Biotech Daily

Monday July 5, 2021

Daily news on ASX-listed biotechnology companies

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*** LUMOS OPENS UP 20% FOR P-O-C DIAGNOSTICS**

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*** CHIMERIC APPOINTS EX-CELGENE DR GEORGE MATCHAM DIRECTOR**

*** MEMPHASYS APPOINTS PROF JOHN AITKEN RESEARCH DIRECTOR**

MARKET REPORT

The Australian stock market edged up 0.09 percent on Monday July 5, 2021, with the ASX200 up 6.4 points to 7,315.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 24 fell and three traded unchanged.

Prescient was the best, up three cents or 13 percent to 26 cents, with 18.1 million shares traded. Dimerix climbed 7.5 percent; Pharmaxis improved 5.75 percent; Next Science and Nova Eye were up more than four percent; Compumedics, Genetic Signatures, Kazia and Proteomics were up more than three percent; Amplia, Cyclopharm and LBT rose more than two percent; with Neuren up 0.3 percent.

Alterity led the falls, down 0.4 cents or 10.3 percent to 3.5 cents, with 28.9 million shares traded. Starpharma fell 8.4 percent; Osprey lost 6.7 percent; Clinuvel shed 5.2 percent; Impedimed and Imugene fell more than four percent; Actinogen was down 3.85 percent; Antisense, Avita, Cynata, Immutep, Medical Developments, Oncosil, Polynovo, Resonance, Universal Bio and Uscom shed more than two percent; Opthea, Paradigm and Telix were down one percent or more; with Cochlear, CSL, Mesoblast, Nanosonics, Pro Medicus and Volpara down by less than one percent.

LUMOS DIAGNOSTICS

Lumos opened at $1.50, a 20 percent premium to its $63 million initial public offer at $1.25 a share, to develop and commercialize its point-of-care diagnostics (BD: Jun 9, 2021).
Under the ASX code of LDX, the Melbourne, Australia and Sarasota, Florida-based Lumos said that the funds comprised $38 million of new shares and $25 million for shares from existing security holders.
Lumos executive chair Sam Lanyon told Biotech Daily that the company's lead point-of-care diagnostic the finger-prick Febridx would differentiate between viral and bacterial infections in 10 minutes and was approved in Europe, Canada and by the Australian Therapeutic Goods Administration.
Mr Lanyon said that a 510(k) application had been filed to the US Food and Drug Administration and was hoped to be granted this year.
Mr Lanyon said that the nasal, naso-pharyngeal or oro-pharyngeal swab-based Covidx would detect severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) in 15 minutes and was also hoped to be FDA-approved this year.
In its prospectus, Lumos said the indicative post-raising market capitalization would be $187.7 million.
The company said the joint lead managers were Wilsons Corporate Finance and Bell Potter Securities.
Lumos closed up six cents or 4.8 percent to $1.31 with 7.2 million shares traded.

CORRECTION: ARGENICA THERAPEUTICS

Friday's article contained three small errors.
Argenica is not a member of the Stroke Alliance as reported, the University of Western Australia researcher is Prof Bruno Meloni and it is the Perron Neuroscience Institute, not Perrin Institute.
All three errors were made by the former Friday sub-editor who has shown a total lack of attention to detail and has been seconded to the Readers Digest 'Spot The Difference' competition page for retraining.
Argenica was up half a cent or 2.3 percent to 22 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has retracted its claim that US payers $US384 billion ($A505.7 billion) over 10 years announcement (BD: Jun 25, 2021).
Proteomics said that after consultation with the ASX and to ensure the findings were not "interpreted as forecast financial information" under ASIC Regulatory Guide 170 it agreed to retract the announcement.
The company said the purpose of the announcement was to report the findings of the economic health benefit study which was to be presented at the American Diabetes Associations the American Diabetes Association's 81st Scientific Sessions.
Proteomics said that the investors "should not rely on the information as a basis for making an investment decision about its shares" and noted that its shares were not traded since the release of its announcement.
Proteomics said the study was undertaken to support its application for a reimbursement code for its Promarkerd test in the US.
The company said the study was conducted by Boston Healthcare Associates and was currently subject to peer review prior to publication.
Proteomics up 3.5 cents or 3.8 percent to 96 cents.

THERAPEUTIC GOODS ADMINISTRATION, STARPHARMA HOLDINGS

The Therapeutic Goods Administration says it has fined Starpharma $93,240 for seven notices of “alleged illegal advertising” of Viraleze, which is not approved in Australia.
The TGA said that Starpharma “allegedly promoted, on two of the company's websites and its Youtube channel, the use and supply in Australia of a nasal spray called Viraleze that was not entered on the Australian Register of Therapeutic Goods”.
The Australian regulator said that The Therapeutic Goods Act 1989 prohibited “advertising to the public for therapeutic goods that are not entered on the ARTG unless a specific exemption, approval or authority applies”.
The TGA said that alleged advertising, on two of Starpharma's websites, included a restricted representation claiming that Viraleze was an anti-viral nasal spray that stopped severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), the virus that causes Covid-19.
The TGA said that “any claims or references to preventing or treating a serious form of a disease, condition, ailment or defect are restricted representations [and under the Act, the use of restricted representations in advertisements for therapeutic goods is unlawful without the prior authorization of the TGA” and no relevant authorization had been granted for the advertised claims in this case.
The regulator said that the advertising “allegedly referred to the substance astodrimer sodium that is included in schedule 3 (pharmacist-only medicine) of the Poisons Standard” which was not permitted in advertising to consumers and was not authorized or required by a government or government authority.
The TGA said that advertisers were responsible for ensuring their therapeutic goods advertising was compliant.
Starpharma said that it had received several TGA infringement notices and “upon becoming aware of these alleged issues, Starpharma immediately acted to prevent Australian consumers from accessing the alleged infringing information from the Viraleze product website, its Starpharma’s corporate website and its Youtube channel.
The company said it took its responsibilities and obligations for compliance with the Therapeutic Goods Act very seriously.
Starpharma said it would “work closely with the TGA to resolve the current matter and how to balance the need to provide information to its shareholders about key company milestones, products and activities, with the requirements of the Act in relation to advertising in Australia”.
Starpharma said that Viraleze contained SPL7013 which was included in its condom coatings and Vivagel bacterial vaginosis which were registered for sale in more than 45 countries, including the UK, Europe, Japan, Australia, South Africa, New Zealand and a number of countries in South East Asia.
The company said that Viraleze was registered for sale in Europe and India, the product website remained accessible to consumers outside Australia, and it was negotiating distribution and marketing for Viraleze in a number of countries.
Starpharma fell 12.5 cents or 8.4 percent to $1.37 with 1.8 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price rose 46.15 percent from 1.3 cents to 1.9 cents on Friday July 2, 2021 and noted a “significant increase” in the trading volume.
Living Cell fell 0.1 cents or 5.9 percent to 1.6 cents with 14.7 million shares traded.

RESPIRI

Respiri has told the ASX its lawyers would investigate “the events surrounding the [Sigma] transaction” and managing-director Marjan Mikel’s share purchases.

In an “aware” query, the ASX asked Respiri about the June 23 announcement that Sigma Healthcare pharmacies would stock its Wheezo asthma diagnostic and share buying by Mr Mikel in a “closed” period for the company.

The ASX said that Mr Mikel bought 517,420 shares on-market at seven cents a share on June 18 during a closed period after the end of the three months to March 31, 2021 and before the release of its June quarterly cash flow report.

The ASX said Respiri’s share price rose 7.1 percent from seven cents at the close on June 22 to 7.5 cents at the close on June 23, with an increase in the trading volume.

Respiri said that on June 7, it had “implicit confirmation” from Sigma that it would sell the Wheezo device and the announcement was delayed to ensure the availability of Wheezo units for the supply agreement.

Respiri said Mr Mikel was aware of the Wheezo sales arrangement with Sigma and its availability through Sigma’s network of pharmacies by late June or early July 2021.

The company said that Mr Mikel “did not turn his mind to the trading policy before executing the [share] transaction, and therefore did not follow the approval processes set out in that policy … [and had] advised the company that he regrets his actions”.

Respiri said the information was not expected to have a material effect on the price or value of its securities and the lawyers were expected to finalize their investigation by August 6, 2021.

In a separate announcement, Respiri said that the supply of its Wheezo units to Sigma had no minimum supply figures and would be through distributor Cipla Australia, as it had no direct supply agreement with Sigma.

Respiri was up 0.1 cents or 1.35 percent to 7.5 cents.

PRESCIENT THERAPEUTICS

Prescient says computer-based immunogenicity testing of Omnicar’s binding components, Spytag and Spycatcher “substantially” de-risk its platform.

Prescient said the immunogenicity testing was to evaluate the immune response against a new therapy which could adversely affect safety and efficacy.

The company said that for chimeric antigen receptor T-cell therapies (Car T), high levels of immunogenicity could adversely impact Car-T cell expansion and persistence, impacting the overall safety and clinical response of the treatment.

Prescient said the results of the computer-modelled, or in-silico, testing showed that both Spytag and Spycatcher had low immunogenicity compared to a panel of humanized therapeutic antibodies approved for human use and equal to circulating human antibodies.

The company said it was developing its Omnicar programs for acute myeloid leukemia; human epidermal growth factor receptor 2-positive (HER2+) solid tumors, which included breast, ovarian and gastric cancers and glioblastoma multiforme.

Prescient managing director Steven Yatomi-Clarke said the testing was “another incremental but important milestone that significantly de-risks the entire Omnicar platform”.

“It gives us confidence that if these therapies are ultimately delivered to patients, that their immune systems will not impair the therapy itself,” Mr Yatomi-Clarke said. “This is essential not only for Prescient’s three in-house Omnicar programs, but also for potential external collaborators, who consider immunogenicity very stringently.”

Prescient was up three cents or 13.0 percent to 26 cents with 18.1 million shares traded.

MEDLAB CLINICAL

Medlab says a 120-patient, randomized, double-blind, placebo-controlled study shows that its NRGBiotic significantly boosts the activity of anti-depressants.
Medlab said the trial of anti-depressants with and without NRGBiotic met both primary outcomes and two of its three secondary outcomes.
The company said that participants taking NRGBiotic, a combination of specific probiotics and magnesium orotate, and an anti-depressant had greater symptom remission during the eight-week treatment period compared to anti-depressants alone ($p = 0.015$).
Medlab said that the trial, with the Queensland University of Technology. showed that both groups were dysbiotic, implying that anti-depressant medication adversely affected the intestinal bacteria, leading to a disruption to the gut micro-biota homeostasis.
The company said the participants taking the combination of its NRGBiotic with an anti-depressant had a greater increase in quality-of life and improvement in non-clinical symptoms compared to those on anti-depressants alone, but a reduction in lipo-poly-saccharides was not observed in either group.
Medlab medical research director Prof Luis Vitetta said that there was a “unique health/disease axis between the gastrointestinal tract and the brain”.
“When this axis is impaired, we see increased inflammatory activity and organ dysfunction, ultimately rendering both brain and gastrointestinal tract as grossly sub-optimal,” Prof Vitetta said.
Medlab was unchanged at 16.5 cents.

NOVA EYE MEDICAL

Nova Eye says it has filed an investigational device exemption application with the US Food and Drug Administration for a study of its retinal rejuvenation therapy 2RT laser.
Nova Eye said the study would evaluate the safety and effectiveness of its 2RT treatment for intermediate age-related macular degeneration.
Nova Eye was up 1.5 cents or 4.8 percent to 33 cents.

AUSTCO HEALTHCARE

Austco says it has a $3.3 million contract to supply its Tacera Nurse Call platform to Singapore’s general and acute care hospital Khoo Teck Puat Hospital.
Austco said the Khoo Teck Puat Hospital was part of Yishun Health which was a network of medical institutions and health facilities under Singapore’s National Healthcare Group.
The company said the integration would include Tacera’s built-in, real-time locating systems, web services interface and software like Tacera Pulse reports and dashboards.
Austco said deployment would begin by April 2022 and be completed by December 2022.
Austco was up two cents or 17.4 percent to 13.5 cents with 1.1 million shares traded.

RECCE PHARMACEUTICALS

Recce says it has received $176,870 from the Canadian Government under the Scientific Research and Experimental Development Tax incentive program.
Recce said the Canadian Government’s 10 percent research and development rebate was in addition to the Australian Federal Government’s 43.5 percent research and development tax incentive program.
Recce fell two cents or two percent to 96 cents.

RESAPP HEALTH

Resapp says it has a one-year agreement with telehealth company Doctors on Demand to use Resappdx and Sleepcheck in video telehealth services.
Resapp said the Brisbane-based Doctors on Demand would implement the Resappdx respiratory diagnostic, and the Sleepcheck at-home obstructive sleep apnoea screening smartphone application by October 2021.
The company said Doctors on Demand had direct-to-consumer and business-to-business services with telehealth including appointments with general practitioners, psychiatrists and dieticians and connection to pharmacies for prescription fulfilment.
Resapp said it did not expect the agreement to have a material impact on its operating results.
Resapp fell 0.2 cents or 4.4 percent to 4.3 cents with 5.4 million shares traded.

FINCLEAR HOLDINGS, ZELIRA THERAPEUTICS

Finclear says it completed the acquisition of Pershing Securities Australia Pty Ltd from the Bank of New York Mellon and lifted restrictions on marijuana company investment.
In a notice to the ASX, Zelira said that following the change in ownership the Bank of New York Mellon Cannabis Securities Policy, which prohibits clients, including a large proportion of Australian brokers, dealing in cannabis related businesses listed on the ASX is lifted" and clients would be able to trade in such securities.
A spokesperson for the Finclear financial services technology company told Biotech Daily that the acquisition of Pershing was completed on July 1, 2021 and the restriction on investments in marijuana companies had been lifted.
Zelira fell 0.3 cents or 6.1 percent to 4.6 cents with 1.3 million shares traded.

CANN GLOBAL

Cann Global says the shipment of Canntab's cannabidiol (CBD) 12.5mg and 25mg pharmaceutical grade hard pill formulations have arrived in Australia.
In March, Cann Global said it had an initial order for six Canntab products including two tetrahydrocannabinol (THC) products, two cannabidiol (CBD) products and two THC/CBD blends (BD: Mar 31, 2021).
Today, the company said the Canntab cannabidiol formulations would be available for ordering by pharmacies after customs clearance and could be available to patients through the special access scheme B and authorized prescriber schemes.
Cann Global was up 0.05 cents or 9.1 percent to 0.6 cents with 55.2 million shares traded.

LITTLE GREEN PHARMA

Thorney and Tiga Trading say they have increased their substantial shareholding in Little Green Pharma from 9,531,649 shares (5.09%) to 16,200,795 shares (6.96%).
The Melbourne-based Thorney Technologies and Tiga said that between June 11 and July 1, 2021 they bought and sold shares, acquiring 7,333,334 shares for $4,400,000 or 60 cents each in the recent placement which raised $27.2 million to buy a Denmark marijuana production facility (BD: Jun 22, 2021).
Little Green fell three cents or 3.3 percent to 88.5 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has appointed former Celgene chief operating officer Dr George Matcham as a non-executive director.

Chimeric said Dr Matcham had more than 30 years' experience in the bio-pharmaceutical industry and cell therapy with Celgene from its beginning in 1988 and was the head of chimeric antigen receptor (CAR) T-cell chemistry, manufacturing, and control development where he oversaw clinical supply.

The company said Dr Matcham was most recently a director and advisor to Instil Bio.

Chimeric said Dr Matcham held a Master of Arts from England's Cambridge University and a Doctor of Philosophy from Cardiff University in Wales.

Chimeric fell 1.5 cents or 4.1 percent to 35 cents with 1.5 million shares traded.

MEMPHASYS

Memphasys says it has appointed the head of its scientific advisory committee Prof John Aitken as the company's research director, effective from July 1, 2021.

Memphasys said Prof Aitken would oversee the evaluation and development of several assisted reproductive biotechnology products and support the commercial development of its Felix sperm separation device.

The company said Prof Aitken's appointment followed his recent retirement from the University of Newcastle.

Memphasys was up 0.1 cents or 1.45 percent to seven cents.