Biotech Daily

Tuesday March 12, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH EVEN: AVITA UP 14%; PARADIGM DOWN 6%**

*** ELLEX LASERS BEAT DROPS FOR OCULAR HYPERTENSION, GLAUCOMA**

*** MHRA BACKS CYNATA CRITICAL LIMB ISCHEMIA TRIAL**

*** STARPHARMA RECEIVES $4m FEDERAL R&D TAX INCENTIVE**

*** MEDIBIO RIGHTS RAISE $923k OF HOPED-FOR $4m**

*** COGSTATE TESTS IN J&J'S US SPRAVATO CIII DEPRESSION TRIALS**

*** SPRINGBOARD PROGRAM FOR 6 AUSTRALIAN BIOTECH WOMEN**

*** US PATENT FOR IMAGION MAGNETIC NANOPARTICLES FOR CANCER**

*** ZELDA, ILERA PARTNER TO CO-DEVELOP MEDICAL MARIJUANA**

*** PHYLOGICA 'PEPTIDES DELIVER ANTISENSE DRUGS IN MICE'**

*** KIT WEI LUI REPLACES INVITROCUE DIRECTOR JAMIE GEE CHOO KHOO**

MARKET REPORT

The Australian stock market slipped 0.09 percent on Tuesday March 12, 2019, with the ASX200 down 5.4 points to 6,174.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and three were untraded.

Avita was the best, up two cents or 14.3 percent to 16 cents, with 21.3 million shares traded. Ellex climbed 10.9 percent; Imugene was up 5.3 percent; Clinuvel, Medical Developments and Prana improved more than four percent; Dimerix, Telix and Uscom were up more than three percent; Starpharma rose two percent; Compumedics, LBT, Mesoblast and Volpara were up more than one percent; with Cochlear, Nanosonics and Resmed up less than one percent.

Yesterday's 10.4 percent best, Paradigm, led the falls, down 8.5 cents or 5.7 percent to $1.405 with 317,715 shares traded. Neuren and Patrys fell more than four percent; Benitec, Immutep and Orthocell were down more than three percent; Airxpanders, Impedimed, Oncosil, Polynovo and Pro Medicus shed more than two percent; Actinogen, Kazia, Opthea, Prescient and Proteomics were down more than one percent; with CSL down 0.14 percent.

ELLEX MEDICAL LASERS

Ellex says a randomized, controlled trial has shown its selective laser trabeculoplasty is “safe and effective” compared to eye drops for ocular hypertension and glaucoma.

Ellex said the multi-centre laser in glaucoma and ocular hyper tension (Light) trial, titled ‘Selective laser trabeculoplasty versus eye drops for first-line treatment of ocular hypertension and glaucoma (LiGHT): a multicentre randomised controlled trial’ was published in The Lancet on March 9, 2019, with the full text of the trial available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32213-X/fulltext.

The study reported that the two groups “had similar endpoint visual acuity, intraocular pressure, and visual field loss mean deviation” but went on to recommend that “selective laser trabeculoplasty should be offered as a first-line treatment for open angle glaucoma and ocular hypertension, supporting a change in clinical practice”.

The researchers reported that more treatment escalations took place in the selective laser trabeculoplasty group than in the eye drops group with 36 eyes in the eye drops group showing algorithm-confirmed disease deterioration compared with 23 eyes in the selective laser trabeculoplasty group.

The study said that 25 cataract extractions were carried out in the eye drops group compared with 13 in the selective laser trabeculoplasty group.

The study reported that the cost of selective laser trabeculoplasty over the duration of the trial was an additional GBP205 ($A383) in the selective laser trabeculoplasty group, while drops for open-angle glaucoma and ocular hypertension cost an additional GBP465 for patients in the eye drops group, and the average cost per patient for ocular surgery over 36 months was significantly less for the selective laser trabeculoplasty group compared with the eye drops group.

“We also demonstrate a greater safety of selective laser trabeculoplasty than previously reported, with low rates of selective laser trabeculoplasty-related adverse events,” the study reported.

“Use of selective laser trabeculoplasty as the first-line treatment resulted in a significant reduction in the cost of surgery and medication for ocular hypertension and [open-angle glaucoma], with an overall cost saving to the [UK National Health Service] of GBP451 per patient in specialist ophthalmology costs,” the researchers said.

“For every patient given selective laser trabeculoplasty first instead of eye drops the cost savings are greater than the cost of selective laser trabeculoplasty for two additional patients, or equal to the cost of five additional ophthalmology specialist appointments,” the study concluded.

Ellex said selective laser trabeculoplasty (SLT) “provided superior intra-ocular pressure stability to drops”, was cheaper and 74 percent of patients were successfully controlled without drops for at least three years after beginning treatment.

Ellex chief executive officer Tom Spurling said the company was “delighted by the findings of Light, which validates the benefits of SLT as a first-line treatment option for untreated, newly diagnosed patients with ocular hypertension and glaucoma across a large, randomized, controlled trial”.

“Not only did patients who received SLT exhibit better control of their disease at three years, none of the SLT patients’ disease progressed to a stage that required surgical intervention and overall the procedure was more cost effective than eye drops,” Mr Spurling said. “This is a significant benefit versus eye drops, and when coupled with compliance, toxicity issues and the increased rate of cataract surgery versus SLT observed in the Light trial, is expected to materially enhance clinician interest for SLT in markets such as the UK where eye drops are recommended as a first-line therapy.”

Ellex was up 6.5 cents or 10.9 percent to 66 cents.

CYNATA THERAPEUTICS

Cynata says the UK Medicines and Healthcare Products Regulatory Agency has supported its 90-patient, phase II trial of CYP-002 for critical limb ischemia.
Cynata said the Agency provided “favorable advice” on CYP-002 manufacturing and quality control, the completed pre-clinical proof-of-concept study, its proposed pre-clinical biodistribution study and said the phase II trial design was “generally acceptable”.
The company said the trial was expected to begin in the UK and Australia by 2020.
Cynata said critical limb ischemia, or advanced stage peripheral artery disease, involved the narrowing of arteries in the limbs, often resulting in amputation.
Cynata product development head Dr Kilian Kelly said the meeting was “highly successful”.
“We are very pleased with this outcome,” Dr Kelly said.
“Perhaps most notably, this confirms Cynata’s understanding that the safety data from the completed phase I trial of Cymerus [mesenchymal stem cells] in graft-versus-host disease support direct progression to phase II trials in other indications,” Dr Kelly said.
“This strengthens our confidence that the manufacturing and preclinical data packages are expected to support progression of CYP-002 into a clinical trial in patients with [critical limb ischemia],” Dr Kelly said.
Cynata was unchanged at $1.60.

STARPHARMA

Starpharma says it has received $4,018,980 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Starpharma said the rebate related to research and development expenditure for the year to June 30, 2018, for work on its Vivagel and dendrimer drug delivery programs.
Starpharma was up two cents or 1.96 percent to $1.04.

MEDIBIO

Medibio says it has raised $923,464.56 of the hoped-for $4.01 million in a one-for-one rights issue at two cents a share.
Medibio said it had applications for 46,173,228 shares of the 202,628,271 shares available in the offer, leaving 156,455,043 shortfall shares.
Last year, the company said it had commitments to raise $2.5 million in convertible notes and hoped to raise an additional $4.01 million in the rights issue (BD: Dec 10, 2018).
Medibio was unchanged at two cents.

COGSTATE

Cogstate says its cognition tests were used in trials of Johnson & Johnson’s Spravato CIII nasal spray with oral anti-depressants for treatment-resistant depression.
Cogstate said that five pivotal phase III trials were conducted involving more than 1,700-patients with treatment-resistant depression.
The company said that a cognitive assessment, including its computerized cognition tests were used to measure the trials’ primary outcomes and its tests measured attention, visual learning and memory and executive function.
The company said that the US Food and Drug Administration had approved Spravato CIII nasal spray for treatment-resistant depression.
Cogstate was up two cents or 7.4 percent to 29 cents.

SPRINGBOARD ENTERPRISES

Springboard Enterprises says its US “expert network of innovators, investors and influencers” will run a program for six Australian women biotechnology executives.

The Washington, DC-based Springboard Enterprises says the Australian Life Science Program was “dedicated to building high-growth companies led by women” and would be held in Melbourne from March 25 to June 30, 2019, with funding from the Victoria Government’s Launch Vic.

Springboard Life Science Program director Larisa Chisholm told Biotech Daily that the program supported “the most promising businesses seeking capital or partnerships for product development and expansion, through a combination of an on-boarding boot-camp followed by a three-month advisory process”.

Ms Chisholm said the US Springboard team was chosen based on the Australian companies’ specific growth needs.

Ms Chisholm said that Springboard Australia had “six years of supporting Australian women-led technology companies … [and had] nearly two decades of helping women entrepreneurs build high-growth businesses”.

Springboard said that since 2012, the 56 women who participated in Springboard programs in Australia had raised more than $207 million.

The company said that the 2019 Springboard participants included Spot Check Technologies chief executive officer Jennifer Barnes, Bard1 chief executive officer Dr Leearne Hinch, Thrivor chief product officer Mardi McMillan, Presagen chief executive officer Dr Michelle Perugini, Navi Medical Technologies chief financial officer Wei Sue and Navbit Pty Ltd chief executive officer Lynette Walter.

For more information about the Springboard Australian Life Science Program, contact Ms Chisholm at: larisa@sbeaustralia.org or telephone +61 403 563 774.

Springboard Enterprises is a not-for-profit company.

IMAGION BIOSYSTEMS

Imagion says the US Patent and Trademark Office has issued a patent for the use of magnetic nanoparticles for the detection and treatment of cancer.

Imagion said the patent, titled ‘Methods and Apparatuses for the localization and treatment of disease such as cancer’ would provide protection until 2029.

The company said the patent would cover the use of magnetic nanoparticles to detect cancer, monitor and guide cancer treatments and to provide treatment such as magnetic hyperthermia, or as a carrier for therapeutic agents such as chemotherapy.

Imagion was up 0.3 cents or 10 percent to 3.3 cents.

ZELDA THERAPEUTICS

Zelda says it has a partnership with US medical marijuana company Ilera Healthcare to licence and co-develop its products and share data.

Zelda said it would access the Newtown Square, Pennsylvania-based Ilera’s more than 80,000-patient US medical marijuana market in Pennsylvania and recent expansion into Louisiana.

The company said no upfront payments would be received initially, but the binding heads of agreement included terms to negotiate commercial contracts.

Zelda fell 0.1 cents or 1.75 percent to 5.6 cents with 1.6 million shares traded.

PHYLOGICA

Phylogica says its first-generation cell penetrating peptides have delivered an anti-sense oligonucleotide drug cargo into cells in different tissue types in mice.

Phylogica said that the results paved the way for assessment of its second-generation peptides by July 2019 and if successful, the company would begin investigational new drug application-enabling studies for clinical development of the peptides.

The company said that anti-sense oligonucleotide cargoes were chosen “because of the potency and precision of this class of molecule”.

Phylogica said that the anti-sense oligonucleotides were “a highly promising therapeutic class whose clinical application has been limited by their inability to reach their target inside cells”.

“Our in-house efforts have been focused on demonstrating that our [peptides] can deliver [anti-sense oligonucleotides] inside cells to reach their target and change the characteristics of those cells as a result,” the company said.

Phylogica said it had undertaken systemic injection into the bloodstream as well as intra-vitreal injection in the eye and both routes of administration “demonstrated effective exon skipping in the target tissues harvested following administration” including exon skipping in the eye, liver and kidney, with other tissues harvested yet to be processed.

Phylogica fell 0.1 cents or four percent to 2.4 cents.

INVITROCUE

Invitrocue says it has appointed Kit Wei Lui as a director, replacing Jamie Gee Choo Khoo.

Invitrocue said Mr Lui was the co-founder and director of consulting company Harford Vantage, an investor in real estate and hospitality businesses, and held director positions in HLN Assets Holding and Jtown Hospitality.

The company said Mr Lui held a Bachlor of Engineering from the University of Newcastle in New South Wales.

Invitrocue was untraded at 7.5 cents.