# Biotech Daily

Monday September 27, 2021

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: IMPEDIMED UP 14%; PRESCIENT DOWN 7%**

*** PACIFIC EDGE UP 22.5% ON ASX IPO FOR BLADDER CANCER TESTS**

*** IMPEDIMED: ADVOCATE HEALTH ADOPTS SOZO HEART PROGRAM**

*** LBT APPOINTS THERMO FISHER US APAS INDEPENDENCE DISTRIBUTOR**

*** FEDERAL $12m FOR GLIOBLASTOMA AGILE TRIAL; KAZIA**

*** ADALTA: 'AD-214 REDUCES KIDNEY FIBROSIS, IN MICE'**

*** EYE CO: 'FA EFFECTIVE FOR MACULAR ATROPHY, IN MICE'**

*** INVEX PARTNERS WITH PEPTRON FOR PRESENDIN**

*** PARADIGM: FDA TRIAL CONCERN ON MOUSE ADRENAL GLAND FUNCTION**

*** NOXOPHARM: US PATENT FOR 'VEYONDA ABSCOPAL RESPONSES'**

*** EXOPHARM PLEADS US PATENT NEWS TO ASX 24.5% PRICE QUERY**

*** STEMCELL UNITED REQUESTS 'JOINT VENTURE' TRADING HALT**

*** ONCOSIL RECEIVES $1.1m FEDERAL R&D TAX INCENTIVE**

*** OVENTUS PLEADS SCHULTZ TO ASX 30% QUERY**

*** M&G BELOW 5% IN MEDICAL DEVELOPMENTS**

*** TDM TAKES 26.7% OF SOMNOMED**

## MARKET REPORT

The Australian stock market was up 0.57 percent on Monday September 27, 2021, with the ASX200 up 41.6 points to 7,384.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 19 fell and seven traded unchanged.

Impedimed was the best, up 1.5 cents or 14.3 percent to 12 cents, with three million shares traded. Dimerix and Nova Eye climbed more than six percent; Actinogen, Patrys and Starpharma improved four percent or more; Uscom was up 3.7 percent; Avita, Compumedics and Imugene rose more than two percent; with Clinuvel, Cochlear, Next Science, Polynovo, Resmed and Volpara up by less than one percent.

Prescient led the falls, down two cents or 6.9 percent to 27 cents, with 6.2 million shares traded. Osprey lost 6.3 percent; Amplia, Cyclopharm and Optiscan fell more than four percent; Paradigm and Universal Biosensors were down three percent or more; Oncosil, Opthea and Telix shed more than two percent; Alterity, CSL, Genetic Signatures, Kazia, Medical Developments and Orthocell were down one percent or more; with Mesoblast, Nanosonics, Neuren and Pro Medicus down by less than one percent.

## PACIFIC EDGE

Pacific Edge opened up 22.1 percent at $1.60 following its $NZ80 million ($A77.51 million) initial public offer at $NZ1.35 ($A1.31) to further commercialize its cancer diagnostics.
The Dunedin, New Zealand-based Pacific Edge said it had a $NZ20 million ($A19.3 million retail share offer for existing investors.
Pacific Edge said it listed on the NZX in 2003 and had developed four urine-based tests (Cxbladder) for urothelial cancer, which were the "first new molecular diagnostic tests to be commercially reimbursed in the US for [urothelial cancer] in 19 years".
The company said it had commercial sales in New Zealand, Australia, Singapore and the US, with US Centers for Medicare and Medicaid Services reimbursement and product specific current procedural terminology (CPT) reimbursement codes for its Cxbladder Detect and Cxbladder Monitor.
Pacific Edge said the annual US market for its Cxbladder was more than $US3.5 billion and its current New Zealand and US capacity could process about 300,000 tests a year, with Cxbladder approved in the US as a laboratory developed test.
The company said the tests were: Cxbladder Triage for use in the primary evaluation of haematuria to rule out patients who do not have cancer; Cxbladder Detect for use by urologists for patients requiring a full urothelial cancer workup to detect cancers; Cxbladder Resolve, which segregated high impact from low impact tumors; and Cxbladder Monitor for urothelial cancer patients being monitored for recurrence of the disease.
Pacific Edge said the majority of the funds would be used to accelerate penetration in the US, as well as increase sales in Southeast Asia, and develop new products "leveraging the company's intellectual property across other cancers that can be detected in urine" and for balance sheet management and working capital.
The company said that its chief executive officer was Dave Darling, chief financial officer Grant Gibson, chief technology officer Justin Harvey, chief scientific officer Parry Guilford, chief operating officer Demi Stefanova and chief information officer Andy McIntosh.
Pacific Edge said the board chair was Chris Gallaher, with directors Dave Darling, Grant Gibson, Mark Green, Anatole Masfen, Sarah Park, Anna Stove and Bryan Williams.
Pacific Edge said that revenue for the year to March 31, 2021 was up 76.2 percent to $NZ7,701,000, with net loss after tax down 25.3 percent to $NZ14,177,000.
The company said it had 729,209,985 shares on issue, with none in ASX escrow.
On its first trading day on the ASX, Pacific Edge climbed as much as 22.5 percent to $1.605 before closing up 23 cents or 17.6 precent at $1.54 with 206,121 shares traded.

## IMPEDIMED

Impedimed says it has begun a Sozo heart failure program at Advocate Aurora Health's Chicago-based Advocate Health Care Heart Institute.
Impedimed said that the Advocate Health Care Heart Institute had over 100 sites, and performed more than 20,000 heart procedures a year, the most in the state of Illinois.
The company said that the use of Sozo for heart failure had "the aim of optimizing fluid levels in heart failure patients, both in-clinic and after discharge".
Impedimed managing-director Richard Carreon said that "after the significant Covid-19 delays it is fantastic to initiate the Sozo heart failure program at such a highly respected [and] credentialed medical institution".
"We are expecting other hospitals to initiate Sozo heart failure programs shortly, adding to the clinical and reimbursement evidence required to underpin widespread commercialization," Mr Carreon said.
Impedimed was up 1.5 cents or 14.3 percent to 12 cents with three million shares traded.

## LBT INNOVATIONS

LBT says Clever Culture Systems has appointed Thermo Fisher Scientific the exclusive US distributor for its automated plate assessment System (APAS) Independence.
LBT said Clever Culture Systems AG was a 50 percent joint venture with Hedditch GmbH and the agreement was a “major milestone” providing a footprint to scale sales in the US.
LBT said that Thermo Fisher would engage in sales and marketing, as well as installation, maintenance and support services.
LBT managing-director Brent Barnes said the agreement was an “important milestone for LBT and represents a major step forward in our commercialization strategy in the US”.
“We have spoken previously about the importance of appointing well-recognized, leading distributors to support our sales efforts in key markets,” Mr Barnes said.
“Thermo Fisher is a leader in microbiology that is recognized globally, and we will benefit greatly from the depth and strength of their sales team in the US,” Mr Barnes said.
LBT was unchanged at 14 cents with 4.3 million shares traded.

## FEDERAL GOVERNMENT, KAZIA THERAPEUTICS

The Federal Government says up to $12 million will be available for companies joining the glioblastoma multiforme adaptive global innovative learning environment trial.
A media release from Federal Health Minister Greg Hunt said that, with the Minderoo Foundation and the Cure Brain Cancer Foundation the Federal Government had opened “a grant opportunity for researchers to undertake the glioblastoma multiforme adaptive global innovative learning environment (GBM Agile) trial for the first time in this country”.
In 2019, Kazia said its lead program GDC-0084, or paxalisib, had joined the phase II/III, multi-drug glioblastoma Agile trial (BD: Dec 11, 2019).
The company said at that time that it expected to begin recruitment of 200 patients by September 30, 2020 with a primary endpoint of overall survival.
Today, Kazia chief executive officer Dr James Garner told Biotech Daily that his company welcomed the news “which stands to benefit patients and clinical researchers in Australia”.
“Kazia’s paxalisib commenced recruitment to GBM Agile in January 2021 and is currently open at several dozen hospitals in the US,” Dr Garner said.
“As an Australian company, we have long been keen to see Australian researchers participate in the development of novel therapies such as paxalisib,” DR Garner said.
“We will closely examine the new grant to see if it provides an opportunity to make paxalisib available to Australian patients before the drug completes its participation in GBM Agile, which is anticipated by the end of 2023,” Dr Garner said.
A spokesperson for Mr Hunt told Biotech Daily that the media release signified the first time the trial would be able to be held in Australia.
In the media release, Mr Hunt said that new cases of brain cancer were increasing each year and accounted for 45 percent of all malignant brain tumors.
“In 2020, 2,000 Australians were diagnosed with brain cancer and tragically, less than a quarter will be alive in five years,” Mr Hunt said.
“The Australian Brain Cancer Mission aims to turn these statistics around, double survival rates and improve the quality of life of patients with brain cancer,” Mr Hunt said.
“This mode of trial will help deliver effective treatments faster for patients,” Mr Hunt said.
The media release said the Agile trial was an adaptable trial design with several treatment arms giving it the potential to change the clinical research process by identifying or disproving therapies more quickly.
More information on the grant round can be found at www.grants.gov.au.
Kazia fell three cents or 1.9 percent to $1.55.

## ADALTA

Adalta says a study of AD-214 for interstitial lung disease shows that it reduces kidney fibrosis and collagen in mice.

Adalta said that chief scientific officer Prof Mick Foley presented the data, titled 'CXCR4 antagonist AD-214 as a therapy for Interstitial Lung Disease', at the 'Discovery on Target' meeting in Boston from September 27 to 30, 2021.

The company said the pre-clinical study used an unilateral ureteral obstruction mouse model, in which one ureter is blocked in each mouse, inducing inflammation and fibrosis and increasing levels of collagen in the kidney.

Adalta said that treatment with AD-214 showed "a statistically significant reduction in the level of collagen and fibrosis in the [unilateral ureteral obstruction] … kidney compared with both no treatment and treatment with a non-CXCR4 specific control i-body".

The company previously told Biotech Daily that I-bodies were proteins from the intermediate group of immunoglobulin or immunoglobulin-like domains (BD: Jul 7, 2016).

Adalta fell 0.4 cents or 4.1 percent to 9.3 cents.

## EYE CO PTY LTD

Eye Co says that its fludrocortisone acetate (FA) is effective in the treatment of macular atrophy associated with wet age-related macular degeneration, in mice.

Eye Co said that research using human cell lines and mice showed the potential of fludrocortisone acetate "in the treatment of geographic atrophy associated with late-stage dry age-related macular degeneration" for which no treatment was available.

The company said the study, titled 'Anti-inflammatory and neuroprotective properties of the corticosteroid fludrocortisone in retinal degeneration' was published in the Journal of Experimental Eye Research and was at https://pubmed.ncbi.nlm.nih.gov/34509498/.

The authors concluded: "Though it should be noted that inflammation is one of several pathways implicated in outer retinal dystrophies, such as AMD, our findings nevertheless suggest that FA may be an efficacious strategy for ameliorating neurodegeneration implicated in such disorders."

Eye Co said that it had completed a safety study using fludrocortisone in humans and results were currently being analyzed.

Eye Co is a private company

## INVEX THERAPEUTICS

Invex says it will partner with the Daejeon, South Korea-based Peptron Inc which will manufacture its Presendin for idiopathic intracranial hypertension.

Invex said that Peptron would provide Invex with its intellectual property, including an extensive pre-clinical and clinical data package, and Presendin for its clinical trials, as well as for commercial use once Presendin was approved.

The company said that the agreement provided a fixed price per dose for the supply of Presendin for clinical studies and for the 10 years following the first commercial sale, as well as granting Peptron exclusive rights to commercialise Presendin for idiopathic intracranial hypertension in South Korea.

Invex chair Dr Jason Loveridge said the collaboration was "a very significant step forward [and Invex will no longer need to undertake additional animal tolerability and human pharmaco-kinetic studies for Presendin, which reduces Invex's development costs and risk and significantly expedites our planned phase III registration study".

Invex was up 6.5 cents or 9.6 percent to 74.5 cents.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says the remaining issue for US Food and Drug Administration approval of its trial of pentosan polysulfate sodium for osteoarthritis relates to adrenal gland function.
Last month, Paradigm said the FDA had accepted five of six responses to questions about its trial application for pentosan polysulfate sodium (PPS) treatment for patients with knee osteoarthritis, but wanted more information (BD: Aug 3, 2021).
Today, the company said that the FDA's one remaining query related to a rat study of adrenal gland function, which was not seen in the adrenal gland of dogs by the company or by drug manufacturer Bene Pharmachem.
Paradigm said that the FDA had requested modifications to Paradigm's adrenal screening and mitigation plan.
The company said that it intended to make the requested changes to its clinical trial protocol and respond to the FDA within a week.
Paradigm chief executive Paul Rennie said that the company understood the FDA's obligations for thorough reviews and he was "confident that the FDA and Paradigm have now attained a pathway to commence our phase III clinical trial in the US".
Paradigm fell eight cents or 3.8 percent to $2.02 with 1.1 million shares traded.

## NOXOPHARM

Noxopharm the US has allowed a patent relating to combining Veyonda and radiotherapy to generate abscopal responses in patients with metastatic prostate cancer.
Noxopharm said that the US Patent and Trademark Office had allowed the patent, titled Radiotherapy Improvements, which would protect its intellectual property until at least April 6, 2037.
Noxopharm was up 1.5 cents or 2.6 percent to 59.5 cents.

## EXOPHARM

Exopharm says that a potential US patent allowance for its ligand-based exosome affinity purification (Leap) technology may have pushed its price 24.5 percent.
The ASX said that Exopharm's shares rose 24.5 percent from 47.0 cents on September 23 to 58.5 cents on September 24, 2021, and noted "a significant increase" in the volume of shares traded.
Exopharm told the ASX that it received an email on September 24, 2021, a public holiday in Melbourne, alerting the company that the US Patent and Trademark Office had said that a notice of allowance had been mailed to the company.
The company said the patent was titled 'Methods and compositions for purification or isolation of microvesicles and exosomes'.
Exopharm was not able to provide the duration of the yet to be granted patent, but the USPTO said the application was filed on January 12, 2021.
Exopharm was up 3.5 cents or six percent to 62 cents with one million shares traded.

## STEMCELL UNITED

Stemcell United has requested a trading halt "pending an announcement in relation to a proposed material joint venture".
Trading will resume on September 29, 2021 or on an earlier announcement.
Stemcell last traded at 1.4 cents.

## ONCOSIL MEDICAL

Oncosil says it has received $1,077,201 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Oncosil said that the tax incentive was related to research and development expenditure in Australia and overseas for the year to June 30, 2021.
Oncosil fell 0.1 cents or 2.2 percent to 4.5 cents with 2.8 million shares traded.

## OVENTUS MEDICAL

Oventus 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 rose 3.5 cents or 30.4 percent from a low of 11.5 cents on September 23 to a high of 15 cents on September 24, 2021 and noted a "significant increase" in trading volume.
Oventus said that it released an investor update on September 15 and two of its directors had bought shares.
Oventus fell one cent or 6.7 percent to 14 cents with 1.4 million shares traded.

## MEDICAL DEVELOPMENTS INTERNATIONAL

M&G Plc says it has ceased its substantial shareholding in Medical Developments.
The London-based M&G said that between October 23, 2019 and September 23, 2021 it bought and sold shares with the single largest sale 65,715 shares for $336,050 or $5.11 a share.
In December and January, Medical Developments said it raised $25 million in a placement at $6.50 a share and $11,768,000 in a share plan (BD: Dec 14, 2020; Jan 21, 2021).
Medical Developments fell 10 cents or 1.9 percent to $5.13.

## SOMNOMED

TDM Growth Partners says it has increased its holding in Somnomed from 21,465,787 shares (25.94%) to 22,127,303 shares (26.74%).
The Sydney-based TDM said that on September 20, 2021, it bought 661,516 shares at $2.33 a share.
Somnomed was up five cents or 2.1 percent to $2.40.