

Biotech Daily

Monday July 25, 2022

Daily news on ASX-listed biotechnology companies

- * ASX EVEN, BIOTECH DOWN: NEUREN UP 14%; POLYNOVO DOWN 14%
- * GREGOR JOHANN MENDEL BICENTENARY
- * NANOSONICS EXPECTS REVENUE UP 17% TO \$120m
- * CRONOS RECEIPTS \$70m
- * CLINUVEL RECEIPTS UP 72% TO \$66m
- * USCOM RECEIPTS DOWN 43% TO \$2.8m
- * US FDA OKAYS ADHERIUM HAILIE FOR GSK ELLIPTA
- * US FDA APPROVES QBIOTICS TIGILANOL TIGLATE SARCOMA TRIAL
- * RESONANCE FERRISCAN 3T MRI COMPATIBLE
- * MEDADVISOR TO BUY GUILDLINK FOR \$9.14m; HOPES TO RAISE \$14.6m
- * MICROBA: FEDERAL \$13.4m OFFSHORE R&D EXPENSE APPROVAL
- * PROTEOMICS: EURO PROMARKERD PATENT EXPANDS USE
- * REALTEK TAKES 12% OF NUHEARA
- * CHIMERIC APPOINTS DR JASON LITTEN CMO
- * MEDADVISOR: ANTHONY TASSONE; JOSH SWINNERTON; ANCILA DESAI

MARKET REPORT

The Australian stock market slipped 0.02 percent on Monday July 25, 2022, with the ASX200 down 1.6 points to 6,789.9 points. Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and two were untraded. All three Big Caps fell.

Neuren was the best, up 61 cents or 14.2 percent to \$4.91, with 486,169 shares traded. Resonance rose 10.3 percent; Universal Biosensors climbed six percent; Alcidion, Dimerix and Impedimed improved more than three percent; Compumedics was up 2.8 percent; with Immutep, Medical Developments, Next Science, Oncosil and Pharmaxis up by more than one percent.

Polynovo led the falls, down 23.5 cents or 13.6 percent to \$1.49, with 5.2 million shares traded. Atomo and Imugene lost more than nine percent; Clinuvel and Nanosonics were down more than seven percent; Kazia was down 6.4 percent; Avita fell four percent; Actinogen, Micro-X and Volpara lost three percent or more; Antisense, Emvision, Mesoblast, Pro Medicus and Telix shed more than two percent; Amplia and Cochlear were down more than one percent; with CSL, Proteomics, Resmed and Starpharma down by less than one percent.

GREGOR JOHANN MENDEL JULY 20, 1822 – JANUARY 6, 1884

By Prof George Fink

Biotech Daily senior medical research adviser

The bicentenary of Gregor Mendel on July 20, 2022, is being acknowledged by the medical research and biotechnology community.

The importance of Mendel's seminal findings was celebrated on his bicentenary, by among others, the journal Nature: https://doi.org/10.1038/s41576-022-00497-2.

Gregor Johann Mendel was a biologist, meteorologist, mathematician, as well as an Augustinian friar and abbot of St Thomas' Abbey in Brunn, Moravia, Austria Hungary (now Brno, Czech Republic).

Genetics is exceedingly complex.

Thus, it seems remarkable that working alone in his monastery garden in the 1850s and 1860s, Mendel's principles of inheritance still stand today.

Friar Mendel's experiments and findings laid the groundwork for genetics, molecular biology, the sequencing and analysis of genomes and how genes interact with the environment.

Mendel's work also led to our understanding of numerous Mendelian disorders, exemplified by Sickle cell anaemia, muscular dystrophy, cystic fibrosis, thalassemia, phenylketonuria, color blindness, skeletal dysplasia and haemophilia.

Perhaps the most dramatic outcome of Mendel's work is the discovery of the crystal structure of DNA by James Watson, Francis Crick, Maurice Wilkins and Rosalind Franklin (although, alas, Franklin did not share the Nobel Prize with Watson, Crick and Wilkins).

Elucidation of the structure of DNA and its role in encoding the genetic code must rate as one of, and possibly the, most important discoveries which revolutionized our understanding of Life and the development of powerful methods for the diagnosis and treatment of previously intractable disorders.

Mendelian genetics and the consequence of Mendel's work must rank of superior importance in Biology, Medicine and Biotechnology.

Mendel developed the Law of Segregation and the Law of Independent Assortment, later known as Mendel's Laws of Inheritance.

A detailed account of Mendel's work in genetics is described by Oxford University geneticist Prof Kim Nasmyth, which was also published in Nature and is available at: https://www.nature.com/articles/s41576-022-00497-2.

NANOSONICS

Nanosonics says it expects revenue for the year to June 30, 2022 to be up 17 percent to \$120.3 million compared to the previous corresponding period.

Nanosonics said that its new installed base of Trophon EPR ultrasound prove cleaning equipment was up by 2,650 units or 11 percent on the prior year to June 30, 2021.

The company said that its planned transition to a more direct sales model was now "substantially complete", having transitioned away from relying on the Boston-based GE Healthcare for sales and supply in North America.

Nanosonics fell 36 cents or 7.8 percent to \$4.26 with 2.8 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says receipts from customers for the year to June 30, 2022 was up 71.5 percent to \$66,400,000 compared to the previous corresponding period.

Clinuvel said receipts from customers for its Scenesse afamelanotide 16mg treatment for erythropoietic protoporphyria for the three months to June 30 was up 61.2 percent to \$24,053,000.

The company said it was \$18,478,000 cashflow positive for the three months to June 30, and had cash equivalents of \$121,509,000 at June 30, 2021, compared to the \$82,691,000 at June 30, 2021.

Clinuvel chief financial officer Darren Keamy said that the company was "pleased with the strong financial results".

"Clinuvel is one of the few life sciences companies on the ASX to generate positive cash flows and profit and seeks to set an example of prudent financial management," Mr Keamy said. "Part of this approach is ensuring we can protect the company from environmental and market pressures, while we execute our long-term plans." Clinuvel fell \$1.30 or 7.7 percent to \$15.54 with 241,850 shares traded.

CRONOS AUSTRALIA

Cronos says its receipts from customers for the year to June 30, 2022 was \$69,607,124. The company said that revenue came from prescriptions for and sales of marijuana products and it was cashflow positive by \$2,638,438 in the three months to June 30, 2022, with cash and equivalents of \$16,077,032.

Last year, Cronos said it had acquired CDA (Cannabis Doctors Australia) Health Pty Ltd (BD: Dec 16, 2021).

Cronos was up seven cents or 31.8 percent to 29 cents.

USCOM

Uscom says that receipts from customers for the year to June 30, 2022 fell 42.9 percent to \$2,765,000, compared to the previous corresponding period.

Uscom said that receipts, primarily from sales of the Uscom 1A ultrasonic cardiac output monitor, for the three months to June 30, 2022 was down 42.1 percent to \$709,000.

The company said it had a cash burn for the three months to June 30 of \$460,000, with cash and cash equivalents of \$4,704,000 at June 30, 2022.

Uscom cited and said it had responded to the effect of the "two-year pandemic, regulatory changes in China, Australia-China trade wars, China lockdowns, the Russian war and fears of a global recession".

Uscom was unchanged at 6.5 cents.

ADHERIUM

Adherium says it has US Food and Drug Administration 501(k) clearance for its Hailie sensor for Glaxosmithkline's Ellipta inhaler.

Adherium said Glaxosmithkline's Ellipta was a dry powder inhaler used to dispense treatments for asthma and chronic obstructive pulmonary disorder (COPD).

Adherium chief executive officer Rick Legleiter said the FDA clearance "to connect Ellipta inhaler users with our new, next-generation Hailie platform represents another step forward in our drug agnostic strategy".

"This further broadens the pathway for doctors and hospital groups in the US to access reimbursement for remote monitoring of patients prescribed Asthma and COPD medications on our path toward building a sustainable, cash flow positive business," Mr Legleiter said.

Adherium was unchanged at 0.9 cents with 3.7 million shares traded.

QBIOTICS GROUP

Qbiotics says the US Food and Drug Administration has approved its 10-patient, phase II trial of tigilanol tiglate, or EBC-46, for soft tissue sarcoma.

Qbiotics said the FDA had accepted its investigational new drug application for the openlabel, US trial evaluating the efficacy and dose ranging in patients with advanced or metastatic soft tissue sarcoma.

The company said that patients in the QB46C-H07 trial would receive up to five intratumoral treatments of tigilanol tiglate, administered four weeks apart, to evaluate the drug candidate's efficacy and safety for soft tissue sarcoma.

Qbiotics said the trial's primary objective was to evaluate the degree of tumor ablation in tumors and/or tumor segments treated with one or more injections of tigilanol tiglate. The company said that the secondary and exploratory objectives were to assess safety and tolerability of tigilanol tiglate, and translational research to evaluate changes in the tumor micro environment, immune responses, and tumor recurrence rate after six months following treatment.

Qbiotics said that tigilanol tiglate was a plant-derived small molecule, administered by injection directly into a solid tumor, which was destroyed by tumor cell necrosis, tumor vascular disruption and immune-mediated mechanisms.

Qbiotics managing-director Dr Victoria Gordon said the trial approval was "an important milestone".

"It is Qbiotics' first FDA [investigational new drug application] and the culmination of a very significant body of work by our team," Dr Gordon said.

"[The] approval is underpinned by a robust data package, including data from our first-in-human QBC46-H01, phase I study, where tigilanol tiglate demonstrated clinically relevant monotherapy activity in 22 patients with a broad range of refractory solid tumors," Dr Gordon said (BD: Dec 10, 2019).

"Qbiotics is also undertaking clinical trials in melanoma and head and neck cancer as part of this broad program," Dr Gordon said.

"Implementing a clinical trial in a third cancer indication is a strong move for the company," Dr Gordon said.

Dr Gordon said that soft tissue sarcomas were rare and heterogeneous solid tumors that occurred in the soft tissues of the body, such as muscles and nerves, with 124,573 new cases globally in 2021.

Qbiotics is a public unlisted company.

RESONANCE HEALTH

Resonance says its Ferriscan liver iron concentration technology is now available on 3.0 tesla (3T) magnetic resonance imaging (MRI) machines.

Resonance said that previously its Ferriscan technology was available only on 1.5 tesla machines.

The company said that the Ferriscan compatibility with 3.0 tesla machines would significantly expand the company's potential sales, with 3T scanners comprising 15 to 18 percent of all MRI systems in Europe and North America.

Resonance said that the greater magnetic power of the 3.0 tesla MRI units offered advantages for clinicians and patients, including shorter scan times and greater image contrast.

Resonance was up 0.7 cents or 10.3 percent to 7.5 cents.

MEDADVISOR

Medadvisor says it will acquire Sydney's Guildlink for \$9.14 million and hopes to raise \$14.6 million in a one-for-4.2 entitlement offer at 14 cents a share.

Medadvisor said the consideration would be in scrip at 16 cents a share to Guildlink's sellers, the Pharmacy Guild of Australia-owned Guild Group, making it the largest shareholder.

The company said the acquisition of Guildlink would enable Medadvisor to provide "a consolidated platform that removes duplication and increases efficiencies for Australian pharmacies and enhances their ability to provide integrated bookings, clinical services, vaccinations and medication management for their patients".

Medadvisor said that the Pharmacy Guild of Australia would assist "develop and deliver new and ongoing health service initiatives, including government programs, to provide and support the health needs of communities across Australia".

The company said that in conjunction with the acquisition, it hoped to raise \$14.6 million in a one-for-4.2 entitlement offer at 14 cents a share in a non-underwritten retail rights offer and a fully underwritten institutional rights offer.

Medadvisor said the Guild Group had committed to take up its full entitlement under the rights offer and to sub-underwrite the institutional entitlement offer, to about \$4.9 million. The company said the institutional offer was underwritten to about \$10 million by joint lead managers MA Moelis Australia Advisory Pty Ltd and Peloton Capital Pty Ltd Medadvisor said the funds raised would be directed to the integration of Guildlink, the expansion of growth initiatives in Australia and the US, and general working capital. The company said the record date for the entitlement offer was July 27, with the offer opening on August 1, and closing August 15, 2022.

Medadvisor was in a trading halt and last traded at 14 cents.

MICROBA LIFE SCIENCES

Microba says the Department of Industry has approved \$13,400,000 in off-shore research and development expenses, which might result in a \$5,829,000 incentive.

Microba said the advanced and overseas finding related to the manufacture of its MAP-315 drug candidate and its engagement of Ginkgo Bioworks for high throughput screening of bacterial strains for its inflammatory bowel disease and autoimmune disease programs for the three years to 2024.

Medlab was up two cents or 7.1 percent to 30 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says the European Patent Office has granted a patent expanding the use of its Promarkerd predictive testing technology to pre-diabetes.

Proteomics said the patent, titled 'Biomarkers Associated with Pre-diabetes, Diabetes and Diabetes Related Conditions', would protect Promarkerd to September 20, 2031

Proteomics managing-director Dr Richard Lipscombe said that the expanded patent was "an important addition to our Promarkerd intellectual property portfolio and provides an exciting opportunity to increase our addressable market in Europe, where we already have [Conformité Européenne] CE mark registration," Dr Lipscombe said.

"There is the potential for the Promarkerd test to be used to determine if a whole new group of people are at risk of developing kidney disease," Dr Lipscombe said. Proteomics fell half a cent or 0.6 percent to 83 cents.

NUHEARA

Realtek Semiconductor Corp says it has become substantial in Nuheara with 14,166,667 shares 11.85 percent of the company.

The Taiwan-based Realtek said that on July 14, 2022, it bought 14,166,667 shares in Nuheara for \$1,700,000, or 12 cents a share.

Nuheara fell one cent or 3.4 percent to 28.5 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has appointed Dr Jason Litten as its chief medical officer.

Chimeric said that most recently, Dr Litten was Artiva Biotherapeutics chief medical officer and previously Dr Litten was Juno Therapeutics head of clinical development.

The company said Dr Litten held a Doctor of Medicine from the Atlanta, Georgia-based Emory University.

Chimeric was up one cent or eight percent to 13.5 cents.

MEDADVISOR

Medadvisor said that Anthony Tassone has been appointed a non-executive director, as Guild Group's nominee, with Josh Swinnerton continuing as a non-board executive. Medadvisor said the appointment of Mr Tassone effective from July 27, 2022 followed the announcement of the Guildlink acquisition (see above).

The company said that Mr Tassone had been a community pharmacist and proprietor of community pharmacies for 16 years, as well as the Victoria branch president of the Pharmacy Guild of Australia since 2013.

Medadvisor said that co-founder and executive director Josh Swinnerton would resign from the board effective July 27, 2022 and remain as an executive, with Ancila Desai to be appointed chief financial officer from October 17, 2022.

Last week, IDT said Ms Desai would resign as chief financial officer later this year "to commence her next career opportunity". (BD: Jul 21, 2022)