



Biotech Daily

Thursday June 17, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: OPTHEA UP 18%; OPTISCAN DOWN 11%**
- * **BRANDON, MINDEROO, UNISEED \$32.5m FOR ENA SARS-COV-2 SPRAY**
- * **TELIX FDA MEETING FOR ILLUCIX: 'NO SUBSTANTIVE ISSUES'**
- * **4D MEDICAL: MICHIGAN UNI BUYS \$787k PERMETIUM SCANNER**
- * **CRESO, RED LIGHT HOLLAND MARIJUANA MERGER FOR HIGHBRID LAB**
- * **VICTORIA: ALL-STAR mRNA ADVISORY GROUP**
- * **AUSCANN LEASES R&D FACILITY TO SOURCE CERTAIN**
- * **CELLMID: RECORD \$1.4m JAPAN TV HAIR LOSS SALES**
- * **BOD: 2 UK ONLINE RETAILERS TO DISTRIBUTE MARIJUANA CBII**
- * **LITTLE GREEN 4.6m 'RIGHTS' EGM**
- * **LITTLE GREEN APPOINTS MEDEZIN POLISH MARIJUANA DISTRIBUTOR**
- * **IMMUTEP REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **ONE FUNDS TAKES 11% OF IDT**
- * **JENCAY REDUCES TO 10.6% OF UNIVERSAL BIOSENSORS**
- * **BIO-MELBOURNE AI MEDICAL TECHNOLOGY FORUM**
- * **CMRI WINS NHMRC IDEAS 2020**

MARKET REPORT

The Australian stock market fell 0.37 percent on Thursday June 17, 2021, with the ASX200 down 27.2 points to 7,359.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 22 fell, four traded unchanged and one was untraded.

Opthea was the best, up 25.5 cents or 18.1 percent to \$1.665, with 4.4 million shares traded. Resonance climbed 9.7 percent; Actinogen, Polynovo and Uscom were up more than three percent; Dimerix, Mesoblast, Patrys and Telix rose more than two percent; LBT, Pro Medicus and Resmed were up more than one percent; with Clinuvel, Cochlear and Orthocell up by less than one percent.

Optiscan led the falls, down three cents or 10.7 percent to 25 cents, with 486,983 shares traded. Impedimed lost 8.7 percent; Antisense, Osprey and Prescient were down more than six percent; Avita and Starpharma fell more than four percent; Alterity, Cynata, Cyclopharm, Medical Developments, Paradigm and Proteomics were down three percent or more; Compumedics, Next Science and Volpara shed more than two percent; Imugene, Kazia, Neuren and Pharmaxis were down more than one percent; with CSL, Nanosonics and Universal Biosensors down by less than one percent.

BRANDON CAPITAL, ENA RESPIRATORY

Brandon Capital says that with the Minderoo Foundation and Uniseed it has raised \$32.5 million for Melbourne's Ena to development INNA-051 for Sars-Cov-2 and other viruses. A media release from Brandon said that the INNA-051 nasal spray reduced severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) replication by up to 96 percent in ferrets. Brandon said that INNA-051 was being developed "to activate innate immunity in the nose, the primary site of most respiratory virus infections".

Ena chief executive officer Dr Christophe Demaison told Biotech Daily the treatment had been in development "for close to a decade as a treatment to fight ... colds and 'flus". "When Covid came along, it was trialled against it and proved to be highly effective in a ferret study," Dr Demaison said.

"INNA-051 stimulates the innate immunity," Dr Demaison said. "It acts directly on epithelial cells in the nasal cavity preparing them to respond more quickly to viral infections."

"As part of this priming effect, epithelial cells release cytokines and chemokines that will mobilize macrophages," Dr Demaison said.

"This cell type will then eliminate epithelial cells that are infected with the virus [and] by priming the local innate immunity at the site of infection, INNA-051 confers an advantage to the body in fighting and eliminating the invading virus," Dr Demaison said.

The Brandon Capital media release said that Ena would initiate its phase I human safety study of INNA-051 in Australia "in the coming weeks".

The media release said that if humans responded similarly to the ferret study, "the spray could be used to protect people very quickly from infection and lower community transmission".

Ena chair Dr Chris Smith said that "in addition to vaccines, the world needs safe, convenient, broad-spectrum anti-viral therapies to win the fight against Covid-19".

"INNA-051 could be incredibly helpful in protecting at-risk populations such as health workers, the elderly and immunocompromised patients against existing and emerging variants," Dr Smith said.

"Because INNA-051 is not virus-specific, it could also play a key role beyond fighting the Covid-19 pandemic, in combating seasonal 'flu or any future respiratory viral outbreaks," Dr Smith said.

Brandon Capital said that the Miami-based COPD Foundation chief scientific officer Dr Ruth Tal-Singer had been appointed as a director.

The company said that Dr Tal-Singer had technical and scientific knowledge in molecular biology, immunology, digital technology and experimental medicine trials.

Ena is a private company.

TELEX PHARMACEUTICALS

Telex says a late-cycle meeting with the US Food and Drug Administration on its prostate cancer imaging product Illucix application had "no substantive review issues".

Telex said the meeting was for the ongoing review of the new drug application for Illucix, the kit for the preparation of 68-gallium, prostate-specific membrane antigen (PSMA) injection (68Ga-PSMA-11).

The company said that with submissions in Australia, Canada, and Europe, Illucix had regulatory processes in progress in 17 countries.

Telex chief executive officer Dr Christian Behrenbruch said that the meeting "sets the stage for the concluding phase of the [new drug application] review process, including alignment on the final Illucix product label".

Telex was up 12 cents or 2.1 percent to \$5.74 with two million shares traded.

4D MEDICAL

4D Medical says it expects to receive \$US600,000 (\$A786,888) from the sale of its Permetium preclinical scanner and scan package to the University of Michigan.

4D said the sale was funded by the US National Institutes of Health to provide the XV technology-based scanner to the University of Michigan Center for Molecular Imaging “to perform safe and quick quantitative imaging of lung function and vascular changes”.

The company said the sale included use of its proprietary software to analyze respiratory scans from the pre-clinical scanner and further scans would generate software-as-a-service revenue, with the scanner to be shipped “within the coming months”.

4D chief executive officer Prof Andreas Fouras said the company was “very pleased to support the University of Michigan’s activities with our XV technology and preclinical scanner”.

“This provides the organization with the only commercially available device for ultra-high-resolution imaging and quantification of cardio-thoracic disease models,” Prof Fouras said.

“The sale of pre-clinical scanners and XV technology software to opinion-leading sites will provide further evidence of the effectiveness of our technology and help drive clinical demand for 4D Medical’s software products,” Prof Fouras said.

4D was up 2.5 cents or two percent to \$1.295.

CRESO PHARMA

Creso says it will merge with Red Light Holland to become the Highbrid Lab for recreational marijuana as well as “applied science, technology and innovation”.

Creso said the Ontario-based Red Light Holland was currently engaged in the production, growth, and sale of “magic truffles” to the legal, recreational market in the Netherlands.

The company said the merged business, the Highbrid Lab, was expected to have an implied value of \$371 million based on the closing price of the two companies’ shares on June 15, 2021 and a cash balance of about \$48 million, and would trade on the Canadian Securities Exchange under the code TRIP.

Creso said its shareholders would receive 0.395 of a Red Light Holland share for one Creso share and 0.257 of a Red Light Holland share for each listed Creso option.

The company said the merger needed to be approved by the Supreme Court of Western Australia, with 75 percent approval from stock holders at the scheme meetings.

Creso said the first court hearing was scheduled for August 13, with the scheme meetings on September 17 and removal from the ASX on October 1, 2021.

The company said after the implementation of the schemes, its former security holders would own about 57.4 percent of the pro forma issued and outstanding Red Light Holland shares, resulting in a reverse takeover of Red Light Holland by the company.

Creso said the Highbrid Lab would be led by Red Light Holland’s current chief executive officer Todd Shapiro as chief executive officer and a director.

The company said that marijuana entrepreneur Bruce Linton would be Highbrid’s non-executive chair with Creso chair Adam Blumenthal appointed a non-executive director along with two other Creso board nominees upon completion of the deal, and Canopy Growth’s William Lay would be appointed chief strategy officer.

Mr Blumenthal said the “transaction follows a considerable amount of due diligence undertaken by both parties, highlighting the strength of both Creso Pharma’s and Red Light Holland’s operations and abilities across a number of key international markets”.

“There are a number of synergies across the businesses, which will allow the combined company to considerably scale-up operations in the near term,” Mr Blumenthal said.

Creso fell three cents or 16.7 percent to 15 cents with 121.1 million shares traded.

VICTORIA GOVERNMENT

The Victoria Government says it has appointed “leading global vaccine experts” to advise on its mRNA manufacturing capability.

The State Government said that the scientific advisory group would be chaired by Victoria’s lead scientist, Dr Amanda Caples and include the US National Institutes of Health Vaccine Research Center deputy director Dr Barney Graham.

A media release from the Victoria Government said that Dr Graham led “ground-breaking research into the spike protein ... a key part of the mRNA Covid-19 vaccine breakthrough” and worked with the Cambridge, Massachusetts-based Moderna to develop its mRNA vaccine.

The media release said that the advisory group included the Doherty Institute director Prof Sharon Lewin, former Monash Institute of Pharmaceutical Sciences Prof William Charman, Burnet Institute director Prof Brendan Crabb, The Walter and Eliza Hall Institute of Medical Research director Prof Doug Hilton, the University of Melbourne’s head of infectious diseases Prof Terry Nolan, Monash Biomedicine Discovery Institute director Prof John Carroll and Murdoch Children’s Research Institute infection and immunity director Prof Andrew Steer.

The State Government said that the scientific advisory group would support the development of mRNA vaccine manufacturing and research in consultation with mRNA Victoria, which would work with industry associations such as Ausbiotech and the Bio-Melbourne Network to establish a panel of industry experts and service providers to complement the expertise of the advisory group.

Victoria’s Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said the “brilliant experts who are part of this group will provide us with an unparalleled understanding of mRNA, which will help Victoria become home to world-class vaccine manufacturing capability”.

AUSCANN GROUP HOLDINGS

Auscann says it will lease its Perth research and development facility, fitted to cultivate medical marijuana to Perth’s Source Certain International.

Auscann said the five-year lease of the facility provided a reduction in its cost base and annual rental income of \$475,000, excluding tax.

The company said it provided the first six months free of rent as an incentive and it had two extension options of five years each.

Auscann said the lease was part of its revised growth strategy to reduce its expenses, maximize asset value, focus its resources on research and development, and commercialization opportunities for higher return on investment.

The company said Source Certain International was responsible for any operating expenses related to the facility and had the first right to purchase if it proposed to sell.

Auscann was unchanged at 11 cents with 1.2 million shares traded.

CELLMID

Cellmid says it has generated \$1.38 million in wholesale revenue for Jo-Ju hair loss products from a 24-hour sales event on Japan’s television shopping channel QVC.

Cellmid said the \$1.38 million compared to events leading to \$1.19 million revenue in June 2020 and \$1.14 million in June 2019 (BD: Jun 16, 2020).

Cellmid was up 0.3 cents or 4.8 percent to 6.5 cents.

BOD AUSTRALIA

Bod Australia says it has 12-month agreements with Lookfantastic and Feelunique for the launch of its marijuana-based CBII fragrances and skincare products in the UK.

Bod said the non-exclusive deal meant that Lookfantastic and Feelunique would stock the entire range of its CBII products on their websites, which had a combined 15 million visitors a month.

Bod was unchanged at 36 cents.

LITTLE GREEN PHARMA

Little Green says its extraordinary general meeting will vote to issue directors and executives up to 4,500,000 performance rights and 105,000 retention share rights.

Little Green said that share-holders would vote on the issue of 1,500,000 “performance rights” each to managing-director Fleeta Solomon, executive director Angus Caithness and chief operating officer Paul Long for nil cash consideration, vesting in three equal tranches, pending 20-day volume-weighted average prices of 95 cents, \$1.10 and \$1.25.

The company said it would vote to issue non-executive chair Michael Lynch-Bell up to 70,000 retention share rights and non-executive director Neale Fong up to 35,000 retention rights, vesting on February 20, 2024.

Little Green said the meeting would vote to issue up to 2,715,000 shares for the acquisition of land in South West Western Australia (BD: Mar 15, 2021).

The company said the meeting would be held at Suite 2, Level 2, 66 Kings Park Road, Perth, Western Australia on July 19, 2021 at 2pm (WST) through a Zoom webinar.

Little Green was up 1.5 cents or 2.3 percent to 66 cents.

LITTLE GREEN PHARMA

Little Green says it has a five-year agreement Medezin Sp for the distribution of its medicinal cannabis oil and high tetrahydrocannabinol flower products in Poland.

Little Green said the Lodz, Poland-based Medezin Sp, a subsidiary of Pelion SA, was targeting the sale of products equivalent to at least 20 percent of the medicinal cannabis oil market and at least 10 percent of the high-THC medicinal cannabis flower market in Poland.

IMMUTEP

Immutep has requested a trading halt pending an announcement “in relation to a proposed capital raising”.

Trading will resume on June 21, 2021 or on an earlier announcement.

Immutep last traded at 61.5 cents.

IDT AUSTRALIA

The Sydney-based One Funds Management says it has increased its substantial holding in IDT from 15,000,000 shares (6.24%) to 25,338,388 shares (10.63%).

One Funds said that on May 31 One Fund Services as trustee for Sandon Capital Activist Fund changed trustee and on June 15 as trustee for Saville Capital Emerging Companies Fund acquired shares for \$66,870.

IDT was up 2.5 cents or 9.1 percent to 30 cents.

UNIVERSAL BIOSENSORS

Jencay Capital says it has reduced its substantial shareholding in Universal Biosensors from 20,792,320 shares (11.72%) to 18,817,214 shares (10.59%).

The Sydney based Jencay Capital said that between August 18, 2020 and June 15, 2021 it bought and sold shares, but did not provide the detail of the purchase and sale prices. Universal Biosensors fell half a cent or 0.7 percent to 73.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its June Bio-Forum will address 'AI-Driven Medical Technology: Device, Data or Service?'.
The Network said the event would discuss trends, how artificial intelligence can be developed and considerations to keep in mind "to position yourself in the market such as data storage, cloud data management, security, confidentiality and intellectual property".

The Network said guest speakers would include Procept chief technology officer Adrian Crouch, Presagen chief executive officer Dr Michelle Perugini, Lofty Consulting director Dr Guillaume Potard, law firm Allens senior associates Lauren John and Robert Munro.

The Bio-Melbourne Network said that the Victorian Government was sponsoring the Bio-Forum which will be held virtually on June 23, 2021 from 4pm to 5:30pm (AEST)

For details and registration, go to: <https://bit.ly/3xpnAKI>.

CHILDREN'S MEDICAL RESEARCH INSTITUTE

The Children's Medical Research Institute says its researchers have won the National Health and Medical Research Council Ideas Grant for 2020.

The CMRI said that Prof Ian Alexander and his team were named as the award winners at the NHMRC awards dinner on June 16, 2021 for their work on gene therapy for spinal muscular atrophy.

The Institute said that Prof Alexander was the head of the Gene Therapy Research Unit, a joint initiative of the CMRI and the Sydney Children's Hospitals Network, and a professor in paediatrics and molecular medicine at the University of Sydney.

The CMRI said the NHMRC grant would fund a three-year project to "exploit immunity to the [adeno-associated virus] vector that is stimulated in infants receiving gene therapy for spinal muscular atrophy and to use this to engineer the next generation of vectors".

The Institute said that spinal muscular atrophy was an inherited neuromuscular disorder that could be fatal, with infants often dying within the first two years of life.

The CMRI said that the researchers would seek to identify the antibodies children were producing against the spinal muscular atrophy gene therapy vector, recover the antibodies by reverse engineering, and to use the antibodies for a process of further re-engineering of AAV vectors that can evade immunity, which would help the proportion of children who developed natural immunity to AAV and for whom the original gene therapy was therefore ineffective.

"In this way we can use a child's immune response to both improve the technology and enhance the treatment opportunities," Prof Alexander said.