



Biotech Daily

Thursday September 3, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: ONCOSIL UP 22%; RESONANCE DOWN 7%**
- * **OPYL: 'AI PREDICTS TRIAL - INCLUDING COVID-19 – RESULTS'**
- * **TELIX, VARIAN PROSTATE CANCER COLLABORATION**
- * **FEDERAL, MTP CONNECT \$10.4m FOR 13 'EARLY STAGE' PROJECTS**
- * **IMUGENE: US APPROVES PD1-VAXX LUNG CANCER TRIAL**
- * **HERAMED EXPANDS COMPLETED HERABEAT FOETAL MONITOR STUDY**
- * **REGENEUS PAYS CEO LEO LEE \$325k KYOCERA BONUS**
- * **NEUROTECH: BRAIN THERAPEUTICS GREECE MENTE AUTISM DISTRIBUTOR**
- * **BIOTRON REQUESTS 'COMPOUND TESTING' TRADING HALT**
- * **AUSTRALIAN ETHICAL DILUTED TO 5.5% IN PRESCIENT**
- * **CHRIS RETZOS REDUCES, DILUTED BELOW 5% IN PRESCIENT**
- * **PIE FUNDS INCREASES, DILUTED TO 5% OF PROBIOTEC**
- * **CHAIR OTTO BUTTULA TAKES 13.6% OF RHYTHM**
- * **CORRECTION: ALTHEA, SG HISCOCK**
- * **SG HISCOCK TAKES 8.6% OF BOD**

MARKET REPORT

The Australian stock market was up 0.81 percent on Thursday September 3, 2020, with the ASX200 up 49.4 points to 6,112.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 16 fell and seven traded unchanged. All three Big Caps were up.

Oncosil was the best, possibly on yesterday's 'investor update', up 2.5 cents or 21.7 percent to 14 cents, with 28.4 million shares traded. Dimerix climbed 11.4 percent; LBT was up eight percent; Telix rose 7.6 percent; Avita and Uscom improved more than five percent; Impedimed, Osprey, Patrys, Polynovo and Starpharma were up four percent or more; Opthea and Resmed climbed three percent or more; Cochlear rose 2.9 percent; CSL, Imugene, Nanosonics and Pro Medicus were up more than one percent; with Clinuvel and Paradigm up by less than one percent.

Resonance led the falls, down one cent or 6.7 percent to 14 cents, with 563,166 shares traded. Compumedics and Proteomics fell more than five percent; Alterity and Universal Biosensors lost more than three percent; Antisense, Immunetep, Medical Developments, Next Science and Volpara shed more than two percent; with Cynata, Mesoblast, Orthocell and Pharmaxis down one percent or more.

OPYL

Opyl says a study of its artificial intelligence clinical trial prediction software has analyzed the probability of Covid-19 vaccine and antibody therapy trial success.

In February, the company said it had completed a proof-of-concept for artificial intelligence to predict the probability of a clinical trial completing each phase (BD: Feb 19, 2020).

Today, Opyl said its forecasting model included 475 Covid-19 trials, but the software could be applied to any therapeutic area or any drug, diagnostic, vaccine or medical device.

The company said its Covid-19 proof-of-concept study found: that therapies showed “a much higher probability of success in clinical studies than vaccines”; the artificial intelligence software “identified the two vaccines most likely to succeed their current stage of development”; and at least one antibody therapy had the best probability of phase III trial success compared to all other programs.

Opyl chief executive officer Michelle Gallaher told Biotech Daily that the identities of the two vaccines and the antibody therapy were “confidential”.

In a media release, Ms Gallaher said Opyl could “see significant value in using the tool to inform clinical and treatment strategies ... procurement decision-making and investments”.

“The early outcome of this software trial ... has delivered results that give us an indication of the power of the predictive platform in identifying the Covid-19 trials, or any drug or device trial, with the greatest chance of success,” Ms Gallaher said.

Opyl said that previous studies showed that 13.8 percent of all drugs in phase I trials eventually won regulatory approval, with vaccines having a higher success rate than most other drugs at 33.4 percent, while cancer drugs had a three percent success rate.

The company said that uncertainty and delays around clinical trials was a significant risk and knowing the predicted probability score and having an opportunity to improve the trial design before beginning the trial would “save hundreds of millions of dollars”.

Opyl said the next step would increase the data from additional clinical sources and expand the variables to further train the algorithm and refine the specificity and reliability.

“Our goal is to improve the efficiency, improve the application of research funding and ultimately the return on investment for scientists, clinicians, health technology developers and investors,” Ms Gallaher said.

Opyl was in a trading halt “pending a response to ASX queries” and last traded up 10 cents or 76.9 percent to 23 cents with 6.1 million shares traded.

TELIX PHARMACEUTICALS

Telix says it will collaborate with Varian Medical Systems to evaluate its prostate cancer imaging within Varian’s radiation treatment planning platform.

Telix said it had a collaboration agreement with the Palo Alto, California-based Varian to leverage its clinical data for imaging prostate-specific membrane antigen (PSMA) with positron emission tomography (PET) within Varian’s radiation platforms to develop image-guided treatment planning, automated analysis and artificial intelligence capabilities.

The company said the aim of the collaboration was to ensure that the latest standard-of-care in prostate imaging could be an integral part of radiation treatment planning.

Telix chief executive officer Dr Christian Behrenbruch said advanced prostate imaging techniques using PET and computerized tomography had become “a new standard of care for imaging patients ... from early through to the advanced stages of disease”.

Varian’s Dr Corey Zankowski said the collaboration would “investigate the potential to incorporate this rich diagnostic information into Varian’s ... treatment planning platforms to generate highly personalized and targeted radiation therapy for men with prostate cancer”.

Telix was up 13 cents or 7.6 percent to \$1.84 with 1.9 million shares traded.

MTP CONNECT, FEDERAL GOVERNMENT

The Federal Minister for Health Greg Hunt and MTP Connect say that Federal grants of \$10.4 million to 13 early stage biomedical projects will generate a total of \$38.4 million. MTP Connect said the funding was provided through the second and third rounds of the Medical Research Future Fund's Biomedical Translation Bridge program, which it ran. MTP managing-director Dr Dan Grant said that \$4.1 million was provided to five Covid-19 projects, including medical devices, diagnostics, prophylactic or therapeutic approaches, that would have an impact in less than 12 months.

Dr Grant said that eight projects and \$6.3 million would support research into treatments and diagnostics for muscular dystrophy, breast cancer, metabolic and fibrotic disease, prostate cancer, ataxia, antimicrobial resistance and the Zika virus.

Dr Grant said the \$10.4 million had "leveraged an additional \$28 million in contributions from industry" taking the total for the projects to \$38.4 million.

MTP Connect said that Bard1 received \$372,654 for liquid biopsy tests for breast cancer, Melbourne's Cincera Therapeutics received \$1,000,000 for a drug treatment for metabolic and fibrotic disease and Envision Sciences received \$1,000,000 for diagnostic and prognostic detection methods for prostate cancer, using blood and tissue samples.

The organization said that LBT Innovations had \$748,000 to develop its Automated Plate Assessment System for anti-microbial resistance using artificial intelligence and Pharmaxis received \$1,000,000 for PXS-4699 for Duchenne muscular dystrophy. MTP said the University of Adelaide received \$675,500 for a needle-free Zika virus vaccine, Melbourne's Florey Institute of Neuroscience and Mental Health won \$500,000 for a device for guiding therapy in ataxia and imbalance and Queensland's Uniquist received \$989,140 for the treatment of prostate and other cancers.

The organization said that Covid-19-related funding went to Dimerix which won \$1,000,000 for a treatment for respiratory complications resulting from Covid-19, Sydney's Speedx Pty Ltd received \$531,411 for its Insignia respiratory virus host response test and Starpharma won \$1,000,000 for its SPL7013 intranasal spray for Covid-19.

MTP said the University of Melbourne received \$605,000 for a ventilated hood for patient isolation for provide respiratory treatment and protect hospital staff and Adelaide's Vaxine Pty Ltd won \$1,000,000 for its proposed Covax-19 vaccine.

IMUGENE

Imugene says it has approval for a 32-subject phase I trial of PD1-Vaxx for non-small cell lung cancer at the New Jersey-based Hackensack University Medical Center.

Imugene said the phase I, multi-centre, dose-escalation trial, would be conducted under the US Food and Drug Administration investigational new drug process.

The company said the trial would test different doses of PD1-Vaxx as a monotherapy and in combination with immune checkpoint inhibitor drugs.

Imugene said the primary aim of the trial was to determine safety and optimal dosage, as well as measuring efficacy and immune response.

The company said recruitment would begin following FDA, which was expected by the end of the year.

Imugene said additional US sites would be opened at the Rochester, Minnesota-based Mayo Clinic and the Columbus-based Ohio State University Medical Centre.

Last month, the company said it had started screening patients in a concurrent phase I trial of PD1-Vaxx for lung cancer in Australia (BD: Aug 21, 2020).

Imugene was up 0.1 cents or 1.9 percent to 5.3 cents with 48.7 million shares traded.

HERAMED

Heramed says it has completed an 80-patient study of its Herabeat foetal and maternal pregnancy heart rate monitor ahead of schedule and will expand the study.

In July, Heramed said it had approval to begin the trial of its Herabeat monitor at Perth's Joondalup Health Campus to evaluate the usability, accuracy and reliability of the device for remote pregnancy monitoring, initially at an antenatal clinic and then at home (BD: Jul 13, 2020).

Today, the company said the data from the study was being finalized and expected to publish the results "in the coming weeks".

Heramed said the researchers had "elected to expand the study, to cover additional case studies, and explore additional applications which could unlock further opportunities for Heramed".

Heramed chief executive officer David Groberman said that "the data generated from the study will provide important clinical validation of proprietary technology that we will leverage across our current as well as other markets to generate new opportunities".

Heramed was unchanged at 18.5 cents with 3.6 million shares traded.

REGENEUS

Regeneus says it will pay chief executive officer Leo Lee a cash bonus of \$325,000 following the signing of an agreement with the Toyko-based Kyocera Corp.

Last month, Regeneus said it had signed a \$26.4 million licence and collaboration agreement with Kyocera for its stem cell platform Progenza OA for knee osteoarthritis, and received an upfront payment of \$1.3 million upon the completion of the agreement (BD: Aug 11, 28, 2020).

Regeneus was unchanged at 18.5 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has appointed the Athens-based Brain Therapeutics to distribute its Mente Autism device in Greece.

Neurotech chief executive officer Peter Griffiths said that "after successfully renewing our [Conformité Européenne] medical registration, this is another milestone for Neurotech in Europe".

"Brain Therapeutics has extensive experience and commercial capabilities in Greece and other regions such as Balkan countries and Eastern Europe, we look forward to working with them to market and promote Mente Autism".

Neurotech was up 0.1 cents or 7.1 percent to 1.5 cents with 7.9 million shares traded.

BIOTRON

Biotron has requested a trading halt pending "an announcement regarding the results of compound testing".

Trading will resume on September 7, 2020 or on an earlier announcement.

Biotron last traded at 9.5 cents.

PRESCIENT THERAPEUTICS

Australian Ethical Investment says its 35,334,878 shares substantial holding in Prescient has been diluted from 6.90 percent to 5.52 percent.

The Sydney-based Australian Ethical said it had been diluted following the issue of shares in relation to a placement.

Last month, Prescient said it had raised \$13.5 million in a share plan and placement at 5.5 cents a share (BD: Aug 21, 26, 2020).

Prescient was unchanged at 6.6 cents with 4.05 million shares traded.

PRESCIENT THERAPEUTICS

The Shepparton, Victoria-based Chris Retzos says he has ceased his substantial shareholding in Prescient, following diluted in a placement (see above).

Mr Retzos said that between April 30, 2019 and August 31, 2020 he bought and sold shares, with the single largest sale on November 27, 2019 of 1,000,000 shares for \$134,258 or 13.4 cents a share.

Mr Retzos said shares were held with the Retzos Executive Superannuation Fund, the Retzos Family Superannuation Fund, Westpark Operations, Colonel West Pty Ltd, Stephen Retzos, Jaclyn Stojanovski and Melissa Martin.

PROBIOTEC

Pie Funds Management says it has increased and been diluted in Probiotec from 3,751,032 shares (5.02%) to 4,498,523 shares (5.02%).

The Auckland, New Zealand-based Pie Funds said it bought shares between June 16 and August 31, 2020 at prices ranging from \$1.79 to \$2.03 a share.

Probiotec fell seven cents or 3.6 percent to \$1.86.

RHYTHM BIOSCIENCE

Rhythm chair Otto Buttula says he has become a substantial shareholder in Rhythm with 27,400,000 shares or 13.61 percent of the company.

Mr Buttula said the share were bought through registered holders Webinvest Pty Ltd and Newfound Investments Pty Ltd between June 28, 2019 and September 3, 2020 for \$1,788,547 or 6.5 cents a share.

Rhythm was up half a cent or 4.8 percent to 11 cents.

CORRECTION: ALTHEA GROUP HOLDINGS

Yesterday's edition incorrectly said that SG Hiscock & Co was Sydney-based, when in fact the company's headquarters is in Collins Street, Melbourne.

The Wednesday sub-editor mistook the address given for the holder of SG Hiscock's shares, HSBC Custody Nominees, for the company itself.

We apologise unreservedly for any offence to SG Hiscock in describing it as a Sydney-based company.

The sub-editor has been admonished and is taking an active part in "learnings" from this most unfortunate episode.

Althea was up five cents or 13.2 percent to 43 cents with 2.2 million shares traded.

BOD AUSTRALIA

SG Hiscock & Company says it has increased its substantial shareholding in Bod from 6,531,766 shares (7.15%) to 7,860,208 (8.60%).

The Melbourne-based SG Hiscock said that between August 18 and September 1, 2020 it bought 1,328,442 shares for \$365,278 or an average of 27.5 cents a share.

Bod was up one cent or 3.5 percent to 29.5 cents.