Biotech Daily

Wednesday May 6, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PARADIGM UP 16%; PROTEOMICS DOWN 6%**

*** TESSARA RAISES $2.7m TO GROW 3-D BRAIN TISSUE**

*** KAZIA SHARE PLAN RAISES $1.8m**

*** CSL DEVELOPS COVID-19 IMMUNOGLOBULIN FOR SARS-COV-2**

*** MESOBLAST DOSES 1st REMESTEMCEL-L COVID-19 ARDS PATIENTS**

*** COGSTATE $3.8m US PAYCHECK PROTECTION LOAN**

*** IMPEDIMED $1.8m US PAYCHECK PROTECTION LOAN**

*** RESPIRI $1m SHARE PLAN RAISES $3.14m; TOTAL $5.14m**

*** ELIXINOL INSTITUTIONAL RIGHTS RAISE $5.3m; RETAIL FOR $5.6m MORE**

*** SIENNA APPOINTS SCIENTLE NZ hTERT BLADDER CANCER TEST DISTRIBUTOR**

*** RESAPP RECEIVES HANDHELD, WEARABLE DEVICE FILES**

*** G MEDICAL: FLORIDA'S ALL COUNTY TO DISTRIBUTE PRIZMA**

*** BOD: HEALTH & HAPPINESS ORDERS $1.4m MARIJUANA FOR UK**

*** EMVISION CEO DR RON WEINBERGER PROMOTED TO M-D**

MARKET REPORT

The Australian stock market fell 0.42 percent on Wednesday May 6, 2020, with the ASX200 down 22.5 points to 5,384.6 points. Nineteen of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and one was untraded. All three Big Caps were up.

Paradigm was the best, up 29.5 cents or 16.0 percent to $2.14, with 3.1 million shares traded. Amplia and Neuren climbed more than 13 percent; Cyclopharm and Mesoblast improved more than 12 percent; Dimerix was up 9.1 percent; Patrys rose 8.3 percent; Optiscan was up 7.9 percent; Imugene and Next Science were up more than six percent; Clinuvel and Polynovo were up more than five percent; Resmed was up 3.6 percent; Genetic Signatures, Impedimed, Kazia and Prescient rose more than two percent; Pro Medicus and Volpara were up more than one percent; with Cochlear, CSL and Opthea up by less than one percent.

Proteomics led the falls, down two cents or 5.9 percent to 32 cents, with 149,793 shares traded. LBT, Oncosil and Uscom fell more than four percent; Starpharma shed two percent; Avira and Medical Developments were down more than one percent; with Cynata and Nanosonics down by less than one percent.

TESSARA THERAPEUTICS PTY LTD

Tessara says it has raised $2.7 million in a “significantly over-subscribed” placement to develop its Realbrain three-dimensional brain tissue technology for drug screening.
Tessara said the placement to Australian and New Zealand sophisticated investors was led by a New South Wales syndicate including medical specialists and a neurosurgeon taking about 55 percent of the investment and appointing Phillip Smith as a director.
The company said that the Realbrain technology of manufactured three-dimensional human mimetic brain tissue had applications in drug screening and in tissue replacement therapeutics.
Tessara’s website said Realbrain was made from human neural stem cells and a proprietary polymer matrix of clinically approved biomaterials and it had the potential “to recapitulate human brain physiology better than any existing 2D or 3D culture system”.
Tessara said Realbrain was a “culture method to grow mature human neurons and networks from primary and [induced pluripotent stem cell]-derived human neural stem cells” with the Realbrain synthetic environment based on a “bio-hybrid polymer matrix that promotes the formation of mature neuronal circuits and the secretion of essential components of the extracellular matrix, which are reminiscent of the human brain environment … [which] captures the complexity of human brain physiology and can be modified to accurately model the biology of human neurodegeneration”.
Tessara said its research and development was in collaboration with the Commonwealth Scientific and Industrial Research Organisation and it had partnered with Bio-Link Australia to support the product development and business development plans.
The company said that the funds would “accelerate the achievement of … development milestones along dual commercial pathways … [and Realbrain had] near-market applications as a drug discovery model and longer-term applications as a tissue replacement therapy”.
Tessara said its chairman was former Chemgenex chief executive officer and current Avecho chairman Dr Greg Collier, with chief executive officer Dr Christos Papadimitriou and Biolink’s executive director Christopher Boyer as head of corporate and strategic development and Biolink executive director Dr Christian Toouli as chief commercial officer.
Mr Smith said that the New South Wales consortium “liked the team and the business model and when the technology also resonated with the doctors, including a neurologist and neurosurgeon that we asked, it became clear that Tessara would be a good fit for our group of investors”.
Dr Collier said that he “knew Tessara was investable from the first time I saw it”.
“To close the round over-subscribed in the current economic environment is, in my view, indicative of the extraordinary potential of the company and our innovative approach to breaking down the barriers that have long prevented the development of therapies for some of the most difficult neurological diseases,” Dr Collier said.
Tessara is a private company.

KAZIA THERAPEUTICS

Kazia says it has raised $1.8 million through a share plan at 40 cents a share, following a placement that raised $7.2 million at the same price (BD: Apr 9, 2020).
Kazia said the funds would be used to progress its paxalisib clinical trial program, to complete analysis of its phase I study of Cantrixil, to provide contributory funding towards four other trials and for working capital.
Kazia was up one cent or 2.6 percent to 39.5 cents.

CSL

CSL says subsidiary CSL Behring will develop a plasma product to treat severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), the virus that causes Covid-19.

CSL said the product, Covid-19 immunoglobulin, would be developed at its Broadmeadows, Victoria advanced manufacturing facility to treat serious complications of Covid-19, particularly for patients requiring ventilation.

The company said it would produce a small batch of the product for the first phase of research, which would develop tests to detect the presence of antibodies that fought Sars-Cov-2.

CSL said the second phase would involve a larger batch of Covid-19 immunoglobulin and would be used in clinical trials in Australian hospitals in order to establish the safety of the product.

The company said it would develop the product using blood plasma donations by people who had recovered from Covid-19, as they had a high level of antibodies in their blood that fought Covid-19.

CSL said the antibodies would be pooled, purified and concentrated to make Covid-19 immunoglobulin, also known as a hyperimmune globulin.

CSL said that up to 800 plasma donations would be required to produce enough Covid-19 immunoglobulin to treat between 50 and 100 patients under the clinical trial.

The company said the blood would be collected by the Australian Red Cross Lifeblood.

Lifeblood chief executive Shelly Park said that developing the treatment required plasma donations from people who had fully recovered from Covid-19 and whose plasma had high levels of antibodies that can fight the Sars-Cov-2 virus that causes Covid-19.

“I would encourage anyone who has recovered from a confirmed case of Covid-19, who thinks they may be eligible, to donate to contact us,” Ms Park said.

CSL said it would seek to register Covid-19 immunoglobulin with the Australian Therapeutic Goods Administration if the trial was successful and subject to a request by Australian governments.

Federal Minister for Health Greg Hunt said that Australia was “playing an important role in the battle against Covid-19”.

“CSL Behring’s manufacturing facility will be one of the first in the world to commence development of a Covid-19 immunoglobulin that may provide benefit to seriously ill Australians in need of treatment,” Mr Hunt said.

CSL chief medical officer Dr Charmaine Gittleson said that CSL’s efforts would “leverage the full spectrum of our onshore capabilities, from research and development, through to advanced manufacturing”.

“Development of a Covid-19 immunoglobulin from plasma donated in Australia is one of many approaches CSL is exploring to help combat the Covid-19 global pandemic,” Dr Gittleson said.

“CSL is part of a previously announced world leading global alliance formed with other companies that manufacture plasma products … [and is] also focused on developing and delivering a Covid-19 immunoglobulin product,” Dr Gittleson said.

“The Australian-based project announced today will take advantage of all possible synergies with the global Alliance project as well as contribute any resulting data from the Australian clinical study to the international effort,” Dr Gittleson said.

CSL said that it would undertake development of the product at no cost to Australian governments in recognition of the public health crisis, and it would work with the statutory agency representing the Australian Government and state and territory governments, the National Blood Authority, to develop the product for the Australian population.

CSL was up $1.06 or 0.35 percent to $306.78 with 631,881 shares traded.

MESOBLAST

Mesoblast says it has dosed the first patients in its 300-patient phase II/III trial of remestemcel-L for Covid-19-related acute respiratory distress syndrome (Ards).

Last month, Mesoblast said it had begun enrolling the trial after it found that 10 of 12 ventilator-dependent Covid-19 patients treated with its allogeneic mesenchymal stem cell product had survived in a trial at New York's Mt Sinai Hospital, with nine no longer requiring ventilator support (BD: Apr 24, 30, 2020).

The company said the primary endpoint was all-cause mortality within 30 days of randomization and the key secondary endpoint was the number of days off mechanical ventilator support.

Today, Mesoblast said the trial would be conducted at up to 30 sites in North America and would be randomized and placebo-controlled for patients on ventilator support.

The company said it expected to complete enrolment within three to four months.

Mesoblast chief executive Prof Silviu Itescu told Biotech Daily that the company had "proprietary media and process optimisation technologies that provide us with the ability to scale up rapidly and sufficiently to meet the commercial needs of Covid-19 Ards patients should the current phase III trial be successful and we are in a position to obtain FDA approval for remestemcel-L".

Mesoblast was up 41 cents or 12.5 percent to $3.69 with 17.2 million shares traded.

COGSTATE

Cogstate says it has received a $US2.44 million ($A3.79 million) loan from Citibank under the US Federal Government Paycheck Protection Program.

Cogstate said the Program allowed businesses and non-profits with fewer than 500 employees to obtain loans of up to $10 million to maintain their current workforce during the Covid-19 pandemic.

The company said the loan was for two years, with a one percent interest rate, deferred for the first six months.

Cogstate said funds used for payroll costs, rent, utilities and other qualifying expenses would be forgiven, provided that no more than 25 percent was attributed to non-payroll costs.

Cogstate was up three cents or 9.5 percent to 34.5 cents.

IMPEDIMED

Impedimed says it has received $US1.1 million ($A1.8 million) from the US Federal Government Paycheck Protection Program.

Impedimed said the Program was administered by the US Small Business Administration to help businesses keep their workforce employed during the Covid-19 crisis.

The company said the loan would be fully "forgiven in circumstances where it maintains or quickly rehires employees and maintains salary levels and where the funds were used for payroll costs, interest on mortgages, rent and utilities and at least 75 percent of the forgiven amount is used for payroll".

Impedimed said loan payments would be deferred for six months and would have a maturity date of two years and interest rate of one percent.

Impedimed was up 0.1 cents or 2.6 percent to four cents with 12.7 million shares traded.

RESPIRI

Respiri says it has raised $5.14 million through an oversubscribed share purchase plan and placement at 5.5 cents a share.
In March, Respiri said it raised $2 million in a placement at 5.5 cents a share and hoped to raise a further $1 million through a share purchase plan (BD: Mar 26, 2020).
Today, the company said the share plan would be scaled back to the revised maximum offer of $3,140,000.
Respiri fell 0.1 cents or 1.4 percent to 6.9 cents.

ELIXINOL GLOBAL

Elixinol says it has raised $5.3 million through the institutional component of its rights offer at 20 cents a share and hopes to raise $5.6 million in the retail component.
Yesterday, Elixinol said the offer at 20 cents a share was a 48.1 percent discount to the last closing price (BD: May 5, 2020).
Elixinol said that lead manager Bell Potter Securities had agreed to fully underwrite the institutional offer and 50 percent of the retail offer.
Elixinol fell 4.5 cents or 11.7 percent to 34 cents with 1.1 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says that Scientle Innovations will distribute its human telomerase reverse transcriptase (hTERT) adjunct diagnostic for bladder cancer in New Zealand.
Sienna said the hTERT test would be sold to pathology laboratories and it would work with the Christchurch-based Scientle to establish the test in several reference laboratories to assist in adoption of the test, pending Covid-19 travel restrictions.
The company said it would provide Scientle with regulatory support, sales, marketing and technical training.
Sienna said the distribution agreement made New Zealand the tenth country to have access to the test.
Sienna was up 0.2 cents or 3.8 percent to 5.5 cents.

RESAPP HEALTH

Resapp says it has received final design files, reports and supporting documents for handheld and wearable devices being developed by Avanti Med and OSI Electronics.
Resapp said the handheld device would be a low-cost option for its respiratory disease diagnosis applications and the wearable monitor would provide an easily worn, unobtrusive platform for up to three days of continuous monitoring for patients with chronic respiratory disease.
The company said it would pay $500,000 for each device in shares, issued at 11 cents a share, which was 80 percent of the 30-day volume weighted average price.
Resapp said the results of a clinical, electrical and usability evaluation currently underway would be combined with the design files for a Conformité Européenne (CE) Mark technical file, on target to be achieved by July 2020.
Resapp was up half a cent or three percent to 17 cents.

G (GEVA) MEDICAL INNOVATIONS

G Medical says the Lauderdale Lakes, Florida-based All County Health Care Inc to market and distribute its Prizma vital sign monitor in the US.
G Medical said All County had a network of 1,400 physicians in South Florida and regularly engaged with hospitals and medical organizations in the region.
G Medical was up 0.7 cents or 7.1 percent to 10.5 cents with four million shares traded.

BOD AUSTRALIA

Bod says it has received a $1.43 million binding purchase order from Health & Happiness Group for its marijuana products to be sold in the UK.
Bod said most of the order was for its premium marijuana products, which would be sold under the CBII brand and included soft gel cap products and marijuana oil products.
Bod was up four cents or 12.9 percent to 35 cents.

EMVISION MEDICAL DEVICES

Emvision says chief executive officer Dr Ron Weinberger has been promoted to managing-director, with executive chairman John Keep moving to non-executive.
Emvision said that it would issue Dr Weinberger 1,000,000 options, exercisable at $1.25 each by May 6, 2023, subject to shareholder approval.
The company said that 50 percent of the options would vest 12 months from the grant date and 50 percent would vest two years from the grant date.
Emvision fell 1.5 cents or 1.7 percent to 87.5 cents.