

Biotech Daily

Monday February 27, 2023

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: AVITA UP 17%; CLINUVEL DOWN 15%
- * MAYNE SELLS US GENERICS TO DR REDDY'S FOR UP-TO \$156m
- * TRAJAN H1 REVENUE UP 83% TO \$80m, PROFIT \$3.2m
- * MICRO-X H1 REVENUE UP 241% TO \$8m, LOSS DOWN 55% TO \$4m
- * LUMOS H1 REVENUE DOWN 2% to \$7.6m, LOSS DOWN 41% TO \$9.7m
- * UNIVERSAL BIOSENSORS REVENUE DOWN 22% TO \$5m, LOSS UP 156% TO \$27m
- * GENETIC TECHNOLOGIES H1 REVENUE UP 103% TO \$4m; LOSS UP 41% TO \$6m
- * CARTHERICS, PETER MACCALLUM CTH-004 OVARIAN CANCER SAFETY TRIAL
- * KAZIA EGM 26% OPPOSE PLACEMENT SHARES
- * ASX TAKES MEDLAB 'CAPITAL RAISING' TRADING HALT TO SUSPENSION
- * NOVA EYE REQUESTS 'CAPITAL RAISING' TRADING HALT
- * LIVING CELL REQUESTS 'CAPITAL RAISING' TRADING HALT
- * PARAMOUNT STAR TAKES 5% OF BIOXYNE
- * JAALA PULFORD REPLACES MTP CONNECT CHAIR SUE MACLEMAN
- * MEDADVISOR APPOINTS CFO ANCILA DESAI CO SEC
- * OSTEOPORE APPOINTS GREG RUDD ADVISER
- * MEDIBIO APPLIES FOR FDA BREAKTHROUGH DEVICE STATUS

MARKET REPORT

The Australian stock market fell 1.12 percent on Monday February 27, 2023, with the ASX200 down 82.2 points to 7,224.8 points. Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and four were untraded.

Avita was the best, for the second trading day in a row, up a further 53 cents or 16.8 percent to \$3.69, with 1.5 million shares traded. Actinogen climbed 11.1 percent; Impedimed was up 7.1 percent, Antisense and Polynovo improved more than four percent; Cynata was up 3.3 percent; Emvision and Starpharma rose more than two percent; Genetic Signatures, Neuren and Universal Biosensors were up more than one percent; with Cochlear and Telix up by less than one percent.

Clinuvel led the falls, down \$3.44 or 14.7 percent to \$19.99, with 237,852 shares traded. Pharmaxis lost 10 percent; Imugene and Medical Developments were down more than seven percent; Amplia, Dimerix, Nanosonics, Next Science and Proteomics fell more than four percent; Immutep, Kazia, Oncosil, Paradigm, Pro Medicus and Uscom shed two percent or more; Mesoblast, Opthea, Orthocell and Resmed were down more than one percent; with CSL and Volpara down by less than one percent.

MAYNE PHARMA

Mayne Pharma says it will sell its US generics portfolio to Dr Reddy's for an upfront payment of \$US90 million (\$A134 million) and up to \$US15 million in milestones. Mayne Pharma said the sale included all 85 generic products and four generic pipeline products in its US portfolio, which generated \$US111 million in revenue for the year ending June 30, 2022.

The company said it was entitled to contingent milestone payments worth up to \$US15 million as part of the agreement with the Hyderabad, India-based Dr Reddy's. Mayne said it expected to incur up to \$US2 million in transaction costs and a \$US10 million one-time restructuring cost.

The company said it expected the transaction to be completed by July 2023. The company said the sale would "accelerate its transformation into a specialty pharmaceutical company with leading positions in women's health and dermatology". Mayne said it would enter a 10-year agreement on "arm's length terms" to supply certain products manufactured at its Salisbury, South Australia facility to Dr Reddy's. The company's chief executive officer Shawn Patrick O'Brien said "divesting the retail generics portfolio is an important step forward for the company as we continue to rationalize our portfolio".

"With this transaction, we free up working capital, allowing us to more exclusively focus resources on core areas of value for business growth, namely our branded verticals in US women's health and dermatology," Mr O'Brien said.

Mayne Pharma was in a trading halt and last traded at \$3.15.

TRAJAN

Trajan says revenue for the six months to December 31, 2022 was up 83.2 percent to \$80,062,000 with net profit after tax up from \$153,000 to \$3,186,000.

Trajan said revenue came from sales of its medical and scientific analysis products, with its Life Sciences Solutions human health range increasing 139.8 percent to \$36.9 million. Trajan said diluted earnings per share was up 2,000 percent from 0.1 cents to 0 2.1 cents, with net tangible assets per share down 52.6 percent to 9.0 cents.

Trajan said it had cash and cash equivalents of \$21,121,000 at December 31, 2022 compared to \$33,082,000 at December 31, 2021.

Trajan was up 10 cents or 5.6 percent to \$1.89.

MICRO-X

Micro-X says revenue for the six months to December 31, 2022 was up 240.9 percent to \$8,029,000 with net loss after tax down 55.0 percent to \$3,911,000.

Last year, Micro-X said it had revenue of \$1,449,000, but did not include \$906,000 in contract engineering services (BD: Feb 24, 2022).

This year, Micro-X said it had \$1,595,000 from sales of its mobile radiology products as well as \$6,434,000 from contracted engineering services from the US Department of Homeland Security and the Australian Stroke Alliance.

The company said diluted loss per share was down 57.95 percent to 0.82 cents with net tangible assets per share down 22.1 percent to 4.45 cents, having re-calculated the prior year net tangible assets per share.

Micro-X said it had cash and cash equivalents of \$11,420,000 at December 31, 2022 compared to \$19,944,000 at December 31, 2021.

Micro-X was unchanged at 13 cents.

LUMOS DIAGNOSTICS

Lumos says that revenue for the six months to December 31, 2022 fell 2.2 percent to \$US5,087,000 (\$A7,552,000) with net loss after tax down 40.8 percent to \$US6,564,000 (\$A9,744,000).

Lumos said that \$US5.0 million of its revenue was from contract development and manufacturing services for its point-of-care tests in the US, and the remainder in revenue was from sales of its tests.

The company said its net loss after tax was down due to a "significant cost reduction program", including the closure of its Sarasota, Florida facility as well as material reductions in employee, administration, and marketing costs.

Lumos said diluted loss per share was down 57.6 percent to 3.13 US cents, with net tangible assets per share negative 0.41 US cents compared to 12.7 US cents in the prior corresponding period.

Lumos said it had cash and equivalents of \$US783,000 at December 31, 2022 compared to \$US10,464,000 at December 31, 2021.

Lumos was up 0.2 cents or four percent to 5.2 cents with 1.2 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says revenue for the year to December 31, 2022 was down 21.7 percent to \$4,524,962 with net loss after tax up 155.6 percent to \$26,854,552.

Universal Biosensors said it had revenue for its Siemens Health blood coagulation testing products of \$2,366,331 compared to \$2,667,541 in the prior corresponding period.

The company said revenue for its laboratory testing services was \$1,145,560, and it received \$1,013,071 in revenue for its Sentia wine analyzers compared to \$1,147,856 in the previous corresponding period.

Universal Biosensors said that along with an increased research and development expenditure it "recorded an \$11,014,785 impairment charge ... [relating to] the previously capitalized Siemens agreement which ends March 2023".

The company said that diluted loss per share rose 133.3 percent to 14 cents with net tangible assets per share up 50 percent to 12 cents.

Universal Biosensors said it had cash and cash equivalents of \$25,977,703 at December 31, 2022 compared to \$15,318,201 at December 31, 2021.

Universal Biosensors was up half a cent or 1.8 percent to 28.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says revenue for the six months to December 31, 2022 was up 102.5 percent to \$4,153,947, with net loss after tax up 40.7 percent to \$5,460,298. Genetic Technologies said \$3,813,482 in revenue came from sales of its Easy DNA paternity test, with the remaining revenue from its Affinity DNA tests and Genetype breast cancer and colorectal cancer tests.

The company said last year's diluted loss per share was up 50 percent to 0.06 cents, with net tangible asset backing per share down 66.7 percent to 0.05 cents.

Genetic Technologies said it had cash and cash equivalents of \$5,045,188 at December 31, 2022 compared to \$13,507,370 at December 31, 2021.

Genetic Technologies fell 0.1 cents or 25 percent to 0.3 cents with 5.95 million shares traded.

CARTHERICS PTY LTD, PETER MACCALLUM CANCER CENTRE

Cartherics says it will conduct an up-to 12-patient safety trial of its Car-T-cell therapy, CTH-004 for ovarian cancer with Melbourne's Peter MacCallum Cancer Centre. In November, Cartherics said it would develop a chimeric antigen receptor t-cell (Car-T-cell) therapy, CTH-001, for cutaneous T-cell lymphoma with the Peter MacCallum Centre (BD: Nov 8, 2022).

Today, the company said that based on pre-clinical data, it and the Peter MacCallum Cancer Centre agreed to focus efforts on CTH-004.

Cartherics said that the phase I trial would enroll patients who had failed prior chemotherapy treatment, with the primary aim to assess the safety of CTH-004.

The company said ovarian cancer was Australia's most lethal gynecological cancer, with a five-year survival rate of 49 percent and responsible for more than 1,000 deaths a year. The Peter MacCallum Cancer Centre cellular immunotherapy director Prof Simon Harrison said that Car-T-cell therapy was a "powerful immunotherapy that is uniquely tailored for

each patient and which re-purposes their own T-cells to fight their cancer".

Cartherics said that the collaborative research was hoped to develop clinical-scale

manufacturing of CTH-004 and conduct a phase I clinical trial, led by the cellular immunotherapy department with manufacturing at Peter MacCallum manufacturing partners Cell Therapies Pty Ltd.

Cartherics is a private company.

KAZIA THERAPEUTICS

Kazia shareholders have passed all four extraordinary general meeting resolutions but with up to 26 percent of votes opposing the issuing of 15,522,073 placement shares. Kazia said 19,197,867 votes (74.18%) supported the issue of the tranche two placement shares, with 6,681,148 votes (25.82%) opposed.

In January, the company said it had raised \$4.5 million a placement at 11 cents a share, in part subject to shareholder approval (BD: Jan 16, 2023).

Today, Kazia said two other placement resolutions were passed by similar margins, but 8,761,171 votes (17.61%) opposed the issue of at-the-market shares.

According to Kazia's most recent filing, the company had 163,428,976 shares on issue, meaning the vote against the at-the-market resolution amounted to 5.36 percent of shares on issue, sufficient to call an extraordinary general meeting.

Kazia fell 0.25 cents or two percent to 4.8 cents.

MEDLAB CLINICAL

The ASX says it has suspended Medlab following Wednesday's trading halt pending an announcement "regarding its proposed capital raising" (BD: Feb 22, 2023).

The ASX said that Medlab securities would "remain suspended until [it was] in a position to provide a satisfactory announcement"

Medlab last traded at \$6.60.

NOVA EYE MEDICAL

Nova Eye has requested a trading halt "pending an announcement in relation to a proposed capital raising".

Trading will resume on March 1, 2023 or on an earlier announcement.

Nova Eye last traded at 23 cents.

LIVING CELL TECHNOLOGIES

Living Cell has requested a trading halt "pending an announcement... regarding the execution of a capital raising".

Trading will resume on March 1, 2023 or on an earlier announcement. Living Cell last traded at 0.95 cents.

BIOXYNE

Singapore's Paramount Star Investments says it has become substantial in Bioxyne with 36,000,000 shares or 5.4 percent.

Paramount Star said it bought 11,000,000 shares on August 3 for \$220,000, or two cents each, and 25,000,000 shares on October 24, 2022 for \$1,000,000, or four cents a share. Bioxyne was unchanged at 2.4 cents.

MTP CONNECT

MTP Connect says it has appointed former Victoria Labor Minister Jaala Pulford as its chair, replacing Sue MacLeman, effective from today.

MTP Connect said that Ms MacLeman was the inaugural chief executive officer in 2015 and in 2018 was appointed chair.

The Federally-funded industry organization said that Ms Pulford was the former Victoria Minister for Innovation, Medical Research and the Digital Economy until her retirement ahead of last year's November State election.

MTP Connect said that Ms Pulford "led the establishment of mRNA Victoria and, with the Federal Government, secured pandemic-scale manufacturing capability through the partnership with Moderna ... [and was] "instrumental in bringing Biontech to Australia to deliver further research and development and manufacturing capabilities".

MTP Connect said that Ms MacLeman would continue to act as an advisor though the initial transition.

"I am delighted to welcome Jaala to the MTP Connect board and the role of chair," Ms MacLeman said. "[Her] leadership, achievements and deep experience in government, public administration and governance will be an asset to MTP Connect and the broader medical technology, biotechnology and pharmaceutical sector across Australia."

MTP Connect said that Ms Pulford was elected to the Victoria Parliament in 2006 and currently was a director of the Children's Cancer Foundation and a member of the Turner Institute for Brain and Mental Health Advisory Council.

The organization said that Ms Pulford held a Bachelor of Applied Management from the University of Ballarat and a Masters of Public Policy from Deakin University.

MEDADVISOR

Medadvisor says chief financial officer Ancila Desai will replace company secretary Naomi Lawrie, effective from March 31, 2023.

Medadvisor fell one cent or 3.85 percent to 25 cents.

OSTEOPORE

Osteopore says it has appointed Greg Rudd to its advisory panel, joining David Yeow, Dr James Tan, Dr Samintharaj Kumar, Dr GK Ananda, Dr Michael Wagels and Joy Song. Osteopore was up 0.5 cents or 4.35 percent to 12 cents.

MEDIBIO (FORMERLY BIOPROSPECT)

Medibio says it has lodged a breakthrough device status application with the US Food and Drug Administration for its sleep analysis of depressive burden study algorithm. Medibio said the submission was for its MEB-001 sleep analysis of depressive burden product for the recognition of major depressive disorder through biomarkers and physiologic parameters.

The company said it expects a reply from the FDA within 60 days from its submission. Medibio non-executive chair David Trimboli said the submission represented "first step for the new management and board of Medibio in pushing for FDA approval and continuing to develop our core MEB-001 technology".

In 2014, the then Bioprospect said it would acquire Invatec for its heart rate variability technology for mental health diagnoses (BD: Sep 8, 2014).

Medibio fell 0.05 cents or 33.3 percent to 0.1 cents with six million shares traded.