Biotech Daily

Wednesday May 4, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: EMVISION UP 3%; ATOMO DOWN 9%**

*** ANKERE: BRANDON, IP GROUP $10m FOR INFLAMMATION**

*** ALCIDION $23m, 6-YEAR DEFENCE FORCE CONTRACT**

*** RHINOMED RAISES $1.1m; TOTAL $4.5m; $532k SHORTFALL**

*** ACTINOGEN XANAMIA TRIAL TAKES FOCUS BACK TO COGNITION**

*** EMVISION: KEYSIGHT 'FAST SWEEP VNAs' FOR BRAIN SCANNER**

*** BOTANIX TO PAY BRICKELL $24m FOR SOFPIRONIUM BROMIDE**

*** CLINUVEL: FINAL DATA BACKS 16mg AFAMELANOTIDE FOR STROKE**

*** RHYTHM CLOSES FINAL TRIAL SITES**

*** IMRICOR 36% AGM OPPOSITION TO DIRECTORS' SHARES**

MARKET REPORT

The Australian stock market fell 0.16 percent on Wednesday May 4, 2022, with the ASX200 down 11.5 points to 7,304.7 points.

Eight of the Biotech Daily Top 40 stocks were up, 22 fell, nine traded unchanged and one was untraded.

Emvision was the best, up 5.5 cents or 2.8 percent to $1.995, with 55,622 shares traded. Proteomics and Universal Biosensors climbed two percent or more; Cochlear, Cynata, Genetic Signatures, Next Science and Volpara were up one percent or more; with CSL and Cyclopharm up by less than one percent.

Atomo led the falls, down one cent or 9.1 percent to 10 cents, with 2.4 million shares traded. Antisense lost 8.7 percent; Nova Eye and Prescient fell more than seven percent; Pharmaxis shed 6.2 percent; Imugene was down 5.6 percent; Impedimed, Kazia, Polynovo and Telix fell more than four percent; Paradigm and Starpharma were down three percent or more; Clinuvel, Mesoblast, Nanosonics and Neuren shed more than two percent; Actinogen, Oncosil, Opthea and Resmed were down more than one percent; with Avita, Medical Developments and Pro Medicus down by less than one percent.

ANKERE THERAPEUTICS

Ankere says it has $10 million in seed investment to develop therapies targeting inflammatory diseases, particularly lung disease.

Ankere said it was based between Melbourne's Monash Institute of Pharmaceutical Sciences (MIPS) and Adelaide's South Australia's Centre for Cancer Biology and was at the "lead optimization stage" with clinical trials expected to begin 2024 to 2025.

The company said that London's IP Group and Melbourne's Brandon Capital led the funding round and would provide support through its pre-clinical development and into clinical trials.

Ankere said its small molecule chemistry was based on a collaboration between MIPS' Prof Bernard Flynn and the University of South Australia's Prof Stuart Pitson, its chief scientific officer.

Ankere said its name was an Arrernte word from Central Australia meaning "spinifex wax" which was used in traditional medicines.

The company said that the use of the name was acknowledgement of its Australian heritage and Prof Flynn had permission to use this word from the Arrernte culture centre, Akeyulerre, in Alice Springs, Northern Territory.

Ankere is a private company.

ALCIDION

Alcidion says it has a $23.3 million, six-year contract to provide the Australian Defence Force's healthcare services with a health knowledge management system.

Last year, Alcidion said it had won a $23 million Federal contract in a consortium led by Leidos Australia, a subsidiary of the Reston, Virginia-based Leidos (BD: Dec 3, 2022).

Today, the company said that as part of the JP2060 Defence contract, its Miya Precision would receive data from Leidos's products and aggregate them into a "a single, consolidated, longitudinal view of participant health status and history".

Alcidion said the system would replace the Australian Defence Force's "legacy electronic health record product with a modern, patient-centric health [product]".

The company said Miya would record, store, aggregate and analyze health data and information for the Australian Defence Force (ADF) to enable better clinical decision-making.

Alcidion managing-director Kate Quirke said the company was "excited to work on this critical project for the Australian Defence Force" with Leidos and our consortium partners.

"Our contribution is pivotal in consolidating data from partner systems to provide clinicians with a comprehensive and meaningful view of the ADF population and their interaction with their healthcare services," Ms Quirke said.

Alcidion was unchanged at 17 cents with 1.2 million shares traded.

RHINOMED

Rhinomed says it has raised $1,098,000 in a one-for-9.87 retail entitlement offer at 19 cents a share.

In April, Rhinomed said it had completed a $3.37 million underwritten institutional rights offer at 19 cents a share, and hoped to raise a further $1.63 million in a retail rights offer at the same price (BD: Apr 7, 8, 2022)

Today, the company said that it intended to place the shortfall of about 2.8 million shares, or about $532,000.

Rhinomed fell two cents or 9.3 percent to 19.5 cents.

ACTINOGEN MEDICAL

Actinogen says the positive results for attention and cognition, or working memory, in its Xanamia part A trial has led to a change in trial priorities and planned expenditures.

Last week, Actinogen said that its 107 healthy, cognitively normal, older adult phase Ib dose-ranging trial of 5mg and 10mg Xanamem for cognition met its primary safety, pharmacodynamic and efficacy endpoints (BD: Apr 27, 2022).

Today, the company said it would prioritize the Alzheimer's disease and major depressive disorder, in which cognition was the primary focus, ahead of the Fragile X syndrome program, where cognition is one of several factors

Actinogen said that it would expedite the Xanamia part B phase II Alzheimer's disease trial, measuring safety and cognitive performance in patients with the early stages of Alzheimer's disease, as well as the major depressive disorder phase II trial, which would measure safety, levels of depression and cognitive performance in patients who were inadequately treated by their anti-depressant medication.

Actinogen said it would suspend trial operations for its more complex, Xanafx Fragile X syndrome trial and reallocate about $12 million to the Alzheimer's and depression trials, and investigate alternative funding for Xanamem for Fragile X.

The company said it had $19.0 million in cash at March 31, 2022, expected a Federal Research and Development Tax Incentive, and was "focused on capital-efficient, Australian clinical trial operations for its clinical trials wherever feasible".

Actinogen managing-director Dr Steven Gourlay said the "strongly positive results" for the Xanamia part A trial triggered the review of priorities for the next 24 months.

"It makes business and scientific sense to devote resources and capability to our clinical programs focused on cognition, given the Xanamia data, and expedite the phase II trials in Alzheimer's disease and depression," Dr Gourlay said.

"The strong scientific rationale for our Fragile X program has not changed and we hope to be able to study Xanamem in this disease with the help of strategic partners in industry or academia," Dr Gourlay said.

Last year, Actinogen said that Xanamem for Fragile X syndrome has been granted US Food and Drug Administration rare paediatric disease designation, with the potential for "a second, transferable priority review voucher" (BD: Feb 5, 2021).

Actinogen fell 0.1 cents or 1.2 percent to eight cents with 8.7 million shares traded.

EMVISION

Emvision says that Keysight Technologies will exclusively supply its "fast sweep" vector network analyzers (VNAs) for its portable brain scanners.

Emvision said the agreement Santa Rosa, California-based Keysight Technologies would provide with technology enabling further miniaturization of its portable brain scanners.

The company said the VNA technology enabled high fidelity imaging and measurement of cerebral blood flow through the speed of the technology's data capture.

Emvision said that Keysight component was the result of a collaboration between the two companies which began in early 2019.

The company said that the 12-month renewable agreement "sets out pricing for the supply of VNA units in the initial term [and] the financial impact to the company in the initial 12-month term [was] not considered material".

Emvision chief executive officer Dr Ron Weinberger said "the integration of the Keysight VNA accelerates our pathway to commercialization, allowing us to bring a best-in-class portable imaging [product] one step closer for patients and clinicians".

Emvision was up 5.5 cents or 2.8 percent to $1.995.

BOTANIX PHARMACEUTICALS

Botanix says it will pay Miami's Brickell Biotech up to $US17 million ($A24 million), plus royalties for sofpironium bromide gel for excessive underarm sweating.

Botanix said that in recent phase III pivotal studies and a 48-week safety study, sofpironium bromide achieved statistical significance in all primary and secondary endpoints and was found to have a favorable safety profile.

Previously the company had been developing marijuana-derived synthetic for a range of dermatological diseases and infections, including BTX1204A for canine atopic dermatitis or eczema, and a 66-patient, phase IIa trial which showed BTX1801 could eradicate Staphylococcus aureus from the nose of healthy participants (BD: Feb 3, Sep 29, 2021).

The company trialled synthetic cannabinoid treatments for atopic dermatitis and acne which failed to meet their endpoints (BD: Oct 23, 2019; Mar 25, 2020).

Today, Botanix said it would pay Brickell $US3 million upfront, $US2 million on receipt of a positive 'Day-74 letter' for a US Food and Drug Administration new drug application, $US4 million if it received FDA approval for the new drug application before September 30, 2023, reducing to zero if it was not approved by February 17, 2024, a further milestone payment of $US4 million on receipt of marketing approval in the European Union (EU) or UK and a further $US4 million for a further indication in the UK, EU or US.

The company said it would pay a milestone should sales of sofpironium bromide gel 15% exceed $US75 million and "pay royalties to Brickell and Bodor that in the aggregate start at 12 percent and rise to 20 percent, above $500 million of annual net sales."

Botanix did not specify whether the royalties began at $500 million dollars or at first sales, nor whether the dollar value threshold was in American or Australian dollars.

The company said it would assume responsibility for the future development of sofpironium bromide, which was licenced to Tokyo's Kaken Pharmaceuticals, which had regulatory approval of sofpironium bromide for excessive underarm sweating in Japan.

The company said that it was entitled to 25 percent of Kaken's royalties and milestones.

Botanix executive chair Vince Ippolito said the acquisition was "the first and only new chemical entity developed for primary axillary hyperhidrosis".

"Having demonstrated statistically significant efficacy and favorable safety in pivotal studies, we are well advanced in preparing sofpironium bromide for FDA approval in the second half of this year and look forward to accelerating Botanix into a commercial dermatology company much sooner than we originally expected," Mr Ippolito said.

Botanix was up 0.9 cents or 11.7 percent to 8.6 cents with 6.4 million shares traded.

CLINUVEL

Clinuvel says the final results from its six-patient, open-label, pilot study of 16mg afamelanotide for arterial ischaemic stroke support the treatment.

In March, Clinuvel said five of six stroke patients in a study of 16mg afamelanotide had improved neurological functions, with no adverse drug reactions (BD: Mar 15, 2022).

Today, Clinuvel said the final results supported its preliminary findings of no adverse reactions and reduction spread of affected tissue.

Clinuvel head of clinical operations Dr Pilar Bilbao said that the final analyses from the CUV801 study showed "that surviving patients who received treatment with afamelanotide all seemed to have recovered well in the six weeks following their brain injury."

"Our clinical team often publicly emphasize the significance of afamelanotide as a safe drug in patients, and in this study, we obtained further data that patients with longstanding cardiovascular disease seem to tolerate afamelanotide well," Dr Bilbao said.

Clinuvel fell 38 cents or 2.35 percent to $15.76 with 82,695 shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has closed the final trial site for its prospective, cross-sectional study of its Colostat colorectal cancer blood sample test.

Last month, Rhythm said its 737-patient sample trial met its primary and secondary endpoints with a sensitivity of 81 percent and specificity of 91 percent (BD: Apr 4, 2022).

Today, Rhythm said the closure of the trial site meant that all operational aspects of the trial had been completed, and that a submission package to the Australia Therapeutic Goods Administration was in its late stages.

Rhythm managing-director Glenn Gilbert said the closure of the operational aspects of the clinical trial program "places the company into a critical phase to deliver Colostat into the market later this year".

"We look ahead with confidence that our lifesaving cancer detection technology will make a meaningful difference to millions of people around the world," Mr Gilbert said

Rhythm was up one cent or 0.8 percent to $1.29.

IMRICOR MEDICAL SYSTEMS

Imricor says that up to 36.4 percent of votes at its annual general meeting opposed the issue of restricted stock awards to three directors.

Last month, Imricor said it proposed to issue a total of $US111,250 ($A148,786), in restricted stock awards "in lieu of higher cash remuneration" to directors Peter McGregor, Mark Tibbles and Anita Messal (BD: Apr 8, 2022).

Today, the company said that the greatest difference was to the issue of restrict stock awards to Mr Tibbles which faced 12,731,245 votes (36.4%) against the issue and 22,245,012 votes (63.6%) in favor, with the other two resolutions carried by a slightly wider margin.

Imricor said the grant of options worth $US288,819 to chief executive officer Steve Wedan was opposed by 7,316,610 votes (19.95%), with 29,356,202 votes (80.05%) in favor.

The company said that all other resolutions, including the election of Mr McGregor, ratification of a placement and the 10 percent placement facility all passed more easily.

According to Imricor's most recent filing, the company had 143,293,937 Chess depositary interests on offer, meaning that the votes against the stock awards amounted to 8.9 percent of the company, sufficient to requisition extraordinary general meetings.

Imricor fell 4.5 cents or 9.6 percent to 42.5 cents.