Biotech Daily

Wednesday September 7, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MICRO-X UP 8%; NEXT SCIENCE DOWN 9%**

*** ANTISENSE EXPEDITES EURO ATL1102 DMD TRIAL; FUNDS REQUIRED**

*** VICTORIA $2.4m FOR MEDTECH COMMERCIALIZATION CENTRE**

*** ETHICS COMMITTEE BLOCKS NEUROSCIENTIFIC EMTINB TRIAL; DOWN 62%**

*** ARGENICA ARG-007 PHASE I TRIAL APPROVED**

*** ORTHOCELL APPOINTS DEVICE TECHNOLOGIES REMPLIR DISTRIBUTOR**

*** PRESCIENT, MD ANDERSON WORK ON OMNICAR, CANCER BINDERS**

*** PHARMAUST ENROLS 1st DOG IN MONEPANTEL LYMPHOMA TRIAL**

*** NAOS TAKES 32% OF BTC HEALTH**

*** JODI SCOTT TAKES 12% OF CRESO**

*** THORNEY, TIGA TAKE 6% OF MICROBA**

*** TIGA, THORNEY INCREASE; DILUTED TO 24.4% IN VISIONEERING**

*** IMUGENE APPOINTS DR JAKOB DUPONT DIRECTOR**

MARKET REPORT

The Australian stock market fell 1.42 percent on Wednesday September 7, with the ASX200 down 97.2 points to 6,729,3 points. Twelve of the Biotech Daily Top 40 stocks were up, 19 fell, five traded unchanged and four were untraded.

Micro-X was the best, up one cent or 7.7 percent to 14 cents, with 394,992 shares traded. Alcidion climbed 7.1 percent; Amplia and Prescient improved five percent or more; Resmed was up 4.2 percent; Medical Developments and Oncosil rose two percent or more; Orthocell, Proteomics and Volpara were up more than one percent; with Clinuvel, Cochlear, Opthea and Polynovo up by less than one percent.

Next Science led the falls, down eight cents or 8.6 percent to 85.5 cents, with 22,958 shares traded. Immutep and Nova Eye lost seven percent or more; Dimerix fell 6.7 percent; Actinogen was down 5.7 percent; Antisense, Kazia and Patrys fell four percent or more; Avita, Mesoblast and Starpharma were down three percent or more; Telix shed 2.2 percent; Genetic Signatures, Impedimed, Nanosonics and Pharmaxis lost more than one percent; with CSL, Neuren, Paradigm and Pro Medicus down by less than one percent.

ANTISENSE THERAPEUTICS

Antisense says it will conduct an expedited 45-patient, phase IIb trial of ATL1102 in non-ambulant boys with Duchenne's muscular dystrophy, and require some funding.

Antisense said the double-blind, placebo-controlled trial would comprise a six-month dosing trial of ATL1102 followed by a six-month open label phase, with the primary endpoint of performance of upper limb 2.0 test (PUL2.0) to be assessed after six months of treatment, compared to 12 months in the phase IIb/III study.

The company said that it previously announced that it was re-evaluating its ATL1102 in DMD plans to focus on the most effective deployment of cash reserves and reduce upfront capital requirements (BD: Dec 14, 2021; Jul 13, 2022).

Last year, Antisense said that the US Food and Drug Administration required further documentation to lift the partial clinical hold limiting dosing of ATL1102 to 25mg per week for six months (BD: Aug 12, 2021).

Today, the company said that following the initial six-month of placebo, 25mg or 50mg once weekly, patients would be invited into a six-month open label follow-up treatment period in which all boys would be on active treatment of ATL1102 at 25mg or 50mg.

Antisense said the additional time in the phase IIb trial would be used "to demonstrate longevity of response as well as collect additional safety data and facilitate streamlining and de-risking of a phase III study".

The company said that "if results from the phase IIb proved to be highly successful, it would then engage with regulatory agencies in relation to obtaining an accelerated approval for the unmet medical need of non-ambulant DMD patients".

Antisense said the phase IIb trial design was modelled on the phase IIb/III study outlined in its paediatric investigation plan and agreed by the European Medicines Agency and the UK Medicines and Healthcare products Regulatory Agency, with a phase IIb/III clinical trial application submitted in Germany (BD: Jul 13, 2022).

"With the regulatory focus now directed to submission of the phase IIb trial applications, no additional phase IIb/III trial submissions are planned at this time," the company said.

Antisense said the next clinical milestone in the planned phase IIb/III trial would have been a futility analysis after about 48 patients had completed six months of dosing, with the blinded analysis to be "either a go or no-go decision to continue dosing as per protocol" but no statistically analyzed efficacy data would have been available at that time.

The company said the revised design brought forward the reporting of unblinded and statistically analyzed data following the completion of the initial six-month dosing.

Antisense said that, if successful, positive data from a controlled trial of ATL1102 in Duchenne muscular dystrophy patients "could add substantial value to the program and, based on previous external feedback, garner serious partnering interest at an earlier point in the development program than previously anticipated".

The company said the revised design allowed for Australian sites as well as the centres in Europe, facilitating a significantly greater proportion of the trial costs as being eligible for the Federal Research and Development Tax Incentive, which should have a material impact on reducing the cash requirements for the conduct of the study.

Antisense said it expected the first sites to be initiated this year, with the last patient to enter the trial about August or September 2023, with the blinded phase completed after six months of dosing, and results to follow shortly thereafter.

The company said the revised plans reduced its costs and with the Tax Incentive, it had funds to October to December 2023, and it had "an approximately mid-single digit A$m additional future cash requirement to get to the time point of the reporting of trial results" and it would confirm the amount and how it would be sourced.

Antisense fell 0.4 cents or four percent to 9.6 cents with 3.3 million shares traded.

VICTORIA GOVERNMENT

The Victoria Government says it has granted And Health $2.4 million to establish the Victorian Connected Health Innovation and Commercialisation Centre.

In 2017, MTP Connect established Australia's National Digital Health (And Health) Initiative to "facilitate and support the development and commercialization of clinically validated digital health" (BD: Apr 7, 2017).

Today, the Victoria Minister for Industry Support and Recovery Ben Carroll said the new centre would "support up to 500 local companies each year, connecting them with healthcare professionals, innovators and investors who can help them fast-track the development of new digital health products".

The media release said that the medical technology sector was one of the fastest growing sectors in Victoria's economy, generating more than $21.4 billion in revenue and supporting more than 31,000 workers, complemented by the more-than 6,000 people working at Victoria's 18 medical research institutes, generating the scientific breakthroughs that informed product development.

Mr Carroll said the Centre would "strengthen Victoria's nation-leading advanced manufacturing capabilities and our status as a growing hub for [medical technology] production".

The Government said that the Centre would support businesses like Global Kinetics whose PKG Watch helped people with Parkinson's disease record and monitor their symptoms and Atmo Biosciences' gas capsule, to report gastro-intestinal data.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says a human research ethics committee has rejected its submission for a phase I trial of Emtinb.

Last year, Neuroscientific said it had appointed Perth's Linear Clinical Research for an up-to 90-participant phase I trial of Emtinb and the study would be used to support future phase II trials in Alzheimer's disease and multiple sclerosis (BD: Jun 23, 2021).

Today, the company said the ethics committee "determined that at this stage, the supporting documentation did not sufficiently address the risk-benefit profile to justify the conduct of the planned phase I clinical trial".

Neuroscientific said the decision "was unexpected and the company is seeking clarification on the rationale for the decision to determine what steps can be taken to proceed with the phase I clinical trial".

Neuroscientific fell 13.3 cents or 61.9 percent to 8.2 cents with 15.5 million shares traded.

ARGENICA

Argenica says it has ethics approval for its 32-subject, dose-escalation, phase I trial assessing the safety and tolerability of intra-venous ARG-007.

Argenica said the trial would take place at the Perth-based Linear Clinical Research, with dosing expected to begin in October.

Argenica managing-director Dr Liz Dallimore said the company was "delighted to receive ethics approval for our first-in-human study of ARG-007".

"This is a pivotal moment for Argenica, as we take ground-breaking research from the Perron Institute and the University of Western Australia into the clinic," Dr Dallimore said.

Argenica said that ARG-007 had shown pre-clinical promise for minimizing brain tissue damage during a stroke (BD: Mar 30, 2022).

Argenica was up half a cent or one percent to 48.5 cents.

ORTHOCELL

Orthocell says it has appointed Sydney's Device Technologies as the exclusive distributor of its Remplir nerve repair device in Australia and New Zealand.

In March, Orthocell said the Australia Therapeutic Goods Administration had approved its Celgro-based Remplir for peripheral nerve repair procedures (BD: Mar 21, 2022).

Today, the company said that under the five-year agreement, Device Technologies would undertake targeted promotion activities, initiate sales, as well as expand Orthocell's network of referring plastic and orthopaedic surgeons.

Orthocell said it planned to receive reimbursement through inclusion on the Australian Prostheses List for approved nerve repair procedures by October this year.

Orthocell managing-director Paul Anderson said "Device Technologies is a leading supplier of innovative medical solutions to hospitals and healthcare professionals throughout Australia and New Zealand".

"Device Technologies have established relationships with plastic surgeons and orthopaedic specialists and a successful track record in driving the market entry of high-quality products," Mr Anderson said.

Orthocell chief scientific officer and Remplir co-inventor Prof Minghao Zheng said the device was "a paradigm shift in product design and application" providing a non-adhesive barrier structure to protect the nerve.

"Remplir reduces the need for suturing, is easy to use and results in consistent and predictable return of muscle function to paralyzed limbs," Prof Zheng said.

Orthocell was up half a cent or 1.25 percent to 40.5 cents.

PRESCIENT THERAPEUTICS

Prescient Therapeutics says it will work with the Houston-based MD Anderson Cancer Centre to combine its Omnicar with one of MD Anderson's blood cancer binders.

Prescient said that under the agreement, it and the MD Anderson Cancer Centre would collaborate to attach a T-cell receptor-like antibody from the Centre's Eclipse sample library for an undisclosed target present on leukaemic blasts and leukaemic stem cells, whose expression correlated strongly with poor outcomes.

The company said that the binder in question did not recognize healthy bone marrow, and consequently could afford "a unique combination of efficacy and safety".

Prescient said costs would be shared equally by it and MD Anderson and both parties would share ownership of the resultant therapeutic product proportionately.

Prescient head of scientific affairs Dr Rebecca Lim said that "a key challenge in developing effective cancer therapies is identifying targets on the surface of these tumor cells, and then being able to bind to these targets."

"This is where the Eclipse platform has yielded some valuable breakthroughs in target identification and creating unique binders to these novel targets - targets that until now have been hidden inside the cancer cells," Dr Lim said.

"An additional challenge in treating most cancers is the heterogeneity of the antigen expression, and the fact that these change over time," Dr Lim said.

"This is where the power of the Omnicar platform comes to the fore," Dr Lim said.

"Omnicar enables novel [T-cell receptor]-like binders to be uniquely combined with Prescient's binders, to result in a multi-valent and controllable cell therapy capable of addressing a much broader array of blood cancer cells in order to get the best chance of optimal patient outcomes," Dr Lim said. "Furthermore, it enables multiple targets to be addressed over time if the patient happens to relapse."

Prescient was up one cent or 5.6 percent to 19 cents with 2.9 million shares traded.

PHARMAUST

Pharmaust says it has enrolled the first of 10 dogs in a US trial of monepantel as a treatment for canine B cell lymphoma.
Last year, Pharmaust said it was expanding its monepantel for dog lymphoma trial to New Zealand in preparation of a pivotal trial expected in May 2022 (BD: Nov 15, 2022).
Today, Pharmaust said that the dog passed a physical exam and standardized staging tests and within the last week had been sent home to commence treatment with monepantel tablets.
The company said the dog would be required to return for appraisal on day-14 and day-28 of treatment.
Pharmaust was up 0.6 cents or 7.9 percent to 8.2 cents.

BTC HEALTH

Naos Asset Management says it has increased its substantial holding in BTC Health from 87,150,604 shares (30.92%) to 91,300,587 shares (32.39%).
The Sydney-based Naos said that on September 5, 2022, it bought 4,150,083 shares for $208,192, or 5.02 cents a share.
BTC was untraded at 5.4 cents.

CRESO PHARMA

Jodi Scott says she has become substantial in Creso with 209,364,678 shares or 11.72 percent of the company.
The Lyons, Colorado-based Ms Scott said that on August 29, 2022, she acquired the 209,364,678 shares at a non-cash 8.3 cents a share, valuing the shares at $17,377,268.
Ms Scott is the co-founder and chief executive officer of Sierra Sage Herbs LLC, acquired by Creso last week (BD: Aug 29, 2022).
Creso was unchanged at 3.6 cents with four million shares traded.

MICROBA LIFE SCIENCES

Thorney Technologies and Tiga Trading say they have become substantial in Microba with 16,674,160 shares, or 6.08 percent of the company.
The Melbourne-based Thorney and Tiga said that between August 18 and September 2, 2022 they bought 6,289,007 shares for $1,290,801, or 20.5 cents a share.
Microba was untraded at 21 cents.

VISIONEERING TECHNOLOGIES

Tiga Trading and Thorney Technologies say they have increased and been diluted from 600,144,797 shares (25.39%) to 6,001,449 post-consolidation shares (24.35%).
Last year, Visioneering said it had completed a 100-to-one consolidation reducing its Chess depositary interests (CDIs) on issue to 22,647,141 CDIs (BD: Jun 28, 2021).
Visioneering was untraded at 27.5 cents.

IMUGENE

Imugene says it has appointed Dr Jakob Dupont as a non-executive director, effective from today.

Imugene said that Dr Dupont had more than 20 years' experience in drug development, and was currently the head of research and development at Atara Biotherapeutics, a director at Apexigen, an adviser to Ambrx, and was previously an executive at Genentech/Hoffman-La Roche and Oncomed Pharmaceuticals.

Dr Dupont's Linkedin page said he held a Bachelor of arts from the Poughkeepsie New York-based Vassar College, a Master of Arts from New York University and a Doctor of Medicine from the Ithaca, New York-based Cornell University.

Imugene was unchanged at 22 cents with 19.7 million shares traded.