Biotech Daily

Monday March 25, 2024

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: SYNTARA UP 5%; ACTINOGEN DOWN 12.5%**

*** DOHERTY CLINICAL TRIALS CENTRE OPENS**

*** LTR PHARMA SPONTAN TRIAL DOSED**

*** ORTHOCELL FINISHES 1st STAGE REMPLIR RAT NERVE REPAIR STUDY**

*** PROTEOMICS BUYS 600 SAMPLES FOR PROMARKERENDO TRIAL**

*** ARCHER DEVELOPS 'PULSED ELECTRON SPIN RESONANCE CHIP'**

*** ARGENICA: ARG-007 FDA RARE PAEDIATRIC STATUS FOR HIE**

*** CLEO OVARIAN CANCER TEST 'OUTPERFORMS CA125'**

*** CANN TELLS ASX 'GOING CONCERN, LOAN BREACH NOT MATERIAL'**

*** CLARITY REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ALLEGRA FILES LATE H1 REPORT; SUSPENSION CONTINUES**

*** RICHMOND HILL TAKES 10.7% OF UNIVERSAL BIOSENSORS**

*** FIL (FIDELITY) INCREASES, DILUTED BELOW 5% OF RHYTHM**

*** COCHLEAR LOSES 14-YEAR DIRECTOR YASMIN ALLEN**

*** GENETIC TECHNOLOGIES APPOINTS KATHRYN ANDREWS CFO, CO SEC**

MARKET REPORT

The Australian stock market was up 0.53 percent on Monday March 25, 2024, with the ASX200 up 41.3 points to 7,811.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and one was untraded.

Syntara (Pharmaxis) was the best, up 0.1 cents or 4.8 percent to 2.2 cents, with 2.1 million shares traded. Emvision and Starpharma climbed more than four percent; Atomo, Medical Developments and Pro Medicus were up more than three percent; Nova Eye rose 2.3 percent; Cochlear, CSL, Neuren and Opthea were up one percent or more; with Cyclopharm, Genetic Signatures, Nanosonics, Telix and Volpara up by less than one percent.

Actinogen led the falls, down 0.4 cents or 12.5 percent to 2.8 cents, with 4.1 million shares traded. Cynata and Resonance lost more than seven percent; Dimerix was down 6.25 percent; Prescient and Universal Biosensors fell four percent or more; Avita and Proteomics were down three percent or more; Alcidion, Orthocell and Percheron (Antisense) shed two percent or more; Clinuvel, Curvebeam, Immutep, Impedimed and Mesoblast were down more than one percent; with Polynovo and Resmed down by less than one percent.

PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY

The Doherty Institute says it has opened Doherty Clinical Trials Ltd in East Melbourne as a challenge trials facility for the development of medicines and vaccines.

The Doherty Institute said human challenge trials were early phase clinical trials that allowed "researchers to test the effectiveness of vaccines and therapeutics for infectious diseases, with the aim of speeding up the development" by administering an infectious agent to healthy volunteers to test the drug or vaccine.

The Institute said the 25-bed, was at the former Peter MacCallum Cancer Centre in East Melbourne and would be moved to the Australian Institute for Infectious Disease in Parkville near the Doherty Institute, the University of Melbourne and the Burnet Institute.

The Doherty Institute said the not-for-profit charity was a subsidiary of the University of Melbourne, funded by philanthropic grants and the Victoria Government.

The Institute said challenge trials included influenza, Streptococcus pyogenes, gonorrhoea and malaria, and would be conducted with research teams.

The Doherty said Dr Deborah Rathjen would chair the organization, with Dr Andrew Brockway as chief executive officer and Prof James McCarthy as chief medical officer.

The Doherty Institute director Prof Sharon Lewin said "the Covid-19 pandemic highlighted the need to accelerate how new vaccines and treatments are developed … this will help us all to get lifesaving medicines more rapidly in future pandemics".

"While human challenge trials have been used to develop new medicines and vaccines globally for decades, our purpose-built facility is the first of its kind in the Southern Hemisphere and will build capabilities right here in Victoria enabling rapid research translation," Prof Lewin said.

Prof McCarthy said "by providing early and rapid efficacy data using small cohorts of participants, human challenge trials can produce more reliable and reproducible results than studies in affected patients where variables are less controlled".

"With these type of studies, vital information about the efficacy of vaccines and potential treatments can be received very quickly and at a significantly lower cost," Prof McCarthy said.

"As most drugs and vaccines fail along the clinical development pathway, it is advantageous to rapidly determine if development of a candidate vaccine or treatment should continue, or if the researchers should pivot to an alternative candidate with a higher chance of success," Prof McCarthy said.

LTR PHARMA

LTR says all 18 patients in its Spontan nasal spray pharmaco-kinetic study for erectile dysfunction have received their second and final dose, completing dosing.

Last year, LTR said it would conduct a study of 5mg Spontan vardenafil nasal spray compared to a vardenafil 10mg tablet for erectile dysfunction (BD: Mar 29, 2023).

Today, the company said the data analysis results were expected in "mid 2024".

LTR said the study was a "critical milestone in the company's strategic, expedited path to commercialization" and that study data would be used to support pre-submission meetings with the US Food and Drug Administration and the Australian early access scheme.

LTR chair Lee Rodne said "with recruitment and dosing now complete, we thank the participants and our partners for contributing to this critical study".

"We are the first and only nasal spray coming to market for the treatment of erectile dysfunction and are extremely excited to bring this key innovation to men worldwide," Mr Rodne said.

LTR was unchanged at 30.5 cents.

ORTHOCELL

Orthocell says it has finished the first stage of its Remplir US market authorization study in rats, with all nerve repair surgeries performed and no adverse events reported.

In 2023, Orthocell said it had begun a comparator study of its Remplir regenerative nerve wrap using rat sciatic nerve injury models in 72 rats across three study groups, with completion expected by April 2024 (BD: Apr 18, 2023).

Today, the company said the study used a rat sciatic nerve injury model to evaluate the safety and effectiveness of Remplir when used as a nerve wrap in peripheral nerve repair, compared to traditional repair methods.

Orthocell said the completion of the first stage allowed it to progress to stage two which would evaluate the recovery of sensory and motor function and then stage three, which would evaluate the quality of nerve reduction.

The company said study outcomes would be assessed at four, eight and 24 weeks post-treatment, and that “key evaluations” included restoration of movement and sensitivity to heat and touch, as well as quality of newly regenerated nerve tissue.

Orthocell said it expected to complete the study by October, and apply to the US Food and Drug Administration to sell Remplir for peripheral nerve repair surgeries this year.

Orthocell chief executive officer Paul Anderson said that “successful completion of stage one gives us confidence that the final two stages of the US market authorization study will be consistent with the pilot study results, and the clinical performance of Remplir to date”.

Orthocell fell one cent or 2.5 percent to 39 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it will buy 600 patient plasma samples from the University of Oxford for its study of the Promarkerendo diagnostic blood test for endometriosis.

In February, Proteomics said it had presented further data confirming the biomarkers used in its endometriosis and oesophageal adenocarcinoma blood tests, and would begin a larger validation study to confirm the accuracy of its tests (BD: Feb 1, 2024).

Today, the company said analysis of the samples was expected to be completed “over the next four months” and was streamlining Promarkerendo to produce a test suitable for clinical use, but did not disclose the commercial terms of the deal.

Today, Proteomics chief executive officer Dr Richard Lipscombe said the samples would “allow us to verify the clinical performance of the Promarkerendo test”.

Proteomics fell four cents or 3.7 percent to $1.05.

ARCHER MATERIALS TECHNOLOGY

Archer Materials says it has developed a pulsed electron spin resonance chip to detect and analyze material.

Earlier this year, Archer said that it had designed a miniature version of its Biochip graphene field effect transistor chip for applications in biotechnology at a commercial foundry, building on its earlier development of a computer chip to detect the electronic signals from genetic sequence reactions, enabling the potential detection of multiple diseases (BD: Jan 23, Mar 11, 2024).

Today, the company said the 0.7mm^2 pulsed electron spin resonance chip was developed with Switzerland’s Ecole Polytechnique Federale de Lausanne, and was designed to detect and analyze the behavior of unpaired electrons, which may lead to the development of quantum sensors, advanced spectrometers and analytical devices.

Archer was up 12.5 cents or 26.6 percent to 59.5 cents with 11.5 million shares traded.

ARGENICA THERAPEUTICS

Argenica says it has US Food and Drug Administration rare paediatric disease status for ARG-007 for hypoxic ischaemic encephalopathy (HIE) in newborn term infants.
Argenica said the designation was for drugs that showed promise in preventing, diagnosing or treating a rare disease or condition in children 18 years of age and younger, and that it could result in the FDA awarding it a “priority review voucher” to for any subsequent marketing application, subject to ARG-007 being approved for hypoxic ischaemic encephalopathy as its first indication.
The company said priority review vouchers could also be sold or transferred to a third party, with sale prices “often in the tens of millions of dollars”.
In November, Argenica said ARG-007 for hypoxic ischaemic encephalopathy had US FDA orphan drug designation (BD: Nov 15, 2023).
Today, Argenica chief executive officer Dr Liz Dallimore said the rare paediatric status grant was “further validation by the FDA on the potential of ARG-007 in [hypoxic ischaemic encephalopathy]”.
“There are currently no therapeutic drugs available to treat this devastating condition,” Dr Dallimore said. “This [designation] will provide the company with potential significant upside at the end of a clinical program in [hypoxic ischaemic encephalopathy] to receive a priority review to get the drug on the market quickly, or the option to sell the voucher to a third party.”
Argenica was up four cents or seven percent to 61 cents.

CLEO DIAGNOSTICS

Cleo says a peer-reviewed dataset of 334 previously-test patients shows its ovarian cancer triage test outperformed the current standard Cancer Antigen 125 (CA125) test.
Cleo said a multi-centre retrospective study assessed its triage test in cases where CA125 had provided an incorrect indication.
The company said CA125 had “poor accuracy, particularly for the detection of early-stage disease and discrimination between benign versus malignant status”.
Cleo said its test “correctly identified the majority of patients with early-stage ovarian cancers” and discriminated between malignant and benign samples.
The company said its test reduced false negative detections by 71 percent for post-menopausal patients and 54 percent for pre-menopausal patients and reduced false positive detections by 57 percent and 75 percent for post-and-pre-menopausal patients, respectively.
Cleo said about 20 percent of ovarian cancers do not express CA125 and that it was often in the “normal” range in patients with early-stage disease.
The company said false negatives were common in non-CA125 expressing patients which can lead to complications related to the referral of cancer patients for surgery.
Cleo said the article, titled ‘Reclassification of patients with ambiguous CA125 for optimized pre-surgical triage’ was published in the journal Diagnostics and was available at: https://www.mdpi.com/2075-4418/14/7/671.
Cleo chief executive officer Dr Richard Allman said the results showed that the ovarian cancer triage test was “far superior to the current standard-of-care using the CA125”.
“Our test will improve the initial clinical investigation process, helping clinicians to triage patients far more effectively than current methods,” Dr Allman said. “The ability to identify early-stage cancers also supports our ultimate goal of an ovarian cancer screening program using Cleo technology.”
Cleo was untraded at 17 cents.

CANN GROUP

Cann has told the ASX that despite its half-year finances it remains a going concern and that breaching the terms of its National Australia Bank loan is not material.
The ASX asked whether Cann believed that its 'Half-Year Report' announced on February 29, 2024 complied with standard accounting practices and gave a "true and fair view of Cann's financial performance and position for the [six months to December 31, 2023]".
The ASX said that the half-year report's independent auditor's review noted a net loss of $14,338,000, a net current asset deficiency of $54,163,000 and net cash outflows of $6,071,000, and that Cann was "unable to confirm its ability to secure … external financial commitments to provide sufficient funding to support the group as a going concern".
The ASX noted that in the company's half-year reports it said was not compliant with the terms of its NAB loan, but that "the lender will not take any further actions" and that the outstanding loan liabilities were classified "as current as a result of the … breach".
Cann said that at March 6, 2024, its directors had "reasonable grounds to believe Cann will be able to secure additional funding and have NAB facility repayment dates extended", and hence be solvent.
The company said it extended its debt facility agreement with NAB, sold $1.7 million of equipment, received a $1.9 million final payment for the sale of its 'Southern' Melbourne marijuana factory, had received a non-binding agreement for an up-to $15 million investment and was "in active discussions with several interested parties to provide additional funding" (BD: Mar 18, 22, 2024).
Cann said that it had received a letter from NAB on February 13, 2024 confirming it had breached its loan agreement, but that NAB would "not be taking action at this time".
Cann was in a suspension and last traded at 6.2 cents.

CLARITY PHARMACEUTICALS

Clarity has requested a trading halt in relation to "an equity raising by way of a pro rata, accelerated, non-renounceable entitlement offer and institutional placement".
Trading will resume on March 28, 2024, or on an earlier announcement.
Clarity last traded at $2.85.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra says revenue for the six months to December 31, 2023 fell 69.0 percent to $484,235, with net loss after tax up 71.8 percent to $1,444,171 and it remains suspended.
Earlier this month, the ASX suspended Allegra for failing to file financial reports, following a voluntary suspension regarding its funding arrangements and sale process of its Sr–Ht–gahnite spinal cage intellectual property (BD: Feb 23, Mar 8, 2024).
In February, Allegra said it had withdrawn its US Food and Drug Administration application for its and hoped to sell its related intellectual property (BD: Feb 6, 2024).
Today, the company said that as a result of the sale of its intellectual property, its financial statement was not "prepared on a going concern basis but [instead] prepared on a realization basis".
Allegra said it had cash and cash equivalents of $153,711 at December 31, 2023 compared to $606,920 at December 31, 2022.
The company said it expected discussions with financiers to take "up to an additional two weeks" and it would remain suspended.
Allegra last traded at 2.9 cents.

UNIVERSAL BIOSENSORS

Richmond Hill Capital Pty Ltd says it has increased its shareholding in Universal Biosensors from 17,304,622 shares (8.15%) to 22,616,067 shares (10.65%).
The Melbourne-based Richmond Hill said that between December 8, 2023 and March 20, 2024 it acquired 5,311,445 Chess depositary interests (CDIs) for $1,372,717, or 25.8 cents a share.
Universal Biosensors fell one cent or 4.8 percent to 20 cents.

RHYTHM BIOSCIENCES

FIL Limited (Fidelity) says it has increased its holding in Rhythm to 11,777,709 shares and was diluted below the five percent substantial threshold due to a capital raise.
The Hong Kong-based FIL said that on October 11 and 12, 2023 it bought 387,575 shares and 292,642 shares at 27.41 cents and 22.59 cents a share, respectively.
Last week, Rhythm said its three-for-10 rights offer at 10 cents a share raised $2,483,947 of a hoped-for $6.6 million and it hoped to place the shortfall (BD: Mar 21, 2024).
According to its most recent filing, Rhythm had 245,982,060 shares on offer, meaning that FIL's 11,777,709 shares amounted to 4.8 percent of the company.
Rhythm was unchanged at 9.3 cents.

COCHLEAR

Cochlear says 14-year, independent, non-executive director Yasmin Allen will resign, effective from March 31, 2024.
Cochlear said Ms Allen joined the board on August 2, 2010 and thanked her for "her significant contribution to Cochlear".
Cochlear was up $5.56 or 1.7 percent to $337.31 with 99,100 shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed Kathryn Andrews as its chief financial officer and company secretary, to replace Tony Di Pietro, effective immediately.
Earlier this year, Genetic Technologies said former chief financial officer and company secretary Mr Di Pietro had resigned (BD: Jan 21, 2024).
Today, the company said Ms Andrews had been Alterity's chief financial officer as well as the chief financial officer and company secretary for Antisense (now Percheron).
According to her Linkedin profile, Ms Andrews held a Bachelor of Commerce from the University of Melbourne.
Genetic Technologies was unchanged at 13.5 cents.