



# Biotech Daily

Monday March 15, 2021

*Daily news on ASX-listed biotechnology companies*

- \* **ASX FLAT, BIOTECH UP: OSPREY UP 17%; IMPEDIMED DOWN 5%**
- \* **VICTORIA \$17m FOR LA TROBE UNI 'DIGITAL, BIO INNOVATION HUBS'**
- \* **OPTHEA TREATS 1<sup>st</sup> PHASE III WET AMD PATIENT, 1979 TO GO**
- \* **S&P ASX INDICES: 11 BIOTECHS UP, 8 DOWN**
- \* **BARD1 GRANTED HTERT AUSTRALIAN PATENT**
- \* **RECCE: PEW ADDS R327 TO ITS 'NON-TRADITIONAL' LIST**
- \* **ELIXINOL TO PAY UP TO \$37m FOR GERMANY'S CANNACARE**
- \* **LITTLE GREEN \$7.5m LAND PURCHASE; MARIJUANA ORDER**
- \* **CRESO TO PAY \$500k, 47m SHARES FOR PSYCHEDELIC HALUCENEX**
- \* **PERENNIAL TAKES 5.35% OF 4D MEDICAL**
- \* **RACE FOUNDER DR WILLIAM GARNER REDUCES TO 8.45%**
- \* **MERCHANT REDUCES TO 6.4% OF RACE**
- \* **DMX TAKES 6% OF CRYOSITE**
- \* **ACTINOGEN APPOINTS DR STEVEN GOURLAY CEO ON \$400k**

## MARKET REPORT

The Australian stock market edged up 0.09 percent on Monday March 15, 2021, with the ASX200 up 6.2 points to 6,773.0 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 14 fell and four traded unchanged.

Osprey was the best, up 0.3 cents or 16.7 percent to 2.1 cents, with 19.7 million shares traded. Opthea climbed 9.1 percent; Actinogen and Patrys improved eight percent or more; Antisense, LBT, Resonance and Universal Biosensors climbed more than six percent; Telix was up 5.7 percent; Clinuvel and Imugene improved more than four percent; Alterity and Mesoblast were up more than three percent; Dimerix, Nanosonics and Optiscan rose two percent or more; CSL, Cynata, Genetic Signatures, Next Science, Orthocell and Pharmaxis were up one percent or more; with Cochlear and Neuren up by less than one percent.

Impedimed led the falls, down 0.5 cents or 4.55 percent to 10.5 cents, with 1.6 million shares traded. Pro Medicus fell 4.3 percent; Oncosil and Volpara were down more than three percent; Compumedics and Medical Developments shed more than two percent; Cyclopharm, Nova, Prescient and Proteomics were down more than one percent; with Avita, Kazia, Paradigm, Resmed and Starpharma down by less than one percent.

## VICTORIA GOVERNMENT

The Victoria Government says it will contribute \$17 million to the \$23 million La Trobe University 'Digital and Bio Innovation Hubs'

A media release from Victoria's Minister for Training, Skills and Higher Education Gayle Tierney said La Trobe would "become a one-stop-shop for the development of innovative products like anti-viral medication, water treatment ... and portable farm technology".

The State Government said the Digital and Bio Innovation Hubs would be housed in the Thomas Chery building at the Bundoora campus, North of Melbourne, and would accommodate research and development by students, start-ups and businesses.

The media release said the hubs would be "a place for learning, integrated research and industry collaboration and [would] provide an invaluable opportunity for businesses to grow and transform as Victoria emerges from the coronavirus pandemic".

The Government said the facility would accommodate up to 10 companies and 40 research and business staff, who would have access to wet laboratories, temperature-controlled storage facilities, laboratories, high-end digital equipment and offices.

The Victoria Government said that the hubs would "enhance La Trobe University's existing support of start-ups and businesses", with construction expected to be finished in 2022.

The media release said that La Trobe University would provide \$6 million for the project which was "one of many pitches from universities to the [\$350 million] Victorian Higher Education State Investment Fund" in response to the coronavirus pandemic on the sector.

## OPTHEA

Opthea says it has treated the first of about 1,980 patients in its two phase III trials of OPT-302 for treatment-naïve, wet, age-related macular degeneration (AMD).

Opthea said it would conduct two randomized, double-blinded, sham-controlled trials, with about 990 patients in each, evaluating OPT-302 in combination with ranibizumab (Lucentis) or OPT-302 with aflibercept (Eylea), compared to ranibizumab or aflibercept alone.

In 2019, Opthea said its 366-patient, phase IIb trial of OPT-302 for wet age-related macular degeneration met its primary endpoints with statistical significance ( $p = 0.0107$ ). (BD: Aug 7, 2019)

Opthea said at that time that the higher dose 2.0mg OPT-302 vascular endothelial growth factor receptor 3 (VEGF-3) with ranibizumab (a VEGF-A inhibitor compound) showed the statistically significant difference at 24 weeks of treatment, compared to both low dose 0.5mg OPT-302 with ranibizumab and control with ranibizumab.

Last year, Opthea said its 144-patient, phase IIa trial of OPT-302 with aflibercept, or Eylea, for diabetic macular oedema met its primary endpoint, but without statistical significance (BD: Jun 10, 2020).

Opthea said that "52 percent of patients in the OPT-302 combination and 60 percent of patients in the Eylea control group gained more than or equal to five letters ... [but] "the trial was not powered to detect differences between the treatment groups".

Today, Opthea chief executive officer Dr Megan Baldwin said that "dosing the first patient in our OPT-302 phase III pivotal clinical program in wet AMD marks a very important achievement for Opthea in accelerating the development of this novel VEGF-C/D inhibitor therapy towards market registration".

The company said it expected to report the results by 2023 and apply for US and European approvals following the 12-month primary efficacy phase of the trial.

Opthea was up 14 cents or 9.1 percent to \$1.68 with 729,727 shares traded.

## STANDARD & POOR'S DOW JONES INDICES

Eleven biotechnology companies have been promoted and eight demoted in changes to the Standard & Poor's ASX300 and All Ordinaries indices.

Standard & Poor's said that Telix had been promoted into the ASX300, with 4DX, Anteotech, Aroa Biosurgery, Cyclopharm, Emvision, Immutep, Imugene, Mach7, Race and Recce promoted into the All Ordinaries Index.

Standard & Poor's said that Alcidion, Atomo, Neuren, Next Science, Probiotec, Painchek, Resapp and Somnomed had been removed from the All Ordinaries Index, with Painchek also removed from the All Technology Index.

Previously, Standard & Poor's has told Biotech Daily that inclusion in the indices is based solely on market capitalization.

The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.

Standard & Poor's said the changes would be effective prior to the open on March 22, 2021.

## BARD1 LIFESCIENCES

Bard1 says it has been granted an Australian patent for its human telomerase reverse transcriptase (hTERT) technology for detecting cancer.

Bard1 said the patent, titled 'Method of Detecting Cancer', would protect its intellectual property until 2035.

The company said the patent covered the use of the hTERT antibody "to resolve inconclusive cytology and detect malignant cells".

Bard1 said its hTERT test was an immune-cyto-chemistry assay to detect hTERT in human epithelial cancers and it would be used as an adjunct to urine cytology to assist in bladder cancer diagnosis.

The company said it had been granted similar patents in Australia, China, Europe, Japan and the US and had similar patent applications pending in Israel and the US.

Bard1 fell 15 cents or 3.8 percent to \$3.84 with 729,081 shares traded.

## RECCE PHARMACEUTICALS

Recce says Pew Charitable Trusts' have added its synthetic antibiotic R327 to its list of non-traditional antibiotic treatments in clinical development.

Recce said the 'non-traditional products in development to combat bacterial infections' register was a part of the non-profit organization's "efforts to help health and medical researchers better understand bacterial infections and address antibiotic resistance".

The company said the Philadelphia, Pennsylvania-based Pew Charitable Trusts' had a "mission to serve the public interest by improving public policy, informing the public and invigorating civic life".

Recce said the register of non-traditional treatments had 36 candidates in clinical development at March 2021 and included new approaches from known interventions such as vaccines and immunotherapies to therapies which had not been approved for use in human medicine.

The company said the list identified each product and its manufacturer, type of approach, potential indications, target or mechanism of action and stage in development.

Recce was up one cent or one percent to \$1.02.

## ELIXINOL GLOBAL

Elixinol says it will pay EUR9.0 million (\$A13.9 million) up front and up-to EUR24 million (\$A37.0 million) for the Düsseldorf, Germany-based Cannacare Health GmbH.

Elixinol said that Cannacare was the owner of Canobo a leading German cannabidiol (CBD) brand.

The company said it would pay EUR3.0 million in cash and EUR6.0 million in shares and on attainment of revenues of EUR12.9 million in the 2021 financial year, the maximum earn-out of EUR15.0 million would be payable in shares taking the total potential consideration to EUR24.0 million.

Elixinol said that the Cannacare vendors were Frank Otto, Annette-Rosa Oplesch and an entity associated with Michael Oplesch, with Mr Otto to be appointed a director.

The company said that the maximum number of shares that could be issued on conversion of performance securities was 165,180,893 shares and if the maximum was issued, the vendors would hold about 39.98 percent of the company.

Elixinol said it would seek shareholder approval at its annual general meeting, expected in mid-May 2021.

The company said that the Cannacare management team would continue to operate the business with Mr Oplesch becoming a consultant to Cannacare and member of its advisory board.

Elixinol said that Germany was Europe's "fastest growing CBD market" and Canobo had more than 4,500 bricks and mortar retail distribution points and a range of 20 products consisting of CBD oils, sprays and skincare products which are manufactured in Europe".

The company said Cannacare had EUR2.6 million of revenue in 2020 with unaudited breakeven earnings before interest, taxation, depreciation and amortization (Ebitda).

Elixinol said that the earn-out component was not triggered until it achieved at least EUR6.5 million revenue in the 2021 financial year and at the maximum 2021 revenue earn-out threshold of EUR12.9 million, Cannacare would contribute more than 100 percent growth on standalone 2020 group revenue.

The company said the EUR3.0 million cash was payable on completion of the transaction and EUR6.0 million in shares at 21.05 cents each, with the first tranche of 43,864,133 shares equal to 14.0 percent of issued capital, subject to voluntary escrow until March 31, 2022, when the second tranche would be payable.

Elixinol chief executive officer Oliver Horn said the deal "leapfrogs Elixinol closer to its vision of becoming a profitable, global, hemp derived consumer goods wellness business". Elixinol was up 1.5 cents or 7.7 percent to 21 cents with 3.7 million shares traded.

## LITTLE GREEN PHARMA

Little Green says it has acquired 1.6 hectares in Western Australia for up to \$7.5 million and received a purchase order from Demecan for cannabis flower.

Little Green said it would acquire four properties with a total land area of about 16,000 square metres (3.95 acre or 1.6 hectare) adjacent to its South West Western Australia cultivation and manufacturing facilities to expand cultivation, doubling production.

Little Green said payment would be 70 percent cash and 30 percent scrip at 66.3 cents a share, and pending market valuations, make the price payable \$5.5 million to \$7.5 million. The company said that failing shareholder approval, the vendors could either require it to pay the 30 percent balance in cash, or terminate the agreement and refund the deposit.

Little Green said Demecan had ordered 9,000 units of 15 grams cannabis flower medicines to be delivered by July 2021.

Little Green fell two cents or 2.9 percent to 68 cents with 2.3 million shares traded.

## [CRESO PHARMA](#)

Creso says it will buy the Windsor, Nova Scotia-based Halucenex Life Sciences for \$500,000 in cash, 29,251,795 shares and 17,551,077 performance shares.

Creso said that pending due diligence, shareholder and regulatory approvals, it would acquire Halucenex for its psychedelic drug program including the mushroom-reived psilocybin for post-traumatic stress disorder, depression and other mental illnesses.

The company said that Halucenex had a supply agreement with Psygen Industries for 11.6 grams of synthetic psilocybin for its phase II and phase III trials.

Creso said that Halucenex had applied for a Canadian 'Controlled Drugs and Substances Dealer's Licence' which would allow it to possess and conduct research and development and clinical studies on psychedelic substances including lysergic acid diethylamide (LSD), psilocybin and methylene-dioxy-meth-amphetamine (MDMA).

The company said it would advance Halucenex \$250,000 as a loan to fund its operations, a further \$1 million to fund its business during the 12 months following the settlement and Halucenex would have the right to nominate a director to Creso's board.

Creso said Halucenex had a 6,000 square feet (557.4 square metre) medical clinic for the treatment of mental illness and was progressing clinical trials to research the efficacy of psilocybin for treatment resistant depression in patients with PTSD and other mental illnesses.

The company said the psychedelic medicine market was "estimated to be worth up to \$US100 billion".

Biotech Daily is not aware of any currently-approved psychedelic drugs.

Creso fell one cent or 4.8 percent to 20 cents with 50.2 million shares traded.

## [4D MEDICAL](#)

Perennial Value Management says it has become a substantial shareholder in 4D Medical with 16,128,334 shares or 5.35 percent of the company.

The Sydney-based Perennial Value Management said that it bought the shares between November 13, 2020 and March 11, 2021 with the largest purchase 1,975,012 shares for \$3,298,270 or \$1.67 a share.

4D was up six cents or four percent to \$1.56 with 887,386 shares traded.

## [RACE ONCOLOGY](#)

Race founder Dr William James Garner says he has reduced his substantial holding in from 13,399,559 shares (10.12%) to 11,723,911 shares (8.47%).

The San Juan, Puerto Rico-based Dr Garner said that between March 4 and March 12, 2021 he sold 1,650,648 shares for \$6,604,026 or \$4.00 a share.

Mr Garner said that the shares were being held directly, by Citicorp Nominees and his spouse Ya Zou.

Race fell 13 cents or 3.25 percent to \$3.87 with 1.3 million shares traded.

## [RACE ONCOLOGY](#)

Merchant Funds Management says it has reduced its substantial shareholding in Race from 10,190,000 (7.87%) to 8,470,000 shares (6.40%).

The Perth-based Merchant said that between February 8 and March 9, 2021, it sold shares, exercised options and was diluted, with the single largest sale 430,495 shares for \$1,376,953 or \$3.20 a share.

## CRYOSITE

DMX Asset Management says it has become a substantial shareholder in Cryosite with 2,770,973 shares or 5.91 percent of the company.

The Sydney-based DMX Asset Management said that between March 8 and 11, 2021 it bought 2,770,973 shares for \$473,446 or an average of 17.08 cents a share.

Cryosite fell half a cent or two percent to 24 cents.

## ACTINOGEN MEDICAL

Actinogen says it has appointed Dr Steven Gourlay as its chief executive officer, effective from today and starting on a base salary of \$400,000 a year.

Actinogen said the Sydney-based Dr Gourlay had more than 30 years' experience in novel therapeutics development, was previously the founding chief medical officer of US-based Principia Biopharma and a partner at Melbourne's GBS Venture Partners co-founded by Actinogen chair Dr Geoff Brooke.

The company said that Dr Gourlay would be paid a base salary of \$400,000 a year including superannuation and leave entitlements, a short-term incentive bonus up-to 35 percent of the annual salary, or more for "exceptional performance", along with interest-free loan shares as a long-term incentive, including 24,181,150 shares at 3.5 cents a share, and 24,181,150 shares at 4.5 cents a share.

Actinogen said Dr Gourlay held a Bachelor of Medicine, Bachelor of Surgery from the University of Melbourne, a Doctor of Medicine from Melbourne's Monash University and a Master of Business Administration from Sydney's Macquarie University.

Actinogen was up 0.2 cents or eight percent to 2.7 cents with 39.4 million shares traded.