Biotech Daily

Wednesday February 2, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMMUTEP UP 6%; USCOM, VOLPARA DOWN 6%**

*** VICTORIA SUPPORTS $17m LUMOS RAPID ANTIGEN TEST FACTORY**

*** VIVAZOME WINS $200k CYTIVA 'BIO-CHALLENGE' PRIZE**

*** BIOME 'PROBIOTIC SIGNIFICANTLY CUTS CHILD ASTHMA EXACERBATIONS'**

*** AVECHO, TEAM SAAS $1.4m US TPM-MARIJUANA EDIBLES DEAL**

*** OPTHEA $105m AT-THE-MARKET EQUITY PROGRAM**

*** IDT TO MANUFACTURE WOKE PSILOCYBIN FOR DEPRESSION TRIALS**

*** AUDEARA LAUNCHES A-02 HEADPHONES, TV BUNDLE**

*** PHARMAUST FORMULATES MONEPANTEL FOR MND TRIAL**

*** JASON CARROLL TAKES 10.15% OF ISLAND**

*** VALE IMMUTEP DIRECTOR GRANT CHAMBERLAIN**

*** DIRECTOR DR ERIC ROSE REPLACES MESOBLAST CMO DR FRED GROSSMAN**

*** RADIOPHARM APPOINTS HESTER LARKIN DIRECTOR**

MARKET REPORT

The Australian stock market was up 1.2 percent on Wednesday February 2, 2022, with the ASX200 up 81.7 points to 7,087.7 points. Fifteen of the Biotech Daily Top 40 stocks were up, 19 fell and six traded unchanged. All three Big Caps were up.

Immutep was the best, up 2.5 cents or 6.2 percent to 43 cents, with 2.99 million shares traded. Kazia and Telix climbed more than five percent; Avita improved 4.1 percent; Polynovo was up 3.7 percent; Alcidion, Compumedics, Cynata, Nanosonics, Oncosil and Pro Medicus rose two percent or more; Cochlear, Cyclopharm, Imugene, Nova Eye and Starpharma were up more than one percent; with CSL and Resmed up by less than one percent.

Uscom and Volpara led the falls, down 5.7 percent to 9.9 cents and 90.5 cents, respectively, with 8,100 shares and 264,590 shares traded, respectively. Atomo and Genetic Signatures fell more than four percent; Next Science, Orthocell, Patrys and Resonance were down more than three percent; Amplia, Antisense, Emvision, Micro-X and Paradigm shed more than two percent; Mesoblast, Neuren and Opthea were down more than one percent; with Clinuvel, Medical Developments and Proteomics down by less than one percent.

VICTORIA GOVERNMENT, LUMOS DIAGNOSTICS

The Victoria Government says it will support Lumos produce up-to 50 million severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid antigen tests a year.

In a media release to the ASX, Lumos said it had an in-principle agreement the Victorian State Government to establish a $17.2 million Diagnostics Manufacturing Facility and Innovation Hub in Victoria and be an early purchaser of the company's Covidx rapid antigen tests, pending Australian Therapeutic Goods Administration approval for over-the-counter sales.

Lumos said the facility could be producing the tests from April 2022.

"The need to establish a local capability for manufacturing rapid diagnostics has been highlighted by the critical shortages of … tests experienced across Australia in recent months," the company said.

"Once established, the aim will be to increase the facility's capabilities by building out production lines, expanding automation and introducing new products," Lumos said.

The company said that the production and assembly facility would be within an existing space provided to Lumos by its founding shareholder, Planet Innovation.

Lumos said it aimed to produce one million tests initially and up to 50 million rapid tests a year by introducing greater automation and expanding production lines subject to market demand.

The company said that the current focus on rapid antigen tests was for the management of Covid-19, but they were "increasingly being used for influenza, infectious diseases, reproductive health and chronic disease management".

Lumos executive chair Sam Lanyon said the company was "proud to collaborate with the Victorian Government to manufacture and deliver critical, rapid diagnostic tests".

"Lumos will leverage its existing partnerships and global experience that has seen it create critical infrastructure and world-class technology in North America, to support the establishment of a Victorian manufacturing and innovation hub for rapid diagnostics," Mr Lanyon said.

"We are thrilled that as an organization that was founded in Victoria, we can support the creation of local jobs whilst future proofing Victoria's needs for rapid testing," he said.

The Victoria Government said that Lumos was "already making [rapid antigen tests] for Canadian and European markets [and would] produce one million tests a month from April, three million a month after July, with full production from October onwards of up to 50 million [tests] each year".

The State Government said it would "secure priority supply of several million tests from Lumos to meet demand in the coming months".

The Government said that through the innovation hub, local start-ups, research and development institutes and small-to-medium businesses would have access to product development and manufacturing support programs.

Victoria Premier Daniel Andrews said that "manufacturing rapid antigen tests in Victoria will protect and secure the state's supply chain and create local jobs".

"Being able to scale-up production so quickly shows the strength of Victoria's advanced manufacturing capabilities," Mr Andrews said.

Victoria's Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said that rapid antigen tests were "a big part of living safely and having a secure, locally-made supply will serve us incredibly well".

The State Government said it had provided $268.5 million to accelerate coronavirus treatment research and was supporting the first mRNA vaccine manufacturing facility in the Southern Hemisphere, to be built in Melbourne by 2024.

Lumos was up 7.5 cents or eight percent to $1.01 with 1.8 million shares traded.

VIVAZOME THERAPEUTICS

Vivazome says it has won the $200,000 top prize in the Cytiva Life Sciences Australia and New Zealand Bio-Challenge.

Vivazome said that the Marlborough, Massachusetts-based Cytiva, formerly known as General Electric Life Sciences, had 32 applications from universities and companies in its inaugural Australia and New Zealand challenge.

The company said that since the Bio-Challenge was launched in 2018, Cytiva had overseen more than 130 projects and provided about $US4 million of products and services to support research, bioprocessing development, and commercialization.

Vivazome said the Australia and New Zealand Bio-Challenge focused on cell engineering, process development and isolation, as well as chromatography and filtration purification.

Vivazome said that its winning entry “depicted the company’s efforts to develop a universal exosome manufacturing process, with an aim is to produce off-the-shelf regenerative medicines without existing hurdles of delivering live cells to patients”.

Vivazome chief executive officer Prof David Haylock said the company’s aim was “to be a global leader in providing novel, valuable and safe exosome-derived therapies for devastating and life-threatening diseases”.

Vivazome is a private company.

BIOME AUSTRALIA

Biome says a 422-patient, randomized, placebo-controlled, double-blind trial of two components of its probiotic for paediatric asthma significantly reduces exacerbations.

Biome said that the eight-week trial of Ligilactobacillus salivarius and Bifidobacterium breve in its Breathe probiotic showed a 64.2 percent fall in asthma exacerbations in the active group compared to the placebo group, with 67 exacerbations in the placebo group, compared to 24 in the active group.

The company said that 50 children (23.8%) children in the placebo group had at least one asthma exacerbation compared to 19 children (9%) in the active group.

Biome said that 17 children (8.1%) in placebo group and five (2.4%) in the active group had two asthma exacerbations.

The company also said that children in the placebo group were more likely to have one asthma exacerbation than children taking the probiotic ($p < 0.001$).

Biome said that children in the placebo group were more likely to have two exacerbations than children in the active group ($p = 0:013$).

The company said that the research, titled ‘The Probiotics in Pediatric Asthma Management (PROPAM) Study in the Primary Care Setting: A Randomized, Controlled, Double-Blind Trial with Ligilactobacillus salivarius LS01 (DSM 22775) and Bifidobacterium breve B632 (DSM 24706)’ and was published in the Journal of Immunology Research and available at: www.hindawi.com/journals/jir/2022/3837418

Biome said the study authors observed that “children with asthma display lung and intestinal dysbiosis”, and posited that this “likely promote[d] the activation of inflammatory pathways and contribute[d] to bronchial obstruction and airway hyperresponsiveness”.

Biome managing-director Blair Norfolk said that the release of the results showing that “the specialized probiotic strains in Biome Breathe can be used to effectively assist in the treatment of asthma in children is a major milestone for us and the health industry”.

“The clinical validation provides significant commercial opportunities for us to work closely with and expand our network of healthcare practitioners to improve the quality of life for asthma patients,” Mr Norfolk said.

Biome was up one cent or 9.5 percent to 11.5 cents with 2.5 million shares traded.

AVECHO BIOTECHNOLOGY

Avecho says it has signed a $US1 million ($A1.4 million) deal with Team Saas LLC to use its tocopheryl phosphate mixture (TPM) for “recreational cannabis distillate”.

Avecho said that under the agreement, the Irvine, California based Team Saas agreed to a licence fee based on net profits after tax, but no less than $US1 million in the first year, $US2.5 million within two years and $US5 million within four years.

The company said it would grant Team Saas an exclusive right to use TPM in the manufacture and distribution of a marijuana distillate for recreational edibles in the US, which Team Saas would buy at a fixed but undisclosed price.

Avecho said Team Saas had receives orders from Big Chief “the largest recreational cannabis supplier in the US” for the TPM marijuana.

Avecho chief executive officer Dr Paul Gavin said the agreement was “a fantastic opportunity for Avecho”.

“We have long held a firm belief that our work and technology in the pharmaceutical cannabinoid space would drive interest in the other cannabis markets, including recreational,” Dr Gavin said.

“There are no significant development costs or timelines required to commercialize this TPM-cannabis product; allowing Avecho to begin deriving revenue in the very near term while we continue to progress the longer pharmaceutical programs,” Dr Gavin said.

Avecho was up 0.3 cents or 23.1 percent to 1.6 cents with 13.1 million shares traded.

OPTHEA

Opthea says it has a $US75 million ($A105 million) at-the-market, draw-down equity facility with the New York-based Jefferies Financial Group.

Opthea said it would determine when and how many American depositary shares (ADSs) would be sold by Jefferies, whether to sell any of the shares and could terminate the agreement at its discretion.

Opthea said each American depositary share was equivalent to eight Australian shares.

The company said that it intended to use any funds raised from the program, with existing cash, to continue the regulatory approval process, and if approved, fund the commercial launch of OPT-302 for the treatment of wet age-related macular degeneration.

Opthea fell two cents or 1.7 percent to $1.13.

WOKE PHARMACEUTICALS PTY LTD, IDT AUSTRALIA

Woke says it has a letter of intent with IDT to manufacture two psilocybin dose forms moderate depression and treatment-resistant depression, respectively.

Woke said that IDT would be the “importer and warehouser of psilocybin” for its two phase IIb trials to begin later this year.

The company said that IDT had the relevant licences from the Federal Office of Drug Control and Victoria’s Department of Health and Human Services for Schedule 9 products, including psilocybin and was importing synthetic psilocybin from the US.

Woke said that IDT would supply the psilocybin active pharmaceutical ingredients to Monash University’s Medicines Manufacturing Innovation Centre to formulate the low-dose capsule for moderate depression and a high-dose tablet for treatment-resistant depression.

The company said it was negotiating a manufacturing agreement with IDT for clinical and subsequent commercial manufacture of both final dose forms.

Woke is a private company.

AUDEARA

Audeara says it has launched the next iteration of its A-02 headphones, the next iteration of its personalized headphone range, in Australia.
Audeara said that the new design incorporated feedback from users of the A-01 product, including larger buttons and Bluetooth 5.0 for greater range and connection strength.
Audeara said it would also offer an A-02 version of its TV bundle, featuring an accompanying TV audio streamer.
Audeara was unchanged at 11 cents.

PHARMAUST

Pharmaust says it expects to complete manufacturing of monepantel in mid-February for a trial of motor neurone disease (MND) to begin in May 2022.
Pharmaust said the active pharmaceutical ingredient would be shipped to the US for formulation and tableting, scheduled for mid-March.
“Implementation of a successful accelerated stability program mid-April should enable the release of finished product in May 2022,” the company said.
Pharmaust said that throughout the manufacturing and development process it had “focused on developing a high-purity specification for the product, suitable for both human and veterinary purposes”.
The company said it had “created a unique manufacturing process to optimize yields, purity and shelf-life stability”.
In 2015, Pharmaust said it would develop a tasteless capsule of monepantel, then known as PPL-1 for human and dog cancer trials (BD: Apr 15, 2015).
The company said at that time “there may be some challenges in patients tolerating the treatment due to the taste”.
In 2020, Pharmaust said that it had received a grant of $881,085 for a phase I trial of monepantel for motor neurone disease from the charity Fight MND, with recruitment to begin in early 2021 (BD: Sep 21, 2020).
Pharmaust has previously trialed monepantel, the Elanco sheep round-worm drench, for cancer in humans and dogs, and has made several announcements claiming pre-clinical efficacy for severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) the virus that causes Covid-19 (BD: May 12, Jun 18, Aug 25, 2020).
Pharmaust chief scientific officer Dr Richard Mollard said that “late May 2022 remains the scheduled timing for recruitment of the first person into the MND clinical trial”.
“We will then follow this up with recruiting for a Covid-19 antiviral clinical trial,” Dr Mollard said. “We are looking forward to a year of working through many milestones.”
“Protocols and ethics [and] regulatory approvals are now in place for the evaluation of monepantel in motor neurone disease,” Dr Mollard said.
“The trial will test safety and tolerability in patients living with MND and look for signs that monepantel can slow its progression,” Dr Mollard said.
Pharmaust was up 0.1 cents or one percent to 10 cents.

ISLAND PHARMACEUTICALS

Jason Carroll says he has increased his substantial shareholding in Island from 7,300,000 shares (9.0%) to 8,250,000 shares (10.15%).
The Melbourne-based Mr Carroll said that between January 13 and 31, 2022 he bought 950,000 shares for $237,611 or 25 cents a share.
Island was unchanged at 25 cents.

IMMUTEP

Immutep says that director Grant Chamberlain died suddenly and unexpectedly on January 28, 2022.
Immutep chair Russell Howard said the company was “shocked and deeply saddened by Grant’s unexpected passing”.
“He was a very well-respected and much-liked member of the Immutep team,” Mr Howard said.
“Serving on our board since August 2017, it was an honor to work closely with him and to know him personally,” Mr Howard said.
“We will all miss his lively presence, his passion for Immutep and his extensive corporate and financial insights,” Mr Howard said.
Immutep said its board and staff extended their sincere condolences to Mr Chamberlain’s family and friends.
Immutep was up 2.5 cents or 6.2 percent to 43 cents with three million shares traded.

MESOBLAST

Mesoblast says it has appointed director Dr Eric Rose to replace Dr Fred Grossman as its chief medical officer.
Mesoblast said that Dr Rose was formerly the chief surgeon at New York’s Columbia Presbyterian Medical Centre, leading its heart transplant program from 1982 to 1992.
The company said that Dr Rose was previously a member of the US National Biodefense Scientific Board and a former executive chair of Siga Technologies.
Mesoblast chief executive Prof Silviu Itescu thanked Dr Grossman for his contributions, “particularly in regard to the regulatory progress of remestemcel-L in children with steroid-refractory acute graft-versus-host disease and his role in the … pivot to Covid-19 acute respiratory distress syndrome”.
The company said that Dr Grossman would continue as an adviser.
Mesoblast fell 1.5 cents or 1.3 percent to $1.16 with 1.7 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has appointed Hester Larkin as a non-executive director, effective from February 3, 2022.
Radiopharm said that Ms Larkin had 30 years’ experience in pharmaceuticals and nuclear medicine in Europe, the Middle East and Africa.
The company said that Ms Larkin previously worked for Bristol-Myers Squibb and DuPont Pharmaceuticals and was currently the managing-director of Hester Larkin Associates Consulting.
The company said that Ms Larkin held a Bachelor of Laws from the University of London, and a Bachelor of Psychology from Belfast’s Queens University.
Radiopharm fell 2.5 cents or 7.1 percent to 32.5 cents.