

Biotech Daily

Thursday August 19, 2021

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH EVEN: TELIX UP 6%; USCOM DOWN 6.5%
- * NOVA EYE REVENUE UP 5% TO \$13m, PROFIT TO \$4.4m LOSS
- * USCOM REVENUE UP 11% TO \$3.9m, LOSS DOWN 31% TO \$924k
- * TELIX H1 REVENUE UP 81% TO \$2.9m, LOSS UP 78% TO \$32.5m
- * ONCOSIL: 1st PANCREATIC CANCER DEVICE REVENUE \$213k
- * TELIX ADDS PHASE I, PHASE II TRIALS TO PHASE III PROSTACT TRIAL
- * RHYTHM STARTS FILING COLOSTAT BLOOD TEST TO TGA
- * DIMERIX TELLS ASX: 'NO LEAK, TRY BROKER OR INVESTORS'
- * BIOTECH DAILY EDITORIAL: CONFIDENTIAL MEANS CONFIDENTIAL
- * NEUROSCIENTIFIC: EMTINB 'REDUCES COVID-19 BIOMARKERS IN-VITRO', HALT
- * EPSILON, TETRA, TERRY WHITE MELBOURNE MARIJUANA CLINIC
- * NOXOPHARM REQUESTS 'VEYONDA COVID' TRADING HALT
- * INCANNEX NASDAQ IPO EGM
- * ROBINS SUPER FUND TAKES 5.9% OF CRYOSITE
- * NIV DAGAN, 10 BOLIVIANOS TAKE 9% OF LIFESPOT
- * VOLPARA APPOINTS ANN CUSTIN DIRECTOR
- * PRESCIENT APPOINTS PROF DONALD O'ROURKE ADVISOR

MARKET REPORT

The Australian stock market fell 0.5 percent on Thursday August 19, 2021, with the ASX200 down 37.5 points to 7,464.6 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and one was untraded.

Telix was the best, up 40 cents or 6.15 percent to \$6.90, with 1.15 million shares traded. Prescient climbed 5.4 percent; Alterity, Clinuvel, CSL and Cynata were up three percent or more; Avita, Genetic Signatures, Next Science, Paradigm and Patrys rose two percent or more; Imugene, Nanosonics, Polynovo and Volpara were up more than one percent; with Cochlear up 0.8 percent.

Uscom led the falls, down one cent or 6.45 percent to 14.5 cents, with 396,462 shares traded. LBT lost 5.7 percent; Neuren and Orthocell fell more than three percent; Actinogen, Amplia, Antisense and Starpharma shed two percent or more; Cyclopharm, Medical Developments, Mesoblast, Proteomics, Resmed and Universal Biosensors were down more than one percent; with Kazia and Pro Medicus down by less than one percent.

NOVA EYE MEDICAL

Nova Eye says revenue for the year to June 30, 2021, was up 4.9 percent to \$13,394,000 with last year's net profit after tax turned to a loss of \$4,356,000.

Last year, Nova Eye said it had completed the \$97.4 million sale of its laser and ultrasound business to the Lannion, France-based Lumibird (BD: Jun 30, 2020).

Today, Nova Eye said its revenue came from the sales and reduction in operating costs in the glaucoma surgical devices division.

The company said its net tangible asset backing per share was down 75.9 percent from 61.5 cents to 14.8 cents.

The company said that diluted loss per share was down 87.8 percent from 24.83 cents to 3.03 cents, but from continuing operations diluted loss per share was down 57.9 percent from 7.19 cents to 3.03 cents.

Nova Eye said it had cash and cash equivalents of \$17,801,000 at June 30, 2021 compared to \$95,649,000 in the previous corresponding period.

Nova Eye was unchanged at 43 cents.

USCOM

Uscom says revenue for the year to June 30, 2021, was up 11.4 percent to \$3,890,224 with net loss after tax down 30.6 percent to \$924,243.

Uscom said revenue came from sales of its Uscom1A ultra-sonic cardiac output monitor, Uscom BP+ blood pressure monitor, Spirosonic pulmonary function test and Ventitest ultrasonic ventilator calibration devices.

The company said that diluted earnings per share was down 33.3 percent to 0.6 cents, net tangible asset backing per share was down 10 percent to 0.9 cents, and it had cash and cash equivalents of \$1,710,554 at June 30, 2021 compared to \$1,920,657 in the previous corresponding period.

Uscom executive chair Prof Rob Phillips said it was the company's "first cash flow positive year from operations, an inflection point for medical technology companies".

"Sales, revenue and receipts also grew strongly, with accompanying profitability in China and Europe," Prof Phillips said.

"This was despite the US and Europe both being inaccessible for more than half of 2020-'21, and with worldwide intermittent regional lockdowns restricting travel, and access to hospitals and sales," Prof Phillips said.

"We also built out our regional subsidiaries adding new operations and distribution," Prof Phillips said.

Uscom fell one cent or 6.45 percent to 14.5 cents.

TELIX PHARMACEUTICALS

Telix says revenue for the six months to June 30, 2021, was up 81.1 percent to \$2,910,000 with net loss after tax up 77.7 percent to \$32,514,000.

Telix said revenue was from licencing its TLX591-CDx for prostate cancer imaging as well as research and development services.

Telix said that diluted loss per share was up 60.1 percent to 11.56 cents, with net tangible asset backing per share down from four cents to negative three cents.

The company said that it had cash and cash equivalents of \$49,615,000 at June 30, 2021, compared to \$24,378,000 at June 30, 2020.

Telix was up 40 cents or 6.15 percent to \$6.90 with 1.15 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has its first revenue of \$213,070 for the implantation of its radiopharmaceutical device for pancreatic cancer.

Oncosil said that 12 patient doses were delivered to patients including commercial and compassionate doses.

Oncosil was unchanged at 5.1 cents.

TELIX PHARMACEUTICALS

Telix says it will conduct a phase I study and phase II study as part of its TLX591 'Prostact' therapeutic program and in parallel with its phase III study.

Telix said the expansion would further evaluate the efficacy and safety of prostate specific membrane antigen (PSMA) targeted lutetium therapy in early-stage, localized disease through to advanced metastatic castrate-resistant prostate cancer.

In May, the company said that the Australian Therapeutic Goods Administration approved the 390-patient, phase III Prostact trial of TLX591-CDx for advanced metastatic prostate cancer, which would use its 68-gallium-PSMA-11 imaging to select patients and compare standard-of-care alone against standard-of-care with TLX591-CDx (BD: May 10, 2021) Today, Telix said the up-to 50 patients, phase I Prostact Select trial would compare 68-gallium-PSMA and 177-lutetium-PSMA, exploring the biodistribution differences between small molecule and antibody-based targeting.

The company said the study would inform optimal patient selection for its antibody-based 177Lu therapy, with the goal of enabling indication expansion for the PSMA therapeutic portfolio.

Telix said that the up-to 50 patients, phase II, Prostact Target trial would evaluate TLX591 in combination with external beam radiation therapy in patients with oligo-metastatic prostate-specific membrane antigen expressing disease, providing data in early prostate cancer relapse.

The company said the study was a collaboration with partner Genesiscare, which would co-fund the study.

Telix said the expanded study program would inform its "long-term clinical and commercialization strategies for the TLX591 therapeutic candidate and generate multiple opportunities for near-term data readouts throughout the program duration".

Telix chief executive officer Dr Christian Behrenbruch said the "ultimate objective is to evaluate the use of our PSMA-targeting radio-nuclide therapies in prostate cancer from first diagnosis to advanced metastatic disease".

"The biology of prostate cancer and clinical utility of radio-nuclide therapy will have distinct application in each of these settings," Dr Behrenbruch said.

RHYTHM BIOSCIENCES

Rhythm says it has submitted its initial documentation for Australian Therapeutic Goods Administration approval for its Colostate colorectal cancer blood test.

Rhythm said the TGA submission required two steps, including the completed manufacturers evidence documentation and filing for an Australian Register of Therapeutic Goods listing.

Rhythm chief executive officer Glenn Gilbert said the filing was "another significant step forward as we move towards commercialization" and the Conformité Européenne (CE) mark filing was "on-track for late this calendar year".

Rhythm was up two cents or 2.2 percent to 92 cents.

DIMERIX

Dimerix has told the ASX it had nothing to do with a leak of information to the Australian Financial Review about its \$20 million placement (BD: Aug 16, 2021).

The ASX said that Dimerix requested a trading halt on August 12 "for the purposes of considering, planning and executing a capital raising" at 8.45am (AEST) and an article titled 'Merchant, Peter Meurs cornerstone \$20m Dimerix Raising' was published by the Australian Financial Review at 9:31pm on August 12, which contained details of the capital raising.

The ASX said Dimerix announced the placement on August 16, 2021 and asked how the information in the announcement appeared in the article and what arrangements it had to ensure compliance with Listing Rule 15.7, prohibiting the provision of information to any party prior to the ASX.

Dimerix said that neither it, nor any of its officers, had contact with the Financial Review and it was not aware of how the information in the announcement was sourced and appeared in the article, which "was published without the knowledge of the company". The company said that Canaccord Genuity (Australia) was the lead manager to the capital raising began a process of "wall-crossing", providing certain institutional and sophisticated investors confidential information after the trading halt "in line with industry standards". "It may be that the information which appeared in the article, was initially disclosed by such person with whom the deal term sheet was shared in the wall-crossing process," Dimerix said.

The company said it had taken "reasonable precautions to prevent the premature dissemination of sensitive information, including ensuring that investors who were wall-crossed were bound by restrictions on disclosure of confidential information".

Dimerix said it understood that Listing Rule 15.7 required it "must not release information that is required to be given to ASX under Listing Rule 3.1 to anyone else, unless and until it has been given to ASX, and the company has received an acknowledgement that the information has been released to the market".

Dimerix was unchanged at 30 cents with 3.1 million shares traded.

BIOTECH DAILY EDITORIAL: CONFIDENTIAL MEANS CONFIDENTIAL

Biotech Daily has been aware for many years that potential capital raisings are frequently mentioned in business news columns, particularly the Street Talk column in the Australian Financial Review.

Companies contacted say that there is little they can do once they have signed a confidentiality agreement with their broker.

Taking the companies on faith, it means that someone in the stock-broking house or a potential investor has leaked the information to the media.

It is a practice that is unfair on the ordinary investor and the rest of the media. It is also a breach of the ASX rules.

This ASX query is the first time that Biotech Daily has seen the ASX take any form of action to restrict the practice.

It should be a warning to all companies to re-double their efforts to ensure that confidential matters remain confidential, whether the leak is in their interest, the broker's interest or whether the broker merely has an unreliable investor.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says Emtinb "significantly reduced ... biomarkers associated with severe Covid-19" by more than 50 percent, in-vitro, and requested a trading halt.

Neuroscientific said that Emtinb reduced biomarkers associated with severe Covid-19 and poor patient prognosis by more than 50 percent compared to controls in human primary cell-based systems (p < 0.05) and was safe and well-tolerated at all dose concentrations.

The company said the studies were conducted at the Luxembourg-based Eurofins US laboratories and the Perth, Western Australia-based Institute for Respiratory Health. Neuroscientific said the data indicated "strong therapeutic potential for Emtinb in

Neuroscientific said the data indicated "strong therapeutic potential for Emtinb in preventing severe immune responses resulting from Covid-19 infections".

Neuroscientific managing-director Matt Liddelow said the results "demonstrate the significant therapeutic utility of Emtinb and its potential modulation of inflammatory processes outside of the central nervous system".

"For the first time, our team have demonstrated an Emtinb-mediated effect on adaptive immune responses as evidenced by regulation of these inflammatory biomarkers," Mr Liddelow said.

The company requested a trading halt "to finalize an announcement detailing further information in regard to the results from pulmonary studies" and said trading would resume on August 23, 2021 or on an earlier announcement.

Neuroscientific last traded up 2.5 cents or 8.6 percent to 31.5 cents with 2.15 million shares traded.

EPSILON HEALTHCARE (FORMERLY THE HYDROPONICS CO)

Epsilon says that subsidiary Tetra Health has launched a face-to-face marijuana clinic with Terry White Chemmart in Melbourne's Hawthorn.

Epsilon said that Terry White Chemmart was "one of the largest medicinal cannabis dispensing pharmacies in Australia".

The company said that the clinic would provide "similar out-of-pocket cost for patients as telehealth ... due to access to Medicare rebates on treatment" with expansion in Sydney and Brisbane later this year.

Epsilon said that patients would be able to visit Terry White Chemmart to see a Tetra doctor, receive prescriptions, and be dispensed medication at the one location. Epsilon was unchanged at 16 cents.

NOXOPHARM

Noxopharm has requested a trading halt pending an update on its "Noxcovid clinical program and Veyonda drug candidate".

Trading will resume on August 23, 2021 or on an earlier announcement.

Noxopharm last traded at 55.5 cents.

INCANNEX HEALTHCARE

Incannex says it will hold an extraordinary general meeting to approve the issue of shares in connection with a US public offer and listing on Nasdaq (BD: Aug 18, 2021).

The meeting will be held online at www.investor.automic.com.au and at the offices of Thomson Geer, Rialto South Tower, Level 39, 525 Collins Street, Melbourne on September 17, 2021 at 11am (AEST).

Incannex was up 2.5 cents or 8.6 percent to 31.5 cents with 10.7 million shares traded.

CRYOSITE

Melbourne's Robins Super Fund says it has become a substantial shareholder in Cryosite with 2,800,000 shares (5.92%).

Gary Robins said he bought 2,504,123 shares for \$400,660 or 16 cents a share on March 10 and 295,877 shares for \$103,557 or 35 cents a share on May 12, 2021.

Cryosite was untraded at 45.5 cents.

<u>LIFESPOT HEALTH</u>

Niv Dagan and 10 Bolivianos say they have increased their holding in Lifespot from 9,618,198 shares (7.14%) to 14,901,280 shares (8.85%).

The Melbourne-based Mr Dagan and 10 Bolivianos said that between January 5 and August 18, 2021 they acquired the shares on market between 9.97 cents and 13.5 cents a share, and in a rights issue at seven cents a share.

Lifespot was untraded at 9.5 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has appointed Ann Custin as an independent, non-executive director, effective from September 1, 2021.

Volpara said that the Philadelphia, Pennsylvania-based Ms Custin was a healthcare general manager and finance executive with a "network of industry contacts from an extensive career in healthcare across Europe, the Americas, and Asia".

The company said that Ms Custin was most recently Siemens Medical's chief financial officer and a director, and previously was Scientx chief operating and financial officer and Draeger Medical Systems chief executive officer.

Volpara said Ms Custin was currently a director of Establishment Labs Holdings, a company focused on women's health, in breast aesthetics and reconstruction.

The company said that Ms Custin would be granted 450,000 options, subject to shareholder approval.

Volpara was up two cents or 1.8 percent to \$1.135.

PRESCIENT THERAPEUTICS

Prescient says it has appointed glioblastoma multiforme specialist Prof Donald O'Rourke to its scientific advisory board. (SAB).

Prescient said that Prof O'Rourke expertise would be valuable for the development of its Omnicar glioblastoma multiforme program.

The company said Prof O'Rourke was currently the chair of the University of Pennsylvania department of neurosurgery and the director of the glioblastoma multiforme translational centre of excellence at the University of Pennsylvania Abramson Cancer Centre.

Prescient said that Prof O'Rourke was leading the University's first-in-human clinical trial using chimeric antigen receptor (CAR) T-cells for treatment of recurrent glioblastoma multiforme and recently completing a clinical trial for newly diagnosed glioblastoma patients, utilizing a combination of CAR-T-cells and programmed death-1 (PD-1) inhibition. Prescient was up one cent or 5.4 percent to 19.5 cents with 5.4 million shares traded.