Biotech Daily

Monday September 4, 2023

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: GENETIC SIGNATURES UP 12%;**
- UNIVERSAL BIOSENSORS DOWN 10.4%

*** S&P INDICES: NEUREN, 4D UP; COGSTATE, IMUGENE, INCANNEX, DOWN**

*** SOMNOMED RAISES $9.75m; EXPECTS $5.7m MORE**

*** EMYRIA 'FIRM BIDS' FOR $2m PLACEMENT; $3.1m ENTITLEMENT OFFER**

*** MAYNE PHARMA $15m FOR RHOFADE FOR ROSACEA**

*** GENETIC SIGNATURES FILES FDA EASYSCREEN GI PARASITE 510k**

*** MEDIBIO STARTS PHASE II SLEEP ANALYSIS FOR DEPRESSION TRIAL**

*** ECHO IQ RECEIVES $670k FEDERAL R&D TAX INCENTIVE**

*** IMUGENE STARTS VAXINIA-COMBINATION TUMOR TRIAL COHORT 2**

*** PROTEOMICS JAPAN PATENT FOR OXIDX OXYGEN TEST**

*** VIVAZOME: XENIA SANGO M-D, DR HAYLOCK CSO, DR FILIPPIS DIRECTOR**

*** IMUGENE APPOINTS DR PAUL WOODARD CMO**

MARKET REPORT

The Australian stock market was up 0.56 percent on Monday September 4, 2023 with the ASX200 up 40.5 points to 7,318.8 points. Seven of the Biotech Daily Top 40 stocks were up, 18 fell, 13 traded unchanged and two were untraded. All three Big Caps fell.

Genetic Signatures was the best, up 5.5 cents or 12.4 percent to 50 cents, with 273,021 shares traded. Volpara climbed 5.4 percent; Mesoblast was up 3.3 percent; Medical Developments and Nanosonics rose more than two percent; Immutep was up 1.75 percent; with Paradigm up by 0.8 percent.

Universal Biosensors led the falls, down 2.5 cents or 10.4 percent to 21.5 cents, with 444,932 shares traded. Compumedics lost 10 percent; 4D Medical was down 5.4 percent; Next Science, Nova Eye and Proteomics fell more than four percent; Dimerix was down three percent; Neuren, Orthocell, Pharmaxis and Polynovo shed more than two percent; Clinuvel, Emvision, Imugene and Opthea were down more than one percent; with Avita, Cochlear, CSL, Pro Medicus, Resmed and Telix down by less than one percent.

STANDARD AND POOR'S DOW JONES INDICES

Standard and Poor's says Neuren has been promoted into the ASX200 Index and 4D Medical into the All Technology Index, with Cogstate, Imugene and Incannex demoted.
Standard and Poor's said the changes would be effective from September 18, 2023, with Imugene to be removed from the ASX200 Index, Incannex removed from the ASX300 Index and Cogstate to be removed from the All Technology Index.
Previously, Standard & Poor's has told Biotech Daily that inclusion in the indices is based solely on market capitalization.
The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.

SOMNOMED

Somnomed says it raised $2.75 million in placements, $7 million in an institutional rights offer and expects a further $5.7 million in a retail rights offer at 60 cents a share.
Somnomed said it had placed a $251,309 shortfall for the institutional rights offer to new and existing institutional investors.
The company said that the capital raising was fully-underwritten by Wilsons Corporate.
Somnomed said the one-for-3.82 accelerated, non-renounceable rights offer was to institutional investors with a take-up rate of 97 percent.
Biotech Daily calculates the offer price was a 21.05 percent discount to the closing price prior to the trading halt.
The company said the funds would be used for working capital and a reduction in the balance of its Epsilon Direct lending debt facility.
Somnomed said the none of the institutional shortfall shares had been allocated to the sub-underwriter and major shareholder TDM Growth Partners Pty Ltd.
Somnomed said its retail entitlement offer would have a record date of September 4 open on September 7 and close on September 21, 2023.
The company said Wilsons Corporate was sole lead manager, bookrunner and underwriter to the entitlement offer, and TDM Growth Partners and other existing institutional shareholders intended to subscribe for any shortfall to the retail offer.
Somnomed fell 16 cents or 21.05 percent to 60 cents.

EMYRIA

Emyria says it has "firm bids" for a $2 million placement at 7.5 cents a share, to be followed by a $3.1 million, non-renounceable, one-for 7.5 shares entitlement offer.
Emyria said the placement price was a 6.25 percent discount to the last traded price on August 30, 2023, and for every two shares purchased under the placement investors would receive one attaching option, exercisable at 12 cents within three years.
The company said Sixty Two Capital Pty Ltd was the lead manager to the placement, and would provide $500,000 for the placement, subject to shareholder approval, and would receive 6,000,000 options under the same terms of the placement options as consideration.
Emyria said the entitlement offer would have a record date of September 13, open on September 18 and close on September 28, 2023.
Emyria said the funds would be used to support its drug development programs, including its phase III clinical trials of 3,4-methylene-dioxy-meth-amphetamine (MDMA) for post-traumatic stress disorder.
Emyria was up two cents or 25 percent to 10 cents with 17.0 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says it has purchased the rights to Rhofade, or oxymetazoline hydrochloride cream, for facial erythema for $US9.5 million ($A14.68 million).
Mayne Pharma said acquisition of the global rights to Rhofade with the Durham, North Carolina-based Novan Inc and Novan's EPI Health LLC included $US8 million cash plus up-to $US1.5 million in associated cure costs.
The company said Rhofade was a topical treatment for persistent facial erythema, a skin condition associated with rosacea in adults.
The US National Library of Medicine website said that rosacea was a chronic inflammatory skin condition with symptoms including flushing, persistent redness and visible blood vessels that manifests on the facial skin.
The US National Library of Medicine said pharmacologic treatments included topical sodium sulfacetamide, topical metronidazole, topical azelaic acid, topic ivermectin and others, as well as systemic medications such as tetracyclines, erythromycin and others.
Mayne Pharma chief executive officer Shawn O'Brien said "the acquisition is a great example of how we're able to leverage our existing dermatology infrastructure to add immediately accretive, well-known brands to our portfolio".
"We're continuing to focus on identifying and taking advantage of strategic expansion opportunities, and Rhofade fits well with our other products that help patients suffering from rosacea," Mr O'Brien said.
Mayne Pharma was up 31 cents or 9.2 percent to $3.68 with 544,378 shares traded.

GENETIC SIGNATURES

Genetic Signatures says it has submitted a 510(k) application to the US Food and Drug Administration for its Easyscreen gastro-intestinal parasite detection kit.
Genetic Signatures said Easyscreen was a polymerase chain reaction-based rapid molecular test that covered the eight most common and clinically relevant gastro-intestinal parasites using its 3base software.
The company said it expected the test be reimbursed for about $US263 ($A407) in the US.
Genetic Signatures said the Easyscreen gastro-intestinal parasite test was already available in Australia, Europe and Canada, with the FDA submission including 1,500 clinical samples collected from three different sites across the US.
Genetic Signatures said the FDA submission had been delayed so it could develop a number of gastro-intestinal pathogen targets that were currently unavailable in existing commercial products.
The company said commercial preparations for the Easyscreen gastro-intestinal parasite test were underway in the US and it expected sales shortly after receiving FDA clearance.
Genetic Signatures chief executive officer Dr John Melki said that "with a greater range of [gastro-intestinal] parasite targets provided in this syndromic solution, and the unique advantages of our 3base technology to detect these parasites, it is the ideal product to launch into the US".
"Our plan to achieve additional product registrations in the US continues, with clinical studies to support a FDA 510(k) application of a second 3base product already underway," Dr Melki said.
"This is a molecular syndromic test for key viral respiratory infections in a single test," Dr Melki said.
Genetic Signatures was up 5.5 cents or 12.4 percent to 50 cents.

MEDIBIO

Medibio says it has begun a 400-participant, phase II trial of its MEB-001 “sleep signal analysis” algorithm for current major depressive episodes at 14 US sleep centres.

In July, Medibio said its 313-subject, phase I trial of MEB-001 showed its heart rate depression test had 71.65 percent sensitivity and, 71.43 percent specificity, but provided no statistical significance (BD: Jul 24, 2023).

Today, the company said the phase II trial followed the “promising results generated from the first trial phase” with the first phase II patient tested at a sleep centre in Blaine, Minnesota.

Medibio said that clinicians would administer a ‘Mini’ international neuropsychiatric interview for each participant and “provide an independent assessment of the underlying status of each subject to establish ground truth regarding current major depressive episode status”.

Medibio said the trial was necessary to prepare for its clinical validation study and US Food and Drug Administration submission, as well as increase the performance of its algorithm when compared to the existing standard-of-care.

The company said based on enrolment it expected to complete the phase II trial by July 2024, and had scheduled a pre-submission meeting with the FDA to seek an agreement on the final clinical validity of MEB-001 through the de-novo regulatory pathway.

Medibio chief executive officer Dr Tom Young said “the initiative is anticipated to generate additional data which provides a much better understanding of MEB-001 and its potential to assist in the objective screening of depression”.

Medibio was up 0.1 cents or 100 percent to 0.2 cents with 4.85 million shares traded.

ECHO IQ

Echo IQ says it has received $667,146 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Echo IQ said the incentive related to research and development expenditure on its decision-support diagnostics for aortic stenosis for the year to June 30, 2022.

Echo IQ fell half a cent or 3.2 percent to 15 cents.

IMUGENE

Imugene says it has begun recruiting cohort two of its phase II trial of intra-tumoral CF33-hNIS, or Vaxinia, for solid tumors in combination with pembrolizumab (Keytruda).

Last year, Imugene said it had dosed the first second cohort patient in the intra-tumoral arm of its phase I trial of Vaxinia virotherapy for metastatic advanced solid tumors (MAST) (BD: Oct 31, 2022).

Earlier this year, the company said both intravenous and intra-tumoral arms of its phase I study of Vaxinia were ready for combination with pembrolizumab (BD: Feb 2, 2023).

Today, Imugene said it was recruiting for cohort two of both arms of the combination trial, and cohort four for both arms of its monotherapy dose escalation.

The company said overall the study aimed to recruit up to 100 patients across 10 trial sites in the US and Australia.

Imugene chief executive officer Leslie Chong said “we’ve now seen a very significant number of patients dosed with Vaxinia as part of the MAST study, with those patients suffering as a result of a variety of tumor types”.

Imugene fell 0.1 cents or 1.5 percent to 6.5 cents with 41.0 million shares traded.

PROTEOMICS INTERNATIONAL

Proteomics says the Japan Patent Office has granted a patent protecting its subsidiary Oxidx Pty Ltd's Oxidx blood test for diagnosing and monitoring oxidative stress levels.
Proteomics said the patent, titled 'Methods for measuring relative oxidation levels of a protein', was the first in a family of patents that would protect its intellectual property until March 2039.
The company said Oxidx diagnosed oxidative stress by "moving beyond measuring protein concentrations to detect subtle changes in protein structures - 'decorations' that sit on the surface of a protein and are known as post-translational modifications".
Proteomics said the finger-prick blood sample used a sensitive ratio-metric method to detect protein bio-markers in the blood that could be collected at home or in a clinic with high specificity to provide a comprehensive product for monitoring oxidative stress levels.
The company said oxidative stress was implicated in more than 70 health conditions, with levels often reflective of a person's health and fitness and was used for assessing treatment efficacy and precision medicine by enabling personalized dosing in clinical trials.
Proteomics said monitoring oxygen stress levels was also useful as an athletic monitoring tool for competition preparedness and to reduce injuries in the professional sports and horse racing industries.
Proteomics fell four cents or 4.5 percent to 85 cents.

VIVAZOME THERAPEUTICS PTY LTD

Vivazome says it appointed Xenia Sango as its managing director and Dr Anthony Filippis director with Dr David Haylock appointed as its chief scientific officer.
Vivazome said Ms Sango had been promoted from her current role as chief operating officer, effective from September 1, 2023, and had been with the company since its inceptions.
The company said Ms Sango had previously been with CSL and Epworth Health.
Vivazome said Dr Haylock had been chief executive officer since November, 2019, and would remain as chief scientific officer to focus on the company's science strategy and operations.
Vivazome said Dr Filippis was chief operating officer at Antisense and a director of Connectivity Traumatic Brain Injury Australia and had previously been chief executive officer of Neurosciences Victoria.
Vivazome is a private company.

IMUGENE

Imugene says it has appointed Dr Paul Woodard as its chief medical officer.
Imugene said Dr Woodard had been chief medical officer at Immune-Onc Therapeutics and had worked at Exelixis, Amgen, Genentech and Bellicum.
The company said Dr Woodard held a Bachelor of Arts in Chemistry and a Doctor of Medicine from the University of North Carolina.