

# Biotech Daily

Tuesday November 30, 2021

### Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: PRESCIENT UP 17%; ACTINOGEN DOWN 7%
- \* VICTORIA, IDT, MIPS MANUFACTURE SARS-COV-2 mRNA VACCINE; IDT UP 45%
- \* EMVISION: '98% ACCURACY' IN STROKE CLASSIFICATION TRIAL
- \* Q-SERA LICENCES RAPCLOT BLOOD COLLECTION TUBES TO TERUMO
- \* COGSTATE TESTS IN JAPANESE SENIORS 'PHONES
- \* BLUECHIIP WINS US FDA, CE MARK FOR CRYOVIALS
- \* RHYTHM COLOSTAT WINS CE MARK
- \* CANN SWAPS ZALM SHARES FOR RUA SHARES
- \* MESOBLAST AGM 26% OPPOSE DIRECTORS OPTIONS
- \* LBT SURVIVES REM REPORT, 25% OPPOSE DIRECTOR SHARES IN LIEU
- \* STARPHARMA AGM 8% OPPOSE DR JACKIE FAIRLEY RIGHTS
- \* PAINCHEK PLEADS SCHULTZ TO ASX 51% QUERY
- \* CRESO REQUESTS 'MATERIAL LICENCE UPGRADE' HALT
- \* MGC REQUESTS 'CAPITAL RAISING' TRADING HALT
- \* STEMCELL FURTHER EXTENDS 'JOINT VENTURE' SUSPENSION
- \* NANOMAB TAKES 8.3% OF RADIOPHARM
- \* DR PAUL COZZI TAKES 6.7% OF VISIONEERING
- \* ROTH CAPITAL TAKES 14.6% OF INCANNEX FOR NASDAQ LISTING

#### MARKET REPORT

The Australian stock market was up 0.22 percent on Tuesday November 30, 2021, with the ASX200 up 16.2 points to 7,256.0 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 10 fell, eight traded unchanged and one was untraded.

Prescient was the best, up 3.5 cents or 17.1 percent to 24 cents, with 4.4 million shares traded. Cynata and Imugene climbed more than seven percent; Compumedics was up 6.25 percent; Antisense, Next Science, Patrys and Proteomics improved more than five percent; Oncosil was up 4.65 percent; Starpharma climbed 3.8 percent; Dimerix, Optiscan, Orthocell, Resmed and Volpara rose two percent or more; Genetic Signatures, LBT, Medical Developments and Pro Medicus were up more than one percent; with Mesoblast, Osprey and Polynovo up by less than one percent.

Actinogen led the falls, down one cent or 7.1 percent to 13 cents, with 7.7 million shares traded. Pharmaxis fell 4.8 percent; Cochlear lost 3.9 percent; Amplia and Immutep shed more than two percent; Avita, Cyclopharm, Opthea and Paradigm were down more than one percent; with Clinuvel, CSL and Telix down by less than one percent.

## IDT AUSTRALIA, VICTORIA GOVERNMENT MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

IDT says it has manufactured severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) mRNA vaccine with Monash University's Institute of Pharmaceutical Sciences. In October, IDT said it would manufacture a SarsCov-2 mRNA vaccine for Melbourne's Monash Institute of Pharmaceutical Sciences (MIPS) (BD: Oct 13, 2021).

Today, the company said the drug product "met all specifications and is now progressing through the release process to be supplied to MIPS for use in their upcoming clinical trial". IDT said the manufacture of drug product "signifies the completion of the material elements of the master services agreement and services order, with ongoing product stability testing the only remaining item".

IDT chief executive officer Dr David Sparling said that the manufactured product was "the first locally developed mRNA Covid-19 vaccine candidate and the first locally manufactured [clinical good manufacturing practice] mRNA drug product".

A media release from the Victoria Premier Dan Andrews said that Victorian scientists and manufacturers had developed "Australia's first mRNA [Sars-Cov-2] vaccine candidate - Australia's first ever mRNA drug product - in just five months, enabling clinical trials to begin in the new year".

The Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said 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".

The media release said that the Victoria Government invested \$5 million to enable manufacture of the vaccine candidate, with a dedicated Nanoassemblr shipped to IDT Australia from Canada (BD: Aug 23, 2021).

The Government said that the Nanoassemblr processed nanoparticles into final liquid drug form, sterilized the product and filled vials with mRNA vaccine.

The Victoria Government said the State was "one of the few places in the world with the capability to develop and manufacture mRNA therapeutics and vaccines and the mRNA-based vaccine breakthrough demonstrates Victoria's leadership in the mRNA sector". The media release said that the project was led by the State-funded mRNA Victoria in partnership with Monash Institute of Pharmaceutical Sciences, the Doherty Institute and IDT Australia calling it "a landmark collaboration between Victoria's renowned medical research and manufacturing sectors".

The Government said that it established mRNA Victoria to drive the establishment of a sovereign mRNA manufacturing industry and earlier this year supported a number of proposals from Victorian industry and consortia as part of the Commonwealth's Approach to Market on mRNA manufacturing capability.

Ms Pulford said the manufacture was "an Australian first that confirms Victoria as a leader in mRNA therapeutics and manufacturing".

"It is an incredible achievement to have made an mRNA vaccine candidate that is ready for clinical trials," Ms Pulford said.

"We're serious about developing our mRNA manufacturing capacity and doing it [as] quickly as we can, because it will save lives," Ms Pulford said.

The Doherty Institute's head of vaccine and immunization Prof Terry Nolan said the manufacture was "a major milestone in Australia's ability to manufacture home-grown Covid-19 mRNA vaccines and we are excited to commence phase I clinical trials of this candidate, along with the protein vaccine candidate developed by the Doherty Institute, in the coming months".

IDT climbed 19.5 cents or 44.8 percent to 63 cents with 13.3 million shares traded.

#### **EMVISION**

Emvision says a 50-patient trial shows its portable brain scanner is 98 percent accuracy in differentiating ischaemic from haemorrhagic strokes, meeting the primary endpoint. Emvision said that rapid neuro-imaging was "key to the diagnosis and treatment of acute stroke [and] proven and effective time-critical therapies require differentiation between ischaemic and haemorrhagic stroke".

The company said that the trial showed that its brain scanner localized targets in the same quadrant as comparator magnetic resonance imaging (MRI) and computerized tomography (CT) with 78 percent accuracy.

Emvision said that the clinical feasibility study met its primary endpoint of "the collection of a dataset of stroke patients" to improve the understanding of stroke on electromagnetic scattering effects in the brain.

The company said the datasets enabled it to advance its electro-magnetic imaging algorithm development and observe the correlation of its scans with "ground truth" CT and/or MRI scans.

Emvsion chief executive officer Dr Ron Weinberger said the results "indicate that the ability to distinguish stroke types was very high".

"This is the most critical element as it goes directly to the type of intervention that needs to be made in hospital and importantly whether clot busting drugs could reliably be introduced in the field in the future in road and air ambulance settings," Dr Weinberger said.

"The results in this respect are very encouraging," Dr Weinberger said.

"The data points towards our ability to achieve positive outcomes in our wider clinical trials planned for next year," Dr Weinberger said.

Emvision was up four cents or 1.5 percent to \$2.75.

#### Q-SERA PTY LTD

Q-Sera says it has licenced its Rapclot rapid serum tube technology to Tokyo's Terumo Corp to manufacture and sell the system in Japan.

Q-Sera said that Rapclot evacuated blood collection tubes produced "high-quality serum in less than five minutes, reducing the turnaround time from sample collection to serum analysis compared with current technologies".

The company said that Rapclot was effective in producing high quality serum from blood samples that contain anti-coagulants such as heparin.

Q-Sera said that up to 10 percent of hospital emergency department admissions were patients on anti-coagulant therapies and current blood collection tubes could not efficiently clot their blood, resulting in a failure to clot or formation of fibrin strands which interfere with analyzers.

The company said that Rapclot tubes' ability to clot anti-coagulated blood samples was "a substantial step forward in patient diagnosis".

Q-Sera said it had adapted prothrombin activators originally found in the venom of some snakes to develop Rapclot, whoch could be produced at industrial scale using recombinant cell lines and standard pharmaceutical manufacturing processes.

Q-Sera said it was actively seeking partners for other regions.

Q-Sera said it was founded to commercialize intellectual property developed at the University of Queensland supported by the Brandon Capital managed Medical Research Commercialisation Fund and Uniseed.

Q-Sera is a private company.

#### COGSTATE

Cogstate says its cognition testing technology will be installed on Japanese smartphones targeting the country's senior population.

Cogstate said that through its distribution partner Eisai Co, its Nouknow cognition testing software would be marketed in Japan as a pre-installed application on the Raku-Raku Smartphone F-52B used widely by the senior population, form February 2022.

The company said the Raku-Raku smartphone had shipped more than seven million units. Cogstate said it would be the first time that Nouknow was used as a function that could be operated on a smartphone and F-52B users would be provided with brain performance checks at no cost, up-to four times a year.

Cogstate was up 10 cents or 4.6 percent to \$2.26.

#### **BLUECHIIP**

Bluechiip says its Cryovials suitable for freezing have received US Food and Drug Administration registration and Conformité Européenne (CE) mark approval. Bluechiip managing-director Andrew McLellan said that FDA registration and CE mark invitro diagnostic certification "means we can sell directly into the US, as well as into Europe and the Asia/Pacific region".

The company said it had launched its Bluechiip-enabled sample management products, including storage consumables, readers, and Stream sample management software. Bluechiip was up 0.6 cents or 10.7 percent to 6.2 cents with 31.8 million shares traded.

#### RHYTHM BIOSCIENCES

Rhythm says Conformité Européenne (CE) mark for its Colostat colorectal cancer blood test is "a major regulatory milestone for the commercialization of Colostat".

Rhythm chief executive officer Glenn Gilbert said the milestone validates "our commercial pathway into significant global markets, with Europe alone representing a massive addressable population of over 231 million people.".

Rhythm was up 18.5 cents or 11.2 percent to \$1.835 with 1.7 million shares traded.

#### **CANN GROUP**

Cann says it will sell its 8.36 percent interest in Zalm Therapeutics to New Zealand's Rua Biocience for Rua scrip.

Cann said that the Gisborne, North Island-based Rua marijuana company would acquire Zalm for \$NZ10 million in scrip.

The company said that Rua would pay "a premium to Cann's carrying value of its investment in Zalm", but did not specify the magnitude of the premium.

Cann said Rua would issue shares in three tranches, with one-third on completion of the transaction and the remaining shares conditional on Zalm achieving production, pricing and regulatory milestones by December 30, 2022 and March 31, 2024 respectively.

The company said the milestones related to its supply of marijuana products to Rua for sale in Germany, under the existing arrangements in place between Cann and Zalm. Cann said chief executive officer Peter Crock and chair Allan McCallum would step down as Zalm directors, with Mr Crock and chief operating officer Shane Duncan joining the transition advisory board, and the master supply agreement and the technical services agreement between Cann and Zalm would remain in place.

Cann Group was up half a cent or 1.8 percent to 28.5 cents.

#### **MESOBLAST**

Mesoblast says all resolutions to its annual general meeting were passed but it faced more than 26 percent opposition to the issue of options to director Philip Facchina. Mesoblast said the resolution to issue Mr Facchina with 200,000 options exercisable at \$2.28 each within seven years was opposed by 37,694,655 votes (26.18%) with 106,262,748 votes (73.82%) in favor (BD: Oct 29, 2021).

The company said the issue of 1,550,000 options, exercisable at \$1.77 within seven years, to managing-director Prof Silviu Itescu faced 18.68 percent opposition, while the election of directors Michael Spooner, Joseph Swedish and Shawn Tomasello and the ratification of previous share issues faced modest dissent, with the remuneration report, the election of Mr Facchina and the proportional takeover provisions passed overwhelmingly.

According to the company's most recent filing, Mesoblast had 648,696,070 shares on offer meaning the opposition to Mr Facchina's options amounted to 5.8 percent of the company, sufficient to requisition extraordinary general meetings.

Mesoblast was up one cent or 0.6 percent to \$1.70 with 1.9 million shares traded.

#### LBT INNOVATIONS

LBT says its annual general meeting passed the remuneration report with 83 percent of the vote, but 25 percent opposed the issue of shares to directors in lieu of cash. Last year, LBT said the remuneration report earned a first strike with 48,391,303 votes or 40.57 percent against (BD: Nov 26, 2020).

Today, the company said that a resolution to issue director Damian Lismore with 68,764 shares was opposed by 27,646,189 votes (24.86%), with the resolution to issue Simon Arkell 57,239 shares opposed by 27,664,189 (24.84%).

LBT said that the 10 percent placement capacity faced 23.88 percent opposition, while the remuneration report and the issue of 1,250,000 options exercisable at 8.1 cents each to chair Joanne Moss and 500,000 options exercisable at 13.6 cents each to director Brian O'Dwyer were opposed by 17 percent of the meeting.

The company said that the election of Mr Lismore, Mr O'Dwyer and Ms Moss were opposed by 19.03 percent, 10.02 percent and 5.87 percent, respectively.

According to LBT's most recent filing, the company had 289,115,164 shares on offer, meaning the opposition to the issue of Mr Lismore's shares amounted to 9.6 percent of the company, sufficient to requisition extraordinary general meetings.

LBT was up 0.1 cents or 1.1 percent to 9.4 cents.

#### <u>STARPHARMA HOLDINGS</u>

Starpharma says all resolutions to its annual general meeting were passed but it faced 8.23 percent opposition to the issue of performance rights to Dr Jackie Fairley Starpharma said the resolution to issue managing director Dr Fairley 493,360 performance rights was opposed by 19,296,444 votes (8.23%) with 215,270,567 votes (91.77%) in favor.

The company said that its remuneration report and the re-election of director Lynda Cheng passed more easily.

According to the company's most recent filing, Starpharma had 406,237,883 shares on offer meaning the opposition to the issue of Dr Fairley's performance rights amounted to 4.75 percent of the company, not sufficient to requisition extraordinary general meetings. Starpharma was up four cents or 3.8 percent to \$1.085.

#### **PAINCHEK**

Painchek 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 increased from 2.3 cents or 51.1 percent from 4.5 cents on November 25, 2021 to 6.8 cents yesterday, and noted a "significant increase" in trading volume.

Painchek fell 0.1 cents or 1.5 percent to 6.4 cents with 6.3 million shares traded.

#### CRESO PHARMA

Creso has requested a trading halt "pending a material licence upgrade".

Trading will resume on December 2, 2021 or on an earlier announcement.

Creso last traded at 9.6 cents.

#### MGC PHARMACEUTICALS

MGC has requested a trading halt "pending the release of an announcement by the company in relation to a capital raising".

Trading will resume on December 2, 2021 or on an earlier announcement.

MGC last traded at 4.1 cents.

#### STEMCELL UNITED

Stemcell has requested a further extension to its voluntary suspension pending the release of announcement in relation to its proposed joint venture.

In September and October, Stemcell requested a trading halt, a voluntary suspension, and a suspension extension pending the announcement (BD: Sep 27, 29; Oct 29, 2021).

Today, the company said it expected the further extension to last until December 10, 2021 or the release of an earlier announcement.

Stemcell last traded at 1.4 cents.

#### RADIOPHARM THERANOSTICS

Nanomab Technology says it has become a substantial share-holder in Radiopharm with 21,111,111 shares (8.33%).

The Shanghai, China-based Nanomab said that on November 18, 2021 it acquired the shares at 60 cents a share.

Last week, Radiopharm listed on the ASX following a \$50 million initial public offer at 60 cents a share (BD: Nov 25, 2021).

Radiopharm fell 1.5 cents or 4.05 percent to 35.5 cents with 4.6 million shares traded.

#### VISIONEERING TECHNOLOGIES

Dr Paul Joseph Cozzi says he has become a substantial holder in Visioneering with 1,591,895 shares or 6.735 percent.

The Sydney-based Dr Cozzi said that the shares were bought on "various" dates and did not disclose the price paid.

Visioneering was up half a cent or 0.6 percent to 89.5 cents.

#### **INCANNEX HEALTHCARE**

Roth Capital says it has become a substantial holder in Incannex with 175,876,390 shares (14.64%) in connection with the company's proposed Nasdaq listing.

In August, Incannex said that it had filed a registration statement with the US Securities and Exchange Commission for a proposed US offer of American depositary shares (ADSs) on the Nasdaq (BD: Aug 18, 2021).

The Newport Beach, California-based Roth Capital said that it held the interest as part of a lock-up agreement with Incannex directors Troy Valentine, Joel Latham, Dr Sud Agarwal, Peter Widdows, and company secretary Madhukar Bhalla.

Incannex was up five cents or 9.6 percent to 57 cents with 2.8 million shares traded.