Biotech Daily

Tuesday March 2, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 5%; LBT DOWN 9%**

*** MESOBLAST RAISES $142m**

*** EMVISION WINS $8m OF MRFF STROKE FUNDING**

*** PALLA $4m PLACEMENT, $8m INSTITUTIONAL RIGHTS ISSUE**

*** NEUROTECH TO RAISE $3.6m; EXPANDS DOLCE CANN LICENCE**

*** OASMIA LICENCES KAZIA'S CANTRIXIL FOR CANCER FOR $59m**

*** ALCIDION WINS $600k NZ CONTRACTS**

*** NOVA EYE STARTS ITRACK AB-INTERNO GLAUCOMA STUDY**

*** CYNATA CYMERUS IDIOPATHIC PULMONARY FIBROSIS MOUSE STUDY**

*** PYC CLAIMS VP-001 PRE-CLINICAL 'SUCCESS FOR RP11'**

*** OSPREY EXPANDS US SALES**

*** NOXOPHARM RECEIVES $4.6m FEDERAL R&D TAX INCENTIVE**

*** CE MARK FOR RESAPP WEARABLE RESPIRATORY TEST**

*** 4D TAKES 'CAPITAL RAISING' HALT TO SUSPENSION**

*** GENETIC TECHNOLOGIES REQUESTS 'MATERIAL DISTRIBUTION' HALT**

*** CRESO APPOINTS CERES US ANIBIDIOL DISTRIBUTOR**

*** MERCHANT FUNDS TAKES 14% OF BARD1**

*** JEFFREY EMMANUEL BELOW 5% IN BARD1**

*** M-D FLETA SOLOMON DILUTED TO 11% OF LITTLE GREEN**

*** ELIXXER REDUCES, DILUTED TO 16% OF LITTLE GREEN**

MARKET REPORT

The Australian stock market fell 0.4 percent on Tuesday March 2, 2021, with the ASX200 down 27.3 points to 6,762.3 points. Twelve of the Biotech Daily Top 40 stocks were up, 23 fell and five traded unchanged.

Oncosil was the best, up 0.5 cents or five percent to 10.5 cents, with 2.4 million shares traded. Avita, Clinuvel, Kazia and Medical Developments climbed more than three percent; Cochlear, Opthea and Universal Biosensors rose two percent or more; Cynata, Next Science and Telix were up more than one percent; with Genetic Signatures and Pro Medicus up by less than one percent.

Yesterday's 9.95 percent best, LBT, led the falls, down 0.9 cents or 8.6 percent to 9.6 cents, with 310,122 shares traded. Osprey, Prescient and Proteomics lost more than five percent; Dimerix, Immutep, Impedimed, Mesoblast and Optiscan fell four percent or more; Neuren, Uscom and Volpara were down more than three percent; Alterity, Nova Eye, Orthocell, Paradigm, Resonance and Starpharma shed more than two percent; Amplia, Compumedics, Cyclopharm and Polynovo were down more than one percent; with CSL, Nanosonics and Resmed down by less than one percent.

MESOBLAST

Mesoblast says it has subscription agreements from "a strategic US investor group" to raise $US110 million ($A141.8 million) in a private placement at $2.30 a share.
Mesoblast said the 60,000,000-share issue price, to the "principals of Surgcenter Development", was a 6.5 percent discount to the closing price on February 25, 2021.
Yesterday, the company said its net loss after tax for the six months to December 31, was $US50,236,000 with cash at December 31 of $US77,528,000 (BD: Mar 1, 2021).
Today, Mesoblast said its cash on hand at December 31, including the placement would be $US187.5 million.
Mesoblast said that the Towson, Maryland-based investors would receive warrants, or options, to buy a further 15,000,000 shares at $2.88 a share, a 25 percent premium to the placement price, to raise a further $43.2 million by March 15, 2028.
The company said it had the right to call on the funds at any time during the term, subject to a trading price of at least $4.32 for 45 consecutive days.
Mesoblast chief executive Prof Silviu Itescu said that Surgcenter was "one of the largest private operators of ambulatory surgical centers in the US specializing in spine, orthopaedic and total joint procedures".
"We expect the deep healthcare knowledge and expertise of this investor group will be of great benefit to the company," Prof Itescu said.
"The network and infrastructure of surgeons and ambulatory centers operated by Surgcenter may provide unique synergies to facilitate development and market access for rexlemestrocel, if approved, in patients with chronic lower back pain," Prof Itescu said.
The company said the placement would fund operational and regulatory initiatives, commercial supply of remestemcel-L for graft versus host disease in children, advancing manufacturing and development of the rexlemestrocel-L platform and for working capital and general corporate purposes.
Mesoblast fell 12 cents or 4.9 percent to $2.34 with 12.2 million shares traded.

EMVISION, FEDERAL GOVERNMENT

Emvision says that it will receive $8 million in non-dilutive cash funding over five years of an Australian Stroke Alliance project “to transform pre-hospital stroke care”.
Yesterday, Federal Health Minister Greg Hunt announced $99 million for three projects, including $40,167,052 for the University of Melbourne Australian Stroke Alliance, but did not mention Emvision and Micro-X (BD: Mar 1, 2021).
Today, Emvision said it expected its share of the funds would support the development and validation of its planned first responder model for air and road ambulances as well as confirmation of its portable brain scanner’s diagnostic capabilities in hospitals.
Emvision said that the Stroke Alliance provided “invaluable global clinical connectivity, expertise and advocacy, including support from the leading minds in stroke care, paramedic services across Australia as well as the Royal Flying Doctor Service”.
The company said it would retain intellectual property rights and would negotiate with the Alliance an appropriate revenue stream for road and air ambulance sales.
Emvision chief executive officer Dr Ron Weinberger said that the alliance “brings together an end-to-end medical program to save and improve the lives of patients of one of the most debilitating medical emergencies in the world”.
“No such consortium exists internationally, and the ASA will become a template for not only managing stroke, but other medical emergencies,” Dr Weinberger said.
Emvision was up 32 cents or 13.2 percent to $2.74 with 815,268 shares traded.

PALLA PHARMA

Palla says it has raised about $4.0 million in a placement to institutional investors and about $8.2 million in a two-for-nine non-renounceable rights issue at 50 cents a share.
Palla said Melbourne-based Morgans Corporate was the lead manager and had fully underwritten the $18 million capital raising including the institutional rights offer.
The company said that the record date for the retail part of the rights issue was March 2, with the offer opening on March 5 and closing on March 22, 2021.
Palla said the proceeds would be used to reduce its existing debts, improve working capital for growth opportunities in UK and Europe and cover the capital raising costs.
Palla fell 8.5 cents or 12.4 percent to 60 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has raised $2 million in “an oversubscribed” placement at 5.5 cents a share and Merchant Opportunities will underwrite $1.57 million in options.
The company said the funds would be used for the development and marketing of its Mente autism device and research into the use of cannabinoids for neurological disorders including autism and attention deficit hyper-activity disorder (ADHD), and for a phase I/II trial program through Monash Children’s Hospital by April 2021.
Neurotech said that Merchant would underwrite the shortfall from 26,122,966 options exercisable at six cents each by March 31, 2021, raising $1.56 million.
The company said that Merchant Group Pty Ltd was the lead manager to the placement and as part of the fee for the underwriting, Merchant would be issued 10,000,000 options exercisable at six cents each by December 31, 2021, subject to shareholder approval.
Neurotech said that as part of the fee for the placement, it would issue Merchant 10,000,000 options exercisable at nine cents each within two years of issue, subject to shareholder approval.
Neurotech fell 0.8 cents or 11.3 percent to 6.3 cents with 8.9 million shares traded.

NEUROTECH INTERNATIONAL

Separately, Neurotech said it had expanded its licence with Dolce Cann Global Pty Ltd to include all neurological disorders to be treated with its marijuana extracts, to “any other disorder, disease or affliction affecting the human brain function” and would issue Dolce Cann Global 15,000,000 shares within 45 business days form March 1 and 15,000,000 shares within 45 business days after completing a small clinical trial based on a neurological disorder (excluding autism, epilepsy or ADHD) within two years.

KAZIA THERAPEUTICS (FORMERLY NOVOGEN)

Kazia says it has licenced, Cantrixil, or TRX-E-002-1, for ovarian cancer to Oasmia Pharmaceutical AB for up to $US46 million ($A59.4 million) plus royalties.

Kazia said that the Uppsala, Sweden-based Oasmia would have worldwide exclusive rights to develop and commercialise Cantrixil for all indications, with an initial focus on ovarian cancer.

The company said it would receive an upfront payment of $US4 million, with milestone payments of up to US$42 million and double-digit royalties on commercial sales.

Kazia said that Oasmia’s lead product, Apealea (paclitaxel micellar), was approved in Europe for adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer, and was in late-stage clinical development in the US, with Oasmia expected to begin a phase II study of Cantrixil in ovarian cancer in 2022.

Kazia chief executive officer Dr James Garner said the transaction followed the release of “very encouraging top-line data from the phase I study of Cantrixil late last year”.

In 2014, the then Novogen announced “potent anti-cancer effects of TRX-1 in mice xenografted with human ovarian cancer stem cells” (BD Mar 18, 2014).

The company began a 25-patient trial of Cantrixil for ovarian cancer in 2016 and last year reported that of the remaining 24 patients there were one complete and two partial responses, but the phase I trial “achieved its primary objective determining the maximum tolerated dose of Cantrixil to be five mg/kg” (BD: Dec 6, 2016; Dec 9, 2020).

Dr Garner said the company had been looking for a partner for Cantrixil’s further development “and we are delighted to … pass the baton to the Oasmia team”.

Kazia said that Cantrixil was a formulation of the potent and selective third-generation benzopyran, TRX-E-002-1, targeting the spectrum of cancer cells, including chemotherapy-resistant tumor-initiating cells, or cancer stem cells, thought to be responsible for disease relapse.

The then Novogen said that Cantrixil was granted orphan designation for ovarian cancer by the US Food and Drug Administration in April 2015 (BD: Apr 22, 2015).

Kazia was up four cents or 3.1 percent to $1.32.

ALCIDION

Alcidion says it has a contract with New Zealand, Te Manawa Taki region’s district health boards for a pilot program of its Openep hospital management software.

Alcidion said the pilot program was worth $600,000 and would be rolled out over six to seven months to the five district health boards at Hauora Tairāwhiti, Taranaki, Lakes, Bay of Plenty and Waikato.

Alcidion said the pilot program would begin at Hāwera Hospital which was part of the Taranaki district health board.

Alcidion was up 1.5 cents or 6.1 percent to 26 cents with 2.3 million shares traded.

NOVA EYE MEDICAL

Nova Eye says it has begun a 160-patient study of the efficacy and safety of Itrack ab-interno canaloplasty compared to the Omni device for mild to moderate glaucoma.

Nova said that the prospective, randomized, single-masked multi-center ab-interno glaucoma study investigating canaloplasty (Magic) trial at eight surgery US centres would take 12-months and enrol patients with mild to moderate, uncontrolled primary open-angle glaucoma on one to four medications.

The company said that the reduction in mean intraocular pressure (IOP) and mean number of anti-glaucoma medications would be assessed, as well as surgical and postoperative complications.

Nova said “the ability to deploy ab-interno canaloplasty as a standalone procedure, and in combination with cataract surgery, supports its versatility in the glaucoma treatment algorithm”.

“The unique mechanism of action of ab-interno canaloplasty, which acts to reduce outflow resistance in all parts of the natural drainage system, further supports its role in the glaucoma treatment armamentarium,” the company said.

The study’s lead investigator Dr Shamil Patel said that “Ab-interno canaloplasty is akin to cardiac angioplasty for the eye”.

“Comprising 360° catheterization of Schlemm’s canal followed by the delivery of viscoelastic into the canal via a process referred to as viscodilation, the multimodal mechanism of ab-interno canaloplasty addresses multiple points of blockage in the conventional outflow pathway,” Dr Patel said.

“This makes it an effective treatment in the majority of my mild-moderate open-angle glaucoma patients, with most patients achieving post-operative pressures in the low teens,” Dr Patel said.

“Despite this, ab-interno canaloplasty has suffered from a misconception that, due to its implant-free and tissue-sparing approach, it does not deliver the same degree of efficacy as other [minimally invasive glaucoma surgery] procedures,” Dr Patel said.

Nova Eye said that ab-interno canaloplasty is a tissue-sparing, implant-free procedure that acts to re-establish the function of the eye’s natural drainage system to effectively reduce intraocular pressure and the medication burden, while also preserving the viability of future treatment options.

“As a result, an increasing number of surgeons are turning to ab-interno canaloplasty to manage their mild-moderate glaucoma patients,” the company said.

Nova Eye fell one cent or 2.9 percent to 33 cents.

CYNATA THERAPEUTICS

Cynata says it will begin a mouse study of its Cymerus stem cells for idiopathic pulmonary fibrosis, including the potential molecular mechanisms involved in efficacy.

Cynata said that the study would add to the company’s “substantial body of knowledge” and the observations were expected to provide useful information relevant to the potential mechanisms of action of its mesenchymal stem cells and be important in leveraging commercial and regulatory activities.

The company said that lung diseases such as idiopathic pulmonary fibrosis were an enormous unmet medical need, as existing treatment options had modest effects on disease progression and survival rates.

Cynata said that the study would be at Melbourne’s Monash Biomedicine Discovery Institute, led by Prof Chrishan Samuel and conclude within six months.

Cynata was up one cent or 1.6 percent to 65 cents.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says its VP-001 is “the first and only treatment to demonstrate restoration of this critical [blood-retinal] barrier function in a patient-derived model”.
PYC said that VP-001 for the treatment of retinitis pigmentosa 11 (RP11) “restored function of the retinal pigment epithelium, the target cells for the therapy, in patient-derived models of the disease”.
PYC chief executive officer Sahm Nasseri said that the result “builds further conviction in VP-001 as we head towards clinical testing”.
“Break-down of the blood-retina barrier is a major driver of vision loss in patients with RP11,” Mr Nasseri said.
PYC was unchanged at 14.5 cents with 2.7 million shares traded.

OSPREY MEDICAL

Osprey says it signed distribution agreements with three groups across seven US states for distribution of its cardiac dye reduction products.
Osprey said it has signed independent sales agency agreements with the Carlsbad, California-based Access Medical, the Newburgh, New York-based Consolidated Medical Supplies and Oakdale, Minnesota-based Drikot Medical.
The company said Access Medical would cover Southern California and Nevada, Consolidated Medical Supplies would cover Arizona and Drikot Medical would cover Minnesota, Iowa, South Dakota and North Dakota.
Osprey chief executive officer Mike McCormick said it could be “a costly process to enter new areas and the introduction of the [independent sales agency] model will enable us to expand across the US in the most cost-effective and sustainable way.”
“I look forward to adding more [agencies] in other regions as we continue to expand,” Mr McCormick said.
Osprey fell 0.1 cents or 5.6 percent to 1.7 cents with 5.5 million shares traded.

NOXOPHARM

Noxopharm says it has received $4,592,251 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Noxopharm said the rebate related to research and development expenditure for the year to June 30, 2020.
Noxopharm fell 1.5 cents or two percent to 72 cents with 2.0 million shares traded.

RESAPP HEALTH

Resapp says it has Conformité Européenne (CE) mark approval for its wearable respiratory device for continuous patient monitoring using cough audio.
Last year, Resapp said it had final design files, reports and supporting documents for handheld and wearable devices being developed by Avanti Med and OSI Electronics (BD: May 6, 2020).
Today, the company said the wearables would be manufactured by OSI Electronics at its facilities in UK and South East Asia
Resapp said the wearable could identify more than 93 percent of cough events and less than one percent were identified as false positives.
Resapp was up fell 0.1 cents or 1.75 percent to 5.8 cents with 5.4 million shares traded.

4D MEDICAL

4D Medical says it has requested a voluntary suspension to follow the February 26, trading halt “regarding the outcome of a material grant” (BD: Feb 26, 2021).
4D said it was working on a capital raising and expected the suspension to last until the release of an announcement which would be “no longer than two trading days”.
4D last traded at $1.73.

GENETIC TECHNOLOGIES

Genetic Technologies has requested a trading halt pending an announcement “in relation to a material distribution agreement”.
Trading will resume on March 4, 2021 or on an earlier announcement.
Genetic Technologies last traded at 1.1 cents.

CRESO PHARMA

Creso says it has a non-binding agreement with Ceres Natural Remedies for the distribution of its cannabidiol and hemp-based products in the USA
Creso said the Burlington, Vermont-based Ceres had three shops in the state, access to 50,000 distribution outlets in US and would distribute its animal health product Anibidiol.
The company said the commercial agreement would be formalized by April 1, 2021
Creso fell half a cent or 2.4 percent to 20.5 cents with 13.8 million shares traded.

BARD1 LIFE SCIENCES

Merchant Funds Management says it has increased its substantial shareholding in Bard1 from 10,604,591 shares (13.29%) to 11,636,358 shares (14.46%).
The Nedlands, Western Australia-based Merchant Funds said that after the 30-to-one consolidation by Bard1 it bought and sold shares between December 3, 2020 and February 26, 2021 with the largest purchase 250,000 shares for $842,383 or $3.37 a share and transferred in 3,900,000 shares for $10,920,000 or $2.80 a share.
Merchant Funds said the shares were held by Merchant Opportunities Funds and Merchant Group Pty Ltd.
Bard1 fell 14 cents or 4.75 percent to $2.81 with 847,367 shares traded.

BARD1 LIFE SCIENCES

Jeffrey Emmanuel says he has ceased his substantial share-holding in Bard1.
In 2019, Mr Emmanuel said he had become a substantial shareholder in Bard1 with 105,179,166 shares or 8.46 percent (BD: Jun 20, 2019).
In January 2020, Mr Emmanuel said he held 33,571,428 shares in Sienna Cancer Diagnostics (BD: Jan 24, 2020)
In April 2020, Bard1 said it had acquired Sienna offering 13 shares for every five shares held in Sienna, implying Mr Emmanuel acquired a further 87,285,713 Bard1 shares, implying he had a total of 192,464,879 Bard1 shares (BD: Apr 9, 2020).
In November 2020, Bard1 conducted a 30-to-one consolidation, implying Mr Emmanuel held 6,415,496 post-consolidation shares (BD: Nov 26,2020).
Today, the Hong Kong-based Mr Emmanuel said that on February 26, 2021 he sold 2,660,678 shares for $8,226,609 or $3.09 a share.
Biotech Daily calculates that Mr Emmanuel holds 3,754,818 shares or 4.7 percent.

LITTLE GREEN PHARMA

Little Green managing director Ms Fleta Solomon says her substantial holding with 19,600,000 shares has been diluted from 14.7 percent to 11.1 percent.
The Zug, Switzerland-based Ms Solomon said the dilution was due to the $22 million placement in February (BD: Feb 9, 2021).
Little Green was up five cents or 7.6 percent to 71 cents with 1.2 million shares traded.

LITTLE GREEN PHARMA

Elixxir Limited says it has reduced its substantial holding and been diluted in Little Green from 28,150,074 shares (20.95%) to 27,410,781 shares (15.5%).
The Montreal-based Elixxir said it sold 739,293 shares for 29 cents a share and was diluted in the February placement (see above).