Biotech Daily

Wednesday February 19, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRO MEDICUS UP 6%; NOVA EYE DOWN 7%**

*** QUEENSLAND UNI TRIALS INOVIQ OVARIAN CANCER TEST**

*** PYC INSTITUTIONAL RIGHTS RAISE $91m; $55m TO GO**

*** IDT H1 REVENUE UP 78% TO $10m; LOSS DOWN 16% TO $3m**

*** OPTISCAN UNVEILS 'INFORM' MICROSCOPE**

*** IMRICOR GEN-2 VISION-MR ABLATION CATHETER CE MARK**

*** VAXXAS ENROLS PHASE I SKIN-PATCH BIRD 'FLU VACCINE TRIAL**

*** NEUREN: FDA FAST TRACKS NNZ-2591 FOR PITT HOPKINS SYNDROME**

*** CLARITY WINS FDA CU-67 SAR-BIS-PSMA THERAPY FAST TRACK STATUS**

*** IMAGION MANUFACTURES MAGSENSE FOR US PHASE II TRIAL**

*** FIL (FIDELITY) TAKES 6.5% OF POLYNOVO**

*** JASON CARROLL INCREASES, DILUTED TO 16.25% OF ISLAND**

MARKET REPORT

The Australian stock market fell 0.73 percent on Wednesday February 19, 2025, with the ASX200 down 61.8 points to 8,419.2 points. Eleven of the Biotech Daily Top 40 companies were up, 22 fell and seven traded unchanged. All four Big Caps were up.

Pro Medicus was the best, up $17.24 or 6.2 percent to $297.14, with 392,279 shares traded. Actinogen, Amplia, Neuren and Proteomics rose more than two percent; Cochlear, Syntara and Universal Biosensors were up more than one percent; with 4D Medical, Clarity, CSL, Cyclopharm, Nanosonics, Polynovo and Resmed up less than one percent.

Nova Eye led the falls, down one cent or 7.4 percent to 12.5 cents, with 1.5 million shares traded; followed by Imugene, down 0.3 cents or 7.1 percent to 3.9 cents, with 40.1 million shares traded. Curvebeam and Prescient lost six percent or more; Alcidion and Genetic Signatures were down more than five percent; Opthea fell four percent; Mesoblast was down 3.1 percent; Immutep, Impedimed, Medical Developments and SDI shed more than two percent; Aroa, Clinuvel, Emvision, Micro-X, Resonance and Telix were down more than one percent; with Avita, EBR, Orthocell and Paradigm down less than one percent.

THE UNIVERSITY OF QUEENSLAND, INOVIQ

The University of Queensland said it will conduct a 1,500-woman study of Inoviq's extracellular vesicle-based ovarian cancer test as a screening tool, this year.

The University said about 1,500 post-menopausal Queensland women, aged more than 45 years, with no prior history of ovarian cancer, would be recruited "to determine [the test's] suitability for population-based screening for ovarian cancer".

Last year, Inoviq said an independent patient validation study showed its Exo-ovarian cancer (OC) blood test had "outstanding test results with accuracy of over 94 percent" after being tested on more than 500 blood samples (BD: Dec 3, 2024).

In December, the University's Centre for Extracellular Vesicle Nanomedicine, director Prof Carlos Salomon Gallo said: "Notably, the EXO-OC test is particularly accurate in identifying early stages of ovarian cancer, achieving a sensitivity of more than 90 percent and specificity of 96 percent for stage I, where women have a 5-year survival rate of over 90 percent"

Today, the University of Queensland said that the five-year program had received a $1.4 million grant from the National Health and Medical Research Council (NHMRC) for the study, in partnership with the Ovarian Cancer Research Foundation and the Lions Medical Research Foundation in collaboration with Mater Research and Queensland Centre for Gynaecological Cancer Research.

Prof Gallo said "rapid and accurate identification of asymptomatic ovarian cancer will dramatically improve survival rates".

"Ovarian cancer ranks as the eighth most prevalent cause of death for women, with the elevated mortality rate primarily because diagnosis usually occurs when the disease is at an advanced stage," Prof Gallo said.

"In this study, we will confirm the performance of the test under real-world conditions which will involve the collection of blood samples from multiple sites throughout Queensland and their shipment to a central laboratory for analysis," Prof Gallo said.

"Another advantage of this test is the extremely low false positive rate of four percent in previous studies, which makes it a suitable candidate as a screening tool," Prof Gallo said.

"If the false positive rate is high, say 10 percent, then too many women would be sent for further diagnostic investigations and biopsies they don't need, and this creates unnecessary anxiety and places an extra burden on the healthcare system," Prof Gallo said.

"We hope this test enables women with ovarian cancer to be diagnosed at the earliest stage, when they have a fighting chance against this silent killer," Prof Gallo said.

PYC THERAPEUTICS

PYC says it has raised $91 million at $1.25 a share in the institutional component of its one-for-four entitlement offer, with a $55 million retail offer to follow.

On Monday, PYC said that it hoped to raise up-to $146 million at $1.25 a share, a 4.9 percent discount to the five-day volume weighted average price, in an underwritten, one-for-four, non-renounceable institutional and retail rights offer (BD: Feb 17, 2025).

Today, the company said the funds would be used to "progress its entire pipeline of four first-in-class drug candidates with disease-modifying potential through major human data read-outs".

PYC managing-director Dr Rohan Hockings said the entitlement offer had "created an opportunity for the company to generate human safety and efficacy data for multiple drug candidates with category-leading potential in areas of major unmet patient need".

PYC was up 1.5 cents or 1.7 percent to $1.30.

IDT AUSTRALIA

IDT says revenue for the six months to December 31, 2024 was up 77.7 percent to $10,237,000, with net loss after tax down 15.8 percent to $3,251,000.
IDT said the improved revenue coincided with “strong demand from returning customers and US-based entities … attracted to Australia because of its high regulatory standards, cost effectiveness and attractive tax credits for research and development”.
The company said pharmaceutical manufacturing sales fell 63.6 percent to $1,025,000 for the six months to December 31, 2024, with specialty oral treatment sales down 7.15 percent to $2,014,000, advanced therapies sales up 11-fold to $3,926,000 and other sales revenue up 658.0 percent to $3,214,000, with $58,000 in interest.
On its website, IDT said its specialty orals business was “a leading manufacturer in the extraction and manufacturing of medicinal cannabis and psychedelics”.
IDT said Australian sales for the six months were up 121.9 percent to $9,600,000, with US sales down 65.1 percent to $490,000, and sales in Asia of $89,000.
IDT said diluted loss per share fell 32.1 percent to 0.76 cents, with net tangible assets per ordinary security down 6.9 percent to 6.21 cents, and it had cash and cash equivalents of $1,056,000 at December 31, 2024 compared $4,158,000 at December 31, 2023.
IDT fell 1.5 cents or 12.5 percent to 10.5 cents with 4.5 million shares traded.

OPTISCAN IMAGING

Optiscan says it has a developed Inform, a “microscopic medical imaging device”, for use in laboratory medicine, pathology practices, point-of-care and digital pathology.
Optiscan said the “first-in-class” microscopic device offered “up-to 1,000 times real magnification at point-of-care, compared to the traditional 40-to-100 times magnification on conventional light microscopes”.
The company said the device produced “digital images instantly and does not use any consumables beyond the topical dye preferred by the pathologist assessing the tissue”.
Optiscan said the device was designed for use in “the full spectrum of anatomical pathology applications … [including] sample diagnoses in the operating room, specimen margin assessment … frozen section biopsy replacement … [and] routine laboratory assessments on fresh or fixed tissue generating digital microscopic images”.
The company said the device could be connected to hospital or laboratory archiving systems similarly to computed tomography and magnetic resonance imaging, and would integrate with its internet cloud-based tele-pathology platform, expected in mid-2025.
Optiscan managing-director Prof Camile Farah said Inform was “a significant advancement in the evolution of digital pathology”.
“Inform has the ability to enhance the entire pathology workflow from bedside to laboratory and beyond, by improving the speed, accuracy and flexibility of testing, analysis and diagnosis,” Prof Farah said.
“It is designed to be the point-of-contact digital workhorse of the pathology laboratory, providing immediate insights to the pathologist, facilitating triaging of samples, immediate decision making and diagnostic potential, and a revolutionary change to the analogue workflows encountered in most pathology labs,” Prof Farah said.
“With Inform, Optiscan is proud to be taking a leading position in this space, as we aim to transform pathology practice with real-time point-of-care digital imaging,” Prof Farah said.
“Our ‘digital first’ approach targets delivery of faster workflows with unparalleled diagnostic yield and high accuracy, when compared to physical glass slide digitization, which adds more steps and cost to an already time-consuming and complicated process,” he said.
Optiscan was up one cent or 6.45 percent to 16.5 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says it has Conformité Européenne (CE) mark approval for its second-generation Vision-magnetic resonance (MR) ablation catheter for type-one atrial flutter.
Last year, Imricor said it had CE mark certification for its Vision-magnetic resonance imaging ablation catheter in the European Union (BD: Mar 6, 2024).
Today, the company said the further certification was “under the new, more stringent” European Medical Device Regulation (MDR), for the treatment of type 1 atrial flutter.
Imricor said the second-generation Vision-MR catheter was involved in both its European Visabl-ventricular tachycardia (VT) trial and US Visabl-atrial flutter (AFL) trial.
The company said the final approval certificate enabled manufacturing of the second-generation catheter and followed an on-site audit in October 2024.
Imricor said that following the certification it expected to submit the second-generation device to the Therapeutic Goods Administration for approval in Australia.
Imricor chair Steve Wedan said the second-generation Vision-MR ablation catheter incorporated “performance and cost improvements developed by Imricor’s engineers over the past decade, and is designed to be our future ablation catheter globally”.
“Achieving CE mark under the more challenging [medical device regulations] regime for our flagship consumable device, the second-generation ablation catheter, is a very positive sign that speaks volumes about the quality and robustness of our design, manufacturing, quality system, and regulatory team,” Mr Wedan said.
Imricor was up six cents or 4.05 percent to $1.54.

VAXXAS PTY LTD

Vaxxas says it has enrolled its 258-participant, phase I trial of its high-density microarray patch (HD-MAP) for delivering avian influenza A vaccine through the skin.
Vaxxas said the trial would evaluate the safety and immune response of 18-to-50-year-old participants to the avian influenza A vaccine when vaccinated using HD-MAP compared to conventional needle and syringe administration.
In 2022, Vaxxas said it had a $US22 million contract with the US Biomedical Advanced Research and Development Authority (BARDA), to develop the device for pandemic influenza, with the trial expected to enrol more than 400 people (BD: Sep 2, 2022)
Today, the company said it was the “largest phase I study” of its HD-MAP technology it had conducted and that volunteers were enroled at sites in Melbourne and Queensland.
Vaxxas said some participants would receive an adjuvant-free formulation, while others would receive an adjuvanted vaccine formulation, with adjuvants “typically used in pandemic vaccines to boost the immune response of participants who have never encountered the targeted virus before”.
Vaxxas said it would be the first trial evaluating adjuvant vaccines delivered using its HD-MAP technology, and that if both formulations were safe and effective it would “develop vaccines with and without adjuvants for administration by its HD-MAP technology to target a wider range of potential infectious diseases”.
Vaxxas chief executive officer David Hoey said that in prior clinical studies for seasonal influenza the company had shown “comparable immune responses to traditional vaccination with as little as one-sixth of the vaccine with no adjuvant by delivering the vaccine directly to the immune cells just below the skin surface”.
“These promising results give us hope that the un-adjuvanted formulation … will be comparable to adjuvanted formulations delivered by needle and syringe,” Mr Hoey said.
Vaxxas is a private company.

NEUREN PHARMACEUTICALS

Neuren says it has US Food and Drug Administration fast track status for NNZ-2591 as a treatment of Pitt Hopkins syndrome.
Neuren said the designation was “designed to facilitate the development and expedite the review of drugs to treat serious conditions”.
The company said the status would grant it more frequent meetings with the FDA, more frequent written communication from the FDA, eligibility for accelerated approval and priority review, if relevant criteria were met and a rolling review, meaning it could submit completed sections of applications for review rather than the entire application.
Neuren was up 34 cents or 2.6 percent to $13.41 with 870,493 shares traded.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has granted its copper-67 Sar-Bis-PSMA fast track designation as a therapy for previously-treated prostate cancer.
Clarity said the fast-track designation was for the treatment of adults with prostate specific membrane antigen (PSMA)-positive, metastatic, castration-resistant prostate cancer previously treated with androgen receptor pathway inhibition (ARPI).
The company said the status would “expedite the development and regulatory review of novel drugs addressing serious conditions with significant unmet medical needs”.
Clarity said the status would “reduce the review time needed to bring this innovative and proprietary molecule to the prostate cancer imaging and therapy markets”.
Clarity was up three cents or 0.9 percent to $3.41 with 1.6 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it has begun manufacturing the Magsense HER2 imaging agent for use in a US phase II breast cancer detection study.
Imagion said that manufacturing the Magsense human epidermal growth factor receptor-2 (HER2) imaging agent was required for a US Food and Drug Administration investigational new drug application (IND), which it expected to file in mid-2025.
In 2023, the company said a 13-patient, phase I trial showed its Magsense HER2 for detecting breast cancer with magnetic resonance imaging (MRI) was “safe and well tolerated” with eight readable results (BD: Oct 18, 2023).
At that time, Imagion said it expected to submit its first investigational new drug application to the FDA by March 31, 2024.
Today, the company said the phase II study would “optimize the dose of the imaging agent and the imaging protocol to establish the diagnostic performance” of Magsense.
Imagion said it expected to begin manufacturing the imaging agent “in mid-April with production being completed in June”.
The company said it expected “being able to file the IND 30-to-60 days after manufacturing has been completed”.
Imagion said it had “sufficient capital to proceed with the activities necessary to achieve filing” but additional funding would be needed for the phase II study once FDA approved.
Imagion executive chair Bob Proulx said he was “very pleased that we have managed to get the manufacturing contract in place so quickly”.
“The receipt of funds from our recent capital raise has provided us with the resources needed to aggressively pursue our goal of filing an IND and preparing for the next phase of clinical testing of our novel imaging technology”, Mr Proulx said.
Imagion was up 0.2 cents or 11.1 percent to two cents with 23.9 million shares traded.

POLYNOVO

FIL Limited (Fidelity Investment Management) says it has become a substantial shareholder in Polynovo with 44,779,690 shares, or 6.48 percent.
The Sydney and Hong Kong-based Fidelity said it bought shares between October 16, 2024 and February 14, 2025 at prices ranging from $1.7853 to $2.3800, with the single largest purchase 4,338,779 shares on February 14 at $1.9883 a share.
Polynovo was up 1.5 cents or 0.8 percent to $1.93 with 1.6 million shares traded.

ISLAND PHARMACEUTICALS

Jason Carroll says he has increased his substantial shareholding and been diluted in Island from 25,591,981 shares (14.16%) to 30,975,750 shares (16.25%).
The Melbourne-based Mr Carroll said that between December 20, 2024 and January 9, 2025 he sold 216,231 shares for $37,724, or 17.4 cents a share, and on February 19, 2025 converted options into 5,600,000 shares for $336,000, or six cents each.
Last year Island said it raised $3.5 million in an institutional placement at seven cents a share and one attaching option per share (BD: Oct 3, 2024).
Island fell half a cent or 3.85 percent to 12.5 cents.