Biotech Daily

Monday September 28, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: RESONANCE UP 18.5%; OSPREY DOWN 10%**

*** ENA: INNA-051 'REDUCES SARS-COV-2 BY 96%'; $12m FOR TRIALS**

*** PARADIGM READY FOR EURO PHASE III ZILOSUL OA TRIALS**

*** VISIONEERING: 'NATURALVUE LENSES REDUCE MYOPIA PROGRESSION 90%'**

*** PATRYS HUMANIZED ANTIBODY PAT-DX3 JOINS DEOXYMAB PIPELINE**

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*** BIONOMICS INSTITUTIONAL RIGHTS RAISE $893k; $1.4m RETAIL TO GO**

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*** STARPHARMA REQUESTS 'CAPITAL RAISING' TRADING HALT**

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*** RESAPP, DIABETES QUEENSLAND PROMOTE SLEEPCHECK**

*** NEUROSCIENTIFIC RECEIVES $375k R&D TAX INCENTIVE**

*** IMMURON 2.7m SHARES IN LIEU, 9m OPTIONS, 50% FEE POOL HIKE AGM**

*** ACTINOGEN APPOINTS JEFF CARTER CFO**

*** CHIMERIC APPOINTS DR NADER SANAI, DR LARRY COUTURE ADVISORS**

MARKET REPORT

The Australian stock market fell 0.21 percent on Monday, September 28, 2020, with the ASX200 down 12.6 points to 5,952.3 points. Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and two were untraded.

Resonance was the best, up 2.5 cents or 18.5 percent to 16 cents, with 1.3 million shares traded. Mesoblast climbed 12.0 percent; Patrys was up 7.1 percent; Paradigm was up 5.7 percent; Avita, Next Science, Opthea and Pharmaxis improved more than three percent; Compumedics, Cynata, Orthocell, Polynovo and Uscom rose two percent or more; Impedimed, Kazia and Proteomics were up one percent or more; with Nanosonics, Pro Medicus, Resmed and Volpara up by less than one percent.

Osprey led the falls, down 0.3 cents or 10 percent to 2.7 cents, with 17.8 million shares traded. LBT lost 7.4 percent; Cyclopharm, Prescient and Universal Biosensors fell more than four percent; Neuren and Optiscan were down more than three percent; Immutep, Imugene and Nova Eye shed two percent or more; Medical Developments was down 1.4 percent; with Clinuvel, Cochlear, CSL, Genetic Signatures and Telix down by less than one percent.

ENA RESPIRATORY, BRANDON CAPITAL PARTNERS

Ena Respiratory says it has raised $11.7 million, wants to raise a further $30 million and its INNA-051 nasal spray could be ready for Sars-Cov-2 trials within four months.

The Sydney-based Ena said that a ferret study showed that INNA-051 nasal treatment reduced the ability of severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) to infect animals and replicate by 96 percent by boosting the immune response prior to infection.

The company said that INNA-051 was a synthetic, pegylated TLR2/6 agonist developed for topical delivery to the airways through a nasal spray "to target the primary site of most respiratory virus infections, including Covid-19, influenza and rhinovirus" and could be used as a stand-alone anti-viral preventative therapy, complementary to vaccine programs, self-administered through a nasal spray once or twice a week.

Ena said that the research article, titled 'Prophylactic intranasal administration of a TLR2 agonist reduces upper respiratory tract viral shedding in a SARS-CoV-2 challenge ferret model' was published on the Cold Harbour Springs Laboratory site, Biorxiv which said it was preliminary and not peer-reviewed, with the article available at: https://www.biorxiv.org/content/10.1101/2020.09.25.309914v1.

The company said the study included authors from London's Public Health England, the Newcastle, New South Wales-based Hunter Medical Research Institute and the University of Melbourne.

Ena said INNA-051 was in development before the Covid-19 outbreak for all types of respiratory infections, including the common cold and influenza, and if human trials were successful, it could be rapidly manufactured to scale and made available.

Ena managing-director Dr Christophe Demaison said the company was "amazed with just how effective our treatment has been".

"By boosting the natural immune response of the ferrets with our treatment, we've seen a rapid eradication of the virus," Dr Demaison said.

Dr Demaison said the benefits of treatment were two-fold.

"Individuals exposed to the virus would most likely rapidly eliminate it, with the treatment ensuring that the disease does not progress beyond mild symptoms," Dr Demaison said. "This is particularly relevant to vulnerable members of the community."

"In addition, the rapidity of this response means that the infected individuals are unlikely to pass it on, meaning a swift halt to community transmission," Dr Demaison said.

Ena director and Brandon Capital senior investment manager Dr Chris Smith said that vaccinations often had challenges as they triggered "a specific response in the adaptive immune system which might not be effective against future mutations of a virus".

"INNA-051 utilises the non-specific innate immune response meaning it is effective against a broad spectrum of viruses," Dr Smith said.

Ena said that the $11.9 million capital raising was led by Melbourne's Brandon Capital Medical Research Commercialization Fund and investment partners, including the Australian Government through the Medical Research Future Fund's Biomedical Translation Fund, Australian Super, Hesta, Hostplus, Statewide Super, CSL and Uniseed.

Uniseed chief executive officer Dr Peter Devine said the results were "very exciting … and demonstrate the potential clinical utility of the Ena drug in the treatment of Covid-19 which will likely require multiple treatment approaches".

"It also underlines the value of facilitating early-stage commercialization of research, which can go on to create a global impact," Dr Devine said.

The company said it was seeking $30 million in additional funding and human trials would be subject to successful toxicity studies and regulatory approval.

Ena is a private company.

PARADIGM BIOPHARMACEUTICALS

Paradigm says that following feedback from the European Medicines Agency it is ready to begin filing for European phase III clinical trials of Zilosul for osteoarthritis.
Paradigm said the September 1 meeting covered key elements of phase III studies and associated pre-clinical and manufacturing processes, which would support a future marketing authorization application.
The company said the EMA had agreed to key aspects of the proposed trial design including for two multi-centre, randomized studies to assess pain reduction from baseline and improved function compared to a saline placebo for moderate to severe osteoarthritis.
In April, Paradigm said it would conduct two phase III trials: one with 750 patients spanning 18 to 20 months, and one with 400 patients over 12 months (BD: April 6, 2020).
Today, the company said that the EMA agreed the primary endpoint would be to evaluate pain and function and there would be no comparator arm, other than a saline placebo arm.
Paradigm said applications to begin trials in European Union countries could begin and it intended to submit the same phase III trial protocol to the US Food and Drug Administration for a type C meeting for planned phase III trials in the US.
Paradigm was up 13 cents or 5.7 percent to $2.41 with 2.4 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it that five-year data on 153-patients shows that its Naturalvue multifocal one-day contact lenses reduce myopia progression in children 90 percent.
Visioneering said it treated the children at 13 US optometry practices for paediatric myopia, or nearsightedness, and found that 93 percent of children experienced a slowing of the progression of their nearsightedness and 65 percent experienced a slowing by more than 70 percent.
The company said all timepoints up to 59 months were statistically significantly different from the baseline ($p < 0.00001$) and the annual lengthening of children's eyes, known as the 'axial length', was reduced to normal levels.
Visioneering chief executive officer Dr Stephen Snowdy said "the long-term effectiveness shown by this new data set for Naturalvue multifocal is very encouraging, especially when combined with the excellent vision experienced by children wearing the lenses".
Visioneering was up 0.1 cents or 2.8 percent to 3.7 cents with 10.9 million shares traded.

PATRYS

Patrys says it has added a full-sized, humanized antibody version of its PAT-DX1 dimerized antibody fragment, PAT-DX3, to its Deoxymab portfolio.
Patrys said initial characterization showed that PAT-DX3 successfully penetrated cancer cell nuclei and was able to bind to the DNA released from solid tumors.
The company said its lead asset, PAT-DX1, was a tumor-agnostic, engineered version of the mouse lupus antibody 3E10, miniaturized to contain just two copies of the binding domain of 3E10 and further modified to improve its binding properties.
Patrys said the PAT-DX3 full-sized version was likely to have different pharmaceutical properties, including pharmaco-kinetics, half-life and tissue distribution, from PAT-DX1 and could provide opportunities for additional clinical applications.
The company said it expected PAT-DX3 to show similar efficacy benefits in animal models of cancer, which it intended to begin following pharmaco-kinetic studies conducted in parallel with ongoing PAT-DX1 pharmaco-kinetic studies.
Patrys was up 0.1 cents or 7.1 percent to 1.5 cents with 20.9 million shares traded.

CORRECTION: SUDA PHARMACEUTICALS

Friday's edition incorrectly reported that the North American rights to Suda's Zolpimist were held by a Singapore company when in fact it is the Englewood, Colorado-based Aytu Bioscience.

The edition said Anagrelide was approved in Europe and the US for high blood platelet levels, but used an incorrect terminology which should have been "essential thrombo-cythaemia" and the company's patents for Anagrelide include Europe as well as Japan and Australia.

The article incorrectly said that Suda had partnered with the paediatric program 'Odessa' which should have said 'Ordesa'.

Biotech Daily apologizes unreservedly to Suda for the errors which were made by the Friday Medical Sub-Editor who has confessed to not reading thoroughly his Mosby's Medical, Nursing and Allied Health Dictionary and has tendered his resignation and is expected to begin work for former Victoria Health Minister Jenny Mikakos.

Suda was unchanged at 4.4 cents.

BIONOMICS

Bionomics says it has raised $893,235 through the institutional component of its pro-rata, non-renounceable, one-for-12.54 entitlement offer at four cents a share.

Last week, Bionomics said it hoped to raise $2,173,320 in the two-part entitlement offer (BD: Sep 24, 2020).

Today, the company said it expected the retail component to close on October 15, with shareholders able to apply for additional shares of up to 100 percent of their entitlement.

Bionomics the funds would be used to partly fund a second phase II trial for post-traumatic stress disorder.

Bionomics fell three cents or 16.7 percent to 15 cents with 1.4 million shares traded.

ANTISENSE THERAPEUTICS

Antisense has requested a trading halt pending an announcement regarding its rare paediatric disease status for ATL1102 for Duchenne muscular dystrophy.

In August, Antisense said that it had applied for US and EU orphan drug status for ATL1102 for Duchenne muscular dystrophy (BD: Aug 3, 31, 2020).

Trading will resume on September 30, 2020 or on an earlier announcement.

Antisense last traded at 11.5 cents.

STARPHARMA HOLDINGS

Starpharma has requested a trading halt pending an announcement regarding an "equity capital raising comprising an institutional placement and share purchase plan".

Trading will resume on September 30, 2020 or on an earlier announcement.

Starpharma last traded at $1.605.

LIFESPOT HEALTH

Lifespot has requested a trading halt "pending an announcement in relation to a capital raising".

Trading will resume on September 30, 2020 or on an earlier announcement.

Lifespot last traded at 4.9 cents.

RESAPP HEALTH

Resapp says with Diabetes Queensland it will promote its Sleepcheck mobile application and raise awareness of lack of sleep and sleep apnoea in diabetics.

Resapp said its Sleepcheck software analyzed breathing and snoring sounds to assess sleep apnoea risk and as part of the agreement, it had launched a Sleepcheck website for patients with diabetes, with content provided by Diabetes Queensland.

The company said studies showed that 50 to 80 percent of people with type 2 diabetes experienced obstructive sleep apnoea and a lack of sleep increased the risk of developing type 2 diabetes "due to their body not properly being able to regulate glucose levels".

Resapp chief executive officer Dr Tony Keating said the partnership with Diabetes Queensland was "excellent validation of our Sleepcheck technology which offers people with diabetes the only clinical grade, regulatory approved screen app that can be used in the comfort of their own home".

"This puts them immediately on a path to treatment, which could potentially improve their quality of life and reduce the risk of adverse health outcomes," Dr Keating said.

The website is at: www.sleepcheckapp.com/diabetes.

Resapp fell half a cent or 4.8 percent to 10 cents with 1.4 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has received $374,816 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Neuroscientific said the rebate related to research and development expenditure for the year to June 30, 2019.

Neuroscientific was up three cents or 10.7 percent to 31 cents.

IMMURON

Immuron says its annual general meeting will vote to issue directors 2,737,500 shares and 9,000,000 options in lieu of cash and increase its directors' fees pool 50 percent.

In April, Immuron said directors' fees would be suspended and replaced with shares "for the foreseeable future", with up to $250,000 in shares issued at eight cents each, at the 5-day volume weighted average price to March 25, 2020 and 9,000,000 options distributed among directors, exercisable at 12 cents each within 48 months (BD: Apr 27, 2020).

Today, the company said it would vote to increase the non-executive directors' fees pool from $500,000 to $750,000 and to approve an executive share option plan.

Immuron said the meeting would vote to issue chairman Dr Roger Aston 712,500 shares at eight cents each, in lieu of $57,000 in fees, and 618,750 shares to non-executive director Daniel Pollock, in lieu of $49,500 in fees.

The company said it would also vote to issue 468,750 shares each to non-executive directors Prof Ravi Savarirayan, Stephen Anastasiou and Peter Anastasiou at eight cents each, in lieu of $37,500 in fees.

Immuron said it would vote to issue 1.8 million unlisted options each to Dr Aston, Mr Pollock, Prof Savarirayan, Stephen Anastasiou and Peter Anastasiou, exercisable at 12 cents within 48 months.

The company said the options would vest immediately with no vesting conditions.

Immuron said it would also vote to adopt its remuneration report, to re-elect Dr Aston as a director, to ratify the prior issue of shares and to approve a 10 percent placement facility.

The meeting will be held via Zoom conference on October 29, 2020 at 4:30pm (AEDT).

Immuron fell two cents or 7.4 percent to 25 cents with 3.2 million shares traded.

ACTINOGEN MEDICAL

Actinogen says it has appointed Jeff Carter as its chief financial officer effective from today.

Actinogen said Mr Carter was currently the part-time chief financial officer of Amplia Therapeutics and previously was chief financial officer, company secretary and ASX liaison officer for biotechnology companies.

The company said Mr Carter was previously employed by Coca Cola Amatil, Santos, Canadian Imperial Bank of Commerce and Touche Ross.

Actinogen said Mr Carter held a Bachelor of Financial Administration from the Armidale, New South Wales-based University of New England and a Master of Applied Finance from Sydney's Macquarie University.

Actinogen was unchanged at 2.6 cents with nine million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has appointed Dr Nader Sanai and Dr Larry Couture to its scientific advisory board.

Chimerix said Dr Sanai was a brain tumor surgeon and a director of the Phoenix, Arizona Ivy Brain Tumor Center.

The company said Dr Couture had more than 30 years' experience in cellular and genetic therapies and was the founding director of the City of Hope's Center for Applied Technology and its Center for Biomedicine and Genetics.

Chimerix said Dr Couture was a member of the US Food and Drug Administration's cellular, tissue and gene therapy advisory committee for six years and worked for Genzyme Corp and Ribozyme Pharmaceuticals.

Last week, Chimeric said it had licenced chlorotoxin chimeric antigen receptor T-cells from California's City of Hope and had begun an about 20-patient phase I trial for glioblastoma (BD: Sep 22, 2020).

Chimeric is a public unlisted company.