Biotech Daily

Wednesday December 2, 2020

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: NEXT SCIENCE UP 9%; ONCOSIL DOWN 12%**

*** FDA APPROVES ACADEMIC USE OF TELIX 68GA-PSMA PROSTATE IMAGING**

*** TGA OKAYS TELIX PROSTATE CANCER THERAPY TRIAL**

*** FDA FAST TRACK FOR MESOBLAST REMESTEMCEL-L FOR COVID ARDS**

*** 4D, MIAMI UNI 'BREAKTHROUGH' LUNG PROGRAM**

*** RHYTHM: BIOTEM TO MANUFACTURE COLOSTAT COLORECTAL CANCER TEST**

*** BARD1 CLARIFIES HTERT TEST TEXAS CUSTOMER; CHINA PATENT**

*** SIMAVITA LOSES DELISTING VOTE, CAPITAL REDUCTION PASSED**

*** ZELIRA, SPRINJENE US MARIJUANA CBD TOOTHPASTE LAUNCH**

*** CRESO $414k ANIMAL MARIJUANA ORDERS TAKE 2020 TOTAL TO $975k**

*** GENETIC TECHNOLOGIES REVISES TALIAZ PREDICTIX DEAL**

*** AMPLIA RECEIVES $533k R&D TAX INCENTIVE**

*** PERENNIAL TAKES 12% OF MICRO-X**

*** MERCHANT REDUCES TO 9% OF RACE**

*** KIM HOGAN, JK BELOW 5% OF INVEX**

*** ONCOSIL 'TERMINATES' CEO DANIEL KENNY; DR CHRIS ROBERTS EXECUTIVE**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Wednesday December 2, 2020, with the ASX200 up 1.7 points to 6,590.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 15 fell and 14 traded unchanged. All three Big Caps fell.

Next Science was the best, up 11.5 cents or 9.2 percent to $1.37, with 471,068 shares traded. Mesoblast and Telix climbed more than seven percent; Dimerix was up 3.9 percent; Clinuvel, Kazia, Orthocell, Polynovo, Proteomics and Volpara were up more than one percent; with Nanosonics up 0.9 percent.

Oncosil led the falls on the "termination" of CEO Daniel Kenny (see below), down two cents or 12.1 percent to 14.5 cents, with 21.3 million shares traded. Compumedics lost 6.7 percent; Immutep, Imugene and Resonance retreated more than three percent; Genetic Signatures, Nova Eye and Starpharma shed more than two percent; Avita, Cochlear, CSL, Cynata, Paradigm, Resmed and Universal Biosensors were down one percent or more; with Medical Developments, Neuren and Pro Medicus down by less than one percent.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has approved the institutional use of 68Ga-PSMA-11 for prostate cancer imaging at the University of California.

Telix said the approval for use at the University of California Los Angeles (UCLA) and the University of California San Francisco (UCSF) was under an “academic new drug application submission”.

The company said the “highly anticipated event within the US nuclear medicine industry … paves the way for the FDA to approve commercially available products, enabling the broader availability of this important technology to American men with prostate cancer”.

Telix quoted the US Prostate Cancer Foundation saying that “with this FDA approval, 68Ga-PSMA-11 PET scanning will be available at only UCLA and UCSF”.

“Radiopharmaceutical companies will likely apply for expedited FDA approval to make 68Ga-PSMA-11 kits so that this technique will eventually be available to more patients throughout the US,” the company quoted the Foundation saying.

Telix chief executive officer Dr Christian Behrenbruch congratulated staff at the University of California “for their success in achieving this limited institutional approval for 68Ga-PSMA”.

Telix was up 28 cents or 7.5 percent to $4.00 with 3.6 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has Australian Therapeutic Goods Administration and ethics approval for a nine-patient, phase I study of TLX592 for the treatment of advanced prostate cancer.

Telix said it had ethics committee approval and TGA clinical trial notification for the three-cohort, dose-escalation first-in-human trial.

The company said that patients would be given three dose levels of 2mg, 10mg and 20mg total antibody mass dose of TLX-592, to determine the safety and tolerability, pharmacokinetics, whole body biodistribution and radiation dosimetry of 64Cu-TLX592 using positron emission tomography (PET) as a proxy for 225Ac-TLX592-TAT.

Telix said that like its existing TLX591 antibody development program, TLX592 targeted prostate specific membrane antigen (PSMA), a target that is almost ubiquitously expressed by prostate cancer cells.

The company said that TLX592 had been engineered to clear more rapidly from a patient’s circulation, making it suitable for use as a targeting agent for actinium-225 (225Ac), and actinium was a potent therapeutic alpha-emitting radionuclide and treatment with alpha-emitting radionuclides, commonly referred to “targeted alpha therapy” or TAT.

The company said that the phase I copper64 PSMA imaging and bio-distribution (Cupid) trial was a single centre, open-label trial to evaluate the safety and tolerability, pharmacokinetics, biodistribution and radiation dosimetry of TLX592 in patients with advanced prostate cancer.

Telix chief executive officer Dr Chris Behrenbruch said the company’s technology “fundamentally underpins our ability to develop new TAT treatments for patients with metastatic cancer”.

“In the case of TLX592, the clinical objective is to treat patients with prostate cancer that have a low disease burden for which alpha therapy is ideally suited, as well as potentially treating patients that no longer respond to conventional lutetium PSMA therapy,” Dr Behrenbruch said.

“Telix has one of the broadest [targeted alpha therapy] pipelines in the industry and we are pleased to see our [research and development] efforts heading into the clinic,” Dr Behrenbruch said.

MESOBLAST

Mesoblast says the US Food and Drug Administration has granted fast track status for remestemcel-L for Covid-19 related acute respiratory distress syndrome (Ards).
Mesoblast said fast track designation was granted when a therapy showed “the potential to address unmet medical needs for a serious or life-threatening disease” and intended to facilitate development and expedite review of therapies to treat conditions with no or limited treatment options so the product could be approved expeditiously.
The company said that under fast track designation, a biologic licence application for remestemcel-L was eligible for both rolling submission and priority review
Mesoblast said that Ards was the primary cause of death in patients with Covid-19 and data provided to the FDA supporting the potential of remestemcel-L to address the unmet medical need of Covid-19 Ards included a pilot study at New York’s Mt Sinai Hospital in which nine of 12 ventilator-dependent patients with moderate to severe Ards were successfully discharged from hospital a median of 10 days after receiving two intravenous doses of remestemcel-L (BD: Apr 24, 2020).
The company said its up-to 300-patient, phase III trial of remestemcel-L for Covid-19 Ards was two-thirds enrolled, with two interim analyses recommending the trial continue, and a final interim analysis planned when 180 patients complete 30 days of follow-up.
Mesoblast was up 30 cents or 7.3 percent to $4.43 with 21.5 million shares traded.

4D MEDICAL

4D says that it will work with the University of Miami Health System to establish a functional lung imaging research program to advance breakthrough lung technologies.
4D said its first US research program would use its XV lung imaging technology to improve assessment and outcomes for patients with chronic lung diseases.
The company said the program would comprise pre-clinical and clinical studies for “a targeted approach to the therapeutic options available to patients”.
4D said the program intended to assist researchers and physicians “to accurately diagnose ventilatory abnormalities in patients, therefore providing treatment and management options that are targeted and more effective”.
The company said lung-related conditions included emphysema, cystic fibrosis, pulmonary hypertension, pulmonary embolism and lung cancer.
4D said its XV LVAS converted sequences of x-ray images into four-dimensional data, allowing physicians to better diagnose and treat patients with respiratory diseases.
4D was up 35 cents or 14.9 percent to $2.70 with 1.5 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has appointed Apprieu, France based Biotem to manufacture its Colostat colorectal cancer test-kit.
Rhythm said that Biotem had more than 40 years immunoassay development and manufacturing experience and would optimize and validate the manufacturing procedure and produce large-scale quantities of the test-kit.
The company said that small-scale manufacturing of a prototype kits would begin this year with Rhythm undertaking quality assurance and product verification.
Biotem chief executive officer Clarence Deffaud said the company understood “the cancer screening opportunity and look forward to leveraging our history in developing and manufacturing antibody diagnostic tests to make Colostat a success”.
Rhythm was up 12 cents or 19.7 percent to 73 cents with 3.6 million shares traded.

BARD1 LIFE SCIENCES

Bard1 says US distributor Statlab Medical Products has converted an existing customer to its hTERT adjunct bladder cancer test, with no minimum sales quantities.

Last week, Bard1 said it had gained an unnamed high-volume Texas-based customer for its human telomerase reverse transcriptase (hTERT) adjunct urine cytology test for bladder cancer (BD: Nov 23, 2020).

Today, the company said the unnamed customer had received their first order from Statlab which was not considered material, and was "not required to purchase a minimum quantity of product from Statlab, nor does it have any binding commitments and therefore the financial benefit is unable to be quantified at this stage".

Bard1 said it had not signed a direct contract with the customer or entered into any new distribution arrangements with Statlab.

Separately, the company said that the People's Republic of China's Patent and Trademark Office had granted a patent titled 'Method of Detecting Cancer' protecting hTERT in China until 2035.

Bard1 said the patent covered the use of the hTERT antibody to resolve inconclusive cytology and detect malignant cells.

Bard1 was up four cents or 6.1 percent to 70 cents.

SIMAVITA

Simavita said its special meeting voted 66.6 percent in favor of delisting from the ASX, but the special resolution required a 75 percent majority.

Simavita said the second special resolution to approve a capital reduction returning up to $20,000 per shareholder was passed with 99.87 percent of votes in favor.

The company said that about 89 percent of all shares were voted at the meeting.

According to the Simavita's annual report 343,571,096 votes opposing the delisting from the ASX amounted to 60.9 percent of the company.

Simavita said it intended "to continue to pursue its reorganization strategy".

Simavita was unchanged at 1.6 cents with 4.3 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it will launch marijuana-based cannabidiol toothpaste Sprinjene in the US.

Zelira said the product was "the first of several scientifically formulated, hemp-derived, oral care products containing cannabinoids, including broad-spectrum CBD, that will be created and launched under the Zelira Oral Care subsidiary" (BD: Sep 8, 2020).

The company said that incorporating cannabidiol into oral and dental care resulted in "health benefits including naturally eliminating decay-causing bacteria, reducing gum inflammation, restoring pH balance and increasing remineralization, reducing bone loss associated with gum disease and helping to improve overall health".

Zelira said the CBD Toothpaste used broad-spectrum, tetrahydrocannabinol-free cannabidiol distillate derived from hemp, providing "the full benefits of a wide array of cannabinoids, with no psychoactive effects".

In September, Zelira said Health and Natural Beauty USA Corp would manufacture the products, including the CBD toothpaste developed by Sprinjene chief executive officer and founder Dr Sayed Ibrahim, and the Piscataway, New Jersey-based Sprinjene gluten-free, cruelty-free, vegan, kosher and halal oral care products were manufactured by Health and Natural Beauty USA Corp, which was located at the same address as Sprinjene.

Zelira was up 0.9 cents or 11.1 percent to nine cents with 11.6 million shares traded.

CRESO PHARMA

Creso says it has three purchase orders for its Anibidiol animal health marijuana products worth $414,000.
Creso did not disclose the source of the orders but said the values were denominated in Swiss Francs and the orders took its total for 2020 for animal marijuana products to about $975,000 “outlining the strong demand for the company’s industry leading products”.
The company said that revenue for the first half of 2020 was $529,687.
Creso was up 1.3 cents or 26.0 percent to 6.3 cents with 272.95 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies has revised the details of its three-year agreement with Israel’s Taliaz to distribute its Predictix depression test in Australia, New Zealand and the US.
Yesterday, Genetic Technologies said it had committed to a minimum 7,000 tests for $30,000, subject to regulatory clearances in Australia and the US, and it expected to make Predictix available in Australia and New Zealand by October 2021.
Today, the company said it had committed to providing 8,000 tests over three years with a minimum cost of $200,000.
Genetic Technologies fell 0.15 cents or 17.65 percent to 0.7 cents with 3.4 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it has received a $533,521 Research and Development Tax Incentive for expenditure in the year to March 31, 2020.
Amplia said the expenditure was primarily incurred in the manufacture and toxicology studies of the its clinical-stage focal adhesion kinase inhibitor AMP945.
Amplia was unchanged at 22.5 cents.

MICRO-X

Perennial Value Management says it has increased its substantial shareholding in Micro-X from 39,868,853 shares (11.16%) to 43,887,744 shares (12.21%).
The Sydney-based Perennial said that it bought the shares between November 4 and 27, 2020, with the single largest purchase 2,071,598 shares for $567,621 or 27.4 cents a share.
Micro-X was up half a cent or 1.6 percent to 32 cents.

RACE ONCOLOGY

Merchant Funds Management says it has reduced its substantial shareholding in Race from 13,356,668 (10.37%) to 11,733,333 shares (9.16%).
The Perth-based Merchant said that between August 1 and November 27, 2020, bought, sold and transferred shares with the single largest sale 1,433,333 shares for $2,424,429 or an average of $1.69 a share.
Race fell six cents or 2.9 percent to $2.01.

INVEX THERAPEUTICS

JK Nominees says it has reduced its holding to below the five percent substantial shareholder level.

In May, the Cotttesloe, Western Australia-based JK said its 4,000,000 share-holding in Invex had been diluted from 7.27 percent to 5.92 percent in the $26.2 million capital raising at $1.30 a share (BD: May 22, 28, 2020).

Today, JK Nominees director Kim Hogan said that between June 24 and December 1, 2020, the company sold 454,000 shares for $256,999 or an average of 56.6 cents a share.

Invex was unchanged at 80 cents.

ONCOSIL MEDICAL

Oncosil says that chief executive officer Daniel Kenny “has been terminated, effective today”, with chair Dr Chris Roberts assuming the role of executive chair.

Oncosil said the board “would like to thank Daniel for his services and contribution to Oncosil over the last six years”.

The company said that it would begin a replacement process.

Oncosil said that former Cochlear chief executive officer Dr Roberts had been the company’s non-executive chair since May 2017.

Oncosil fell two cents or 12.1 percent to 14.5 cents with 21.3 million shares traded.