



Biotech Daily

Monday August 22, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PRESCIENT UP 7.5%; ANTISENSE DOWN 17%**
- * **FEDERAL 'CRITICAL TECHNOLOGIES' LIST CONSULTATION OPENS**
- * **CARDIEX PLACEMENT RAISES \$4.33m; SHARE PLAN FOR \$1m MORE**
- * **RECCE: 6,000mg R327 'SAFE, WELL-TOLERATED'**
- * **OPTISCAN FILES INVIVAGE ORAL SCOPE US FDA 510(K) SUBMISSION**
- * **CLARITY OPENS SAR-BOMBESIN PROSTATE CANCER IMAGING TRIAL**
- * **CRESO CANADA AMENDMENT FOR PSILOCYBIN PTSD TRIAL**
- * **ASX SUSPENDS IQ3, OSPREY, OVENTUS ON LISTING FEES**
- * **HERAMED REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **PLATINUM BELOW 5% IN ANTISENSE**
- * **CREDIT SUISSE TAKES 5.1% OF HEXIMA**

MARKET REPORT

The Australian stock market fell 0.95 percent on Monday August 22, 2022, with the ASX200 down 67.6 points to 7,046.9 points. Ten of the Biotech Daily Top 40 stocks were up, 23 fell, six traded unchanged and one was untraded. All three Big Caps were up.

Prescient was the best, up 1.5 cents or 7.5 percent to 21.5 cents, with 7.4 million shares traded. Both Compumedics and Uscom climbed 7.1 percent; both Micro-X and Universal Biosensors were up 3.45 percent; Cyclopharm, Polynovo and Telix rose more than two percent; Paradigm was up 1.6 percent; with Cochlear, CSL, Oncosil and Resmed up by less than one percent.

Antisense led the falls, down two cents or 16.7 percent to 10 cents with 5.5 million shares traded. Alcidion lost 9.7 percent; Cynata and Volpara fell more than four percent; Medical Developments, Next Science, Orthocell and Patrys were down more than three percent; Avita, Emvision, Nanosonics and Pharmaxis shed more than two percent; Clinuvel, Genetic Signatures, Immutep, Impedimed, Imugene, Mesoblast, Proteomics and Starpharma were down one percent or more; with Neuren, Opthea and Pro Medicus down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it has opened consultation on the List of Critical Technologies in the National Interest to clarify technologies it considers “vital”. In a media release, the Federal Minister for Industry and Science Ed Husic said it was “vital for Australia’s continued and future prosperity that emerging and critical technologies are promoted and protected”.

The media release said that businesses, researchers and the broader community were encouraged to provide feedback on the List of Critical Technologies in the National Interest, which would run for six weeks and close on September 30, 2022.

The media release said the list built on the 2021 list which featured 63 technologies across seven categories which were vital for Australia’s interests today or within the next decade, and that interested parties could visit its website to learn more or participate:

<https://consult.industry.gov.au/critical-technologies-2022>.

The Federal Government said it was focused on the “potential of these future technologies to accelerate Australia’s productivity growth and create well-paying jobs”, in addition to their role in national security and social cohesion.

“It is vital we understand and send a clear signal about what technologies we should be focusing on and where our strengths lie - and that is exactly what this consultation is all about,” Mr Husic said. “By identifying technologies that will play a vital role in our national industrial and scientific progress, the list provides focus and forms the basis for further discussions around investment and collaboration across all sectors of the economy.”

CARDIEX

Cardiex says it has ‘firm commitments’ for \$4.33 million in a placement at 30 cents a share and will offer a share plan to raise a further \$1 million.

Cardiex said the placement and share plan offer price of 30 cents a share was a 14.3 percent discount to the closing price on August 17, 2022.

The company said that more than \$1 million of the placement was ‘corner-stoned’ by directors, subject to approval, with investors to receive one unlisted option for every three shares issued, exercisable at 45 cents a share within one year of the issue date.

Cardiex said that Sydney’s MST Financial Services Pty Ltd was the lead manager.

The company said it would offer a \$1 million share plan at the same price, but without the attaching option, and it would release further information on August 24, 2022.

Cardiex said it would use the funds raised to support and accelerate Conneqt products, corporate initiatives in the US and to provide additional working capital and to meet further regulatory requirements.

Cardiex fell three cents or 8.6 percent to 32 cents.

RECCE PHARMACEUTICALS

Recce says the seventh cohort 6,000mg dose of intravenous synthetic antibiotic candidate R327 in 10 healthy male subjects showed “good safety and tolerability”.

Recce said the cohort was a 120-fold increase on the 50mg dose of R327 through a one-hour infusion in cohort one, and a review of the data by an independent safety committee was expected to recommend recruitment for the eight cohort.

Last year, the company said it had approval for an 80 volunteer, phase I, ascending-dose, randomized, placebo-controlled, double-blind, safety and pharmaco-kinetics trial of intravenous R327 synthetic anti-infective (BD: Oct 25, 2022).

Recce was up 1.5 cents or 1.75 percent to 87 cents.

OPTISCAN IMAGING

Optiscan says it has submitted its 510(k) application to the US Food and Drug Administration for its Invivage confocal microscope for oral tissue imaging.

The company said its Invivage device was a “non-invasive, instantaneous form of oral imaging, targeting the severe health consequences of late-stage diagnosis of oral cancers and precancerous lesions ... [allowing] real-time, non-destructive [three-dimensional] in-vivo imaging at the sub-cellular level”.

Optiscan managing-director Prof Camile Farah said he was “delighted to announce the submission of our 510(k) application for Invivage, a truly landmark achievement for the company”.

“This is a key step towards strengthening the commercialization of the Invivage device and bringing our revolutionary imaging and real-time pathology technology to the world,” Prof Farah said.

“This submission strengthens the path for commercialization of Invivage, which is aligned with our new strategic direction,” Prof Farah said.

Optiscan was unchanged at 12.5 cents.

CLARITY PHARMACEUTICALS

Clarity says an investigator-led imaging trial has begun recruitment for an up-to 30-patient, phase II study of copper-64 SAR-Bombesin for patients with prostate cancer.

Clarity said the ‘Bop’ trial would assess the safety of CU-64 SAR-Bombesin, as well the diagnostic potential for men with negative prostate specific membrane antigen (PSMA) positron emission tomography (PET) or low PSMA expression disease in patients with suspected biochemical recurrence of their prostate cancer, and patients with metastatic castrate-resistant prostate cancer who were not eligible for PSMA therapy.

The company said the trial at Sydney’s St Vincent’s Hospital would conduct imaging with CU-64 SAR-Bombesin on the day of administration as well as at later times.

Clarity said that the trial built on data generated in PSMA-negative prostate cancer patients imaged under the Therapeutic Goods Administration special access scheme, and its ‘C-Bobcat’ pilot breast cancer trial of SAR-Bombesin (BD: Oct 19, 2021).

Principal Investigator Prof Louise Emmett said “the data we acquired to date for SAR-Bombesin through [special access scheme], published as a case study, has demonstrated diagnostic imaging potential in PSMA-negative prostate cancer and highlighted potential utility of the product as a theragnostic agent”.

“At St Vincent’s Hospital we imaged four men with Cu-64 SAR-Bombesin under [the special access scheme] ... they had rising [prostate specific antigen] levels but no detectable disease using currently available imaging techniques,” Prof Emmett said.

“SAR-Bombesin was able to detect disease in these patients which successfully led to changes in management of the patient and their disease,” Prof Emmett said.

Clarity chair Dr Alan Taylor said “the early data we are generating on our SAR-Bombesin product is already changing the lives of patients with cancer”.

“We are looking forward to progressing the development of this product in Australia and the US for diagnostic and therapeutic applications, hoping that it will provide new options for cancer patients who have few treatment options available to them at present,” Dr Taylor said. “We believe that SAR-Bombesin has potential to provide large patient populations with accurate and precise detection and treatment of cancers that express the target and deliver clinical, environmental and logistical benefits enabled by the copper isotope pairing.”

Clarity was up 6.5 cents or 10.2 percent to 70 cents.

CRESO PHARMA

Creso says Health Canada has amended its clinical trial authorization for its up-to 20 patient, phase II trial of psilocybin for post-traumatic stress disorder.

Last month, Creso said its subsidiary Halucenex Life Sciences had expanded its up-to 20 patients, phase II trial of psilocybin for treatment-resistant post-traumatic stress disorder, and would apply for amendments to its approved clinical trial authorization to include cohorts currently using selective serotonin reuptake inhibitors (SSRIs or anti-depressants), and not require patients to stop using prescribed medications for a week prior to the potential trials' commencement (BD: Jul 18, 2022) (AVW: Jul 22, 2022).

Today, the company said that the adjustment, granted by Health Canada, would provide a "number of benefits, including a broadened patients scope, as well as data on how psilocybin interacts when used in combination with other medication utilised by [post-traumatic stress disorder] sufferers".

Creso managing-director William Lay said the amendment was "a major step forward" for Creso, Halucenex and patients with post-traumatic stress disorder while on medication. Creso fell 0.1 cents or 2.6 percent to 3.7 cents with 6.9 million shares traded.

IQ3 CORP, OSPREY MEDICAL, OVENTUS MEDICAL

The ASX has suspended IQ3, Osprey and Oventus due to unpaid annual listing fees, with companies to be removed from the ASX List if fees are not paid by August 26, 2022.

Earlier this month, the DVT group as administrators said it had accepted a proposed deed of company arrangement, with likely no return to shareholders, after IQ3 entered into voluntary administration in March (BD: Mar 11, Aug 1, 2022).

IQ3 last traded at 12 cents.

In June, Osprey said it would restructure its business "to honor customer, employee and supplier commitments" but was unsure of any share value retention (BD: Jun 1, 2022).

At that time, Osprey said cash from ongoing operations was expected to provide sufficient liquidity to support its continuing business operations, minimizing disruption to customers until completion of the restructure after June 30, 2022.

Osprey last traded at 20 cents.

In June, Oventus said it had entered voluntary administration and in July, it said administrators Grant Thornton had been granted an extension to January 12, 2023 for "sufficient time for a recapitalization of Oventus Medical to take place or, failing this, for the sale of the companies' business and/or assets to occur" (BD: Jun 14, Jul 14, 2022).

Oventus last traded at two cents.

HERAMED

Heramed has requested a trading halt "for the purposes of considering, planning and executing a capital raising".

Trading will resume on August 24, 2022 or on an earlier announcement.

Heramed last traded at 15 cents.

ANTISENSE THERAPEUTICS

Platinum Investment Management says it has ceased its substantial shareholding in Antisense, selling 1,367,188 shares for \$163,792 or 12.0 cents a share

Last year, Platinum said it held 34,406,340 shares (5.23%) (BD: Nov 8, 2021).

Antisense fell two cents or 16.7 percent to 10 cents with 5.5 million shares traded.

HEXIMA

Sydney's Credit Suisse Holdings Australia says it has become substantial in Hexima with 8,497,650 shares or 5.09 percent.

In June, Hexima fell 84.6 percent to four cents on news that its phase II clinical study of pezadeftide (HXP124) for onychomycosis was "inconclusive ... [and did] not support moving directly into a phase III program" (BD: Jun 24, 2022).

In July, Hexima fell a further 48.15 percent to 1.4 cents on news that following the failure of HXP124 to show efficacy for nail fungus it had begun the process of winding-up activities (BD: Jul 11, 2022).

Today, Credit Suisse said that it bought and sold shares between May 4 and August 16, 2022, and that on May 4 it bought 7,337 shares for \$2,054 or 28 cents a share, on June 24, it bought 1,690,771 shares for an average of 6.045 cents a share, on July 11, it bought 1,603,565 shares for an average of 1.54 cents a share, with the most recent purchase of 249,313 shares for \$2,887 or 1.16 cents a share.

Hexima was up 0.05 cents or four percent to 1.3 cents.