Biotech Daily

Monday November 29, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 5%; OPTISCAN DOWN 10%**

*** BIOME $8m IPO FOR PROBIOTICS**

*** MAYNE: TGA APPROVES NEXTSTELLIS COMBINATION ORAL CONTRACEPTIVE**

*** RESAPP COUGH COUNTER WINS TGA APPROVAL, CE MARK**

*** VECTUS APPROVED TO 4th VB0004 DOSE COHORT**

*** KAZIA: GBM AGILE STUDY TAKES PAXALISIB TO CANADA**

*** BARD1, GRIFFITH UNI WORK ON EXOSOME OVARIAN, BREAST CANCER TESTS**

*** VGI TO USE ENDRA TAEUS FOR LIVER FAT SCREENING, MEASUREMENT**

*** ACTINOGEN ENROLS XANAMIA TRIAL**

*** ADALTA: I-BODY CAR-T-CELL IN-VITRO DATA, 2 PATENTS**

*** EPSILON REQUESTS 'VALENS AGREEMENT' TRADING HALT**

*** IMRICOR PAYS $280k FOR 2% OF MIRTLE MEDICAL**

*** ELLERSTON TAKES 8.7% OF ATOMO**

*** RACE FOUNDER DR WILLIAM GARNER BELOW 5%**

*** MERCATOR, WASHER FAMILY DILUTED IN EMYRIA**

*** EMYRIA APPOINTS DR KAREN SMITH EXECUTIVE DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.54 percent on Monday November 29, 2021, with the ASX200 down 39.5 points to 7,239.8 points. Nine of the Biotech Daily Top 40 stocks were up, 26 fell and five traded unchanged.

Pharmaxis was the best, up 0.5 cents or five percent to 10.5 cents, with 2.1 million shares traded. Dimerix climbed 4.35 percent; Actinogen was up 3.7 percent; Kazia and Osprey rose more than two percent; Volpara was up 1.8 percent; with Neuren, Opthea, Pro Medicus and Resmed up by less than one percent.

Optiscan led the falls, down two cents or 10 percent to 18 cents, with 176,684 shares traded. Resonance, Telix and Uscom fell more than four percent; Alterity, Avita, Cyclopharm and Paradigm lost more than three percent; Antisense, Cynata, LBT, Medical Developments, Oncosil, Patrys, Prescient, Proteomics and Starpharma shed two percent or more; Clinuvel, Compumedics, CSL, Genetic Signatures, Immutep, Nanosonics, Next Science, Orthocell and Universal Biosensors were down one percent or more; with Cochlear and Mesoblast down by less than one percent.

BIOME AUSTRALIA

Biome says it has raised $8 million at 20 cents a share to list on the ASX under the code BIO tomorrow to commercialize its “bio-therapeutics and complementary medicines”.
Founded in 2018, Biome said that capital raising valued it at $40 million and the funds would be used “to accelerate commercialization and product development”.
The company said it developed, licenced, commercialized and distributed “evidence-based live bio-therapeutics and complementary medicines with health benefits backed by clinical research”.
Biome said that the complementary medicine industry was worth about $5.69 billion and “seven in 10 Australians regularly use complementary medicines”.
Biome founder and managing-director Blair Norfolk said the company had “clinical evidence paired with a unique distribution and sales strategy that is disrupting the market”.
“We are not a vitamins company simply selling probiotics,” Mr Norfolk said.
“We are a commercialized biotech company specializing in precision probiotics that are backed by clinical evidence and support health professionals improve the health outcomes of their patients,” Mr Norfolk said.
“At least 40 percent of the share register are health industry experts, including doctors, surgeons, pharmacists and health practitioners,” Mr Norfolk said.
“This community of health experts have seen the science behind Biome’s products and they’re backing us,” he said.
“Probiotics is the one category in complementary medicine that stands out in terms of the level of clinical evidence available to prove its efficacy, and we’re at the forefront of this,” Mr Norfolk said.
In a media release, Biome said that its “strain-specific probiotics and complementary medicines go beyond just gut health and have a measurable effect on helping to prevent and support the management of a number of serious diseases and health concerns, including poor bone health, iron malabsorption, mild eczema, [irritable bowel syndrome] and mood and sleep disturbances”.
The company said that 11 of its products were listed with the Australian Therapeutic Goods Administration, and it distributed 22 products through more than 2,300 community pharmacies, health practitioners and health food shops in Australia, New Zealand and the UK, with some products available online.
“Our products sit on the most valuable shelf in the pharmacy, next to the pharmacist at the script-in counter,” Mr Norfolk said. “This is a strategic decision, not a regulatory one.”
A Biome spokesperson told Biotech Daily the company’s lead brand Activated Probiotics was a “practitioner only” product only available “with a prescription or recommendation by a health professional” and some products could be recommended by naturopaths.
Mr Norfolk told Biotech Daily that “at this point in time we're not developing any medicines that require a qualified medical practitioner's prescription”.
“Our practitioner-only Activated Probiotics range is backed by clinical research and is currently positioned within the S3 category in pharmacy to facilitate adjunct prescribing opportunities by pharmacists and other health professionals, who can also access the products via various distributors outside of pharmacy,” Mr Norfolk said.
“Biome is currently involved in two ongoing placebo-controlled, randomized, double-blind clinical trials on two of its products in Australia and, depending on the outcomes, would increase the [intellectual property] associated with those two products within the Australian market,” Mr Norfolk said.
The company said its chair was Ilario Faenza with directors Mr Norfolk and former Circadian-Opthea director Dominique Fisher.
Cannacord Genuity (Australia) was the lead manager to the offer.

MAYNE PHARMA GROUP

Mayne Pharma says that the Australian Therapeutic Goods Administration has approved Mithra Pharmaceuticals' Nextstellis combination oral contraceptive.
In April, Mayne said the US Food and Drug Administration had approved the 3mg of dropirenone and 14.2mg of plant-based native oestrogen, oestetrol, developed with the Liege, Belgium-based Mithra Pharmaceuticals (BD: Apr 16, 2021).
In 2019, the company said it would pay Mithra up-to $US295 million over 20 years to commercialize the combination contraceptive in the US (BD: Oct 2, 2019).
Today, Mayne said it expected the commercial launch of Nextstellis by mid-2022, which would have five years of market exclusivity because it contained a new chemical entity.
Mayne chief executive officer Scott Richards said it was 10 "years since Australian women have had a new contraceptive hormone to consider with their doctor".
"Nextstellis offers an effective, safe and well-tolerated pill with excellent cycle control and has demonstrated low impact on certain parts of the body," Mr Richards said.
Mayne fell one cent or 3.45 percent to 28 cents with 5.9 million shares traded.

RESAPP HEALTH

Resapp says its cough counter smartphone app has Australian Therapeutic Goods Administration clearance and Conformité Européenne (CE) mark certification.
Resapp said the software would aid in diagnosing and managing respirator disease, and was already being used by Astrazeneca for patient monitoring in a lung cancer clinical trial and an Asthma management support program.
Resapp managing-director Dr Tony Keating said the ability to measure cough frequency using only a smartphone application was highly scalable that had a number of clinical applications.
"After our success in partnering with Astrazeneca, we are particularly excited about the opportunity in supporting clinical trials, where cough can provide important insight into the progression of disease and efficacy of treatment," Dr Keating said.
Resapp was up 0.3 cents or 5.4 percent to 5.9 cents with two million shares traded.

VECTUS BIOSYSTEMS

Vectus says the third of five planned cohorts in its phase I trial of VB0004 for high blood pressure has been reviewed and cleared to proceed to its next dose level.
Vectus said the phase I/Ib, double-blind, randomized, placebo-controlled, dose escalating study of VB0004 had dosed the first three cohorts at 2mg, 10mg and 30mg, respectively, daily for 14 days, with the fourth cohort to receive 100mg.
The company said that there had been no adverse events reported to date.
Vectus said that oral VB0004 was being administered to healthy volunteers and to patients with mild to moderate hypertension with low cardiovascular risk.
The company said that interim pharmaco-kinetic analysis showed that plasma concentrations increased to maximal concentration about eight hours after dosing and VB0004 had a plasma half-life of 9.5 to 10 hours.
Vectus said the preliminary data suggested that VB0004 would be amenable to once daily dosing "a desirable feature in medications for chronic conditions such as hypertension, heart failure, kidney failure and pulmonary fibrosis".
Vectus fell 11 cents or 7.6 percent to $1.34.

KAZIA THERAPEUTICS

Kazia says the GBM (glioblastoma multiforme) Agile study has added its first Canadian site evaluating its Paxalisib for glioblastoma, with more sites to follow.
Kazia said that the GBM Agile study was a multi-drug platform study designed to identify promising new therapies for glioblastoma (BD: Dec 11, 2019).
The company said that it expected the trial to expand to Europe and China to occur in the "coming months".
Kazia was up three cents or 2.2 percent to $1.41.

BARD1 LIFE SCIENCES

Bard1 says it has a research agreement with the Gold Coast, Queensland-based Griffith University to develop an exosome-based RNA test for ovarian and breast cancers.
Bard1 said that plasma, or blood, exosomes would be isolated at its US facility using its Exo-Net technology and transferred to Griffith University's mucosal immunology research group for analysis "using custom-built Nanostring expression assays".
The company said the project aimed to develop exosome-based RNA tests for earlier detection of breast and ovarian cancers by combining its Exo-Net exosome capture and biomarker technologies.
Bard1 chief scientific officer Dr Greg Rice said that aim of the agreement was "to enable the targeted profiling of exosomal RNAs, thereby providing a more informative liquid biopsy for the presence of cancer".
Bard1 was up 3.5 cents or 3.4 percent to $1.075.

VGI HEALTH TECHNOLOGY (FORMERLY AZURE BIOTECHNOLOGY, INVICTUS)

VGI says it will use Endra's 'thermo acoustic enhanced ultrasound' to support patient screening and biomarker measurement in its trial of IVB001 for fatty liver disease.
VGI said that the Ann Arbor, Michigan based Endra Life Sciences 'thermo acoustic enhanced ultrasound' (Taeus) was a "cost-effective, non- invasive … [technology, expected] to deliver time and cost savings for the study through simpler, faster and non-invasive biomarker measurements of liver fat".
The company said it expected its 80-patient, randomized, controlled, phase II trial of IVB001 for fatty liver disease to begin early next year (BD: Sep 14, 2021).
On the National (formerly Newcastle) Stock Exchange, VGI was untraded at 25 cents.

ACTINOGEN MEDICAL

Actinogen says that it has reached its target of 105 participants for its Xanamia trial assessing the efficacy of Xanamem for Alzheimer's disease.
Actinogen said the trial would assess the efficacy of both 5mg and 10mg daily doses of Xanamem compared to placebo in patients aged between 50 and 80 years, over six weeks, to confirm the minimum effective dose to improve cognition.
The company said it expected results of the trial by July 2022.
Actinogen managing-director Dr Stephen Gourlay said that completing enrolment was "a significant milestone in the company's program to evaluate its lead molecule, Xanamem, for Alzheimer's disease, Fragile X syndrome and depression".
"We look forward to the Xanamia trial's confirmation of the effects of Xanamem on working memory and other measures of cognitive ability," Dr Gourlay said.
Actinogen was up half a cent or 3.7 percent to 14 cents with 12.9 million shares traded.

ADALTA

Adalta says that its i-body chimeric antigen receptor-T-cell therapy is capable of killing glioblastoma and colorectal cancer without attacking original cells, in-vitro.
In August, Adalta said it had a collaboration with Adelaide's Carina Biotech to develop i-body enabled chimeric antigen receptor T-cells (Car-T-cells) (BD: Aug 24, 2021)
Adalta previously said that i-bodies were proteins from the intermediate group of immunoglobulin or immunoglobulin-like domains.
Today, the company said that 97 percent of T-cells in culture incorporated the i-bodies chimeric antigen receptor to become i-Car-T-cells "which then expanded during manufacturing at the rates expected".
Adalta said that i-body enabled Car-T-cells were capable of "killing a cell line engineered to overexpress the i-body's target, but did not kill the original cells", in vitro.
The company said that "i-body enabled Car-T cells were capable of … killing of two colorectal cancer cell lines and, less effectively, a glioblastoma brain cancer cell line known to express the i-body's target" in-vitro.
Adalta managing-director Dr Tim Oldham said the company looked forward to "first experimental results on agreed targets under the collaboration" by July 2022.
In the same announcement, Adalta said that it had been issued patents from Singapore's Intellectual Property Office and IP (intellectual property) Australia, titled 'CXCR4 binding molecules' relating to the i-body sequence used in its lead product, AD-214 for idiopathic pulmonary fibrosis, providing protection until January 8, 2036.
Adalta was up 0.2 cents or 2.5 percent to 8.2 cents.

EPSILON HEALTHCARE

Epsilon has requested a trading halt "pending the release of an announcement with respect to an update on the company's agreement with the Valens Company".
In September, Epsilon said it had a partnership with the Kelowna, British Columbia-based Valens to manufacture Valens marijuana at the Epsilon Southport Queensland facility and Valens had ordered $540,000 of marijuana (BD: Sep 9, 17, 20, 2021).
Trading will resume on December 1, 2021 or on an earlier announcement.
Epsilon last traded at 11.5 cents.

IMRICOR MEDICAL SYSTEMS

Imricor says it has paid $US200,000 ($A280,360) for about two percent of the North Andover, Massachusetts-based Mirtle Medical.
Imricor said that in return for the investment, as well as its two percent equity, it would receive three of Mirtle's 12-lead electrocardiogram systems, worth $US125,000 each for use in its European ventricular tachycardia ablation trial, non-voting board observer rights, as well as a right of first negotiation to purchase Mirtle following a third-party offer for Mirtle or to exclusively licence of Mirtle's technology to a third party for magnetic resonance imaging (MRI) enabled cardiac ablation.
The company said the board observer position would terminate should Mirtle raise $US10 million or more, close an initial public offer or be acquired.
Imricor fell two cents or 1.6 percent to $1.20.

ATOMO DIAGNOSTICS

Sydney's Ellerston capital says it has increased its holding in Atomo from 41,586,285 shares (7.31%) to 49,329,568 shares (8.68%).
Ellerston said that between September 16 and November 24, 2021, it bought shares with the largest single purchase 2,747,700 shares for $523,110 or 19.0 cents a share.
Atomo was unchanged at 20 cents.

RACE ONCOLOGY

Race founder Dr William Garner says he has decreased his substantial shareholding from 9,230,000 shares (6.39%) to below the five percent substantial level.
In two announcements, the San Juan, Puerto Rico-based Dr Garner said that between August 6 and November 22, he sold 1,281,150 shares for $4,420,908 or $3.45 a share and between November 23 and 26, 2021 he sold 492,893 shares for $1,627,335 or $3.31 a share and was diluted in share issues.
Race fell four cents or 1.2 percent to $3.28 with 382,280 shares traded.

EMYRIA

Craig Darby, Dr Stewart and Dr Patrizia Washer, Dr Mal Washer and Mercator Shipwrights Pty Ltd say their holdings in Emyria have been diluted.
Last week, Emyria said it had raised $5 million from the Dr Andrew 'Twiggy' Forrest-controlled Tattarang which would hold 7.3 percent of the company (BD: Nov 22, 2021).
Today, Dr Stewart and Dr Patrizia Washer said their 48,550,499 share-holding had been diluted from 21.87 percent to 17.99 percent.
Mr Darby, the husband of Elaine Darby, Dr Mal Washer's daughter and Dr Stewart Washer's sister, said his 22,709,790 shares in Emyria had been diluted from 10.74 percent to 8.28 percent following the placement.
Dr Mal Washer said that his 19,600,000 share-holding had been diluted from 9.27 percent to 7.15 percent.
Mercator Shipwrights, believed to be a vehicle for director Matt Callahan, said its 19,600,000 share-holding in Emyria had been diluted from 9.27 percent to 7.15 percent.
Emyria was up four cents or 9.1 percent to 48 cents with 2.8 million shares traded.

EMYRIA

Emyria says it has appointed Dr Karen Smith as an executive director to lead the company's US-based marijuana and psychedelic programs.
Emyria said that Dr Smith had previously overseen more than 100 clinical trials and 20 drug registrations and was previously Jazz Pharmaceuticals chief medical officer and worked for Allrgan Plc, Astrazeneca and Bristol-Myers Squibb.
The company said that Dr Smith held a Bachelor of Medicine and Bachelor of Surgery from England's University of Warwick, a Master of Law from England's University of Salford, a Master of Business Administration from the Armidale, New South Wales-based University of New England and a Doctor of Philosophy from the University of California Los Angeles and the University of Western Australia.