Biotech Daily

Tuesday December 14, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: POLYNOVO UP 15%; MESOBLAST DOWN 17%**

*** CSL $17b FOR VIFOR**

*** NOVARTIS TERMINATES $1.9b MESOBLAST DEAL**

*** VICTORIA: 'HOME OF mRNA VACCINE MANUFACTURING'; MODERNA**

*** IDT REQUESTS 'FEDERAL mRNA NEWS RESPONSE' TRADING HALT**

*** BIONOMICS HOPES FOR $35m NASDAQ IPO;**

*** ANTISENSE: UK, EMA APPROVE ATL1102 FOR DMD TRIAL**

*** ALTERITY: NZ OKAYS ATH434 PHASE II MSA TRIAL**

*** PROTEOMICS RECEIVES $1.2m FEDERAL R&D TAX INCENTIVE**

*** POLYNOVO: 'SALES UP, MORALE UP'; SHARE PRICE UP**

*** STARPHARMA: SAUDI ARABIA REGISTERS VIRALEZE NASAL SPRAY**

*** RHYTHM $750k TO EXPAND CANCER DIAGNOSTICS**

*** IMUGENE: CHINA ALLOWS HER-VAXX PATENT**

*** NOXOPHARM: 1st VEYONDA COHORT ENROLLED**

*** ADALTA TAKES 'CAPITAL RAISING' TRADING HALT TO SUSPENSION**

*** AUSCANN: TOD McGROUTHER CHAIR, LOSES DR KATE ADAMS, GEOFF STARR**

MARKET REPORT

The Australian stock market slipped 0.01 percent on Tuesday December 14, 2020, with the ASX200 down 0.9 points to 7,378.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and two were was untraded.

Polynovo was the best, up 21 cents or 15.4 percent to $1.57, with 8.1 million shares traded. Optiscan climbed 8.6 percent; Actinogen, Next Science, Pro Medicus and Starpharma were up more than three percent; Amplia, Oncosil, Opthea, Patrys and Volpara rose more than two percent; Nanosonics, Resmed and Universal Biosensors were up one percent or more; with Clinuvel, Cochlear, Cyclopharm and Telix up by less than one percent.

Mesoblast led the falls, down 29.5 cents or 17.35 percent to $1.405, with 10.4 million shares traded. Imugene and Prescient lost more than six percent; Neuren and Osprey fell five percent or more; Uscom was down 4.35 percent; Cynata, Genetic Signatures and Orthocell fell more than three percent; Antisense, Impedimed and Paradigm shed more than two percent; Compumedics and Medical Developments were down more than one percent; with Avita down 0.3 percent.

CSL

CSL says it will acquire the St Gallon, Switzerland-based Vifor Pharma for $US11.7 billion ($A16.4 billion) for its renal disease and iron deficiency expertise.

After the market closed, CSL said that it would launch “an all-cash public tender offer” to acquire all publicly held Vifor shares for $US179.25 per share, a 40 percent premium to the “unaffected 60 trading day volume weighted average price” to December 1, 2021.

The company said that the $US12.3 billion ($A17.2 billion) all-cash acquisition would be funded by a $6.3 billion fully underwritten placement, $8.4 billion new debt and existing cash and a non-underwritten share plan at $273.00 a share for up to $750 million.

CSL managing-director Paul Perreault said the acquisition “brings an outstanding team and a leading portfolio of products across renal disease and iron deficiency and a proven partnering and business development and licencing strategy”.

“Vifor Pharma will also expand our presence in the rapidly growing nephrology market, while giving us the opportunity to leverage our complementary scientific expertise,” Mr Perreault said. “The combination with Vifor Pharma is expected to be financially compelling for our shareholders while expanding and diversifying our revenue base.”

CSL last traded at $297.27.

MESOBLAST

Mesoblast says the Basel, Switzerland-based Novartis “has chosen to terminate” its remestemcel-L for acute respiratory distress syndrome (Ards) deal prior to closing.

Last year, Mesoblast said it had a potential more than $US1,355 million ($A1,858.3 million) deal with Novartis for its stem cell treatment for Ards (BD: Nov 20, 2020)

The week before announcing the Novartis deal, Mesoblast said that an independent review had approved its 300-patient, randomized, controlled phase III trial of remestemcel-L for ARDS to continue unchanged (BD: Nov 11, 2020).

A month later, the company said the data safety monitoring board recommended halting the trial when the analysis of 180 patients found the trial was “not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment”. (BD: Dec 18, 2021).

In April, Mesoblast said that a subgroup of 123 patients in the trial had a 46 percent reduced mortality; and in July said that at 90 days, the under 65-year-olds in the trial had mortality reduced by 48 percent, and “two doses of remestemcel-L at days three to five conferred durable survival benefit through at least 90 days in … patients under age 65 [years]” ($p = 0.048$), while remestemcel-L reduced 90-day mortality by 77 percent in patients on dexamethasone as part of their standard of care, compared to controls under 65 years who received dexamethasone ($p = 0.0037$) (BD: Apr 30, Jul 19, 2021).

Today, the company said it was “highly focused on executing on our short-term objective to bring remestemcel-L to market for patients with acute respiratory distress syndrome due to Covid-19”.

Mesoblast said that “the observed mortality reduction with remestemcel-L in patients aged under 65 [years] in the completed Covid-19 Ards trial, despite having missed the primary endpoint, is considered … to be a sufficiently strong signal to support pursuing an emergency use authorization, the most direct path to market”.

The company said it was preparing “to initiate a pivotal phase III trial that may support a Covid-19 Ards [emergency use authorization]”.

Mesoblast said that Covid-19 was “likely to remain a serious global problem and to provide a major commercial opportunity … with a steady state of intensive care unit Ards patients irrespective of vaccines and anti-viral treatments”.

Mesoblast fell 29.5 cents or 17.35 percent to $1.405 with 10.4 million shares traded.

VICTORIA GOVERNMENT, FEDERAL GOVERNMENT

Victoria says it will be “the first place in the Southern Hemisphere to manufacture mRNA vaccines” following an agreement with the Federal Government and Moderna.

A media release from Victoria’s acting Premier James Merlino said that the in-principle agreement with Prime Minister Scott Morrison and Moderna, meant that the company’s new manufacturing and finishing facilities, and Australian research centre would be based in Victoria.

A spokesperson for Mr Merlino told Biotech Daily that a site had not been decided and that was a matter for Cambridge, Massachusetts-based Moderna.

The Victoria Government media release said that the manufacturing plant would be capable of producing up to 25 million vaccine doses a year from 2024, with the capacity to scale up to 100 million doses a year to combat future pandemics.

The Government said the factory and research institute were expected to create up to 500 jobs during construction and about 500 ongoing roles, “driving the development of a local messenger RNA (mRNA) ecosystem that does not currently exist in Australia”.

The media release said that as well as mRNA vaccines against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), the new factory would be able to produce therapeutics for cancer, rare diseases, cellular engineering and protein-replacement therapy.

The State Government said that Victorian scientists and manufacturers had developed Australia’s first mRNA SARS-COv-2 vaccine candidate - Australia’s first mRNA drug product - in five months, enabling clinical trials to begin in the new year.

Two weeks ago, IDT Australia said it had manufactured SarsCov-2 mRNA vaccine with Monash University’s Institute of Pharmaceutical Sciences (MIPS) (BD: Nov 30, 2021).

The Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said in November that 450 doses of the vaccine candidate had been produced at IDT’s factory in Boronia, enabling 150 people to take part in phase I clinical trials at the Doherty Institute, with results expected “later in 2022”.

Today, the spokesperson for Mr Merlino told Biotech Daily that the Victoria Government was supporting both the IDT-MIPS mRNA program and the Moderna proposal.

Mr Merlino said that “being able to manufacture mRNA vaccines and treatments locally will lock in vaccine security both on our shores and across our region”.

Prime Minister Scott Morrison said mRNA technology would play an important and growing role in response to future health issues and securing a sovereign on-shore mRNA technology was critical.

“This investment will continue to secure Australia’s future economic prosperity while protecting lives by providing access to world-leading mRNA vaccines made on Australian soil,” Mr Morrison said.

A media release from Mr Morrison said the Federal Government would “also invest up to $25 million …in the 2021 mRNA Clinical Trials Enabling Infrastructure Grant Opportunity”.

Neither government disclosed funding arrangements for the Moderna agreement.

IDT AUSTRALIA

IDT says it has requested a trading halt to respond to a “public announcement by the Australian Government in relation to … an onshore mRNA manufacturing capability”.

IDT said it would respond to “Australia’s mRNA translation and manufacturing ecosystem more generally”.

Trading will resume on December 16, 2021 or at an earlier announcement.

IDT last traded at 48 cents.

BIONOMICS

Bionomics hopes to raise $US25 million ($A35.2 million) through the issue of 1,620,000 million American depositary shares to list the Nasdaq under the code BNOX.
Bionomics said that each American depositary share (ADS) would be equivalent to 180 ordinary shares, implying an Australia share price of 12.1 cents a share.
The company said it would grant the underwriters an option to purchase up to 243,000 ADSs, and Evercore ISI and William Blair would be the lead book-running managers, with Cantor, Berenberg and H.C. Wainwright & Co book-running managers
Bionomics was unchanged at 12 cents with 1.2 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has received regulatory approval in the UK and Europe for a phase IIb/III trial of ATL1102 in children with Duchenne muscular dystrophy.
In November, Antisense said it had received a positive decision from a committee of the the European Medicines Agency on its paediatric investigation plan for a 114-patient trial of ATL1102 for Duchenne muscular dystrophy in non-ambulant boys, which subsequently had been ratified by the EMA (BD: Nov 1, 2021).
Today, the company said that a separate application to the UK Medicines and Healthcare Products Regulatory Agency (MHRA) had received a positive decision, meaning that its current European study was being “run in accordance with the EMA and now the MHRA’s expectations for future product approval”.
Antisense said that both the EMA and the MHRA’s decisions would hold for future studies in paediatric studies of ambulant Duchenne muscular dystrophy patients.
The company said it was finalizing test sites in Europe and the UK and expected patient recruitment to commence mid-next year.
Antisense fell half a cent or 2.7 percent to 18 cents with 3.8 million shares traded.

ALTERITY THERAPEUTICS

Alterity says New Zealand has authorized its 60-patient, randomized, double-blind, placebo-controlled phase II trial of ATH434 for early-stage multiple system atrophy.
Alterity said the New Zealand authorization was its first approval for the trial which would treat patients with the Parkinsonian disorder for 12 months, to explore the effects of ATH434 on imaging and protein biomarkers important to multiple system atrophy.
The company said the endpoints were efficacy, safety and pharmacokinetics.
Alterity chief executive officer Dr David Stamler said the decision was “a significant achievement as it clears the way to initiate the study in the first quarter of next year.”
In October, the company said that it was planning the 60-patient trial of ATH434 in patients with early-stage multiple system atrophy in Australia, New Zealand, Europe, and the US (BD: Oct 19, 2021).
Alterity was unchanged at 2.3 cents with 10.6 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has received $1,240,156 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Proteomics said the rebate related to research and development expenditure for the year to June 30, 2021.
Proteomics was unchanged at $1.13.

POLYNOVO

Polynovo says it has had “record US sales in July and November” improved staff morale and appointed additional sales staff.

Polynovo said that sales in October and November 2021 of $4.66 million was 133 percent higher than for October and November 2020.

In November, the company said that managing-director Paul Brennan has resigned with chair David Williams saying there had been “increasing differences with the board in relation to Paul’s … management style” (BD: Nov 5, 2021).

Today, Polynovo said that interim chief executive officer Max Johnston “has had a significant impact on morale and is closely engaged with the management team, staff, customers, and all stakeholders”.

“The feedback and engagement from staff have been overwhelmingly positive,” the company said.

Mr Williams said there had been “a significant uplift in intensity in all areas of the business in the last month”.

“We are adding immediately significant scale to our US salesforce and some important new hires in the UK and other parts of the business,” Mr Williams said.

Polynovo said it had appointed Dan King as US head of marketing, effective from December 20, 2021 and had appointed Dr Javier Guirola as North America clinical lead along with two new marketing positions to support our increased penetration in other uses of its Novosorb biodegradable temporizing matrix (BTM) for wound treatments.

The company said it would recruit a group purchasing organization contract liaison officer and had added two sales appointments to increase coverage in Greater London, and would increase its US sales staff by 10 to 54.

Polynovo was up 21 cents or 15.4 percent to $1.57 with 8.1 million shares traded.

STARPHARMA

Starpharma says that Saudi Arabia has registered its Viraleze anti-viral nasal spray and it is in negotiations for local distribution.

Starpharma chief executive officer Dr Jackie Fairley said the registration of Viraleze in Saudi Arabia was the company’s “first in the Middle East [and] marks another important milestone for the product”.

Starpharma said Viraleze contained SPL7013, a broad spectrum anti-viral, which was the active ingredient in Vivagel BV for bacterial vaginosis and its Vivagel condom coatings.

Starpharma climbed 4.5 cents or 3.5 percent to $1.345.

RHYTHM PHARMACEUTICALS

Rhythm says it will invest $750,000 to assess whether its Colostat bowel cancer test has promise for breast, cervical, lung, gastric and pancreatic cancers.

Rhythm said the lead biomarker for its Colostat test was “believed to possess multi-cancer detection properties that could provide a foundation for platform technology expansion”.

Rhythm managing-director Glenn Gilbert said that “as we move closer to the launch of our initial cancer detection product Colostat in 2022, the company is making positive progress with respect to its broader strategy to leverage our cancer detection technology into other global cancer markets”.

“Ultimately, Rhythm believes it can make a meaningful impact for improved health outcomes across millions of people around the world,” Mr Gilbert said.

Rhythm was up six cents or 3.6 percent to $1.73.

IMUGENE

Imugene says the People's Republic of China Patent Office has allowed a patent relating to its HER-Vaxx in development for HER-2 positive gastric cancer.
Imugene said that the patent, titled 'A Vaccine Composition and Uses Thereof' would protect its intellectual property until 2036.
The company said that about 75 percent of all gastric cancer diagnoses were in Asia.
Imugene fell 3.5 cents or 6.7 percent to 48.5 cents with 46.1 million shares traded.

NOXOPHARM

Noxopharm says it has completed enrolment of the first cohort of three patients in its 'Direct and abscopal response to radiotherapy' (Darrt-2) trial of Veyonda for metastatic cancers.
Noxopharm said the 100-patient, phase II trial would assess the efficacy of a combination of Veyonda and low-dose radiation therapy in initiating an "abscopal immune response" and would be held at sites in Australia, Europe and North America.
The company said the first cohort of three patients had been dosed with 1200mg of Veyonda and, based on a clinical assessment, patients would progress to doses of 1600mg and 2400mg.
The company said that along with Los Angeles's Beverley Hills Cancer Centre and Houston, Texas's MD Anderson Cancer Centre, the first Australian trial site had opened.
Noxopharm was up one cent or 2.7 percent to 37.5 cents with 1.2 million shares traded.

ADALTA

Adalta says it has requested a voluntary suspension to follow the trading halt requested for a capital raising on Friday (BD: Dec 10, 2021)
Today, Adalta said it was "concluding some administrative items and so is not in a position to come out of a trading halt before opening of trading today".
The company said it expected the suspension to be lifted on December 16, 2021.
Adalta last traded at 8.1 cents.

AUSCANN

Auscann says it has appointed Tod McGrouther as its chair, with Dr Kate Adams and Geoff Star resigning as non-executive directors.
Auscann said Krista Bates would step down as interim chair and continue as a director
Auscann said Mr McGrouther had 35 years' experience in equity capital markets and corporate advisory and was previously an associate director of Bankers Trust Australia and a director of Prudential Bache Securities Australia.
The company said that Mr McGrouther was currently a principal at KTM Capital, the chairman of the National Stock Exchange of Australia, and a director of European Cannabis Corp as well as the ASX-listed NSX, Urbanise and Love Group.
Auscann said that Mr McGrouther held a Bachelor of Laws from the University of Sydney and a Bachelor of Finance from the University of New South Wales,
Auscann was up 0.1 cents or 1.2 percent to 8.6 cents.