

Biotech Daily

Tuesday August 9, 2022

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: ACTINOGEN UP 13%; ANTISENSE DOWN 8%
- * VALE OLIVIA NEWTON-JOHN
- * MESOBLAST PLACEMENT RAISES \$65.5m
- * VICTORIA \$5.4m FOR \$9.1m mRNA INNOVATION HUB
- * POLYNOVO: VICTORIA \$500k FOR NOVOSORB SYNPATH
- * SONIC TO DISTRIBUTE PROTEOMICS PROMARKERD IN US
- * EVERGREEN TO MANUFACTURE CLARITY COPPER ISOTOPES
- * NOXOPHARM 800mg VEYONDA 'SAFE, WELL-TOLERATED'
- * DIMERIX FILES DMX-700 COPD PATENT FAMILY
- * CHIMERIC TELLS ASX: NEWS MARKED PRICE SENSITIVE 'IN ERROR'
- * CRESO INVESTORS BACK SIERRA SAGE ACQUISITION
- * GUILD GROUP TAKES 18% OF MEDADVISOR
- * PERENNIAL REDUCES TO 8.8% OF LUMOS

MARKET REPORT

The Australian stock market was up 0.13 percent on Tuesday August 9, 2022, with the ASX200 up 9.2 points to 7,029.8 points. Twenty of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and one was untraded.

Actinogen was the best, up 0.9 cents or 13.4 percent to 7.6 cents, with 4.7 million shares traded. Paradigm climbed 12.3 percent; Proteomics was up 11.2 percent; Micro-X rose eight percent; Compumedics improved 7.7 percent; both Alcidion and Prescient climbed 6.1 percent; Polynovo was up 4.95 percent; Uscom improved 3.3 percent; Atomo, Clinuvel and Starpharma rose more than two percent; Immutep, Impedimed, Nanosonics, Opthea, Orthocell, Pro Medicus and Universal Biosensors were up more than one percent; with CSL and Medical Developments up by less than one percent.

Yesterday's 16.7 percent best, Antisense, led the falls, down 0.8 cents or 7.6 percent to 9.7 cents, with 583,731 shares traded. Mesoblast lost seven percent; Imugene shed 5.3 percent; Patrys fell four percent; both Dimerix and Emvision were down 3.1 percent; Cyclopharm and Nova Eye shed more than two percent; Amplia, Avita, Cynata, Next Science, Resmed and Volpara were down one percent or more; with Cochlear, Neuren and Telix down by more than one percent.

VALE OLIVIA NEWTON-JOHN 26.9.1948 – 8.8.2022

Best known as a singer, actor and entertainer, Olivia Newton-John led the funding for a specialist cancer centre at Melbourne's Austin Hospital.

According to its website, the Olivia Newton-John Cancer Wellness & Research Centre is a partnership between Austin Health and the Olivia Newton-John Cancer Research Institute, and as a "comprehensive cancer centre" it treats cancer and carries out research and clinical trials.

The Olivia Newton-John Centre was opened in 2012, "as the result of a combination of government and philanthropic support, as well as donations from 200,000 members of the public totalling \$17 million".

Ms Newton-John said that she was diagnosed with breast cancer in 1992, "the same weekend my father died of cancer".

Ms Newton-John was also a campaigner for the legalization of marijuana to ease cancer pain.

A spokesperson for Austin Health said the organization was "deeply saddened to learn that Olivia Newton-John has passed away overnight".

"Olivia touched the lives of many people across Australia and the world, but none more so than our cancer services staff and patients at the Olivia Newton-John Centre, who she encouraged, inspired and supported every day," Austin Health said.

"Her generous support and [undisclosed] gift provided hope and changed the lives of thousands of cancer patients here at Austin Health," the organization said.

"The ONJ Centre was her dream, and we are proud of everything we achieved together. We will continue our work to honor her legacy," Austin Health said.

MESOBLAST

Mesoblast says it has raised \$US45 million (\$A65.5 million) in a placement at 75 cents a share, a five percent discount to the 30-day volume-weighted average price.

Mesoblast said the placement was led by its largest shareholder, the London-based M&G Investments, and it would use the funds to launch and commercialize its remestemcel-L for the treatment of children with steroid-refractory acute graft-versus-host disease, as well as begin a second phase III trial of rexlemestrocel-L to confirm a reduction in chronic low back pain associated with degenerative disc disease.

According to its most recent Appendix 4C, Mesoblast said it had loan facilities of \$US130 million, with \$US90 million from Oaktree Capital Management and \$US40 million from Novaquest Capital Management LLC, and at June 30, 2022, it had drawn \$US90 million. Mesoblast chief executive officer Dr Silviu Itescu said "we are very appreciative of the ongoing strong support from our major shareholders who recognize the potential of our technology to make a difference to patients with severe inflammatory conditions". Mesoblast fell 6.5 cents or seven percent to 86.5 cents with 4.9 million shares traded.

VICTORIA GOVERNMENT

Victoria says it will invest \$5.4 million in a \$9.1 million Victorian mRNA Innovation Hub with the University of Melbourne, Monash University and the Peter Doherty Institute. A media release from the Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said that funding through the mRNA Victoria Activation Program and with the Monash Institute of Pharmaceutical Sciences, the Peter Doherty Institute for Infection and Immunity, the University of Melbourne and Monash University, the Hub would support 27 mRNA researchers.

The release said that the Victoria mRNA Innovation Hub would advance the technologies involved in messenger-ribonucleic acid (mRNA) vaccines and therapeutics production, produce new mRNA therapeutics and vaccines, as well as "enable the next generation of mRNA researchers to learn from some of the world's best scientists".

The release said that mRNA technology had been applied to vaccines and had the potential to be applied across a range of diseases and conditions, including Alzheimer's disease, cancer and muscular dystrophy.

The release said that the \$21 million mRNA Victoria Activation Program was part of the government's \$50 million investment to build a "world-leading mRNA ecosystem in Victoria".

Ms Pulford said "this world-first collaboration between researchers in Victoria has the potential to create major breakthroughs in RNA-based medical treatments".

"Victoria has proven itself to be the home of mRNA in the Southern Hemisphere and this Hub will only lead to more improved health outcomes and jobs," Ms Pulford said.

POLYNOVO, VICTORIA GOVERNMENT

temporizing matrix] product for patients".

Polynovo says it has a \$500,000 grant from the Victoria Government's Medtech Manufacturing Capability Program to manufacture Novosorb Synpath.

Polynovo said that the aim of the grant was to "help expand production and to position Victoria as a global leader in healthcare innovation and manufacturing".

The company said that it planned to use the funding to "support the purchase of new equipment and the upgrading of existing equipment used for manufacturing [the] Novosorb Synpath product, used for amongst other things diabetic foot ulcers". Polynovo chief executive officer Swami Raote said that surgeon demand for a diabetic foot ulcer product meant they were "cutting and adapting our existing [biodegradable

"Patients with [diabetic foot ulcers], many with significant co-morbidities that complicate treatment, place an enormous burden on the patient and the healthcare system," Mr Raote said.

"Developing innovative products to avoid devastating effects such as lower limb amputation is incredibly important," Mr Raote said.

"Synpath is an adaptation of the Novosorb platform for a specific [diabetic foot ulcer] solution for surgeons," Mr Raote said.

Polynovo chair David Williams said that Synpath had "significant health economic and healing benefits over biologic-based products in the treatment and wound closure of diabetic foot ulcers and venous leg ulcers".

"The global diabetic foot ulcer addressable market was valued at \$US7.03 billion in 2019 and is projected to reach \$US11.05 billion by 2027," Mr Williams said.

"The much-appreciated government grant will support manufacturing the new product at our Port Melbourne plant from where we will ship to the world," Mr Williams said. Polynovo was up 10 cents or 4.95 percent to \$2.12 with 4.5 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has a letter of intent with Sonic Healthcare USA for an exclusive US licence for its Promarkerd test for diabetic kidney disease.

Proteomics said the letter with the Austin, Texas-based Sonic Healthcare, outlined milestones, including preparing a submission to secure a proprietary laboratory analysis reimbursement code for the Promarkerd test, as well as forecasting sales targets for Promarkerd in the US.

The company said it expected to complete the milestones "within the next two to five months".

Proteomics did not disclose the commercial terms of the agreement, but said the letter of intent described royalty terms on commercial sales of the test.

Proteomics managing-director Dr Richard Lipscombe said it was a "pivotal point in the global roll-out of Promarkerd".

"We have been working with Sonic Healthcare USA towards this goal for fifteen months, and now look forward to building upon this foundation and taking our world first predictive test for diabetic kidney disease into not only the US, but also Europe where the test already has regulatory approval," Dr Lipscombe said.

Proteomics was up 10 cents or 11.2 percent to 99 cents.

CLARITY PHARMACEUTICALS

Clarity says it has an updated agreement with Evergreen Theragnostics Inc to distribute and manufacture its copper isotope products for US clinical trials.

Last year, Clarity said the Springfield, New Jersey-based Evergreen would manufacture and distribute Cu-67 Sartate for its neuroblastoma study currently underway at multiple sites across the US and Cu-64 SAR-Bombesin for the planned trials for cancer in the US (BD: Sep 30, 2021).

Today, the company said Evergreen would manufacture and Copper-67 and Copper-64-SAR-Bombesin for prostate cancer and Cu-67 Sartate for neuroblastoma.

Clarity did not disclose the commercial terms of the agreement.

Clarity executive chair Dr Alan Taylor said the company was "excited to be progressing the [targeted copper diagnostics and therapeutics] platform with our third therapeutic product, 67-Cu-SAR-Bombesin".

"We plan to file an investigational new drug application with the US Food and Drug Administration for a trial with this product shortly," Dr Taylor said.

Clarity was up two cents or 3.45 percent to 60 cents.

NOXOPHARM

Noxopharm says the first cohort dosed with 800 milligrams Veyonda, in its 30-patient, 'CEP-2' trial for sarcoma showed safety and tolerability.

In February, Noxopharm said the phase I, open-label, dose-escalation and expansion study of Veyonda, or NOX66, in combination with doxorubicin, for the treatment of metastatic soft tissue sarcoma, had treated the first of 30 patients at the Duarte, California City of Hope Cancer Centre (BD: Feb 28; Jul 5, 2022).

Today, the company said it would continue enrolment to progress to the next patient cohort with an increased dose of 1200mg Veyonda.

Noxopharm chief executive officer Dr Gisela Mautner said "it is pleasing to see that the CEP-2 trial has passed its first safety milestone with this positive data review".

Noxopharm was up one cent or 4.3 percent to 24.5 cents.

DIMERIX

Dimerix says it has lodged a patent family for DMX-700, for the treatment of chronic obstructive pulmonary disease with IP (intellectual property) Australia.

Last month, Dimerix said that DMX-700 showed a "statistically significant" 80 percent reduction in chronic obstructive pulmonary disease lung injury in mice (p < 0.01) compared to the control group (BD: Jul 4, 2022).

Today, the company said that the patent application, titled 'Dosage regimen for the treatment of COPD' and if granted would protect its intellectual property beyond 2043. Dimerix said the patent had a priority date of August 2, 2022 and would not become public until about 18 months after the priority date.

The company said that subject to approvals, it expected to begin a clinical study of DMX-700 in the first half of 2023.

Dimerix managing-director Dr Nina Webster said "the DMX-700 study identified some very surprising outcomes, which we believe further strengthens our {intellectual property] position moving forward".

Dimerix fell half a cent or 3.1 percent to 15.5 cents.

CHIMERIC THERAPEUTICS

Chimeric has told the ASX it marked an announcement detailing the granting of a Japanese patent for CHM 1201 as price sensitive "in error".

In an aware query, the ASX said that an announcement on August 3, 2022 regarding the granting of a patent for CHM1201, was submitted as price sensitive.

The ASX said that according to the Japan Patent Office, the decision to grant the patent was made on May 10, 2022 and the certificate of patent was issued on June 21, 2022.

The ASX asked Chimeric if it considered the information would have a material effect on the price or value of its securities, and if not, then why was the information released in a "standalone price-sensitive announcement"?

Chimeric said it did not "consider the patent grant information for Japan alone to be information that reasonable person would expect to have a material effect on the price or value of its securities" and that patent protection in the two major commercial markets, the US and European Union, were the only geographically-specific patent news "we would deem as market sensitive and have been disclosed as so previously to the ASX".

Chimeric said that "the announcement was marked as price sensitive in error".

"Although the granting of patent protection in Japan for CHM1201 is a key development milestone it is not of material value to the commercial potential of the asset and therefore investors would not attribute a significantly different value for [shares] based on additional Japanese patent rights," the company said.

The ASX did not note any significant change in price or volume of shares traded. Chimeric was up half a cent or 3.7 percent to 14 cents.

CRESO PHARMA

Creso's extraordinary general meeting overwhelmingly backed the acquisition of Sierra Sage Herbs LLC, with more than 98.4 percent of investors voting for all resolutions. In February, Creso said it would buy the Lyon, Colorado-based Sierra Sage for \$US21 million (\$A29.5 million) in shares, with additional milestone payments (BD: Feb 3, 2022). Today, Creso said that the greatest dissent was opposition from 4,690,912 votes or 1.88 percent of votes cast at the meeting.

Creso fell 0.1 cents or 2.6 percent to 3.8 cents with 14.5 million shares traded.

MEDADVISOR

Guild Group Holdings says it has increased its substantial holding in Medadvisor from 57,118,490 shares (13.0%) to 92,005,130 shares (18.0%).

In July, Medadvisor said it would acquire Sydney's Guildlink for \$9.14 million and had raised \$10 million in its institutional one-for-4.2 rights offer at 14 cents a share, with a further \$4.6 million expected in an underwritten retail offer (BD: Jul 25; 27, 2022).

Last week, the Melbourne-based Guild Group said that on May 27, 2022, it received 57,118,490 shares for 100 percent of Guildlink (BD: Aug 2, 2022).

Today, Guild Group said that on August 3, 2022, it participated in Medadvisor's institutional entitlement offer, and bought 34,886,640 shares for \$4,797,486, or 13.75 cents a share.

Medadvisor was unchanged at 16 cents.

LUMOS DIAGNOSTICS

Perennial Value Management says it has reduced its substantial holdings in Lumos from 23,227,675 shares (12.06%) to 18,476,450 shares (8.80%).

The Sydney-based Perennial said that between June 27, and August 8, 2022, it bought and sold shares, with the single largest sale on August 8, of 3,055,548 shares for \$163,112 or 5.3 cents a share.

Lumos was up 0.05 cents or 0.9 percent to 5.55 cents with 2.1 million shares traded.