Biotech Daily

Tuesday June 22, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: UNIVERSAL BIOSENSORS UP 7%; PATRYS DOWN 7%**

*** ZUCERO: FDA CANCER TRIAL APPROVAL DELAYS $30m IPO**

*** IDT: TALKS WITH mRNA VICTORIA, STATE GOVERNMENT, MIPS**

*** FDA APPROVES ACRUX GENERIC JUBLIA**

*** LITTLE GREEN RAISES $27m FOR DENMARK MARIJUANA FACILITY**

*** SUDA RAISES $3.7m FOR T-CELL PLATFORM**

*** 'POTENTIAL' CLARITY IPO FOR CANCER DIAGNOSTICS, THERAPIES**

*** MICRO-X APPOINTS ROESYS EMEA ROVER DISTRIBUTOR**

*** CARDIEX, LIFEQ DEAL FOR WEARABLE BAND**

*** IDT, CLEVER LEAVES MARIJUANA THC FLOWER SUPPLY DEAL**

*** ANTISENSE: EMA REQUIRES ADDITIONAL DMD TRIAL INFORMATION**

*** BAKER BROTHERS REDUCES TO 8.5% OF OPTHEA**

*** CHAIR DR MICHAEL MONSOUR TAKES 23.7% OF ANALYTICA**

*** NEUROSCIENTIFIC APPOINTS PARADIGM CEO PAUL RENNIE CHAIR**

*** NUHEARA APPOINTS NICK O'LOUGHLIN, KATHRYN PENNO EXECUTIVES**

MARKET REPORT

The Australian stock market rebounded 1.48 percent on Tuesday June 22, 2021, with the ASX200 up 106.9 points to 7,342.2 points. Eighteen of the Biotech Daily Top 40 stocks were up, 18 fell and four traded unchanged.

Universal Biosensors was the best, up five cents or 6.7 percent to 80 cents, with 1.4 million shares traded, followed by Next Science up 6.1 percent to $1.56, with 300,445 shares traded. Immutep climbed 5.6 percent; Amplia, Avita and Dimerix improved more than four percent; Oncosil and Pro Medicus were up more than three percent; Mesoblast and Optiscan rose more than two percent; Compumedics, Cyclopharm, Genetic Signatures, Nova Eye, Orthocell, Proteomics and Resmed were up more than one percent; with Cochlear, Nanosonics and Neuren up by less than one percent.

Patrys led the falls, down 0.4 cents or 7.3 percent to 5.1 cents, with 56.1 million shares traded, followed by Prescient down 7.1 percent to 19.5 cents, with 25.05 million shares traded. Actinogen and Osprey lost more than six percent; Impedimed, Resonance and Volpara fell four percent or more; Uscom was down 3.45 percent; Imugene and Telix shed more than two percent; Alterity, CSL, Kazia, Opthea, Paradigm and Polynovo were down more than one percent; with Cochlear, Medical Developments and Starpharma down by less than one percent.

ZUCERO THERAPEUTICS

Zucero says that the US Food and Drug Administration approval of a 61-patient, phase II cancer trial has contributed to delaying a proposed $30 million initial public offer.

Melbourne's Zucero said the FDA had approved its investigational new drug application for a phase II 'basket' trial of its PG545, or pixatimod, in combination with Bristol Myers Squibb's PD-1 inhibitor nivolumab, or Opvido, in patients with PD-1 relapsed and/or refractory metastatic melanoma and non-small cell lung cancer (NSCLC) and micro-satellite stable metastatic colorectal cancer (MSS mCRC).

The company said its phase Ib study showed that the combination of pixatimod and Nivolumab induced meaningful anti-cancer activity in patients with micro-satellite stable metastatic colorectal cancer (BD: Jul 29, 2019).

Today, Zucero said that the phase II, open-label, single-centre basket study would be conducted by the University of Pittsburgh Medical Centre, with Dr Diwakar Davar as the principal investigator.

The company said that 31 subjects would be enrolled in stage 1 of the trial, 13 with metastatic colorectal cancer, nine with melanoma and nine with non-small cell lung cancer, with the potential to enrol a further 30 subjects in stage 2, 14 with metastatic colorectal cancer, eight with melanoma and eight with non-small cell lung cancer.

Zucero said that for PD-1 relapsed and/or refractory metastatic melanoma and NSCLC subjects, intravenous pixatimod would be dosed at 25mg weekly with intravenous nivolumab dosed at 480mg every 4 weeks.

The company said that the metastatic colorectal cancer would also receive a metronomic or low-dose dose of 50mg cyclophosphamide.

Zucero said the primary end point was the objective response rate with secondary endpoints including duration of response, progressive free survival and overall survival.

Zucero chief scientific and operations officer Dr Keith Dredge said the phase Ib preliminary data "showed meaningful anti-cancer activity in patients with MSS mCRC who traditionally have not responded to immune checkpoint inhibitors in a monotherapy setting".

"These data demonstrate that by providing an extra signal to the immune system, in addition to checkpoint blockade, pixatimod may boost the effectiveness of immune checkpoint inhibitors not only for MSS mCRC but for other cancers where immune checkpoint inhibition alone has limited or no benefit," Dr Dredge said.

Zucero managing director Chris Burrell said the company had been hoping to raise up to $30 million at 30 cents a share.

Mr Burrell said that although the institutional and broker firm offer was oversubscribed the company could not complete the listing in the time frame required.

Mr Burrell said that the time when it could list was dependent on not having to re-issue the prospectus as material events relating to our business occurred.

Mr Burrell said that the FDA approval was a factor that might have required a re-issue of the prospectus.

Mr Burrell said that pixatimod and ZUC002 appeared to be "coronavirus agnostic and offer broad anti-viral activity based on their mechanism as heparan sulfate (HS) mimetics".

He said that Zucero was continuing to refine its anti-viral clinical development plan reflecting a 'pandemic preparedness' approach and was considering the best time for the company to list.

Last year, Zucero said that in-vitro studies of ZU545, or pixatimod, had shown it had "potent antiviral activity" against Covid-19 (BD: Jun 26, 2021).

Zucero is a public unlisted company.

IDT AUSTRALIA, VICTORIA GOVERNMENT

IDT says it is in discussions with the Victorian Government, mRNA Victoria and the Monash Institute of Pharmaceutical Sciences for potential vaccine manufacture.
IDT said it could potentially provide “manufacturing services to progress the development of Australia’s first local mRNA [Sars-Cov-2] vaccine candidate”.
Monash University’s Prof Colin Pouton said that pre-clinical evaluation of an mRNA vaccine had progressed well and “we are now keen to partner with an experienced pharmaceutical manufacturer to produce a product for clinical evaluation”.
“We look forward to working with IDT to establish mRNA vaccine manufacturing capability in Australia,” Prof Pouton said.
IDT chief executive officer Dr David Sparling said that the company had put forward its clinical good manufacturing practice (cGMP) manufacturing facilities and capabilities “to get behind the Victorian Government’s landmark commitment and initiative to develop an mRNA manufacturing capability, as we believe it will build upon the existing scientific and medical strengths in Victoria and will deliver essential capabilities for Australia”.
“Manufacturing clinic-ready vaccine candidates coming out of world class research such as Prof Pouton’s at Monash University allows IDT to develop the critical skills and infrastructure at a sovereign cGMP manufacturing site here in Australia,” Dr Sparling said.
“These capabilities will then be locally available for clinical and commercial applications for Covid-19 as well as a broad range of other diseases,” Dr Sparling said.
IDT was up 5.5 cents or 16.4 percent to 39 cents with 7.9 million shares traded.

ACRUX

Acrux says the US Food and Drug Administration has approved its generic version of Jublia 10 percent topical solution for onychomycosis, or fungal toenail infections.
In 2019, Acrux said it had settled Valeant Pharmaceuticals-initiated patent litigation for its generic equivalent to Jublia or efinaconazole topical solution (BD: Apr 3, 2019).
Today, the company said the abbreviated new drug application (ANDA) submission required data to show the FDA that its generic product was bio-equivalent to Jublia, which had US sales of more than $217 million a year.
The company said it would progress negotiations with an unnamed licensee and expected its product to provide a lower cost alternative to Jublia in the US.
Acrux was up 2.5 cents or 21.7 percent to 14 cents with 5.2 million shares traded.

LITTLE GREEN PHARMA

Little Green says it has commitments to raise $27.2 million in a placement at 60 cents a share to buy a Denmark marijuana production facility.
Little Green said it had received a $15 million commitment from Hancock Prospecting which would hold 10 percent of the company.
The company said the Denmark facility was being acquired from Canopy Growth Corporation for $C20 million ($A21.5 million) with $C10 million to be paid at completion and the remaining payable in 12 months with an imputed interest rate of 12.5 percent.
Little Green said the funds would cover the initial payment, capital expenditure works to permit scaling of the Denmark Facility to 50 percent capacity, build its European sales team and as working capital requirements.
The company said the 60 cents a share offer was a 9.8 percent discount to its 10-day volume-weighted average price with Canaccord Genuity (Australia) the lead manager.
Little Green was up seven cents or 10.8 percent to 72 cents with 1.5 million shares traded.

SUDA PHARMACEUTICALS

Suda says it has raised $3.65 million in a “heavily oversubscribed placement” at 3.8 cents a share, a 5.6 percent premium to the closing price on June 17, 2021.
Last Friday, Suda said it hoped to raise $3 million for a “non-dilutive” licence with Imperial College London for an “invariant natural killer T-cell therapy” platform for blood cancers, to support development of the T-cell platform, which included hiring personnel and manufacturing critical components of the product (BD: Jun 18, 2021).
The company said the placement to institutional and sophisticated investors was led by Baker Young as the lead manager.
Suda was up 1.6 cents or 44.4 percent to 5.2 cents with 51.05 million shares traded.

CLARITY PHARMACEUTICALS

Biotech Daily understands that Clarity is considering a potential initial public offer to fund development of its nuclear medicine program and list on the ASX.
Clarity has been developing copper-ion based technologies for the diagnosis and treatment of cancers.
The company was unable to comment when contacted by Biotech Daily.
Clarity is a public unlisted company.
Biotech Daily editor David Langsam holds shares in Clarity.

MICRO-X

Micro-X says it has appointed agreement with Roesys Medtec GmbH to distribute its Rover mobile x-ray unit in Europe, the Middle East and Africa.
Micro-X said the Espelkamp, Germany-based Roesys had a non-exclusive, three-year distribution licence to promote, market, distribute and sell its Rover unit in hospitals through its sub-distributor operations which would build the company’s brand and increase awareness of the Rover product.
The company said the Rover was currently being exhibited at the Arab Health 2021 medical equipment exhibition at the Dubai World Trade Centre, hosted by Roesys.
Micro-X was unchanged at 31.5 cents.

CARDIEX

Cardiex says its subsidiary Conneqt Inc has an agreement with Lifeq to develop an “artificial intelligence powered” wearable Conneqt Band to provide biometric data.
Cardiex said Conneqt would be responsible for building the Conneqt Band device, obtaining 510(k) clearance from the US Food and Drug Administration, commercialization and marketing of the product.
The company said the Alpharetta, Georgia-based Lifeq would be responsible for integrating the device’s software for data analytics, synchronization to Conneqt’s and Lifeq’s internet cloud networking and promote the sales and distribution of the product.
Cardiex said Lifeq would be paid an undisclosed consulting service fee to cover costs with the payments staggered over the course of development, with 75 percent of the fee was subject to the successful completion of its obligations.
The company said it would receive 100 percent of sales and revenue share opportunities existed between the companies for the subscription-based portion of revenue generated from the device from sale of premium features through the Conneqt software application.
Cardiex was up 0.3 cents or four percent to 7.8 cents with 3.2 million shares traded.

IDT AUSTRALIA

IDT says Clever Leaves will supply two varieties of high tetrahydrocannabinol (THC) marijuana flowers from Clever Leaves' Portugal facility.
IDT said the New York-based Clever Leaves had shipped the first batch of its dried flower, which would be packaged in its certified facility, undergo stability assessment, and be launched as a medical marijuana flower-in-bottle product through unnamed Australian distributors.
The company said the products would "complement [its] pre-existing medicinal cannabis processing, extraction and conversion to finished dosage form activities".
IDT chief executive officer Dr David Sparling said that "Australia currently has limited access to quality and affordable [current good manufacturing practice] medicinal cannabis flower products for patients in need".
"Clever Leaves is a dependable and reputable supplier which meets IDT's stringent … requirements and we see this partnership as a strategic solution which creates a great opportunity for both companies," Dr Sparling said.

ANTISENSE THERAPEUTICS

Antisense says the European Medicines Agency has provided feedback requiring additional information on its phase IIb Duchenne muscular dystrophy trial.
In February, Antisense said it had filed a paediatric investigation plan to the European Medicines Agency for its ATL1102 for non-ambulatory Duchenne muscular dystrophy (DMD) (BD: Feb 25, 2021).
Today, the company said the feedback from the EMA was "in-line with expectations" and key features of the study protocol remained as noted in the February paediatric investigation plan.
Antisense said it was preparing responses to the EMA's Paediatric Development Committee's information requirements and expected the trial design to be finalized with the committee by October 2021.
The company said it had submitted a fast-track designation request to the US Food and Drug Administration to advance its ATL1102 Duchenne muscular dystrophy program.
Earlier this month, Antisense said the US Food and Drug Administration "expects" it to conduct a nine-month monkey toxicology trial of ATL1102 for Duchenne muscular dystrophy (BD: Jun 1, 2021).
Antisense said its nine-patient trial at Melbourne's Royal Children's Hospital showed safety and efficacy and was adequate to support larger studies, with the FDA saying that "it could consider the exploration of higher doses of ATL1102 beyond 25mg per week subject to adequate justification" (BD: Dec 17, 2019).
Antisense said positive feedback from the FDA and EMA has provided the "opportunity to streamline the regulatory processes in Europe and the US and to the extent possible harmonize the company's overall global clinical development plans".
Antisense was unchanged at 19.5 cents with 1.6 million shares traded.

OPTHEA

New York's Baker Brothers Advisors LP says it has decreased its substantial shareholding in Opthea from 34,020,359 shares (9.86%) to 29,696,496 shares (8.46%).
Baker Brothers said between November 17, 2020 and June 21, 2021 it sold and converted shares, with the single largest sale 470,626 shares for $671,039 or $1.43 a share.
Opthea fell 2.5 cents or 1.9 percent to $1.305 with 1.9 million shares traded.

ANALYTICA

Analytica chair Dr Michael Monsour says he has increased his substantial shareholding from 879,475,914 shares (19.99%) to 1,093,761,628 shares (23.71%).
The Maryborough, Queensland-based Dr Monsour said on June 18, 2021 he bought 214,285,714 shares at 0.35 cents a share.
Analytica was unchanged at 0.2 cents with 2.5 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has appointed Paradigm's Paul Rennie as its non-executive chair, replacing interim chair Dr Anton Uvarov who will continue as an executive director.
Neuroscientific said Mr Rennie was currently Paradigm's chief executive officer and founder of Paradigm and previously Mesoblast's chief operating officer.
The company said subject to shareholder approval, Mr Rennie would receive 5,000,000 options exercisable at 40 cents within five years, with 1,000,000 options vesting on appointment, 2,000,000 options vesting at one year from grant and the remaining 2,000,000 options vesting two years from grant.
Neuroscientific was up five cents or 16.1 percent to 36 cents with 1.6 million shares traded.

NUHEARA

Nuheara says it has appointed Nick O'Loughlin as chief innovation officer and Kathryn Penno as director of hearing health to its newly established innovation team.
Nuheara said Mr O'Loughlin was recently Sharkninja's head of product development and previously was with Sunbeam Australia rising to design and engineering general-manager.
The company said clinical audiologist Ms Penno was currently a lecturer at the University of Western Australia and was the founder of a tele-health consulting company.
Nuheara fell 0.3 cents or 6.25 percent to 4.5 cents with 7.2 million shares traded.