Biotech Daily

Tuesday March 3, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: DIMERIX UP 24%; USCOM DOWN 7.5%**

*** AVITA STARTS RECELL SOFT TISSUE RECONSTRUCTION PIVOTAL TRIAL**

*** NEXT SCIENCE BACTISURE WINS CE MARK**

*** DIMERIX DMX-200 COMPASSIONATE USE**

*** CANADA PATENT FOR CYNATA**

*** CLINUVEL, FDA SCENESSE FOR VITILIGO MEETING**

*** BIONOMICS COMPLETES $3m FRENCH SUBSIDIARIES SALE TO DOMAIN**

*** CORRECTION: PATRYS**

*** NOXOPHARM DOSES LAST VEYONDA CANCER TRIAL PATIENT**

*** COHEN GROUP ENDS CRESO ISRAEL J-V; POTENTIAL LEGAL ACTION**

*** PROBIOTEC CEO WES STRINGER SELLS 1.7m SHARES**

*** THC EXPANDS MEDICAL MARIJUANA SUPPLY FOR 6k PATIENTS**

*** PHARMAUST OPENS 2 MORE DOG CANCER TRIAL CENTRES**

*** CRESO APPOINTS FARMAGON SCANDINAVIA MARIJUANA DISTRIBUTOR**

*** MGC EXTENDS, AMENDS ONIX BRAZIL DISTRIBUTION AGREEMENT**

*** DR DAVID MAZZO REPLACES VISIONEERING CHAIR FRED SCHWARZER**

*** CHOW YEE HOK REPLACES INVITROCUE DIRECTOR GEOFFREY THOMAS**

MARKET REPORT

The Australian stock market rebounded 0.69 percent on Tuesday March 3, 2020, with the ASX200 up 44.2 points to 6,435.7 points. Thirty of the Biotech Daily Top 40 stocks were up, five fell, four traded unchanged and one was untraded. All three Big Caps were up.

Dimerix was the best, up three cents or 24 percent to 15.5 cents with 2.5 million shares traded. Opthea climbed 14.7 percent; Neuren improved 13.2 percent; Next Science was up 10.45 percent; Immutep rose 9.9 percent; Alterity and Compumedics were up more than eight percent; Medical Developments and Orthocell recovered more than seven percent; Clinuvel climbed 6.4 percent; Cochlear, Kazia, Osprey, Proteomics and Resmed improved five percent or more; Actinogen, Cyclopharm, Impedimed and Nanosonics were up four percent or more; Resonance was up 3.6 percent; CSL, LBT, Mesoblast, Polynovo, Telix and Volpara rose more than two percent; Genetic Signatures, Paradigm and Pharmaxis were up more than one percent; with Antisense, Ellex, Pro Medicus and Starpharma up by less than one percent.

Uscom led the falls, down three cents or 7.5 percent to 37 cents, with 3.98 million shares traded. Patrys lost 6.25 percent; Oncosil fell 3.6 percent; with Avita and Cynata down by less than one percent.

AVITA MEDICAL

Avita says it has enrolled the first patient of up to 65 patients in a pivotal study of Recell spray-on skin for soft tissue reconstruction at the Arizona Burn Center.

Avita said that the stud at the Phoenix-based Valleywise Medical Health Center would evaluate the safety and effectiveness of Recell as an adjunct to meshed autografts in patients undergoing reconstruction of skin defects not associated with a burn injury.

Avita chief executive officer Dr Mike Perry said that the start of the trial was “an important milestone for Avita and a critical step toward making the Recell system broadly available to help patients heal from traumatic or soft tissue wounds with the use of less donor skin than the standard of care”.

The company said that skin grafting was the standard of care for full-thickness, soft tissue reconstruction, including post-trauma and post-surgical skin reconstruction, but skin grafting required the harvesting of donor skin, resulting in an additional wound.

Avita said that significant pain, delayed healing, risk of infection, the need for multiple procedures, discoloration and scarring were associated with donor site wounds.

The company said that skin grafting was commonly associated with burns, in 2017 about 80 percent of acute wounds that required skin grafting were non-burn related injuries accounting for more than 200,000 procedures in the US.

Avita said that the prospective multi-centre trial of at least 65 patients would compare the clinical performance of conventional skin grafting to the use of the Recell system in combination with more widely meshed autografts on acute full-thickness non-burn skin defects.

The company said that the two primary effectiveness endpoints were: superior donor skin sparing, evaluated by comparing the actual expansion ratios of donor skin used to treat the wounds; and non-inferior incidence of healing by eight weeks post treatment, evaluated by a clinician blinded to the treatment allocation.

Avita said that additional long-term safety and effectiveness data collected during the 52-week study would include blinded evaluation of scar outcomes and patient treatment preference.

The company said that in its studies leading to the US Food and Drug Administration approval for Recell for acute thermal burns showed it used 97.5 percent less donor skin when used alone in second-degree burns, and 32 percent less donor skin when used with autograft for third-degree burns, and burns treated with Recell achieved healing comparable to the burn wounds treated with standard of care.

Avita fell half a cent or 0.8 percent to 59.5 cents with 31.7 million shares traded.

NEXT SCIENCE

Next Science says it has Conformité Européenne (CE) mark for its Bactisure surgical lavage, or cleanser, for the removal of bacteria and debris from wounds.

On its website, Next Science said that Bactisure removed “structurally resistant forms of bacteria [or biofilm] through physical deconstruction of the extracellular polymeric substance matrix, making bacteria more susceptible to traditional antibiotics and the body’s normal defense mechanisms”.

The company said that Bactisure would be sold in Europe by its international distributer, the Warsaw, Indiana-based Zimmer Biomet.

Next Science managing-director Judith Mitchell said that “CE mark approval marks a major milestone for Next Science as we pursue our mission to heal patients and save lives worldwide by addressing the impacts of biofilms on human health”.

Next Science rose 21 cents or 10.45 percent to $2.22 cents with 493,367 shares traded.

DIMERIX

Dimerix says patients in its phase II trials of DMX-200 will continue treatment under the Therapeutic Goods Association's compassionate use special access scheme.
Dimerix said that patients in the double-blinded, placebo-controlled, cross-over trials for focal segmental glomerulosclerosis and diabetic kidney disease could continue to be treated with DMX-200 following completion of the study protocol and recommendation by their physicians.
Dimerix chief executive officer Dr Nina Webster said it was "pleasing that physicians have requested extended treatment of their patients with DMX-200".
The company said that final patient dosing for the focal segmental glomerulosclerosis trail was expected in June 2020, with final patient dosing for the diabetic kidney disease trial scheduled for July 2020, with results later in 2020.
Dimerix was up three cents or 24 percent to 15.5 cents with 2.5 million shares traded.

CYNATA THERAPEUTICS

Cynata says the Canadian Intellectual Property Office has granted a patent relating to its Cymerus mesenchymal stem cell technology.
Cynata said that the patent, titled 'Generation of clonal mesenchymal progenitors and mesenchymal stem cell lines under serum free conditions', would provide intellectual property rights until March 16, 2031.
The company said this patent would extend its intellectual property protection of Cymerus and allow the company to manufacture mesenchymal stem cells for therapeutic stem cell products.
Cynata said the patent was owned by the Madison-based Wisconsin Alumni Research Foundation at the University of Wisconsin.
Cynata fell half a cent or 0.6 percent to 89.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will meet with the US Food and Drug Administration on April 29, 2020 to discuss the design protocol for its phase II and III trials of Scenesse for vitiligo.
Clinuvel said the FDA meeting would review the study design, endpoints and development needed for market authorization for the treatment of vitiligo, or skin pigment loss disorder, with Scenesse in combination with narrowband type-b ultraviolet light (NB-UVB).
The company said no pharmaceutical product was approved for vitiligo in the US.
Clinuvel was up $1.09 or 6.4 percent to $18.19 with 548,839 shares traded.

BIONOMICS

Bionomics says it has completed the sale of its French subsidiaries, Neurofit and Prestwick Chemical, to Domain Therapeutics for EUR1,790,029 ($A3,043,357).
Bionomics said the sale price of EUR1,790,028.97 was the final amount of inter-company debt owed by Bionomics to the subsidiaries for the scientific research conducted by them on Bionomics drug candidates and is assumed by Domain at the close.
Last year, the company said it would sell the subsidiaries to repay the debt owed to the subsidiaries for scientific research on its drug candidates (BD: Dec 11, 2019).
Bionomics executive chairman Dr Errol De Souza said the company would focus "on the clinical development of BNC210 for post-traumatic stress disorder".
Bionomics was up 0.6 cents or 13.6 percent to five cents with 4.6 million shares traded.

CORRECTION: PATRYS

Last night's edition said PAT-DX1-NP improved the delivery of nanoparticles across the blood-brain-barrier by 260 percent compared to the unconjugated PAT-DX1.
In fact, Patrys said that PAT-DX1-NP improved the delivery of nanoparticles across the blood brain barrier by 260 percent compared to unconjugated nanoparticles.
The mistake was made by the financial reports sub-editor, who was confused by the late announcements and the announcement failed to cross her blood-brain-barrier.
She was given a Bex, a cup of tea and ordered to have a good lie down.
Patrys fell 0.1 cents or 6.25 percent to 1.5 cents with 5.1 million shares traded.

NOXOPHARM

Noxopharm says it has enrolled and dosed the final prostate cancer patient in its 56-patient phase I/II clinical trial of Veyonda with radiation therapy.
Noxopharm said the study administered Veyonda in combination with the radio-pharmaceutical, 177-lutetium-prostate specific membrane antigen-177 (177-Lu-PSMA-617), to patients with late-stage, metastatic, castration-resistant prostate cancer that had failed to respond to all standard therapies and had limited survival prospects.
The company said that further interim data from the study was expected later this year, with a final read-out expected in mid-2021.
Noxopharm fell 1.5 cents or 6.25 percent to 22.5 cents.

CRESO PHARMA

Creso says its Israeli joint venture agreement with the Cohen Propagation Nurseries and Asaf Cohen to grow marijuana for medical purposes has been terminated.
In 2018, Creso said that through subsidiary Creso Pharma Switzerland GmbH, it would own 74 percent of the joint venture (BD: May 16, 2018).
Today, the company said that both "parties had been negotiating the agreed scope of the Cohen Group's responsibilities and entitlements … for some time".
Creso said that the parties could not reach a resolution, which led to the termination of the agreement by the Cohen Group.
The company said that the Cohen Group intended "to seek damages in respect of alleged breaches by Creso GmbH of its obligations under the Israeli [joint venture] agreement".
Creso said it "disputes the claims made by the Cohen Group regarding any breaches by Creso GmbH and intends to strongly defend these claims and any formal proceedings".
Creso was up 0.7 cents or 8.75 percent to 8.7 cents with 2.7 million shares traded.

PROBIOTEC

Probiotec says that entities associated with chief executive officer Wesley Stringer have sold 1,715,000 shares, or about 2.3 percent of the company.
Probiotec said that Mr Stringer remained a substantial shareholder with more than 4.9 million shares held in entities associated with him.
The company said that Mr Stringer sold the shares "to repay debt related to prior option exercises, meet upcoming and future tax obligations and manage family financial matters".
Probiotec said that Mr Stringer was "fully committed to the business".
The company said the sell down was conducted by Shaw & Partners which increased "the depth and liquidity of Probiotec's register".
Probiotec fell eight cents or 3.7 percent to $2.07.

THC GLOBAL

THC says it has an expanded commercial cultivation permit and has increased production of marijuana-based medicines to supply 6,000 Australian patients.
THC said that the expanded permit was granted by the Australian Office of Drug Control for its Bundaberg, Queensland cultivation facility.
THC chief executive officer Ken Charteris said that the company expected “to supply at least an initial 6,000 patients using Canndeo medicinal cannabis on an ongoing basis commencing from [April to May] 2020”.
THC was up four cents or 12.9 percent to 35 cents with one million shares traded.

CRESO PHARMA

Creso says it has appointed Farmagon as the distributor of its marijuana-based products for Norway, Denmark, Swedent and Finland.
Creso said the Oslo-based Farmagon would initially distribute its Cannaqix50 and Cannaqix10 for pain management.
The company said it that through the agreement it would have access to the necessary licences for distribution and Farmagon’s established retail distribution channels.
Creso did not state minimum quantities or commercial terms, but said the agreement could be terminated by either party with three months’ notice.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has amended its distribution agreement with the Brazil-based Onix Empreendimentos e Participações to include minimum orders.
Last year, MGC said it had a three-year agreement with Onix to distribute Cannepil and Cognicann for dementia and Alzheimer’s disease in Brazil (BD: Jun 19, 2019).
Today, the company said that Onix had agreed to order a minimum of 20,000 units in the first year, valued at $1.65 million and an immediate down payment of about $107,000 for the first order of 4,000 units.
MGC said that for the second and third years of the agreement, the minimum order would be increased to 50,000 units, worth at least $4.1 million.
The company said that the initial three-year minimum term had been extended to seven years, with the option to renew for an additional five years by mutual agreement.
MGC said that the amended agreement included a deposit payment from Onix for each order of up to 50 percent, with the remaining balance to be paid within 30 days.
MGC managing-director Roby Zomer that the agreement amendment “with Onix is a clear commitment of minimum order volumes over the next seven years, and confirmation that Onix are the partners we are looking for in the region”.
“This is a significant milestone for MGC Pharma and will have an immediate positive impact on the company’s cashflows,” Mr Zomer said.
MGC was up 0.2 cents or eight percent to 2.7 cents with 11.05 million shares traded.

PHARMAUST

Pharmaust says Brisbane’s Animal Referral Hospital will participate in its trial of monepantel in dogs with treatment-naïve B-cell lymphoma.
Pharmaust said the trial had five sites in Melbourne, Sydney, Perth and Brisbane.
Pharmaust was up 0.8 cents or 9.8 percent to nine cents.

VISIONEERING TECHNOLOGIES

Visioneering says Dr David Mazzo as chairman, replacing Fred Schwarzer, who resigned effective from December 31, 2019.

Visioneering said Dr Mazzo was chief executive officer of Caladrius Bioscience and a director of Eyepoint Pharmaceuticals, formerly Psivida, and Seneca Biopharmaceuticals, and had previously been an executive at Regado Biosciences, Aterna Zentaris and Chugai Pharma USA LLC.

The company said Dr Mazzo held a Bachelor of Arts and a Bachelor of Science from the Radnor, Pennsylvania-based Villanova University, and a Doctor of Philosophy from the Amherst-based University of Massachusetts.

Visioneering was up 0.2 cents or 6.25 percent to 3.4 cents.

INVITROCUE

Invitrocue says company secretary Chow Yee Koh will replace Geoffrey Thomas as a director, and will receive $30,000 a year for his role.

Mr Thomas was appointed as a director last September (BD: Sep 10, 13, 2019).

Today, the company said Mr Thomas was resigning to concentrate “on his other personal business interests”.

Invitrocue said Mr Koh had more than 20 years’ experience in accounting, auditing and corporate finance and was a director of Stemcell United.

The company said Mr Koh held a Bachelor of Arts from Glasgow’s University of Strathclyde.

Invitrocue was in a suspension and last traded at six cents.