



Biotech Daily

Thursday May 6, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: NEXT SCIENCE UP 7%; PRESCIENT DOWN 9.5%**
- * **CSL \$583m UNIQUE DEAL FOR AMT-061 FOR HAEMOPHILIA-B**
- * **MEDADVISOR RAISES \$5.25m; \$11.7m LOAN**
- * **NYRADA RECEIVES \$976k R&D TAX INCENTIVE**
- * **MACH7 \$730k VERMONT UNI MEDICAL CENTRE EUNITY DEAL**
- * **STARPHARMA: VIRALEZE ONLINE IN EUROPE**
- * **ZELIRA LAUNCHES MARIJUANA HOPE FOR AUTISM IN US**
- * **RHYTHM IMPROVES COLOSTAT WITH LIFESTYLE RISK FACTORS**
- * **CLARITY: US SAR-BIS-PSMA FOR PROSTATE CANCER PATENT**
- * **CRESO: HALUCENEX, NUCRO-TECHNICS PSILOCYBIN R&D DEAL**
- * **MGC REQUESTS 'FURTHER ARTEMIC FINDINGS' TRADING HALT**
- * **OPTISCAN APPOINTS ORCHID'S PROF CAMILE FARAH DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.48 percent on Thursday May 6, 2021, with the ASX200 down 34.1 points to 7,061.7 points. Fifteen of the Biotech Daily Top 40 stocks were up, 19 fell and six traded unchanged.

Next Science was the best, up 11.5 cents or 6.7 percent to \$1.825, with 609,772 shares traded, followed by Imugene up 6.1 percent to 26 cents with 36.7 million shares traded. Actinogen and Resonance climbed more than five percent; Impedimed and Patrys were up more four percent or more; Amplia and Cyclopharm rose two percent or more; Medical Developments, Polynovo, Starpharma and Telix were up more than one percent; with Genetic Signatures, Orthocell, Pro Medicus and Resmed up by less than one percent.

Prescient led the falls, down 0.9 cents or 9.5 percent to 8.6 cents, with 7.5 million shares traded, followed by Optiscan down 9.3 percent to 39 cents, with 2.2 million shares traded. Compumedics lost 7.8 percent; Uscom was down 6.45 percent; Immutep, Oncosil and Paradigm fell four percent or more; Alterity, Avita, LBT, Mesoblast, Nanosonics and Universal Biosensors were down more than three percent; Cynata, Neuren and Proteomics shed more than two percent; Pharmaxis and Volpara were down more than one percent; with Clinuvel, Cochlear and CSL down by less than one percent.

CSL

CSL says it has finalized its \$US450 million (\$A582.5 million) commercialization and licencing agreement for Uniqure's AMT-061 for haemophilia-B.

Last year, CSL said it would pay the Lexington, Massachusetts-based Uniqure \$US450 million upfront for the rights to AMT-061, or etranacogene dezaparvovec, an adeno-associated virus (AAV) gene therapy program which used AAV to carry a gene cassette with the patent-protected Padua variant of factor IX (FIX), the blood clotting protein lacking in people with haemophilia-B (BD: Jun 25, 2020).

Today, the company said that AMT-061 was in phase III clinical trials and had been shown to result in near-normal levels of factor IX.

CSL said the agreement had been finalized following the completion of anti-trust reviews of the transaction in the US, the UK and Australia.

The company said that Uniqure would receive regulatory and commercial sales milestone payments and royalties as AMT-061 was developed and commercialized.

CSL said that Uniqure would complete the phase III Hope-B trial of AMT-061 and scale-up manufacture for initial commercial supply while CSL Behring would be responsible for regulatory submissions and commercialization.

CSL chief executive officer Paul Perreault said that AMT-061 had "the potential to be the first-ever gene therapy approved for haemophilia-B and help CSL Behring deliver on our ongoing commitment to improving the lives of those living with haemophilia-B".

CSL fell 77 cents or 0.3 percent to \$276.89 with 658,833 shares traded.

MEDADVISOR

Medadvisor says it has raised \$5.25 million in a placement at 30 cents a share and has a \$US9 million (\$A11.7 million) loan at 10.25 percent from Partners for Growth.

Medadvisor said the placement share price was a 7.1 percent premium to the last traded price and a 4.4 percent discount to the 5-day volume weighted average price.

The company said the placement was supported by existing institutional shareholders, Perennial Value Management and Jencay Capital.

Medadvisor chief executive officer Robert Read said the funds "puts Medadvisor in a strong cash position as we continue to execute on significant growth opportunities and fast-tracking strategic digital US initiatives".

Medadvisor said the up-to \$US9 million three-year loan from San Francisco's Partners for Growth included a \$US5 million loan to be funded at the close of the transaction and an up-to \$US4 million revolving line of credit.

The company said the loan would repay the \$US5 million in outstanding convertible notes on issue to Syneos, as part of the Adheris acquisition (BD: Nov 12, 2020).

Medadvisor said it would use the remaining loan facility for investment in growth.

Medadvisor was unchanged at 28 cents with 4.4 million shares traded.

NYRADA INC

Nyrada says it has received \$976,372 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Nyrada said the rebate related to research and development expenditure for the year to June 30, 2020.

Nyrada fell one cent or 3.1 percent to 31 cents.

MACH7 TECHNOLOGIES

Mach7 says the University of Vermont Medical Centre will pay an additional \$730,000 to licence its Eunity enterprise diagnostic viewer platform for five years.

In 2017, Mach7 said it had licenced its imaging platform to the University of Vermont Medical Centre, with \$US1,200,000 (\$A1,513,984) expected in the first year of the agreement (BD: Sept 22, 2017).

Today, the company said the Eunity platform would be integrated with the Mach7 enterprise imaging platform, providing the Burlington-based University of Vermont Medical Centre (UVM) with end-to-end enterprise imaging management.

Mach7 chief executive officer Mike Lampron said that the “combination of Mach7's enterprise data management solution and Eunity will suit UVM's data management, workflow and enterprise diagnostic viewing needs now and adapt as their needs evolve”.

Mach7 was unchanged at \$1.15 with 976,543 shares traded.

STARPHARMA

Starpharma says its Viraleze anti-viral SPL7013 nasal spray for Covid-19 and other viruses is available in Europe through its webstore.

In February, Starpharma said Viraleze had been registered for sale in Europe and the UK and laboratory studies had shown it could “inactivate a broad spectrum of respiratory viruses, including more than 99.9 percent of [severe acute respiratory syndrome coronavirus-2] ... the virus that causes Covid-19” (BD: Feb 23, 2021)

In March, the company said it had appointed the Coventry, UK-based Lloyds Pharmacy as the UK distributor of Viraleze nasal spray (BD: Mar 25, 2021).

Today, Starpharma chief executive officer Dr Jackie Fairley said the spray had “been very well received in the UK, and we hope that Viraleze will provide European consumers with added peace of mind”.

“In addition to making Viraleze available direct to consumers in Europe via www.viraleze.co, commercial discussions for distribution continue in parallel,” Dr Fairley said.

Starpharma was up 2.5 cents or 1.4 percent to \$1.805 with 703,605 shares traded.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says its Hope branded range of medical marijuana products for autism have been approved for sale in Washington DC and 32 other US states.

Zelira said that Washington DC had reciprocity with 32 other US States with approved medical cannabis programs, expanding access for the Hope products to patients in all 32 states.

In 2019, the then Zelda said it would merge with Ilera to form Zelira, with access to the Hope portfolio for autism and last year, said it had appointed Alternative Solutions LLC to distribute Hope products in Washington DC (BD: Nov 20, 2019; Dec 14, 2020).

Today, Zelira said the Hope range was available at the Washington, DC-based National Holistic Healing Center, a medical marijuana dispensary which assisted patients in treating their symptoms through “ailment-strain alignment”.

The company said it would receive a licencing fee and ongoing royalties on sales of Hope products in Washington DC

Zelira said it aimed to expand the distribution of Hope through licensing agreements in each approved market in the US.

Zelira was up 0.3 cents or 5.7 percent to 5.6 cents with 3.95 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has improved the sensitivity of its Colostat blood test for colorectal cancer by five percent to 88 percent by adding lifestyle risk factors to the algorithm.

In March, Rhythm said its sixth study of Colostat showed “very high accuracy for the detection of colorectal cancer” with 84 percent sensitivity and 95 percent specificity when tested against 300 cancerous and healthy blood samples (BD: Mar 16, 2021).

Today, the company said that “a number of lifestyle related factors have been linked to the incidence risk of colorectal cancer” including diet, weight, exercise, smoking and type 2 diabetes.

Rhythm said that preliminary testing of the addition of lifestyle related risk factors increased the sensitivity of the test from 84 percent to 88 percent, with specificity remaining the same at 95 percent.

The company said that the potential of the lifestyle factors enhancement would be “further developed and tested on a larger number of samples where a decision will be made for its availability in the final Colostat test-kit”.

Rhythm chief executive officer Glenn Gilbert said that the company had “shown that Colostat is already superior in detecting colorectal cancer when compared to the current market standard faecal test”.

“The capability to broaden the effectiveness of our core cancer detection technology, via a simple addition of commonly measured data, is extremely exciting in the context of our objective to reduce the social and economic burden of colorectal cancer globally,” Mr Gilbert said.

Rhythm was up 10.5 cents or 12.1 percent to 97 cents.

CLARITY PHARMACEUTICALS

Clarity says it has a US patent for its sarcophagene-bis-prostate specific membrane antigen (SAR-bis-PSMA) and variants for prostate cancer.

Clarity said the patent, titled ‘Radiopharmaceuticals, radio-imaging agents, and uses thereof’ provided intellectual property protection until June 5, 2038.

The company said the SAR-bis-PSMA combined its prostate specific membrane antigen (PSMA)-targeting peptides, sarcophagene (SAR) technology and its copper-64 isotope (64-Cu) for imaging and copper-67 isotope (Cu-67) for therapy.

Clarity said that the copper pairing enabled diagnosis, staging and subsequent treatment of prostate cancers that expressed PSMA.

Last year, Clarity said the US Food and Drug Administration had granted orphan drug designation and rare paediatric disease designation for its 64-Cu Sartate for paediatric neuroblastoma, and it had treated the first paediatric neuroblastoma patient with 67-Cu Sartate in its 34-patient phase I/II trial at New York’s Memorial Sloan Kettering Cancer Centre (BD: May 20, Sep 9, Nov 20, 2020).

Clarity executive chairman Dr Alan Taylor said that the SAR-bis-PSMA patent followed the FDA approval of its investigational new drug application for a 44-patient, phase I/IIa trial of 64-Cu and 67-Cu SAR-bis-PSMA for prostate cancer (BD: May 4, 2021).

“With our diagnostic trial of 64-Cu SAR-bis-PSMA in previously diagnosed but yet untreated patients prior to surgical removal of the prostate in the start-up phase, we are now ready to embark on two clinical trials of SAR-bisPSMA in the next few months,” Dr Taylor said.

Clarity is a public unlisted company.

CRESO PHARMA

Creso says it has an agreement with Nucro-Technics to test the stability and shelf life of psilocybin liquid formulations for use in the Halucenex phase II clinical trial.

Creso said the deal was through its wholly-owned subsidiary Halucenex Life Sciences Inc, which it acquired in March for its psychedelic drug program including the mushroom-derived psilocybin for post-traumatic stress disorder, depression and other mental illnesses (BD: Mar 15, 2021).

Today, the company said the Toronto, Ontario-based Nucro-Technics was a contract research organization which would “provide microbiology and chemistry test work for a salient delivery solution using synthetic psilocybin” for the trial.

Creso said the proposed Halucenex trial was an up-to 20 patient, single-arm feasibility trial of psilocybin in adults with treatment-resistant post-traumatic stress disorder.

The company said the trial would begin pending the receipt of a dealer’s licence from Health Canada and the application for clinical trial authorization.

Creso fell half a cent or 2.5 percent to 19.5 cents with 7.2 million shares traded.

MGC PHARMACEUTICALS

MGC has requested a trading halt pending an announcement “in relation to further findings on Artemic”, its anti-inflammatory food additive for Covid-19.

Previously, MGC said the artemisinin, curcumin, Boswellia serrata, and vitamin C-based Artemic was safe and could prevent the deterioration of Covid-19 patients and achieve faster clinical improvement, based on a 50-patient trial (BD: Dec 15, 2020; Mar 3, 2021).

Trading will resume on May 10, 2021 or on an earlier announcement.

MGC last traded at 6.1 cents.

OPTISCAN

Optiscan says it has appointed Prof Camile Farah as a director to represent major investor Orchid Capital Investments on the board.

Last year, Optiscan said it hoped to raise up to \$9,813,499 through a placement at 8.25 cents a share, with Singapore’s Clermont Group taking \$7,382,513 as a cornerstone investor, with a binding subscription agreement with Orchid, a member of the Clermont Group, to apply for 15 percent of total issued shares in the company, giving Orchid the right to appoint a non-executive director, subject to maintaining a 10 percent interest in Optiscan (BD: Sep 22, Oct 2, 2020).

Today, the company said Prof Farah had 25 years’ experience healthcare, biotech and medical research and was currently the executive director of the Australian Centre for Oral Oncology Research and Education.

Optiscan said Prof Farah had previously worked as a physician and pathologist at Fiona Stanley Hospital, the Hollywood Private Hospital, Qscan Radiology Clinics, Australian Clinical Labs, and Genomics for Life and was a Dean at Perth’s University of Western Australia.

Optiscan fell four cents or 9.3 percent to 39 cents with 2.2 million shares traded.