

Biotech Daily

Monday August 7, 2023

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH DOWN: NEXT SCIENCE UP 4%; MESOBLAST DOWN 13%

- * FIREBRICK NASODINE 'REDUCES SARS-COV-2 VIRAL LOAD'
- * MEMPHASYS: VITROLIFE JAPAN FELIX IVF SYSTEM DISTRIBUTOR
- * CLARITY: SLOAN KETTERING 'PRE-TARGETING' CANCER ANTIBODY
- * MEDIBIO 'COMMITMENTS' FOR \$2.25m
- * ONCOSIL APPOINTS DOUG CUBBIN, TO REPLACE CHAIR OTTO BUTTULA
- * DR JAMES GARNER STARTS AS ANTISENSE M-D

MARKET REPORT

The Australian stock market fell 0.22 percent on Monday August 7, 2023, with the ASX200 down 16.1 points to 7,309.2 points.

Seven of the Biotech Daily Top 40 stocks were up, 27 fell, four traded unchanged and two were untraded. All three Big Caps fell.

Next Science was the best, up two cents or 3.7 percent to 56 cents, with 14,256 shares traded.

Both Atomo and Kazia climbed 3.45 percent; Pharmaxis and Resonance rose more than two percent; with Polynovo and Pro Medicus up by less than one percent.

Mesoblast led the falls, for the second trading day in a row, losing a further six cents or 12.8 percent to 41 cents, with 53.3 million shares traded.

Patrys lost 10 percent; Medical Developments, Micro-X and Starpharma were down more than eight percent; Cynata and Universal Biosensors shed more than six percent; 4D Medical and Resmed fell more than four percent; Genetic Signatures, Nanosonics, Nova Eye and Volpara were down more than three percent; Cyclopharm, Dimerix, Impedimed, Imugene, Paradigm and Prescient shed more than two percent; Antisense, Avita, CSL, Neuren, Orthocell and Proteomics were down one percent or more; with Clinuvel, Cochlear, Emvision, Opthea and Telix down by less than one percent.

FIREBRICK PHARMA

Firebrick says its 39-patient, phase II trial shows that Nasodine nasal spray for Covid-19 reduces viral load 100 percent compared to 48 percent for placebo (p = 0.028). Firebrick said the trial of the Betadine-based Nasodine achieved its primary endpoint reducing viral load of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) over four days based on culturable virus from throat and nasal swabs.

The company said that the "small number of subjects meant that it was not possible to detect statistically significant outcomes on the secondary endpoints, which included the impact on Covid symptoms and the number of days to a [rapid antigen test]-negative test, assessed over five days from start of treatment".

Firebrick said it was not planning further covid-19 studies or intending to pursue regulatory approval for Nasodine use in the disease, but expected to continue to undertake research that extended evidence for Nasodine for upper respiratory infections.

Firebrick chief executive officer Dr Peter Molloy said "the treatment ran over two and a half days and then on the fourth day, 100 percent of the Nasodine subjects were clear of virus".

"Achieving statistically significant results in viral shedding, in spite of the small number of subjects, is what we hoped for, and Nasodine did not disappoint," Dr Molloy said. "This is an important finding that extends the body of evidence about Nasodine's mechanism of action in treating upper respiratory infections," Dr Molloy said. "Our focus

remains on Nasodine as a treatment for the common cold ... [and] we look forward to closing our current phase III trial and announcing the results this quarter." Firebrick was up 1.5 cents or 8.1 percent to 20 cents.

MEMPHASYS

Memphasys says it has appointed the Vitrolife Japan KK to distribute its Felix sperm separation system for in-vitro fertilization in Japan.

Memphasys said the Gothenburg, Sweden-based Vitrolife subsidiary was a provider of medical devices, consumables and genetic testing services for the human in-vitro fertilization (IVF) and reproductive health market.

The company said Vitrolife had the exclusive right to sell and distribute the Felix system in Japan for five years, with Vitrolife supporting marketing, sales and training with "an initial focus on key clinicians and high-volume clinics in Japan's private health sector". Memphasys did not disclose the commercial terms of the agreement.

The company said that Felix was an "automated device with single-use cartridges for preparing sperm for human IVF procedures ... [and] gently separates sperm from a semen sample in six minutes using electrophoresis and size exclusion membranes without causing damage to sperm DNA".

Memphasys chief executive officer Alison Coutts said the agreement was "a significant milestone" for the commercialization of Felix.

"We are thrilled to have reached this agreement to collaborate with Vitrolife, a recognized leader in the global fertility sector," Ms Coutts said.

"This strategic collaboration enhances the availability of cutting-edge fertility treatment for men in Japan, a major IVF market, where population levels have been on the decline for many years," Ms Coutts said.

Ms Coutts said Memphasys had a long-standing relationship with Vitrolife, which supported the development of the Felix device including providing its media for use in Felix clinical trials.

Memphasys was up 0.15 cents or 11.1 percent to 1.5 cents with 10 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has a licenced a "pre-targeting" antibody from the New York-based Memorial Sloan Kettering Cancer Center for the diagnosis and treatment of cancer. Clarity said the technology amplified the uptake of radio-pharmaceutical products in cancerous tissue while reducing healthy tissue exposure to radiation through the use of a "click chemistry" reaction.

The company said it would use the technology to tag an antibody, which targets cancer cells, and then use a chaser compound of its copper-64, "which only attaches to the antibody tag" to enable position emission tomography imaging of the cancer burden before using its copper-67 to kill the tumors.

Clarity said a clinical trial studying copper-64 with the pre-targeting technology titled "PET Imaging Using Cu-Tz-SarAr and hu5B1-TCO in People with Pancreatic Cancer", was open for recruitment at the Memorial Sloan Kettering Cancer Center.

The company said it was "a first-in-human diagnostic trial, utilizing copper-64 and a sarcophagine chelator, core to [its] SAR technology".

Clarity did not disclose the commercial terms of the licence.

Clarity chief executive officer Dr Alan Taylor said pre-targeting was "an exciting and ground-breaking avenue ... to develop next-generation products that improve treatment outcomes for children and adults with cancer".

"Pre-targeting holds promise of overcoming the safety issues of antibody-based radiopharmaceuticals, opening up a massive opportunity to use the large cache of antibodies developed over the last 20 years," Dr Taylor said.

"Combining this approach with the 'perfect pairing' of copper-64 and copper-67 represents an untapped opportunity to deliver significant payloads to cancers in a safer and more effective way," Dr Taylor said.

"The trial will validate the technique, and, if positive, will pave the way for a whole new area of development, not only for Clarity, but the entire field of antibody-based therapy," Dr Taylor said.

Clarity was up one cent or 1.1 percent to 90 cents.

<u>MEDIBIO</u>

Medibio says it has firm commitments to raise \$2.25 million through a placement at a price of 0.15 cents a share, with one attaching option for every two shares bought.

Medibio said the placement, at a 25 percent premium to the 15-day volume weighted average price of 0.12 cents a share, was "well supported" by a range of investors, including commitments from chair David Trimboli and other management personnel for a collective total of \$100,000, subject to shareholder approval.

The company said the placement options would be exercisable at 0.4 cents by June 15, 2025.

Medibio said the funds would "fast-track [its] phase II clinical trial for its sleep signal analysis for current major depressive episodes study" to validate its MEB-001 algorithm to assist in the screening and diagnosis of major depressive episodes.

Medibio said the additional funds would be used to progress MEB-001 through US Food and Drug Administration regulation, as well as the commercial roll-out of Stager, its software for providing research groups with data metrics in sleep studies.

The company said the Perth-based JP Equity partners was the lead manager to the placement and would receive a six percent fee of the total funds raised, as well as 100 million advisor options, exercisable on the same terms as the placement options. Medibio was up 0.05 cents or 33.3 percent to 0.2 cents with 17.7 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has appointed Doug Cubbin as a non-executive director effective from today, and he will replace retiring chair Otto Buttula on August 31, 2023.

In May, Oncosil said non-executive chair Mr Buttula would retire at its annual general meeting (BD: May 24, 2023).

Today, the company said Mr Buttula would be replaced by Mr Cubbin following the lodgment of its annual report, and that Mr Buttula would continue to work closely with the board to ensure a smooth transition during this period.

Oncosil said Mr Cubbin had previously been the Telix chief financial officer and the chair of nuclear medicine at the Australian Nuclear Science and Technology Organisation.

According to his Linkedin page, Mr Cubbin held a Bachelor of Business Administration from the Bathurst, New South Wales-based Charles Sturt University.

Oncosil fell 0.1 cents or 7.7 percent to 1.2 cents with 16 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says Dr James Garner has commenced work as its chief executive officer and managing director.

In May, Antisense said it had appointed Dr Garner as its chief executive officer and managing director, effective from August 7, 2023, following Mark Diamond's announced retirement last year (BD: May 8, 2023).

The company said as part of its leadership transition, Dr Charmaine Gittleson would step back from executive responsibilities and would resume her role as non-executive chair. Dr Garner said his first priorities as chief executive officer would be to ensure the continued momentum of the ATL1102 study, to build on partnering outreach and to begin the process of preparing ATL1102 for potential commercialization.

Antisense fell 0.1 cents or 1.9 percent to 5.2 cents with one million shares traded.