

Biotech Daily

Wednesday October 5, 2022

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: TELIX UP 12%; AMPLIA, NOVA EYE DOWN 5%
- * VICTORIA PROMISES \$5-6b FOR HOSPITALS, RESEARCH PRECINCT
- * IMMUNEXPRESS APPLIES TO TGA FOR SEPTICYTE RAPID APPROVAL
- * VGI STARTS IVB001 FATTY LIVER DISEASE DOSING
- * IMAGION EXPANDS MAGSENSE TO PROSTATE CANCER IMAGING
- * RESPIRI CHAIR, CEO REDUCE PAY BY \$180k
- * ANATARA RECEIVES \$480k FEDERAL R&D TAX INCENTIVE
- * REGAL CONVERTS NOTES TO TAKE 9% OF VECTUS
- * EX-DIRECTOR BERNARD STANG REDUCES; DILUTED TO 5.4% OF VECTUS
- * STARPHARMA LOSES 11-YEAR DIRECTOR ZITA PEACH
- * ANTISENSE APPOINTS DR ANTHONY FILIPPIS CCO

MARKET REPORT

The Australian stock market was up 1.74 percent on Wednesday October 5, with the ASX200 up 116.4 points to 6,815.7 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 12 fell, five traded unchanged and one was untraded. All three Big Caps rose.

Telix was the best, recovering 58 cents or 11.65 percent to \$5.56, with 3.1 million shares traded. Actinogen, Mesoblast and Paradigm climbed seven percent or more; Nanosonics improved 6.55 percent; Kazia and Next Science were up more than five percent; both Alcidion and Universal Biosensors improved four percent; Antisense, Medical Developments, Micro-X, Neuren, Pro Medicus and Resmed were up more than three percent; Cochlear, Compumedics, Oncosil, Prescient and Volpara rose more than two percent; with Clinuvel, CSL, Pharmaxis, Polynovo and Starpharma up by more than one percent.

Amplia and Nova Eye led the falls, both down 4.8 percent to 10 cents and 20 cents, respectively, with 110,215 shares and 25,421 shares traded, respectively. Both Emvision and Genetic Signatures fell 4.6 percent; Dimerix, Opthea and Orthocell were down more than three percent; Cyclopharm, Cynata, Immutep and Proteomics shed more than one percent; with Avita down by 0.6 percent.

VICTORIA GOVERNMENT

The Victoria Government says it will spend \$5 billion to \$6 billion upgrading the Royal Melbourne Hospital and Royal Women's Hospital and building the Arden medical precinct. A media release from Victoria Premier Daniel Andrews said the spending would "deliver the biggest hospital project in Australia's history", with upgrades to the Royal Melbourne and Royal Women's Hospitals and the building of a new Arden medical precinct, giving patients across Victoria "the very best of care, connected by a brand-new train line". The Government said it was currently building the Metro Tunnel which would link new stations at Parkville and at the Western end of Arden Street, North Melbourne "making it a two-minute trip between hospital campuses".

The media release said that each year, more than 45,000 patients were transferred from our regions and suburbs to the Royal Melbourne Hospital and the Royal Women's Hospital delivered more than 9,000 babies and cares for more than 2,000 babies in its neonatal intensive care unit each year, as well as treating women from across the State. The media release said that when in Government in the 1990s and 12 years ago the opposition Liberal Party had cut funding health funding.

"That's why the Andrews Labor Government will embark on Australia's biggest ever health infrastructure project, beginning a \$5 billion to \$6 billion upgrade and expansion that will deliver a total of more than 1,800 beds and treatment spaces," the media release said. "The Labor Government will make an initial investment of \$2 billion to \$2.5 billion to start what will be a 12-year project, establishing a new medical precinct in the future suburb of Arden which will be home to new campuses of both hospitals," the release said. The Government said the Arden campuses would be centres for elective surgery,

outpatient treatment, clinical trials, rehabilitation and low-risk women's healthcare services, while the Parkville sites would focus on emergency, trauma and acute care. "Put simply, if you're seeing a heart specialist, you'll visit your doctor at RMH Arden and if you're having a heart attack, you'll be taken to the RMH Parkville," the media release said.

"Similarly, pregnant women will have their outpatient appointments at the Women's Arden campus, and if they are experiencing complications, give birth at the Women's campus in Parkville," the Government said.

The State Government said that the project would deliver additional education and research space "to ensure the hospitals are training our future healthcare workers to work at health services across the state".

"The redevelopment will support further collaboration with the Walter and Eliza Hall Institute and other medical research partners to work on ways to better integrate teaching, training and research with patient care," the Government said.

The State Government said that with the University of Melbourne there would be "a massive investment in the future of biomedical research facilities as part of the redevelopment of the adjoining Parkville precinct".

The Government said that the redevelopment would include a dedicated clinical trials centre with additional research space at Arden and establish the Victorian Digital Health Command, with a new medical and health sciences school for the University.

The Government said it would release the Parkville Precinct Opportunity Statement, to "keep Victoria at the forefront of medical research".

Mr Andrews said the State was "developing some of the best medical research and education precincts in the world, and all of that means the very best of care for Victorians". "Victorians have worked hard to earn our reputation as a global leader in biomedicine, and now, we're cementing our status as a global powerhouse of research and development," Mr Andrews said.

A State election is scheduled for Victoria on November 26, 2022.

IMMUNEXPRESS PTY LTD

Immunexpress says it has applied for Australian approval of its Septicyte Rapid test distinguishing sepsis from system inflammation response syndrome (Sirs).

Immunexpress chief executive officer Dr Rolland Carlson told Biotech Daily that the application to the Australian Therapeutic Goods Administration, last week, followed US Food and Drug Administration approval and Conformité Européenne (CE) mark and he hoped to have the product approved in Australia by July 2023.

Dr Carlson said that Immunexpress was founded by Dr Ros Brandon, its original chief executive officer, and Dr Richard Brandon, who was currently the company's chief scientific officer.

According to the company's website Dr Richard Brandon was "a listed inventor on most Immunexpress patents" and the architect of the company's intellectual property strategy. Dr Carlson said that the Septicyte measured gene expressions in white blood cells to determine the probability that a patient in an intensive care unit had sepsis and not system inflammation response syndrome (Sirs) which presented similarly but without the consequent mortality and morbidity of sepsis.

Dr Carlson said that Sirs could be the result of trauma, cardiac events, stroke or chronic pancreatitis and while these could be serious illnesses, they did not have the urgency of treating sepsis.

He said that 30 percent of Covid-19 deaths were due to viral sepsis and the Septicyte test could differentiate between bacterial, viral and fungal infections.

Dr Carlson showed the hand-held blood sample diagnostic unit and said that the hardware units to assess the sample were about the same size as a desktop computer.

Dr Carlson declined to estimate the cost per unit, but said that in the US each test would cost about \$US200 and the systems could run eight tests at a time.

Dr Carlson said that ideally every intensive care unit would have several Septicyte systems to assist physicians determine whether a patient had sepsis or sirs.

He said that the US and European approvals meant the company was moving from development to commercialization stage and was considering funding and exchange listing options.

Immunexpress is a private company.

VGI HEALTH TECHNOLOGY (FORMERLY AZURE HEALTH, INVICTUS)

VGI says its subsidiary Invictus Ops Pty Ltd has begun dosing its 80-patient, phase II trial of its IVB001 for non-alcoholic fatty liver disease.

In July, VGI said it had begun recruitment for the trial at Brisbane's Gallipoli Medical Research Foundation and the Royal Melbourne Hospital (BD: Jul 5, 2022).

Today, the company said dosing of IVB001 had begun at the Gallipoli Medical Research Foundation and at the John Hunter Hospital in New South Wales.

VGI said that IVB001 was based on "the non-invasive and direct delivery of tocotrienols using Invictus' ... transmucosal delivery platform".

VGI chief scientific officer Dr David Kingston said that "unlike many other phase II clinical studies, the present study is based on efficacy signals derived from clinical studies on orally administered tocotrienols rather than animal studies and we have seen some promising results in [non-alcoholic fatty liver disease/non-alcoholic steatohepatitis] patients who have been administered a dietary supplement which is closely aligned to the drug candidate IVB001".

On the National (Newcastle) Stock Exchange VGI was untraded at three cents.

IMAGION BIOSYSTEMS

Imagion says that in-vitro and mouses studies show the potential for the use of its Magsense for prostate cancer imaging.

Imagion said the data was presented by research and pre-clinical development head Dr Marie Zhang at the World Molecular Imaging meeting in Miami, Florida from September 28 to October 1, 2022.

The presentation said that the company had previously reported the success of developing an in-vivo anti-human epithelial growth factor receptor-2 (HER2) targeted super-para-magnetic iron oxide nanoparticles (Spion)-based imaging agent for super-para-magnetic relaxometry (SPMR) and magnetic resonance imaging (MRI) detection, which was "currently in clinical testing for the detection of nodal metastases in HER2-positive breast cancer".

"Leveraging the same targeted Spion platform, the purpose of this current study is to demonstrate a [prostate-specific membrane antigen] target-specific imaging agent can be used for magnetic imaging in prostate cancer," the presentation said.

The presentation said that SPMR showed in-vitro cell binding and a higher binding signal in mice, with cell-binding shown in the magnetic resonance imaging (MRI) of mice. The poster concluded that "together, these results suggest that our anti-PSMA nanoparticles can provide targeted and specific delivery to cancerous tissue and generate measurable signal by SPMR".

"The same anti-PSMA nanoparticles demonstrated utility as a tumor specific molecular contrast agent in MRI, showing that Spions can provide non-radioactive detection of prostate cancer," the poster concluded.

"These studies lay out groundwork for potential future clinical prostate cancer tumor detection as well as monitoring therapy response," the presentation said.

In a media release last week, Imagion said the pre-clinical research showed "strong evidence that the company's magnetic nanoparticle technology has the potential to target prostate cancer tumors expressing the prostate specific membrane antigen with high specificity, accumulating preferentially in tissues expressing PSMA and not in other vital organs".

The company said that the research showed the imaging agent was detectable by both MRI and its magnetic relaxometry technology.

Imagion executive chair Bob Proulx said the data was "very encouraging".

"With our Magsense HER2 imaging agent for breast cancer advancing in clinical testing, we have been expanding our [research and development] pipeline," Mr Proulx said.

"The results ... provide strong support for us to continue the development of a Magsense imaging agent for prostate cancer," Mr Proulx said.

"The lack of specificity of standard [prostate specific antigen] blood testing for identifying malignant prostate cancer results in an unnecessarily large number of prostate biopsies being performed, wasting more than \$US1 billion in costs and associated morbidity, including risk of erectile dysfunction and urinary incontinence," Mr Proulx said.

"Knowing we have [an] imaging agent that can work with multiple forms of magnetic imaging and does not use radioactivity will address the large unmet need of making non-invasive detection of prostate cancer more accessible and affordable and could reduce the need for prostate biopsies for many men, saving costs and improving patient care," Mr Proulx said.

Imagion said that further studies would be needed to substantiate the imaging agent's ability to detect clinically significant disease.

Imagion fell 0.1 cents or 1.25 percent to 8.1 cents.

<u>RESPIRI</u>

Respiri says executive chair Nicholas Smedley and chief executive officer Marjan Mikel will reduce their annual renumeration by \$180,000.

Respiri said the reduction would affect the cash component of Mr Smedley and Mr Mikel's renumeration packages, with Mr Smedley forgoing \$80,000, and Mr Mikel \$100,000. According to the company's 2022 annual report Mr Mikel received \$428,306 in cash salary and fees, with Mr Smedley receiving \$245,455.

Respiri said it would pay short term incentives of up to \$105,000 to Mr Smedley and \$150,000 to Mr Mikel, based on the number of patients that the company had contracted by June 30, 2023.

The company said it had also cancelled a total of 22.5 million options held by both Mr Smedley and Mr Mikel but which had not vested.

Respiri said it would align a significant proportion of the foregone cash remuneration "in [the year to June 30, 2023] to the successful contracting of patients using Wheezo", with a view to 'maximizing the rollout of the US commercialization strategy".

Respiri chief executive officer Mr Mikel said "We are committed to converting the extensive R&D and technology development work our team has delivered into real commercial success for shareholders."

"To this end we are happy to link those deliverables to our renumeration. We appreciate the long-standing support of our shareholders and are wanting to closely align our performance to providing value to their investment.

Respiri fell 0.1 cents or 2.3 percent to 4.2 cents.

ANATARA LIFESCIENCES

Anatara says it has received \$479,984 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Anatara said the rebate related to research and development expenditure for the year to June 30, 2022.

Anatara was untraded at 5.5 cents.

VECTUS BIOSYSTEMS

Regal Funds Management says it has become substantial in Vectus with 4,457,782 shares (9.43%).

The Sydney-based Regal said that on September 28, 2022, it converted 4,114,714 convertible notes.

On September 28, 2022 in a notice titled 'Appendix 2A & Cleansing Notice – Issue of Shares, Vectus said it had issued 8.940,000 shares to 20 not holders converting 8,940,000 notes at 50 cents a share, with six percent interest through the issue of 1,278,207 shares at 66.8 cents a share.

Vectus was up two cents or 2.9 percent to 70 cents.

VECTUS BIOSYSTEMS

Former Vectus director Bernard Stang says he has reduced his substantial holding and been diluted from 2,562,000 shares (10.93%) to 2,560,500 shares (5.419%).

The Sydney-based Mr Stang said that on January 5, 2021, he sold 1,500 shares at \$1.22 a share and was diluted by the conversion notes into shares on September 28, 2022 (see above).

STARPHARMA

Starpharma says non-executive director Zita Peach will retire following the company's annual general meeting on November 29, 2022.

Starpharma said Ms Peach had been a director for 11 years and her retirement was "part of the board's renewal process and follows a transition period after the appointment of Dr Jeff Davies".

Starpharma chair Robert Thomas said Ms Peach "made an invaluable contribution to Starpharma's growth and development during her tenure, particularly as chair of the remuneration and nomination committee, and her fellow directors sincerely thank Zita for her detailed pharmaceutical industry and commercial insights and commitment." Starpharma was up one cent or 1.65 percent to 61.5 cents.

ANTISENSE THERAPEUTICS

Antisense Therapeutics says it has appointed Dr Anthony Filippis as its chief commercial officer, effective from mid-November.

Antisense said Dr Filippis was currently Neurosciences Victoria managing-director and chair of the Australian Stroke Alliance's commercialization committee and was previously a consultant to Takeda Pharmaceuticals, Mundipharma, and Solasia KK; and a director for Impel Neuropharma Australia, Cerebral Therapeutics, Anaptysbio, Mingsight Pharmaceuticals, Qponics and Connectivity.

The company said Dr Filippis held a Bachelor of Science and a Masters of Business Studies from Latrobe University and a Doctor of Philosophy from the University of Melbourne.

Antisense was up 0.3 cents or 3.6 percent to 8.6 cents.