Biotech Daily

Monday October 9, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHARMAXIS UP 15%; PATRYS DOWN 11%**

*** SANOFI BACKS $280m GRIFFITH UNIVERSITY MRNA VACCINE HUB**

*** CMRI, BLOOMSBURY COLLABORATION FOR GENETIC LIVER CONDITION**

*** AMPLIA FAK NARMAFOTINIB (AMP945) KILLS OVARIAN CANCER, IN MICE**

*** IMAGION MAGSENSE DETECTS OVARIAN CANCER, IN MICE**

*** ADHERIUM PRODUCES HAILIE FOR GSK**

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*** RADIOPHARM: PHASE I RAD204 FOR NSCLC TRIAL APPROVED**

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*** BTC 2nd STRIKE BOARD SPILL, 10m CHAIR OPTIONS AGM**

*** BOTANIX CEO DR HOWIE MCKIBBON TERMINATION BENEFITS AGM**

*** VISIONEERING REQUESTS 'CAPITAL RAISING, DATA' TRADING HALT**

*** AROVELLA REQUESTS 'IN-LICENCE' TRADING HALT**

*** FIVEPHUSION APPOINTS IAIN ROSS DIRECTOR**

*** CYNATA TO LOSE 3-MONTH DIRECTOR DR DAVID ATKINS**

MARKET REPORT

The Australian stock market was up 0.23 percent on Monday October 9, 2023, with the ASX200 up 16.0 points to 6,970.2 points.

Eighteen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and three were untraded. All three Big Caps were up.

Pharmaxis was the best, up 0.5 cents or 14.7 percent to 3.9 cents, with 94,000 shares traded.

Micro-X and Nova Eye climbed more than seven percent; Actinogen, Imugene and Medical Developments improved more than four percent; Volpara was up 3.1 percent; Nanosonics and Polynovo rose more than two percent; Avita, Clinuvel, CSL, Immutep, Opthea and Telix were up more than one percent; with Cochlear, Emvision, Neuren, Pro Medicus, Resmed and SDI by less than one percent.

Friday's 28.6 percent best, Patrys, led the falls, down 0.1 cents or 11.1 percent to 0.8 cents, with 970,000 shares traded.

Cyclopharm and Next Science lost 10 percent or more; Alcidion and Dimerix shed more than eight percent; Proteomics was down 6.2 percent; Amplia and Atomo fell more than four percent; with 4D Medical and Antisense down by one percent or more.

SANOFI SA, GRIFFITH UNIVERSITY, QUEENSLAND GOVERNMENT

The Paris-based Sanofi says it is progressing a partnership with Brisbane's Griffith University opening a vaccine research and development site at the Gold Coast campus.
Sanofi said that the $280 million translational science hub would bring vaccine research and development to the Gold Coast, with scientists from its mRNA Centre of Excellence in France and the US to develop the next generation of immunizations.
The company said that the $280 million partnership with the Queensland Government, Griffith University, and the University of Queensland would put Queensland "at the forefront of mRNA vaccine development and biomedical research in Australia".
Sanofi said that Griffith University had "state-of-the art technology and leading experts in infectious disease, vaccine development and mRNA technology … strong foundations for successful research collaboration in mRNA science".
Griffith University vice-chancellor Prof Carolyn Evans said the partnership "sees Griffith University as a burgeoning biotech hub on the Gold Coast, paving the way for research and discoveries that can change people's lives for the better".
"Griffith is already producing innovative research and a partnership of this ilk is a sign the Gold Coast is at the epicentre of groundbreaking science," Prof Evans said.
Sanofi said researchers would use mRNA "to produce better vaccines and expand its use in the development of therapies to treat a variety of diseases" including chlamydia, acne and some cancers, plus improved vaccines for influenza and respiratory syncytial virus.
Sanofi Australia and New Zealand medical lead Dr Iris Depaz said the Gold Coast site for the translational science hub "provides a space for our scientists to be physically located close to our collaborators at Griffith University to facilitate engagement and exchange".
"We want to play a major role in growing the scientific ecosystem in Queensland because … [it has] a strong talent pool of some of the brightest medical minds," Dr Depaz said.

CHILDREN'S MEDICAL RESEARCH INSTITUTE, BLOOMSBURY GENETIC THERAPIES

Sydney's Children's Medical Research Institute says that with London's Bloomsbury Genetic Therapies it is working on a gene therapy for a liver metabolic condition.

The Children's Medical Research Institute said it hoped to enter clinical trials within months "providing hope for children who … [require] liver transplantation".

The Institute said the collaboration evolved from work with University College London and the Great Ormond Street Hospital, with the researchers developing gene therapies for the rare metabolic liver diseases known as urea cycle defects, including ornithine trans-carbamylase (OTC) deficiency, in which the liver was unable to convert toxic ammonia, produced by protein breakdown, into relatively harmless urea, which could be cleared from the body in urine.

The Institute said that in untreated patients, ammonia could accumulate to toxic levels causing severe brain damage and even death.

CMRI's Prof Ian Alexander said the program had received early funding from the UK Medical Research Council and was then licenced to Bloomsbury Genetic Therapies and the resultant gene therapy was "likely to reach clinical trials within a matter of months".

AMPLIA THERAPEUTICS

Amplia says that its focal adhesion kinase (FAK) inhibitor narmafotinib (AMP945) beats the standard-of-care chemotherapy-resistant high-grade ovarian cancer, in mice.

Amplia said the data was presented as a poster, titled 'Maintenance therapy inhibition of ptk2 yields decreased disease in preclinical models of HRP/HRD models of recurrent HGSOC', at the American Association for Cancer Research (AACR) Special Conference In Cancer Research: Ovarian Cancer meeting, in Boston, over the weekend.

The company said research by collaborators at the University of California, San Diego was presented by lead researcher Prof Dwayne Stupack.

Amplia said that narmafotinib was active in mouse models of chemotherapy-resistant ovarian cancer with improved tumor growth inhibition activity and tolerability compared to a [poly-adenosine diphosphate ribose polymerase] PARP inhibitor (niraparib), the current standard-of-care agent for this chemotherapy-resistant patient population".

The company said that narmafotinib "showed promising activity in a model where niraparib therapy is ineffective".

Amplia said that the results "build on previous research by Prof Stupack and his collaborators showing that activity of the FAK enzyme is upregulated in chemotherapy-resistant ovarian cancer and that FAK inhibition resensitizes the cancer to standard-of-care chemotherapy and immunotherapy as well".

Prof Stupack said that PARP inhibitors were widely used for high-grade serous ovarian cancer and worked well in a subset of patients with homologous recombinant deficient high-grade serous ovarian cancer, until drug resistance occurred.

"We have shown in our pre-clinical models that narmafotinib has better activity across the non-[homologous recombinant deficient] disease, and importantly works in PARP inhibitor-resistant disease as well," Prof Stupak said. "It appears to be very well tolerated."

Amplia managing-director Dr Chris Burns said the results were "extremely exciting and clearly demonstrate that our best-in-class FAK inhibitor narmafotinib has significant potential in the treatment of ovarian cancer".

"The clinical potential of FAK inhibition in ovarian cancer was demonstrated earlier this year with the first-generation FAK inhibitor defactinib showing promising activity in patients with low-grade serous ovarian cancer," Dr Burns said.

Amplia fell 0.4 cents or 4.55 percent to 8.4 cents.

IMAGION BIOSYSTEMS

Imagion says its Magsense folate receptor nanoparticles can detect ovarian cancer with magnetic resonance imaging, in mice.

Imagion said a poster of the results showed Magsense could create molecular T2, or transverse relaxation time, contrast in magnetic resonance imaging, similar to that observed in its phase I study of the device for detecting metastatic human epidermal growth factor receptor-2 (HER2) breast cancer.

The company said Magsense was delivered intravenously and intra-peritoneally and accumulated in high concentrations at the ovarian tumor sites and showed successful folate receptor targeting.

Imagion said delivery and binding of Magsense to ovarian tumor cells was detectable using magnetic resonance imaging, showing that the device had the "potential to offer a non-radioactive and non-invasive approach using molecular [magnetic resonance imaging] MRI for earlier detection of ovarian cancer".

Imagion said the in-vitro cell binding assay showed Magsense could target folate receptor alpha, which was overexpressed in more than 90 percent of ovarian cancer patients.

The company said the folate receptor nanoparticle accumulation was three-to-10 times higher in mice with directly implanted tumors in the ovaries or fallopian tubes than those with flank implanted tumors.

Imagion said the poster, titled 'In vivo Ovarian Cancer Detection using Folate Receptor-a Targeted Iron Oxide Nanoparticles' was presented at the American Association for Cancer Research Special meeting on Ovarian Cancer in Boston, from October 5-to-7, 2023 by research and development head Dr Marie Zhang and would be available through: https://info.imagionbio.com/ovarian-aacr-2023-poster-request.

Imagion chief executive officer Dr Isaac Bright said the results were a "very exciting proof of concept … given the lack of early-stage detection for ovarian cancer".

"To be pioneering this research utilising the widely available [magnetic resonance imaging] modality combined with our Magsense imaging agent is something our team is proud of," Dr Isaac Bright said. "These additional data … have enabled us to complete all the proof-of-concept studies for Magsense folate nanoparticles in ovarian cancer detection … [paving] the way for advancing the program to future [investigational new drug]-enabling studies, whilst also providing the potential future partnership and collaborations opportunities given the need for better detection of ovarian cancer."

Imagion fell 0.2 cents or 11.8 percent to 1.5 cents with 7.8 million shares traded.

ADHERIUM

Adherium says it has begun production and market release of its Glaxosmithkline Ventolin, Advair and Flovent-connected Hailie asthma inhaler sensor.

Adherium said the Hailie sensors could be connected to Glaxosmithkline's pressurized metered dose inhalers including its Ventolin, Advair/Flixotide and Flovent/Seretide inhalers for monitoring asthma and chronic obstructive pulmonary disease.

The company said the Hailie sensor allowed doctors to bill for long-term, remote patient management under existing US reimbursement codes, and that it was paid for sensor sales and monthly per patient fees for generating and transmitting respiratory data.

Adherium chief executive officer Rick Legleiter said purchase orders were "in-house with a fast-growing pipeline for our sensors with expanded data capabilities".

"This latest market release expands the portfolio by adding more inhalers covered with physiological parameter capabilities," Mr Legleiter said.

Adherium was unchanged at 0.4 cents with 1.75 million shares traded.

EMYRIA

Emyria says it has dosed the first patient in its trial of 3,4- methylene-dioxy-meth-amphetamine (MDMA) for post-traumatic stress disorder (PTSD).
In July, Emyria said it had recruited the first of up-to 70 patients in its phase IIb trial of MDMA for post-traumatic stress disorder (BD: Jul 10, 2023).
Today, the company said the "significant milestone" occurred without any safety concerns.
Emyria lead psychiatrist Dr Jon Laugharne said "for individuals grappling with PTSD, the current treatment landscape can feel limiting".
"By initiating active MDMA-assisted therapy within an operational private clinic, as opposed to traditional academic settings, we aim to prioritise real-world patient well-being and learning in order to develop a viable delivery model that can scale," Dr Laugharne said.
Emyria was unchanged at seven cents with 2.5 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has ethics approval for an Australian, dose-escalation, phase I study of RAD204 for non-small cell lung cancer (NSCLC).
Radiopharm said the study would be conducted at Brisbane's Princess Alexandra Hospital and evaluate the safety and efficacy of RAD204 in programmed death ligand-1 (PDL1)-positive non-small cell lung cancer.
The company said the study was supported by Sydney's Genesiscare and was "expected to start shortly".
Radiopharm said about 12,200 Australian patients were diagnosed with lung cancer each year, with more than 2.2 million cases of lung cancer estimated worldwide in 2020, with non-small cell lung cancer accounting for about 85 percent of total cases.
Radiopharm managing-director Riccardo Canevari said non-small cell lung cancer carried "a poor prognosis for patients currently".
Radiopharm fell 0.5 cents or 3.85 percent to 12.5 cents.

CLEO DIAGNOSTICS

Cleo says it has finalized the selection of biomarkers to be used in its ovarian cancer test-kit along with completing the development for a prototype of its scoring algorithm.
In August, Cleo raised $12 million at 20 cents a share to list on the ASX to commercialize its blood tests for ovarian cancer (BD: Aug 22, 2023).
Today, the company said the test's performance was evaluated in a 334-patient clinical study and expected to have the results published in a peer-reviewed journal before 2024.
Cleo said it was preparing a patent application based on the findings.
The company said its objective was to develop its own antibodies and target proteins which would allow control of supply, quality, cost and high-performance of the key reagents that would underpin the consistent and reliable manufacture of test kits.
Cleo said the analysis showed that the core antibodies of its CXCL10 active ratio test were binding to their respective targets with "high affinity and are suitable for commercial assay development and upscaling in commercial manufacturing".
Cleo chief executive officer Dr Richard Allman said "the commercial foundation for our ovarian cancer test-kit targeting the initial surgical triage market is coming together quickly".
Cleo was unchanged at 18 cents.

PHARMAUST

Pharmaust says top-line data from its monepantel dog study shows the drug has an "overall clinical benefit of 35 percent" in dogs with B-cell lymphoma.
Pharmaust said the open-label, single-arm, dose finding study showed monepantel was "safe and well-tolerated" with no treatment-related death or severe adverse reactions.
The company said 54 dogs in five cohorts were assessed over 28 days, and the study found a loading dose of 100 milligrams per kilogram (mg/kg) followed by a maintenance dose of 25mg/kg was the optimal dose.
Pharmaust said overall clinical benefit of the 40 evaluable dogs was 35 percent, defined as a complete or partial response or stable disease, but none had a complete response.
The company said the study also showed monepantel had a median time to progression of 28 days, which compared favorably to the recent US Food and Drug Administration approved product for B-cell and T-cell lymphoma Laverdia.
Pharmaust said the data would support an investigational new animal drug application to the US Food and Drug Administration Centre for Veterinary Medicine for pivotal studies.
Pharmaust chief executive officer Dr Michael Thurn said the potential for the company to "achieve a major value inflexion point by advancing monepantel through to product registration with the Centre for Veterinary Medicine makes good business sense".
"As our monepantel tablet has a comparable efficacy profile to Laverdia and offers significant advantages in quality of life and safety for both the dog and the owner, we are confident in the commercialization of monepantel for canine cancer," Dr Thurn said.
Pharmaust fell 0.1 cents or 1.2 percent to eight cents.

ANTISENSE THERAPEUTICS

Antisense says it has established an unmarketable parcels facility for holders of shares worth less than $500, or 0.07 cents each, at the record date of October 6, 2023.
Antisense said that shareholders at the record date of October 6 would be able to sell shares without brokerage or handling costs and allow the company to reduce administrative costs, by November 24, 2023.
Antisense fell 0.1 cents or 1.4 percent to 6.9 cents.

NOXOPHARM

Noxopharm told the ASX that it was notified of its CRO-67 grant on October 3, 2023, and the data announcement on October 4, 2023 explained the trading in its securities.
The ASX said that Noxopharm's shares rose 47.6 percent from 42 cents on October 2 to a high of 62 cents a share on October 3 and noted a "very significant increase" in the volume of shares traded.
The ASX said that Noxopharm announced it had US Food and Drug Administration orphan drug designation for CRO-67 the following day on October 4, 2023.
Noxopharm told the ASX the announcement contained information that "a reasonable person would expect to have a material effect on the price or value of its securities".
The company said it had it had undertaken its FDA application for CRO-67 with an independent outside regulatory consultant, who was the sole method of communication between it and the FDA in respect to the status and outcome of the application.
Noxopharm said it first became aware of the information from its consultant by email at 12.04pm (AEDT) October 3, 2023, and noted it announced on September 28 data showing that CRO-67 had success in reducing cancer growth.
Noxopharm fell 0.5 cents or 4.35 percent to 11 cents with 4.85 million shares traded.

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 rose 45.8 percent from 4.8 cents a share to 7.0 cents a share today and noted the "significant increase" in the volume of shares traded from October 6 to today.
Painchek was up 1.1 cents or 22.9 percent to 5.9 cents with 8.7 million shares traded.

BTC HEALTH

BTC's annual general meeting will vote on a potential second-strike board spill, along with the issue of 10,000,000 options to executive chair Dr Richard Treagus.
Last year, BTC said its annual general meeting voted 83.7 percent for a remuneration report first strike (BD: Nov 30, 2022).
Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 a company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election at a meeting within 90 days.
If the spill vote fails, the trigger is reset to no opposition.
The company's notice of meeting said that the company proposed to issue Dr Treagus 10,000,000 options in three tranches over three years, exercisable at 4.9 cents each within five years from the date of shareholder approval.
BTC said that shareholders would vote to re-elect Dr Treagus as a director, ratify the prior issue of 42,276,954 shares to investors, approve the company's 10 percent placement facility and adopt the remuneration report.
The meeting will be held online on November 10, 2023 at 2pm (AEDT).
BTC was up 0.1 cents or 2.5 percent to 4.1 cents.

BOTANIX PHARMACEUTICALS

Botanix says its annual general meeting will vote to approve chief executive officer Dr Howard McKibbon's potential termination benefits, including 12-months salary.
In August, Botanix said it promoted chief operating officer Dr Howie McKibbon to chief executive officer, on a base salary of $US400,000 a year (BD: Aug 25, 2023).
At that time, the company said Dr McKibbon would receive a fixed remuneration, performance based short term incentives of 35 percent of remuneration and a long-term incentive of up-to 56 million share rights pending a series of performance hurdles.
Today, Botanix said shareholders would vote on whether, in the instance of Dr McKibbon's termination his 56,000,000 performance rights would not immediately lapse and their conditions may be reduced or waived at the discretion of the board.
Botanix said the meeting would vote on whether Dr McKibbon would receive 12-months of base salary in the event his employment was terminated without cause and a pro rata portion of his target bonus, equal to 35 percent of his annual base salary, for the year in which termination of employment occurs.
The company said shareholders would vote to elect directors Vincent Ippolito and Matthew Callahan, adopt the remuneration report, approve the additional 10 percent placement capacity and approve the employee awards plan.
The meeting will be held at BDO, Level 9, Mia Yellagonga Tower 2, 5 Spring Street, Perth, Western Australia on November 8, 2023 at 9am (AWST).
Botanix fell half a cent or 3.3 percent to 14.5 cents with 8.3 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it has requested a trading halt for the purpose “planning and executing a capital raising and analysing data …of the Protect clinical trial”.
Last year, Visioneering said it had completed enrolment of its 144-patient Protect trial, evaluating the efficacy of Naturalvue multi-focal lenses for slowing the progression of myopia in children (BD: Dec 7, 2022).
Trading will resume on October 11, 2023, or on an earlier announcement.
Visioneering last traded at 40 cents.

AROVELLA THERAPEUTICS

Arovella says it has requested a trading halt “pending an announcement regarding a proposed in-licence agreement”.
Trading will resume on October 11, 2023, or on an earlier announcement.
Arovella last traded at 7.8 cents.

FIVEPHUSION PTY LTD

Fivephusion says it has appointed Iain Ross as a non-executive director.
Fivephusion said that Mr Ross was a biotechnology executive and currently the chair of UK and US publicly-listed and private biotech companies.
The company said that Mr Ross had experience in corporate governance, strategy and execution, including licencing, merger and acquisition deals and capital raising.
Fivephusion said that Mr Ross had worked for Sandoz AG, Hoffman La Roche and Celltech Plc, was most recently the chair of Kazia Therapeutics, formerly Novogen, and currently the executive chair of Reneuron Group Plc.
The company said that Mr Ross held a Bachelor of Science from London University.
Fivephusion is a private company.

CYNATA THERAPEUTICS

Cynata says director Dr David Atkins will retire and not stand for re-election at its annual general meeting on November 13, 2023.
Cynata thanked Dr Atkins “for his contribution since his appointment in July 2023”.
Cynata was unchanged at 13 cents.