Biotech Daily

Tuesday March 5, 2024

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: UNIVERSAL BIO UP 11%; COMPUMEDICS DOWN 11%**

*** TELIX TO ACQUIRE ARTMS FOR $126m**

*** MACH7, PENN STATE HEALTH $3.1m ENTERPRISE RENEWAL**

*** NOVA EYE RECORD MONTHLY US SALES UP 20% TO $1.5m**

*** LA TROBE UNI: MASON $720k FOR CHRONIC FATIGUE SYNDROME**

*** INVEX $1.2m UK TAX REBATE DELAYED INDEFINITELY**

*** IMMUTEP: 90mg EFTI 'SAFE' IN 6 BREAST CANCER PATIENTS**

*** CYNATA DOSES 1st PHASE II CYP-001 GvHD PATIENT**

*** INVION INV043 COMBO '80% ANAL CANCER FREE, IN MICE'**

*** IMMURON REQUESTS 'TRIAL RESULTS' TRADING HALT**

*** SALTER BROTHERS TAKE 5% OF ALCIDION**

*** USCOM CHAIR PROF ROBERT PHILLIPS TAKES 32.5%**

*** UNIVERSAL BIOSENSORS CEO JOHN SHARMAN TO EXERCISE 1.4m OPTIONS**

*** SERVATUS APPOINTS RODNEY LOONE DIRECTOR**

*** BIO-MELBOURNE: A.I. SYMPOSIUM 2 WEEKS TO GO**

MARKET REPORT

The Australian stock market fell 0.15 percent on Tuesday March 5, 2024, with the ASX200 down 11.6 points to 7,724.2 points. Twenty-five of the Biotech Daily Top 40 stocks were up, nine fell, five traded unchanged and one was untraded.

Universal Biosensors was the best, up 1.5 cents or 10.7 percent to 15.5 cents, with 361,105 shares traded. Dimerix climbed 10 percent; Alcidion, Atomo, Clarity, Genetic Signatures and Next Science were up eight percent or more; Nova Eye and Paradigm rose more than seven percent; Cynata, Immutep and Medical Developments improved more than five percent; 4D Medical, Impedimed and Syntara (Pharmaxis) were up more than four percent; Avita, Nanosonics and Resmed were up more than three percent; Cyclopharm rose 2.8 percent; CSL, Mesoblast, Opthea, Polynovo, Resonance and Telix were up more than one percent; with Pro Medicus and Volpara up less than one percent.

Compumedics led the falls, down 3.5 cents or 10.6 percent to 29.5 cents, with 80,522 shares traded. Actinogen lost 9.1 percent; Curvebeam and Prescient fell more than four percent; Emvision and Percheron (Antisense) shed more than two percent; with Clinuvel, Cochlear, Neuren and Proteomics down by less than one percent.

TELIX PHARMACEUTICALS

Telix says it will acquire the Burnaby, British Columbia-based ARTMS Inc and its radioisotope production technology for up-to $US82.0 million ($A126.1 million).

Telix said ARTMS was a private, commercial-stage company specializing in the physics, chemistry and materials science of cyclotron-produced radio-nuclides, and its technology was used by major manufacturers to optimize a range of medical technologies.

According to the ARTMS website, the company's name stands for Alternative Radioisotope Technologies for Medical Science.

Telix said the acquisition was expected to "enhance the vertical integration of Telix's supply chain and manufacturing by providing a greater level of control and security over each of the company's diagnostic isotopes".

The company said it would acquire ARTMS's production facility and clean rooms and was expected to continue to operate and expand ARTMS's research and development and production capabilities to support in-house and customer needs.

Telix said the purchase price included an upfront payment of $US42.5 million through the issue of 5,674,636 Telix shares and $US15.0 million in cash, with up-to $US24.5 million in earn-out payments payable pending clinical or commercial milestones.

The company said it would also pay cash earn-outs, representing low single to low double-digit percentage of net sales of ARTMS products or products manufactured using ARTMS products, for no longer than 10 years after the acquisition; and the transaction was subject to customary conditions, including regulatory approvals.

Telix managing-director Dr Christian Behrenbruch said the company hoped "that by closely aligning this powerful technology with pharmaceutical development, we will transform the cost, market access and utility of diagnostic and therapeutic radiopharmaceuticals".

"Cyclotron and accelerator-based isotope production has the potential to significantly increase the capacity and lower the cost of commercially important isotopes, serving as an important adjunct to reactor-based production," Dr Behrenbruch said.

Telix was up 14 cents or 1.2 percent to $12.00 with 1.2 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has signed a $3.1 million renewal agreement with the Hershey, Pennsylvania-based Penn State Health for its Enterprise imaging platform.

Mach7 said Penn State Health was an academic medical centre and that the three-year renewal consisted of a $1.1 million capital software licence fee and $2.0 million in maintenance and support fees.

The company said the agreement provided for minimum annual studies and offered "further upside should volume continue to exceed current contract minimums".

Mach7 chief executive officer Mike Lampron said Penn State Health had been a customer since 2015 and the partnership showed the success of the company's "land and expand" strategy, with the renewed agreement representing an almost double in annual studies since the start of the contract.

"The capital licence agreement forms part of a large renewal program in 2023-'24 which has demonstrated our strong customer retention," Mr Lampron said.

"It also highlights that some customers will continue to choose a capital model despite the broader industry trend towards subscription licences, especially in North America," Mr Lampron said. "Mach7's willingness to offer both payment models is a competitive advantage as we continue to expand our footprint across our core markets."

Mach7 was up 1.5 cents or 2.1 percent to 72 cents.

NOVA EYE MEDICAL

Nova Eye says it has record US monthly sales of its glaucoma surgical devices for February, up 20 percent on the prior month to $US990,000 ($A1,522,000).
Nova Eye said US revenue for the two months to February 29, 2024 was $US1.82 million, up 65 percent compared to the prior corresponding period, with US sales for the eight months up 64 percent on the previous corresponding period to $US6.88 million.
The company said the performance was driven by US surgeons' uptake of its Itrack Advance since its launch in May 2023, and it continued to receive "excellent feedback on the product's performance from new and existing customers".
Nova Eye said the sales showed "normalization of customer purchasing patterns following the uncertainty created by the Medicare Administrative Contractor announcements".
Nova Eye was up 1.5 cents or 7.3 percent to 22 cents with 2.3 million shares traded.

LA TROBE UNIVERSITY

La Trobe University says the Mason Foundation has granted $720,000 to two researchers working on myalgic encephalomyelitis, or chronic fatigue syndrome.
La Trobe University said the two projects were selected for funding from the foundation's $1.4 million 2024 research grants program.
The University said that the studies would examine how signatures from the gut microbiota, immune system or peripheral blood cells could be used to diagnose or develop treatments for myalgic encephalomyelitis (ME) or long Covid.
La Trobe University's Prof Paul Fisher said myalgic encephalomyelitis and long Covid were poorly understood and did not have definitive diagnostic tests or effective treatments.
"Both of these projects at La Trobe will help to address these deficits," Prof Fisher said.
"The project my group is working on will reveal if the molecular and cellular signature of [myalgic encephalomyelitis] is evident in blood cells from post-Covid [myalgic encephalomyelitis] patients," Prof Fisher said.
"It will reveal whether non-Covid and post-Covid [myalgic encephalomyelitis] are the same illness, and it will give us insights into how these diseases work," Prof Fisher said.
La Trobe University research officer Dr Daniel Missailidis said his team would investigate symptoms of La Trobe University's more holistically by analyzing the gut and blood of patients with new technology.
"We want this research to lead to the development of a diagnostic test and the discovery of treatments that will help a large community that is sadly too often left behind," Dr Missailidis said.
The University said the Mason Foundation was one of the first philanthropic funders to recognize the importance of myalgic encephalomyelitis research, with funding to solve the challenge of the illness, which can have a devastating impact on people's lives.
La Trobe said that the since inception the Mason Foundation had awarded more than $26 million for myalgic encephalomyelitis and Alzheimer's disease funding.
According to the Equity Trustees website the Judith Jane Mason & Harold Stannett Williams Memorial Foundation (the Mason Foundation) was a charitable trust established by Judith Jane Mason and named in honor of her father Harold Stannett Williams.
Equity Trustees said the 2024 program would fund two other projects for up to $120,000 a year for three years, with University of New South Wales Prof Lucette Cysique studying the kynurenine pathways in the management of cognitive and physical fatigue in myalgic encephalomyelitis; and the University of Melbourne's Dr Natalie Thomas researching the steroid 'hormone fingerprint' of myalgic encephalomyelitis and hormone related events.

INVEX THERAPEUTICS

Invex says its expected UK research and development tax rebate of GBP633,000 ($A1,235,100) has been delayed with “no certainty as to the timing of receipt of funds”.
Invex said expected to receive the rebate by December 31, 2023, but “due to changes introduced from April 2023, the processing of claims by the UK [His Majesty’s] Revenue and Customers Office has been significantly delayed”.
The company said it had no guidance on the timeline, but was confident it would be paid.
Invex was untraded at 7.9 cents.

IMMUTEP

Immutep says results from a six-patient, safety lead-in of its phase II/III trial of 90mg eftilagimod alpha, or efti, for metastatic breast cancer shows it is “safe and well tolerated”.
Last year, Immutep said it had dosed six-patients in its up-to 58 patient phase II trial of efti with paclitaxel for breast cancer, with no safety issues (BD: Nov 6, 2023).
At that time, the company said it had dosed the breast cancer patients with a 90mg dose of efti, formerly IMP321, in combination with paclitaxel chemotherapy, in the open-label, safety lead-in part of its phase II/III trial and had reported “no safety or tolerability issues” with no dose limiting toxicities.
Today, Immutep said there were no treatment-emergent serious adverse events, and all treatment-emergent adverse events during the safety observation period had been “mild”.
The company said the safety lead-in of 90mg efti led to a 100 percent disease control rate in the six patients, with three having stable disease, two having a partial response and one patient with a complete response.
Immutep said “acknowledging the early nature of these results, efti with paclitaxel historically has shown a dose-dependent effect in [metastatic breast cancer] and has in some cases also led to stable disease patients becoming partial responders”.
The company said the safety lead-in part of the trial had enrolled 23 patients to date, and that determining the optimal biological dose of efti was “directly tied to the [US Food and Drug Administration’s] Project Optimus initiative and is relevant for the entire efti program”.
Immutep was up two cents or 5.6 percent to 38 cents with 3.0 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has dosed the first of about 60 patients in its phase II trial of its stem cell therapy CYP-001 with steroids for high-risk acute graft versus host disease (GvHD).
Cynata said the study of its off-the-shelf, induced pluripotent mesenchymal stem cell CYP-001 would randomize patients to either CYP-001 with steroids or steroids with placebo.
The company said the trial would be conducted at clinical centres in Australia, the US and Turkey, with the first patient enrolled in the US.
Cynata said the study followed a phase I trial which showed “encouraging safety and efficacy results” and the US Food and Drug Administration had cleared an investigational new drug application for CYP-001 and granted it orphan drug designation.
Cynata chief executive officer Dr Kilian Kelly said “the treatment of the first patient in this phase II trial marks a milestone moment in the clinical development journey of CYP-001 for [acute graft versus host disease]”.
“We are continuing to open additional clinical centres, and we anticipate completion of enrolment by the end of this calendar year, with primary results available in the second half of 2025,” Mr Kelly said.
Cynata was up one cent or 5.3 percent to 20 cents.

INVION

Invion says a study of a topical INV043 combination for anal squamous cell carcinoma led to about 80 percent of mice being tumor-free (p = 0.0037).

In 2022, Invion said in-vitro tests showed that its photo-activated INV043 was effective against six squamous cell carcinoma (SCC) cell lines that cover the spectrum in anal cancers (BD: Sep 15, 2022).

Today, the company said the study of its Photosoft-derived INV043 in combination with immune checkpoint inhibitor therapy was conducted at Melbourne's Peter MacCallum Cancer Centre in about 40 mice with human anal squamous cell carcinomas.

Invion said the study showed that combining the standard-of-care immune checkpoint inhibitor therapy with INV043 enhanced the clinical response in tumors that were unlikely to trigger a strong immune response, called 'cold tumors'.

The company said that six-to-eight-week-old mice were dosed with a sub-cutaneous injection of anal squamous cell carcinoma in four groups with between eight-to-10 mice per group and treated with an anti-programmed cell death 1 therapy, INV043 alone, a combination of INV043 and immune checkpoint inhibitor therapy and a control group.

Invion said 80 percent of tumors treated with the combination therapy showed tumor control, with 70 percent showing no tumor volume at the end of the testing period.

The company said 10 percent of tumors increased in volume but were subsequently found in histological analysis to be pus and contained no evidence of cancer.

Invion said no effect on mouse wellbeing or weight gain over time was observed, and that no visible scarring was observed in the mice with complete tumor control.

Invion executive chair Thian Chew said the findings showed "the potential of INV043 for use in combination with immune checkpoint inhibitors, to substantial improve patient outcomes".

"The high impact opportunity to improve widely used [immune checkpoint inhibitor] therapies, and ability to develop new combined [intellectual property] with potential partners, provides us multiple pathways to commercialize Photosoft technology, which we look to further demonstrate in our clinical trials," Mr Chew said.

Invion was up 0.1 cents or 20 percent to 0.6 cents with 12.5 million shares traded.

IMMURON

Immuron has requested a trading halt to allow it to "analyze and interpret data prior to making an announcement of phase II IMM-124E clinical trial top-line results".

Trading will resume on March 7, 2024, or on an earlier announcement.

Immuron last traded at 6.6 cents.

USCOM

Uscom chair Prof Robert Phillips says he has increased his substantial shareholding from 47,233,937 shares (24.79%) to 79,531,873 shares (32.51%).

The Singapore-based Prof Phillips said that on March 4 and 5, 2024 he purchased 32,297,936 shares in a rights issue for $1,195,023, or 3.7 cents a share.

Last month, Uscom said it hoped to raise about $2,014,000 through an underwritten, non-renounceable two-for-seven rights offer at 3.7 cents a share (BD: Feb 5, 2024).

Uscom was untraded at 2.3 cents.

ALCIDION GROUP

Salter Brothers Emerging Companies says it has become substantial in Alcidion with 68,549,365 shares, or 5.11 percent of the company.
The Melbourne-based Salter Brothers said that between October 30, 2023 and February 29, 2024 it bought shares at “market price” but did not disclose the price of the trades as required under the Corporations Act 2001.
Alcidion was up 0.4 cents or 8.5 percent to 5.1 cents with 1.5 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says chief executive officer John Sharman intends to exercise 1,364,666 options at 20 cents each as part of his long-term incentive plan.
Mr Sharman said he was “committed to the success of Universal Biosensors and am pleased to be able to demonstrate my confidence in our future growth prospects”.
“My ambition is to work with the board and Universal Biosensor staff to create significant value to its stakeholders,” Mr Sharman said.
Universal Biosensors was up 1.5 cents or 10.7 percent to 15.5 cents.

SERVATUS

Servatus says it has appointed Rodney Loone as a director.
Servatus said Mr Loone was currently chair of the Workforce Health Assessors Group International, and was previously a principal at Crow Horwath, chief executive of WHK Group and a partner at Garrotts.
The company said Mr Loone held a Bachelor of Business from the University of Tasmania.
Servatus is a public unlisted company.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says there two weeks remaining before its symposium on artificial intelligence (A.I.) decision-making on March 18, 2024.
The Bio-Melbourne Network said the symposium, titled ‘‘Crossing the Rubicon in A.I. Decision-Making: A Clinical Dilemma’ would explore “the intersection of artificial intelligence with clinical decision-making and the role of the patient”.
The Network said the event included four sessions, would be held online and at Monash College, Level 2 Auditorium, 750 Collins Street, Docklands, from 8.45am to 6.30pm (AEST) and would include networking.
For details and registration, go to: https://bit.ly/3vWYsiP.