

Biotech Daily

Wednesday July 14, 2021

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: OSPREY UP 7%; ACTINOGEN DOWN 8%
- * DOHERTY, PETER MAC STOP SARS-COV-2 REPLICATION, IN-VITRO
- * PLANET INNOVATION OPENS \$1m CLEAN-ROOM
- * USCOM RECEIPTS UP 20% TO \$5m
- * NUHEARA WELCOMES US PRESIDENT BIDEN O-T-C HEARING AID ORDER
- * PROTEOMICS REQUESTS 'PROMARKERD STUDY' TRADING HALT
- * PYC TRIALS VP-001 FOR RETINITIS PIGMENTOSA, IN RABBITS
- * HEXIMA EXPECTS EURO PATENT FOR PEZADEFTIDE FOR TOE FUNGUS
- * I'ROM BELOW 5% OF IDT
- * AZURE (INVICTUS) CHANGES NAME TO VGI

MARKET REPORT

The Australian stock market was up 0.31 percent on Wednesday July 14, 2021, with the ASX200 up 22.6 points to 7,354.7 points. Fourteen of the Biotech Daily Top 40 stocks were up, 22 fell and four traded unchanged. All three Big Caps were up.

Osprey was the best, up 0.1 cents or 7.1 percent to 1.5 cents, with 843,831 shares traded. Uscom climbed 6.25 percent; Clinuvel, Opthea, Optiscan and Universal Biosensors rose more than two percent; Cochlear, Nanosonics, Pharmaxis, Proteomics, Resmed and Volpara were up more than one percent; with CSL, Cyclopharm, Immutep, Kazia and Telix up by less than one percent.

Actinogen led the falls, down one cent or eight percent to 11.5 cents, with 3.8 million shares traded. Nova Eye lost 7.7 percent; Alterity shed 5.6 percent; Genetic Signatures, Impedimed, LBT and Polynovo fell more than four percent; Next Science and Oncosil were down more than three percent; Antisense, Dimerix, Imugene, Prescient and Pro Medicus shed two percent or more; Avita, Compumedics, Cynata, Paradigm, Patrys and Starpharma were down one percent or more; with Medical Developments and Orthocell down by less than one percent.

PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY PETER MACCALLUM CANCER CENTRE

The Doherty Institute says that it has stopped severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) replicating in infected human cells, in-vitro.

In a media release, the Doherty said that with researchers from the Peter MacCallum Cancer Centre built on research in 2019 when the Cancer Centre's Dr Mohamed Fareh and Prof Joe Trapani showed a DNA clustered regularly interspaced short palindromic repeats, or CRISPR, gene-editing tool could be used to eliminate abnormal RNAs that drove children's cancers.

The Doherty said that its director Prof Sharon Lewin and Dr Wei Zhao used the same approach to suppress replication of the RNA virus Sars-Cov-2 and its "variants of concern" in a test tube model.

The Institute said that the CRISPR-Cas13b enzyme bound to target RNA and degraded part of the virus' genome needed to replicate inside cells.

The research article, titled 'Reprogrammed CRISPR-Cas13b suppresses Sars-Cov-2 replication and circumvents its mutational escape through mismatch tolerance' was published in Nature Communications and the full article is available at: https://www.nature.com/articles/s41467-021-24577-9.

The Doherty Institute said that the collaborating team would test the approach in animal studies and eventually a clinical trial.

Prof Lewin said that while the pandemic response was focussed on rolling out protective vaccines, there remained an urgent need for treatments specific to Covid-19 patients. "The flexibility of CRISPR-Cas13, which only needs the viral sequence, means we can look to rapidly design antivirals for Covid-19 and any new emerging viruses," Prof Lewin said.

Dr Fareh said the "unlike conventional anti-viral drugs, the power of this tool lies in its design-flexibility and adaptability, which make it a suitable drug against a multitude of pathogenic viruses including influenza, Ebola, and possibly HIV".

PLANET INNOVATION

Melbourne's Planet Innovation says it has opened a 130-square metre, state-of-the-art clean-room, at its Box Hill facility.

In a media release, Planet Innovation said the clean-room was part of an investment to build its internal medical technologies manufacturing capabilities for the production of sterile consumables and regulated products.

The company said it spent more than \$1 million on building and fitting out the clean-room. Planet Innovation chief executive officer Stuart Elliott said the company "bridges a critical gap in Australia's [medical technologies] sector, providing product development and manufacturing capabilities needed to create and commercialize sophisticated, connected products of the future".

"The opening of our new clean-room will benefit hundreds of suppliers, start-ups and ... innovators in the local ecosystem, encouraging more local companies to remain in Australia as they progress towards commercialization, keeping valuable skills and [intellectual property] on-shore," Mr Elliott said.

Opening the facility, Victoria Minister for Innovation Jaala Pulford said that early in the Covid-19 pandemic, the Government looked to local manufacturers to produce ventilators and "we were more than proud to see Planet Innovation deliver the first Notus ventilators in June 2020".

Planet Innovation is a public unlisted company.

USCOM

Uscom says that receipts from customers for the year to June 30, 2021 was up 20.5 percent to \$4,845,000 compared to previous corresponding period.

Uscom said that receipts for the three months to June 30, 2021 improved 35.2 percent to \$1,224,000, primarily from sales of the Uscom 1A ultrasonic cardiac output monitor.

The company said it had a cash burn for the three months to June 30, 2021 of \$310,000, with cash and cash equivalents of \$1,711,000 at June 30, 2021.

Uscom was up one cent or 6.25 percent to 17 cents.

NUHEARA

Nuheara says it welcomes US President Joe Biden's executive order setting a 120-day deadline to allow hearing aids to be sold over-the-counter.

Nuheara said that President Biden ordered the US Department of Health and Human Services to publish a proposed rule to allow over-the-counter hearing aid sales.

Nuheara chief executive officer Justin Miller said the company was "delighted with the Biden administration's effort to establish a definitive timeline in issuing the ... guidelines".

"We expect the revised guidelines will have a material impact on the US hearing market, by ensuring hearing aids become more affordable and accessible," Mr Miller said.

Nuheara has developed a range of sound filtering and hearing devices.

A US White House 'Fact sheet: Executive Order on Promoting Competition in the American Economy' said that hearing aids were "so expensive that only 14 percent of the approximately 48 million Americans with hearing loss use them".

"On average, they cost more than \$US5,000 per pair, and those costs are often not covered by health insurance," the White House said.

"A major driver of the expense is that consumers must get them from a doctor or a specialist, even though experts agree that medical evaluation is not necessary," the White House said.

"Rather, this requirement serves only as red tape and a barrier to more companies selling hearing aids," the fact sheet said.

"The four largest hearing aid manufacturers now control 84 percent of the market," the White House said.

Nuheara was unchanged at 4.3 cents with 3.7 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested a trading halt pending the release of a conference abstract on diabetic kidney disease to presented with Janssen Research and Development.

Proteomics said the abstract outlined "the key findings from the second stage collaborative study to target treatment of diabetic kidney disease".

Earlier this month, the company said it retracted its claim that US payers \$US384 billion (\$A505.7 billion) over 10 years (BD: Jun 25, Jul 5, 2021).

Proteomics said that after consultation with the ASX and to ensure the findings were not "interpreted as forecast financial information" under ASIC Regulatory Guide 170 it agreed to retract the announcement.

The company said the announcement intended to report the findings of the economic health benefit study by Boston Healthcare Associates which was to be presented at the American Diabetes Association's 81st Scientific Sessions.

Trading will resume on July 16, 2021 or on an earlier announcement.

Proteomics last traded up 1.5 cents or 1.5 percent to 99.5 cents.

PYC THERAPEUTICS

PYC says it has begun a trial of VP-001 for retinitis pigmentosa type 11 (RP11) in rabbits, with results expected by October, 2021.

PYC said that there would be further studies in rabbits and non-human primates by October with results by the end of the year.

The company said that the studies would provide information about the safety and tolerability, including defining the maximum tolerated dose ahead of the clinical trial, pharmacokinetic properties, informing the planned dosing interval in the clinical trial and biodistribution of VP-001 in larger animal eyes.

PYC said it expected to submit an investigational new drug (IND) application to the US Food and Drug Administration in mid-2022.

PYC was unchanged at 15 cents.

HEXIMA

Hexima says it expects to be granted a European patent covering the use of pezadeftide for the treatment of onychomycosis, or toe fungus, today.

Hexima said that the patent, titled 'A Method of Treatment' would provide protection covering the therapeutic use of pezadeftide, as well as topical formulations containing pezadeftide, for the treatment of onychomycosis, until 2035.

The company said it expected an additional up-to five years of market exclusivity through the supplementary patent certification, and it had similar granted patents in the US, Japan, Singapore and Australia.

Hexima was unchanged at 16.5 cents.

IDT AUSTRALIA

Tokyo's I'rom Group says it has ceased its substantial share-holding in IDT on March 19, 2021, selling 4,259,845 shares for \$1,202,160 or 28.2 cents a share.

In 2013, IDT said that I'rom would take an 18.8 percent strategic cornerstone stake in the company and be issued 10,000,000 shares at 20 cents a share (BD: May 7, 2013). In 2015, I'rom said it had increased its holding from 12,460,000 shares to 15,793,001 shares but was diluted from 16.49 percent to 8.89 percent (BD: Jan 18, 2015). In 2016, the company sold its Adelaide-based CMax clinical trial business to I'rom for \$14 million (BD: Oct 28, 2016).

IDT was unchanged at 31 cents.

VGI HEALTH TECHNOLOGY (FORMERLY AZURE HEALTH TECHNOLOGY)

VGI says shareholders approved its name change from Azure to VGI on July 9, 2021, effective on the National (formerly Newcastle) Stock Exchange from today. In April, the then Azure, which merged with Invictus Biotechnology, said it had raised \$2,497,000, with the VGI Group investing \$2,250,000 (BD: Apr 20, 2021). Azure said at that time that "in recognition of the importance of the VGI Group becoming a substantial shareholder" it would change the name to VGI Health Technology. On the NSX, VGI was untraded at 20 cents.

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