Biotech Daily

Wednesday December 14, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PATRYS UP 20%; PHARMAXIS DOWN 8%**

*** CLARITY 64-CU-SAR-BIS-PSMA 'SAFE, IDENTIFIES PROSTATE CANCER'**

*** PROTEOMICS UK PROMARKERD 'NICE ADVICE' AIDS RECOMMENDATION**

*** INDONESIA APPROVES STARPHARMA VIRALEZE NASAL SPRAY**

*** ONCOSIL APPOINTS HIND WING CHINA DISTRIBUTOR**

*** EMA APPROVES INVEX PAEDIATRIC IIH TRIAL DESIGN**

*** RESPIRI ENROLS 1st MINNESOTA REMOTE WHEEZO PATIENTS**

*** HEXIMA OPPOSES MERCHANT, TILLET EGM RESOLUTIONS**

*** HEXIMA RECEIVES $6m FEDERAL R&D TAX INCENTIVE**

*** PATRYS PLEADS SCHULTZ TO ASX 28% QUERY**

*** BVF DILUTED TO 14.6% OF PHARMAXIS**

*** RACE: DAMIAN CLARKE-BRUCE M-D ON $475k; PHIL LYNCH DIRECTOR**

*** PHARMAXIS APPOINTS DR SIMON GREEN DIRECTOR**

*** INOVIQ LOSES DIRECTOR PROF ALLAN CRIPPS**

MARKET REPORT

The Australian stock market was up 0.67 percent on Wednesday December 14, 2022, with the ASX200 up 48.0 points to 7,251.3 points. Thirteen Biotech Daily Top 40 stocks were up, 15 fell, 10 traded unchanged and two were untraded. All three Big Caps rose.

Patrys was the best, closing up half a cent or 20 percent to three cents, with 30.6 million shares traded. Medical Developments climbed five percent; Proteomics and Starpharma improved more than four percent; Antisense and Prescient were up more than three percent; Polynovo rose two percent; Clinuvel, Cynata, Impedimed, Resmed and Telix were up more than one percent; with Cochlear, CSL, Pro Medicus and Volpara up by less than one percent.

Pharmaxis led the falls, down 0.5 cents or 7.7 percent to six cents, with 605,118 shares traded. Nova Eye lost 6.8 percent; Imugene shed 5.1 percent; Kazia fell 4.3 percent; Alcidion, Dimerix, Genetic Signatures and Paradigm were down more than three percent; Mesoblast and Universal Biosensors shed two percent or more; Avita and Opthea were down more than one percent; with Emvision, Neuren and Next Science down by less than one percent.

CLARITY PHARMACEUTICALS

Clarity says its 30-patient, phase I, 'Propellor' trial shows that 64-copper SAR-bis-PSMA (prostate-specific membrane antigen) is safe and identifies primary prostate cancer.
Clarity said that 64-copper SAR-bis-PSMA was safe and well-tolerated and was "efficacious in detecting primary prostate cancer".
The company said it had identified a dose of 200 megabecquerels as the optimal dose for future trials.
Last year, Clarity said that the 30-patient, positron emission tomography (PET) imaging trial of participants with confirmed prostate cancer using 64-Cu-SAR-bis-PSMA was a blinded, dose-ranging, non-randomized study prior to radical prostatectomy, with primary endpoints of safety, tolerability and efficacy in the detection of primary prostate cancer compared to histopathology (BD: Aug 10, 2021).
In December 2021, the company said that the main goals of the trial were to determine the safety and tolerability of 64Cu SAR-bis-PSMA in patients with untreated, confirmed prostate cancer and planned for radical prostatectomy, examine 64Cu SAR-bis-PSMA at different dose levels, determine the ability of 64Cu SAR-bis-PSMA to detect primary prostate cancer and compare diagnostic properties of 64Cu SAR-bis-PSMA against 68-gallium PSMA-11, which was the standard-of-care for prostate cancer imaging in Australia (BD: Dec 1, 2021).
Today, Clarity executive chair Dr Alan Taylor said that the initial Propellor data "further substantiates the utility of 64-copper SAR-bis-PSMA in the diagnosis of prostate cancer".
"We have already commenced work towards our diagnostic phase III trials with 64-copper SAR-bis-PSMA and we look forward to engaging with the US Food and Drug Administration shortly as we get closer to our ultimate goal of improving treatment outcomes of people with cancer," Dr Taylor said.
Clarity was up four cents or 4.3 percent to 97.5 cents.

PROTEOMICS

Proteomics says the UK National Institute for Health and Care Excellence (Nice) medical technology briefing on Promarkerd is a "step towards … recommendation".
Proteomics said the Medtech Innovation Briefing was known as 'Nice advice' and was distributed to clinicians, managers and procurement professionals, confirming that Promarkerd was effective at predicting renal function decline in people with type 2 diabetes.
The company called it a "major milestone" towards reimbursement and widespread use in the UK, and that it would work towards the inclusion of the test in the Institute's guidelines.
Proteomics said that "independent experts appointed by Nice" advised that the technology was novel and was expected to be used in addition to standard care tests.
The company said that the Nice experts said that Promarkerd might allow the identification of high-risk patients earlier, which would alter the treatment they receive, leading to a decrease in the number of people developing end-stage renal disease, reducing hospitalization and the need for dialysis.
Proteomics managing-director Dr Richard Lipscombe said the briefing was "a major milestone".
"Selection of the test as an innovative technology worthy of Nice advice is an important step towards future recommendation for clinical use of Promarkerd in the UK," Dr Lipscombe said.
Proteomics was up four cents or 4.7 percent to 89.5 cents.

STARPHARMA

Starpharma says that Indonesia has approved marketing authorization for its Viraleze anti-viral nasal spray.
Starpharma said that it was in discussions with potential Indonesian distribution partners and was continuing regulatory processes in other South East Asian countries.
Starpharma chief executive officer Dr Jackie Fairley said that Indonesia was “the largest and most populous country in South East Asia, with more than 280 million people … [and was] an exciting market opportunity for Starpharma’s Viraleze nasal spray”.
“We have seen strong interest in Viraleze across Asia, including in Vietnam, and in Hong Kong and Macau where the product recently launched through major pharmacy chains, Mannings and Watsons, as well as selected supermarkets,” Dr Fairley said.
Starpharma was up 2.5 cents or 4.8 percent to 55 cents.

ONCOSIL

Oncosil says Hong Kong’s Hind Wing will distribute its Oncosil 32-phosphorus isotope for advanced pancreatic cancer in specified Chinese markets.
Oncosil said that under the three-year agreement, Hind Wing would have exclusive distribution rights to Hong Kong, Macau and China’s Greater Bay Area and Hainan special economic zone.
The company did not specify the commercial terms or minimum sales figures but said that “pricing will be based on agreed wholesale pricing and the agreement is subject to standard termination clauses”.
Oncosil was unchanged at 4.6 cents with 1.9 million shares traded.

INVEX THERAPEUTICS

Invex says it has the European Medicines Agency has accepted its paediatric investigation plan of presendin for idiopathic intracranial hypertension.
Invex said the plan outlined a study design for a 40-patient, 24-week trial, with a primary endpoint of change in pailloedema, or swelling of the optic disc, as measured by optical coherence tomography.
The company said the European Medicines Agency had accepted its request for a deferral, allowing it to begin the trial “after the receipt of positive data from … [its] phase III clinical trial in the adult [intracranial idiopathic hypertension] population”.
Invex said the study would be in in pubescent boys and girls aged less than 18 years and would not need to measure intracranial pressure (ICP) as an endpoint, “given that the positive effect of Presendin on ICP will have already been established in the … [adult] trial”.
Invex was unchanged at 58 cents.

RESPIRI

Respiri says the first patients in its two-month, Minnesota-based remote patient monitoring program have been enrolled.
Respiri said the pilot program, based at Minneapolis’ Minnesota Lung Centre, would use its Wheezo asthma device.
The company said it would receive remote patient monitoring revenues on a per patient per month basis, as well as sales revenues for its Wheezo devices.
Respiri was up 0.2 cents or five percent to 4.2 cents.

HEXIMA

Hexima says its board recommends that shareholders vote against all items of business, namely the removal of three existing directors and the appointment of a new director.
Hexima said that Daniel Tillet and Merchant Group had requisitioned an extraordinary general meeting to remove Scott Robertson, Michael Aldridge and Jason Nunn as directors and replace them with Merchant's chief financial officer and company secretary Chris Mews (BD: Dec 5, 2022).
Race Oncology executive director and chief scientific officer Dr Daniel Tillet acknowledged that he had joined the Perth-based Merchant Group in requisitioning the meeting and told Biotech Daily that he lived in Sydney.
Hexima said the meeting request was "a selfish use of company funds by the requisitioning shareholders" and unanimously recommended that shareholders vote against all resolutions at the meeting.
The company said that "to limit the cost of having to convene this general meeting, the meeting will be held as a physical meeting only" in Melbourne.
In June and July, Hexima fell on news that its phase II study of pezadeftide (HXP124) for onychomycosis was "inconclusive … [and did] not support moving directly into a phase III program" and it had begun the process of winding-up (BD: Jun 24; Jul 11, 2022).
According to Commsec, Hexima currently has six directors and one alternate director.
The meeting will be held at the offices of Arnold Bloch Leibler, Level 21, 333 Collins Street, Melbourne on January 31, 2023 at 10am (AEST).
Hexima was up 0.4 cents or 21.05 percent to 2.3 cents.

HEXIMA

Hexima says it has received $6,011,090 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Hexima said the rebate related to research and development expenditure for the year to June 30, 2022.
The company said the funds would be used to settle about $4.5 million of outstanding liabilities and it would then have cash and receivables between $2.95 million and $3.05 million and no other material tangible assets or liabilities.

PATRYS

Patrys 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 28.0 percent from 2.5 cents on December 13 to 3.2 cents today, and noted a "significant increase" in trading volume.
Patrys was up half a cent or 20 percent to three cents with 30.6 million shares traded.

PHARMAXIS

Mark Lampert and BVF say their substantial shareholding of 104,789,174 shares in Pharmaxis has been diluted from 16.59 percent to 14.58 percent.
The San Francisco and Grand Cayman Islands-based BVF said the dilution was the result of a placement of 84,295,725 by Pharmaxis on December 5, 2022.
In October, Pharmaxis said it hoped to raise $10 million in a two-tranche placement to institutional investors at six cents a share (BD: Oct 19, 2022).
Pharmaxis fell half a cent or 7.7 percent to six cents.

RACE ONCOLOGY

Race says Damian Clarke-Bruce has been appointed managing-director and chief executive officer, effective from February 1, 2023.
Race said Mr Clarke-Bruce was most recently the Warren, New Jersey-based Pharming Healthcare's head of marketing and rare disease commercial lead, and previously worked for Celgene, Novartis, Zimmer Spine, Biogen IDEC, BJC Health and Pharmacia/Searle.
The company said that Mr Clarke-Bruce would receive a base salary of $475,000 with a performance-based short-term incentive of up-to 40 percent of the base salary and, subject to shareholder approval, it would issue 755,671 long-term incentive options, exercisable at $3.30 each within five years.
Race said that interim chief executive officer Phil Lynch would return to his role as a non-executive director, and would work with Mr Clarke-Bruce to ensure a smooth transition.
Race fell three cents or 1.4 percent to $2.15.

PHARMAXIS

Pharmaxis says it has appointed Dr Simon Green as an independent, non-executive director, effective from December 16, 2022.
Pharmaxis said Dr Green worked for Genentech and Chiron Corp before joining CSL in 1998, where he was head of plasma research and development, and general-manager of CSL's manufacturing plants in Germany and Australia.
The company said that Dr Green was the founder and chief executive officer of Immunosis Pty Ltd a partner at Bioscience Managers and a director of Clover Corp.
Pharmaxis said that Dr Green held a Bachelor of Science from Melbourne's Monash University, and a Doctor of Philosophy from the University of Melbourne.

INOVIQ

Inoviq says director Prof Allan Cripps has resigned "due to health issues", effective immediately.
Inoviq said Prof Cripps had been a director at the company since 2020.
Inoviq chair Dr Geoff Cumming said the company was "sad to announce Allan's resignation, but are grateful for the significant contribution he has made in helping advance the company's cancer diagnostics pipeline and our commercialization strategy".
"His input has also been important in our transformation to a precision diagnostics company."
"I thank Allan for his passion and dedication to the company, and wish him all the best as he now focuses on his health and family."
Inoviq fell 5.5 cents or 7.4 percent to 68.5 cents.