Biotech Daily

Tuesday March 30, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: KAZIA UP 10%; ACTINOGEN DOWN 13%**

*** KAZIA $382m+ SIMCERE PAXALISIB BRAIN CANCER CHINA DEAL**

*** DORSAVI, MEDTRONIC $432k WEARABLE SENSORS EXTENSION**

*** SWANSON REED: RDTI REGISTRATION CLOSES APRIL 30**

*** ANALYTICA CHINA PERICOACH J-V**

*** RACE TRIALS BISANTRENE FOR EXTRA-MEDULLARY AML**

*** BOTANIX BTX1702 FOR INFLAMMATORY ROSACEA TRIAL APPROVAL**

*** DIMERIX TAKES $5m PETER MEURS LOAN**

*** AVITA: 15 RECELL ABSTRACTS AT AMERICAN BURN MEETING**

*** RECCE GRANTED EUROPEAN R327, R529 PATENT**

*** CANN GLOBAL: CANNTAB MARIJUANA EXPORT LICENCE**

*** NOXOPHARM DILUTED TO 24% OF NYRADA**

*** ALTNIA DILUTED TO 7% OF NYRADA**

*** ELEANORE GOODRIDGE BELOW 5% IN NYRADA**

*** TRUDELL TAKES 19% OF ADHERIUM**

*** ONE FUNDS DILUTED TO 6% OF ADHERIUM**

MARKET REPORT

The Australian stock market fell 0.9 percent on Tuesday March 30, 2021, with the ASX200 down 61.1 points to 6,738.4 points. Seven of the Biotech Daily Top 40 stocks were up, 26 fell and seven traded unchanged. All three Big Caps fell.

Kazia was the best, up 14.5 cents or 10 percent to $1.595, with 714,785 shares traded. Antisense climbed five percent; Imugene and Paradigm improved four percent or more; Next Science was up 3.9 percent; Oncosil rose 2.2 percent; with Neuren up 1.4 percent.

Actinogen led the falls, down 0.5 cents or 12.8 percent to 3.4 cents, with 10 million shares traded. Prescient lost 9.1 percent; Immutep was down 8.4 percent; Starpharma and Universal Biosensors were down more than six percent; Medical Developments fell 5.3 percent; Compumedics, Impedimed, Optiscan, Pro Medicus and Resonance retreated four percent or more; Alterity, Dimerix, Nanosonics, Orthocell, Patrys and Proteomics were down three percent or more; Amplia, Avita, Clinuvel, Cynata, Mesoblast and Opthea shed two percent or more; Cochlear, CSL, Polynovo and Telix were down more than one percent; with Cyclopharm and Resmed down by less than one percent.

KAZIA THERAPEUTICS

Kazia says it has a more than $US292 million ($A381.6 million) deal with Simcere Pharmaceutical Group to commercialize paxalisib for brain cancers in Greater China.
Kazia said it would receive an upfront payment of $US11 million, comprising $US7 million in cash and a $US4 million equity investment at a 20 percent premium to recent trading, along with milestone payments of up to $US281 million for glioblastoma, with further milestones payable for indications beyond glioblastoma, and mid-teen percentage royalties on commercial sales.
The company said that Simcere would assume responsibility for the development, registration, and commercialization of paxalisib in Greater China, including the People's republic of China, Hong Kong, Macau and Taiwan.
Kazia said it retained the rights to the development and commercialisation of paxalisib, formerly GDC-0084, in all other territories and will continue to drive forward the GBM AGILE pivotal study as planned, including in China.
The company said the funds would be applied to the further development of paxalisib.
Kazia said that Simcere was one of China's leading pharmaceutical companies, with more than 40 marketed products and an extensive development pipeline, with a primary focus in oncology, central nervous system disease and autoimmune disease.
Kazia said that paxalisib was currently the subject of six other brain cancer studies beyond glioblastoma.
Kazia chief executive officer Dr James Garner said that China was "one of the world's largest pharmaceutical markets, with specific requirements and opportunities for innovative oncology products".
"Simcere's track record of success is unrivalled, and they bring to paxalisib first-class capabilities in clinical development, regulatory affairs, and commercialization," Dr Garner said.
Kazia said that the transaction satisfied the conditions for the fourth milestone in its 2016 purchase of Glioblast Pty Ltd and would result in the issue of escrowed shares to Glioblast shareholders.
The company said that a phase II study of paxalisib in patients with newly diagnosed glioblastoma with unmethylated MGMT gene promotor status showed "highly encouraging signals of clinical efficacy" (BD; Apr 7, 2020).
In January, Kazia said recruitment had begun for paxalisib in the glioblastoma Agile platform study, which was expected to serve as the basis for registration in key territories (BD: Jan 17, 2021).
Kazia was up 14.5 cents or 10 percent to $1.595 with 714,785 shares traded.

DORSAVI

Dorsavi says its agreement with Medtronic has progressed to the second stage of optimizing its wearable sensors, valued at about $US330,000 ($A430,982).
Last year, Dorsavi said it had an initial up-to 12-month agreement with the Dublin-based Medtronic to evaluate and test its wearable sensors to assess patients undergoing surgical evaluation (BD: Dec 9, 2020).
Today, the company said it would work with Medtronic to optimize the technology following data capture and data analysis.
Dorsavi said the project was expected to be conducted in about 12 months and would involve data analysis of patients wearing its medical grade wearable sensors.
Dorsavi fell 0.3 cents or 7.3 percent to 3.8 cents with 15.3 million shares traded.

SWANSON REED

Research and development tax advisor Swanson Reed says that last year's Covid-19 related extended research and development tax incentive deadline no longer applies.
Swanson Reed director Damian Smyth told Biotech Daily that last year the Federal Government extended the deadline from April 30 to June 30, but that no longer applied and the deadline for this year's applications would be April 30, 2021.
Mr Smyth said that the Research and Development Tax Incentive registration applications were due 10 months after the end of an income year, so the statutory deadline for companies to register research and development activities for the year to June 30, 2020 would be April 30, 2021.
Mr Smyth said that applications must provide Ausindustry with details of the experimental process of core research and development activities: hypothesis, observations and conclusions; why the technical knowledge generated by a core activity is new; how registered supporting research and development activities specifically relate to a corresponding core activity; and how a company has identified research and development activities within a project, rather than registering all project activities.
Swanson Reed said that the Australian Taxation Office had published draft Taxation Determination TD 2020/D1, setting out how the 'at-risk rule' applies to Jobkeeper payments received by a company registering research and development activities and firms should be "mindful of this position".

ANALYTICA

Analytica says it has a joint venture with two companies to manufacture and distribute its Pericoach intra-vaginal pelvic floor monitor in China, Macau, Hong Kong and Taiwan.
Analytica said the joint venture with the Hebei province Nacol Bio-Technology Co and Shijiazhuang Biosphere Pty Ltd would see the Pericoach pelvic floor exercise system for stress urinary incontinence registered as a class II medical device with the Chinese Food and Drug Administration which would allow it to be a prescription treatment.
Analytica said Pericoach would be distributed through the partners' networks of hospitals and postpartum organizations in 100 cities and more than 30,000 professionals.
The company said it would hold 20 percent of the joint venture with Heibei Nacol holding 65 percent and Shijiazhuang Biosphere with 15 percent, it would be entitled to 15 percent royalty income from joint venture sales, would have two board seats in the company, and would retain rights outside the Greater China area.
Analytica was up 0.1 cents or 33.3 percent to 0.4 cents with 182.8 million shares traded.

RACE ONCOLOGY

Race says the New South Wales University of Newcastle will investigate the use of Bisantrene for extra-medullary acute myeloid leukaemia, in mice.
Race said the study would be led by Prof Nikki Verrills who previously ran its pre-clinical breast and ovarian program (BD: Nov 24, 2020; Feb 23, Mar 9, 2021).
The company said the study aimed to provide data for Bisantrene to be classified as an orphan drug by the US Food and Drug Administration under the 505(b)(2) process.
Race said that extra-medullary acute myeloid leukaemia occurred when the leukaemia spread from the bone marrow and formed solid tumors in the skin, breast, kidney, brain or other organs, with up to 22 percent of acute myeloid leukaemia patients having the extramedullary form of the disease.
Race was unchanged at $3.84 with 345,441 shares traded.

BOTANIX PHARMACEUTICALS

Botanix says it has approval for a 120-patient, phase Ib trial of synthetic cannabidiol BTX1702 for inflammatory rosacea and an expansion study.

Botanix said that papulo-pustular, or inflammatory, rosacea was a highly visible and distressing chronic inflammatory skin disease characterized by inflamed skin and acne-like breakouts across the face.

The company said that two different formulations of BTX1702 combining its Permetrex drug delivery system with a synthetic cannabidiol would be used in the randomized, double-blind, vehicle-controlled study in patients with moderate to severe papulo-pustular rosacea, which planned to enrol patients at 11 dermatology sites in Australia and New Zealand and begin by July 2021.

Rosacea is a chronic inflammatory skin disease that often begins with a tendency to blush or flush more easily than other people, but can progress into many subtypes, including papulo-pustular rosacea, and affected more than 16 million Americans and up to 415 million people worldwide, with women more likely to have rosacea than men and more than 85 percent of patients over the age of 30 years.

Botanix executive chair Vince Ippolito said that moderate to severe papulo-pustular rosacea patients were “greatly in need of new therapies to treat the signs and symptoms of the disease which has such a tremendous emotional impact”.

The company said that synthetic cannabidiol had “powerful anti-inflammatory and antimicrobial actions in skin, two key activities that are critical to successfully treating rosacea”.

Botanix said adults would be treated with BTX1702 over eight weeks with the primary endpoint a safety and tolerability assessment, along with exploratory endpoints including absolute change and percentage change in inflammatory lesion counts (papules and pustules) from baseline to day 57; change from baseline in the investigator’s global assessment (IGA-PP) scale at days 29 and 57; and reduction of erythema, or redness, severity assessments by each patient and investigator.

The company said two different concentrations of BTX1702 would be tested along with a separate control arm.

Botanix was unchanged at 10 cents with 1.96 million shares traded.

DIMERIX

Dimerix says substantial shareholder Peter Meurs has provided a loan of $5 million to advance its phase III trial of DMX-200 for focal segmental glomerulosclerosis.

Dimerix said the unsecured loan was expected within five days and it would pay compound interest at one percent a month.

The company said the loan would be repaid by the earlier of December 31, 2021 or a capital raising or transaction exceeding $10 million, or receipt of research and development rebate exceeding $5 million.

Dimerix said the funds would be used for the phase III trial, clinical site start-up activities and protocol agreement for the US Food and Drug Administration and the European Medicines Agency.

The company said it reported a cash position of $4.9 million as of December 31, 2020.

Dimerix said that Mr Meurs held 13.4 percent of the company.

Dimerix fell one cents or 3.8 percent to 25.5 cents.

AVITA MEDICAL

Avita says the American Burn Association has accepted 15 abstracts related to its Recell system for autologous cell harvesting

Avita said the abstracts highlighted the clinical and cost-saving benefits of Recell.

Avita chief executive officer Dr Mike Perry said this year's meeting had "the highest number of presentations on the clinical and health economic benefits of the Recell system since its US Food and Drug Administration approval in 2018".

"The acceptance and adoption of Recell is reflected in these physician-initiated presentations, representing the collective experience of 20 burn centers," Dr Perry said.

"With more than 80 percent of burn surgeons in the United States now certified in the use of the Recell system, we are encouraged by their continuing exploration of Recell in the treatment of various burn depths and sizes, and we remain committed to enabling the realization of the full potential of this innovative platform technology," Dr Perry said.

Avita fell 11 cents or 2.1 percent to $5.13 with 539,882 shares traded.

RECCE PHARMACEUTICALS

Recce says the European Patent Office has granted a patent for its synthetic antibiotic R327 and anti-viral formulation R529.

Recce said the patent, titled 'Anti-Virus Agent For Treatment Of Viral Infections' would protect its intellectual property until February 2037.

The company said the patent allowed the use of R327 and R529 as a treatment for viruses such as severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), corona viruses, influenza, HIV, hepatitis, Ross River and herpes viruses.

Recce said the patent covered administration of R327 and R529 by oral, injection, inhalation and transdermal dose applications.

Recce was unchanged at 96.5 cents.

CANN GLOBAL

Cann Global says joint venture partner Canntab Therapeutics has an export permit from Health Canada for distribution of its marijuana hard pills in Australia.

Cann Global said it had an initial order for six Canntab products including two tetrahydro-cannabinol (THC) products, two cannabidiol (CBD) products and two THC/CBD blends.

Cann Global said it had received an import permit and expected the products to be available for distribution in Australia in April.

The company said the products would be available to patients through the special access scheme B and authorised prescriber schemes, accessed through health practitioners.

Cann Global said it would further make the products available to the Cannabinoid Medicine Observational study which would collect data from 20,000 participants to assess the safety and efficacy of medicinal cannabis products for refractory conditions.

Cann Global was unchanged at 0.8 cents with 80.6 million shares traded.

NYRADA

Nyrada says Noxopharm's substantial share-holding of 33,373,245 Chess depository interests (CDIs) has been diluted from 30.51 percent to 24.09 percent.

Earlier this month, Nyrada said it had commitments to raise $11 million in a placement at 26 cents per CDI (BD: Mar 22, 2021).

Nyrada was up 1.5 cents or five percent to 31.5 cents.

NYRADA
Nyrada says Altnia Holdings' substantial holding of 9,921,725 CDIs has been diluted from 9.07 percent to 7.16 percent in a placement (see above).

NYRADA
Nyrada says Eleanore Goodridge' has ceased her substantial holding reducing and diluted from 5,974,832 CDIs (5.39%) to 5,474,832 CDIs (3.95%) (see above).

ADHERIUM
Trudell Medical says it has increased its substantial shareholding in Adherium from 89,364,179 shares (13.44%) to 165,364,179 shares (19.47%).
The London, Ontario-based Trudell Medical said on March 24, 2021 it acquired 76,000,000 shares through a placement offer for $1,140,000 or 1.5 cents a share.
Earlier this month, the company said it had commitments to raise $18 million at 1.5 cents a share (BD: Mar 18, 2021).
Adherium was unchanged at 1.6 cents.

ADHERIUM
One Funds Management says its 48,808,957 Adherium shares have been diluted from 7.34 percent to 5.75 percent due to a placement (see above).