Biotech Daily

Tuesday February 8, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: KAZIA UP 12%; NANOSONICS DOWN 5%**

*** REDHILL 'ADJUNCT OPAGANIB REDUCES COVID MORTALITY 70%'**

*** RECCE: R327 SYNTHETIC ANTIBIOTIC 'SAFE AT 500mg'**

*** CHIMERIC: 'ENCOURAGING CLTX-CAR-T SAFETY DATA'**

*** ANTISENSE ATL1102 FOR UNNAMED MUSCLE DISEASE MOUSE STUDY**

*** NEUROSCIENTIFIC COMPLETES IN-VITRO EMTINB STUDIES**

*** BCAL BREAST CANCER TEST 'BACKED BY INDEPENDENT ANALYSES'**

*** AUSCANN FDA GUIDANCE FOR CPAT-01 FOR DOG OSTEOARTHRITIS**

*** NANOSONICS REVISES GE DISTRIBUTION DEAL, AGAIN**

*** CRESO'S HALUCENEX CANADA PSILOCYBIN SUPPLIER**

*** HONG KONG PATENT FOR VGI TOCOTRIENOL DELIVERY**

*** TESSARA HIRES PETER GIRLING, PAUL ADLARD, MARK GREENOUGH**

*** ALLEGRA LOSES DIRECTOR ANTHONY HARTNELL**

MARKET REPORT

The Australian stock market was up 1.07 percent on Tuesday February 8, 2022, with the ASX200 up 75.9 points to 7,186.7 points. Nineteen of the Biotech Daily Top 40 stocks were up, 11 fell and 10 traded unchanged.

Kazia was the best, up 11 cents or 12.2 percent to $1.01, with 118,174 shares traded. Antisense and Micro-X climbed more than six percent; Paradigm improved five percent; Amplia, Dimerix, Impedimed, Opthea, Pro Medicus, Proteomics and Telix rose two percent or more; Clinuvel, Cochlear, Immutep, Imugene, Medical Developments, Mesoblast and Starpharma were up one percent or more; with Avita, CSL and Universal Biosensors up by less than one percent.

Nanosonics led the falls, down 24 cents or 4.8 percent to $4.80, with nine million shares traded. Alcidion fell 4.1 percent; Cyclopharm lost 3.25 percent; Prescient and Volpara shed more than two percent; Compumedics, Emvision and Genetic Signatures were down one percent or more; with Neuren, Next Science, Polynovo and Resmed down by less than one percent.

REDHILL BIOPHARMA

Redhill says two analyses from its oral opaganib phase II/III trial for severe Covid-19 shows a 70.2 percent reduction in mortality, with remdesivir and corticosteroids.

Last year, Redhill said its 475-patient trial of opaganib for Covid-19 showed “consistent trends … [but] the endpoints did not achieve statistical significance” (BD: Sep 15, 2021).

In October, the company said that sub-group data from the trial showed a 62 percent reduction in mortality and other improved outcomes (BD: Oct 5, 2021).

Today, Redhill said one pre-specified analysis showed that opaganib “significantly reduced mortality” when given with the standard-of-care remdesivir and cortico-steroids.

The company said that a second analysis showed that opaganib “delivered a significant benefit in time to recovery”.

Redhill said that it was advancing regulatory discussions in multiple countries, with potential emergency and marketing authorization applications being planned for certain countries in the first half of 2022.

The company said that the pre-specified mortality analysis, undertaken for all patients from the phase II/III study who were receiving remdesivir and corticosteroids at baseline, showed a significant 70.2 percent mortality benefit for opaganib-treated patients, with a mortality rate of 6.98 percent, or three of 43 patients for the opaganib arm with standard-of-care, compared to 23.4 percent or 11 of 47 patients for placebo plus the standard-of-care by day-42 ($p = 0.034$).

Redhill said that the second analysis showed opaganib delivered a significant 34 percent benefit in time to recovery, defined as achieving a score of 1 or less on the World Health Organisation’s ordinal scale by day-14, with 86 of 230 of opaganib-treated patients (37.4%) reaching this event compared to 65 or 233 patients (27.9%) treated with placebo and standard-of-care ($p = 0.013$).

Redhill chief scientific officer Dr Mark Levitt said the analyses and data showing opaganib’s “improved median time to viral RNA clearance, provide strong support for the promising results observed in the phase II/III study post-hoc analysis”.

“Oral opaganib has now shown an ability to reduce deaths, speed up recovery and clear viral RNA, all with a safety and tolerability profile similar to placebo,” Dr Levitt said.

“Strikingly, opaganib has delivered these benefits over and above the very best level of current standard-of-care, with patients receiving both remdesivir and corticosteroids.”

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

On the Nasdaq, Redhill fell 14 US cents or 5.53 percent to $US2.39 ($A3.35) with 1.3 million shares traded.

RECCE PHARMACEUTICALS

Recce says that the third cohort of seven patients in the intra-venous trial of its R327 synthetic antibiotic at 500mg, indicated a “good safety and tolerability profile”.

Recce said the seven male subjects in the 500mg cohort had “no clinically significant changes in vital signs or adverse events”.

The company said the study included eight cohorts ascending from 50mg to 16,000mg and was on-track to be completed by July 2022.

Recce chief executive officer James Graham said the results were “an excellent outcome for this clinically-invasive method of administration, with a few additional participants to strengthen a compelling safety profile, and serves well for regulatory and synergistic program potential”.

Recce was up two cents or 1.6 percent to $1.26.

CHIMERIC THERAPEUTICS

Chimeric says it has “encouraging initial data” for the second cohort in its chlorotoxin chimeric antigen receptor T-cells (CLTX-Car-T-cells) phase I dose escalation study.
Chimeric said the second dose cohort at the Los Angeles’ City of Hope, received intra-tumoral and intra-ventricular administration at 88 $x10^6$ CLTX-Car-T-cells.
The company said that “positive initial safety was seen as patients generally well tolerated the dual routes” and all patients advanced past the 28-day follow-up without dose-limiting toxicities.
Chimeric said there was an “encouraging” activity signal with two of three evaluable patients achieving local stability of disease.
The company said that it was enrolling patients in the third dose cohort, which would “administer CLTX-Car-T-cells to patients through the dual routes of administration at an increased total dose of 220 $x10^6$ CLTX-Car-T-cells”.
Chimeric was unchanged at 21.5 cents with 1.9 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says it has begun dosing mice with an ATL1102 equivalent antisense drug for an unnamed inflammatory muscle disease.
Antisense said the study was part of the collaborative research agreement with Melbourne’s Murdoch Children’s Research Institute’s to investigate the potential of ATL1102 in the new muscle disease, which had no effective treatments.
The company said that the mice had first dose of the antisense CD49d drug, a mouse equivalent of ATL1102, or saline.
Antisense said that ATL1102 had been shown to be clinically active in non-ambulant Duchenne muscular dystrophy patients, while antisense inhibition of CD49d has also demonstrated activity in a muscular dystrophy mouse model of Duchenne muscular dystrophy, reducing both the CD49d target in the muscle and muscle damage.
The company said it had filed patents for the use of ATL1102 in the new indication, which had not been named “as further important intellectual property protection could be generated through the successful conduct of the study program”.
Antisense said that the inflammatory muscle disease was “a rare muscle disease that effects both children and adults with no effective marketed therapy, no disease modifying agents in advanced development and where ATL1102’s observed immune-modulatory activity would be suggestive of potential treatment benefits”.
The company said results from the first phase of the program were expected by July 2022, with the second chronic phase of the program to study the drug effects over a longer dosing period in the animals where the antisense inhibition of CD49d target effects in reducing muscle damage, as determined by fat content in the muscle, would be assessed.
Antisense said that preventing an increase in fat levels in the muscle was “a key clinical goal for patients with this inflammatory muscle disease” and ATL1102 had been show to stabilizing fat levels in the muscle of patients.
The company said that the collaboration would assess the potential of antisense inhibition of CD49d effects in the Duchenne muscular dystrophy model in combination with a dystrophin restoration drug to improve therapeutic outcomes beyond that achieved by the single agent alone, with the study on-track to begin by July with results by October 2022.
The company said dystrophin restoration drugs were used in combination with steroids, but were yet to demonstrate to be effective in further delaying loss of ambulation beyond the use of steroids alone, underlining the opportunity for a new combination therapy.
Antisense was up one cent or 6.1 percent to 17.5 cents with 1.3 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has completed in-vitro geno-toxicity studies and plasma protein-binding studies on Emtinb for neurodegenerative diseases.
Neuroscientific said that both studies were undertaken at the Lancaster, Philadelphia laboratories of the Luxembourg-based Eurofins.
Neuroscientific managing-director Matt Liddelow said that “the positive outcomes from these studies are important for progressing our lead drug candidate Emtinb into first-in-human, clinical studies”.
“The geno-toxicity results are another significant step in developing the safety profile of Emtinb prior to testing in humans and confirming the protein-binding profile of Emtinb in human plasma is important for accurately guiding selection of the first-in-human dose,” Mr Liddelow said.
Neuroscientific was up 1.5 cents or 4.8 percent to 33 cents.

BCAL DIAGNOSTICS

Bcal says its breast cancer screening data has been “independently by its Australian team and by a highly regarded team of international diagnostic experts”.
Bcal said it could reduce the number of biomarkers in the test from 18 to between six and 10 biomarkers.
The company said that BSC-Medical analyzed the blinded data and the findings showed “strikingly internally consistent results across all datasets” with an overall accuracy of 77 percent achieved in the independent validation.
Bcal said the analyses supported its goal of reaching a refined algorithm and facilitating acceleration of test development in a format “attractive both clinically and commercially”.
The company said the analyses meant that “a considerably reduced number of markers … can be used to distinguish between blood samples of breast cancer patients and normal control samples”.
Bcal was up 0.75 cents or 6.25 percent to 12.75 cents.

AUSCANN

Auscann says the US Food and Drug Administration Centre for Veterinary Medicine has provided formal guidance for its marijuana CPAT-01 for dog osteoarthritis.
Auscann said it discussed the development program for the approval of CPAT-01 as veterinary medicine for the management of pain, inflammation and quality of life in dogs with osteoarthritis.
The company said the pre-submission conference meeting package included an overview of the CPAT-01 program, with specific questions that related to the technical sections required for a new animal drug application for approval as a veterinary medicine.
Auscann said it received “favorable recommendations” relating to its approach to a titration regimen for CPAT-01 to address the variability of cannabinoids, as well as confirmation that the development plan for safety and toxicology would be sufficient, reducing the time and cost required for the program.
The company said it had begun the design phase for its clinical effectiveness trial to generate final pilot data to inform the design of its pivotal program.
Auscann was up 1.3 cents or 18.75 percent to 8.3 cents with two million shares traded.

NANOSONICS

Nanosonics says it is changing its Trophon sales model with GE Healthcare in North America from February 2022, until the expiry of the current agreement in June 2022.

Nanosonics said discussions with Chicago's GE Healthcare were underway for a new "original equipment manufacturer" (OEM) capital reseller agreement for the Trophon ultrasound probe cleaning system, to come into effect from July 1, 2022.

The company said it would expand direct operations and its sales team in North America to continue its expansion momentum.

In 2015, Nanosonics said it had a North American direct sales operation to drive sales of the Trophon EPR ultrasound probe cleaner alongside distribution partner GE Healthcare, with GE Healthcare to continue as a non-exclusive distributor of Trophon EPR and its consumables in the US and Canada (BD: Feb 6, 2015).

In 2017, the company said it had a new three-year Trophon EPR reselling agreement providing GE Healthcare "capital reseller" rights in North America (BD: Aug 25, 2017).

Today, Nanosonics said that under the revised North American agreement, GE would "consume inventory and transition to a pass-through sales model for its ongoing sales of Trophon to be made exclusively through its ultrasound sales team".

The company said it would manage inventory, ship, install and train new GE Trophon customers who would become its customers for the ongoing provision of consumables.

Nanosonics said that GE would begin the transition of all existing GE Trophon customers to Nanosonics for the ongoing provision of all consumables.

The company said it had "a well-established logistics operation based in Indianapolis and with the planned expansion of these resources will be well positioned to manage the transition and ensure the ongoing continuity of supply to customers".

Nanosonics said that there would be "no impact on sales of consumables to customers … as a result of the revised sales model".

The company said that in the year to June 30, 2021, consumables and service revenue was 76 percent of North American revenue and about 80 percent of total sales to GE in North America were consumables and service, with the remainder being capital sales.

Nanosonics said that a one-off impact on North American revenue was expected in the six months to June 30 2022, primarily associated with GE transitioning from a stocking distributor where a quantity of inventory of consumables and capital was normally held.

The company said that GE would no longer hold inventory.

The company said that a one-off impact on revenue in the year to June 30, 2022 was expected to be in the range of $13.0 million to $16.0 million.

Last year, Nanosonics said revenue for the year to June 30, 2021 rose 3.0 percent to $103,079,000 with profit after tax down 15.4 percent to $8,578,000 (BD: Aug 24, 2021).

Today, the company said that the increase in operating expenses associated with the North American expansion was expected to be about $1.0 million, but over time was expected to result in a corresponding increase in revenue and margin.

Nanosonics said it expected to report revenue of $60.6 million for the six months to December 31, 2021, up 41 percent compared with the prior corresponding period.

Nanosonics chief executive officer Michael Kavanagh said the revised model was "another significant milestone … and is consistent with our evolution to an increasingly direct sales model and OEM capital reseller channel strategy over time".

"Through this new sales model and expansion of our direct operations, Nanosonics will now manage all Trophon customers with the expectation that the majority of future capital sales will come through the direct channel as well as 100 percent of consumables," Mr Kavanagh said.

Nanosonics fell 24 cents or 4.8 percent to $4.80 with nine million shares traded.

CRESO PHARMA

Creso says that subsidiary Halucenex Life Sciences has been recognized as a licenced psilocybin supplier under Health Canada's special access program.
Creso said that the Windsor, Nova Scotia-based Halucenex could provide psychedelic compounds to researchers and patients under the special access program.
The company said that the special access program was a Federal Canadian program allowing healthcare professions to apply for medications that have not been approved for sale, intended for patients with severe or life-threatening illnesses.
In January, Creso said Halucenex would apply to become a supplier to Canada's special access program (BD: Jan 16, 2022).
Creso was up 0.1 cents or 1.15 percent to 8.8 cents with 2.2 million shares traded.

VGI HEALTH TECHNOLOGY

VGI says the Hong Kong Patent Office has granted a patent covering the delivery of its vitamin E-derived tocotrienols.
VGI said that the patent, titled 'Transmucosal delivery of tocotrienols' would provide intellectual property rights until 2033.
The company said the patent was granted to its wholly-owned subsidiary Invictus Biotechnology Pty Ltd and was directed to the treatment or prevention of delayed onset muscle soreness.
VGI said that it had filed a divisional patent application in China which if granted "will expand the scope of patent coverage in both Hong Kong and China".
The company said it had corresponding patents granted in the US, Canada, the European Union, Japan, Australia, New Zealand, Singapore and South Africa.
On the National (Newcastle) Stock Exchange VGI was untraded at 25 cents.

TESSARA THERAPEUTICS

Tessara says it has appointed Peter Girling as chief operating officer, Prof Paul Adlard as chief scientific officer and Dr Mark Greenough as principal scientist.
Tessara said that Mr Girling most recently was Cellntec Advanced Cell Systems co-founder and chief executive officer.
The company said that Mr Girling would focus on the "rapid commercialization of [its] Realbrain drug screening platform".
According to his Linkedin profile, Mr Girling held a Bachelor of Science from the University of Tasmania.
Tessara said that Prof Adlard had worked at Melbourne's Florey Institute of Neuroscience and Mental Health, the University of California Irvine's Institute for Brain Aging and Dementia and had acted as a consultant to CSL, Alterity and Armaron Bio.
According to his Linkedin profile, Prof Adlard held a Bachelor of Science and a Doctor of Philosophy, from the University of Tasmania.
The company said that Dr Greenough previously worked at Melbourne's Mental Health Research Institute, the University of Melbourne and the Florey Institute of Neuroscience and Mental Health.
According to his Linkedin profile, Dr Greenough held a Bachelor of Science from La Trobe University and a Doctor of Philosophy from the University of Melbourne.
Tessara is a private company.

ALLEGRA ORTHOPAEDICS

Allegra says that director Anthony Hartnell has resigned, effective from February 7, 2022.
Allegra said Mr Hartnell had been an “instrumental member of [its] board since November 2014”.
The company said that it was “extremely grateful for Tony’s contributions to the company resulting from his extensive experience in the areas of corporate and commercial law.”
Allegra fell two cents or 11.8 percent to 15 cents.