jansen said it could not "be disputed that both Shane Tanner and Ben Jansen have been instrumental in the creation of the business that we know today as Vitura Health".

In September, Vitura said it received a notice from Elizabeth Sarah Jansen as trustee for the Stanford Investment Trust, under section 249N of the Corporations Act 2001, to appoint Mr Tanner, Nathan Hight and Mr Jansen as directors (BD: Oct 6, 2023).

Last month, the company said its annual general meeting would vote to issue chief executive officer Rodney Cocks an additional 80 percent of his \$450,000 annual salary in performance rights, chief commercial officer Guy Headley 60 percent of his \$382,000 annual pay in rights and elect three board opposed potential directors (BD: Oct 27, 2023).

At that time, Vitura said its board "unanimously recommends" shareholders vote against the resolutions to elect Mr Tanner, Mr Hight and Mr Jansen as directors.

Today, Dr Jansen said after CDA Health and the then Cronos merged in December 2021, he raised the issue at the annual general meeting "that the directors of the proposed merger were getting over 24 million shares and options while the remaining 82 employees were sharing only 2.7 million shares".

In 2021, Cronos said its annual general meeting passed the CDA merger and issue of performance rights by more than 99.7 percent of votes (BD: Dec 16, 2021).

"That was not in my view fair and equitable ... [and] I remain of the view including in respect of the proposed resolutions," Dr Jansen said.

Vitura fell one cent or 3.2 percent to 30.5 cents.

LBT INNOVATIONS

LBT says non-executive director Damian Lismore will retire, effective from its annual general meeting on November 29, 2023.

Last month, LBT said its annual general meeting would vote to issue 500,765 shares to Mr Lismore and re-elect him as a director (BD: Oct 25, 2023).

Today, the company said it had withdrawn the resolution to re-elect Mr Lismore as a director and it was in "advanced stages of due diligence with a replacement non-executive director with overlapping skills and competencies".

LBT chair Rebecca Wilson thanked Mr Lismore for his "nearly five years of dedicated contributions to the company".

LBT was unchanged at 0.5 cents with 1.4 million shares traded.

[BIO-MELBOURNE NETWORK](#)

The Bio-Melbourne Network says that nominations for the 2024 Women in Leadership Awards will open at its seminar on leadership tomorrow, Tuesday November 28, 2023. The Network said that the two-hour seminar, titled '2024 Women in Leadership Awards Launch: Shifting Focus to The Great Retention' would address "the transitioning from 'the great resignation' to embracing the concept of 'the great retention', an attitude and approach to leadership that benefits both employers and employees".

The Bio-Melbourne Network said that speakers included Stem Sisters founder and director Dr Ruwangi Fernando, Peter Doherty Institute director Prof Sharon Lewin, Central Pharmacy Logistics Pty Ltd chief executive officer Rima Darwiche and Commonwealth Scientific and Industrial Research Organisation director Prof Susie Nilsson.

The Network said online tickets were still available for the event which would be held at the law firm Allens, 37th floor, 101 Collins St, Melbourne, on November 28, from 4pm to 6pm (AEDT) with additional time for networking.

For details and registration go to: <https://bit.ly/40YWJF6>.