

Biotech Daily

Wednesday May 5, 2021

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: IMUGENE UP 22.5%; ACTINOGEN DOWN 10%
- * SDI EXPECTS REVENUE UP 18% TO \$80m, PROFIT UP 77% TO 101%
- * ALCIDION 'OVER-SUBSCRIBED' SHARE PLAN RAISES \$3m, TOTAL \$18.4m
- * RACE 'OVER-SUBSCRIBED' PLACEMENT RAISES \$5.4m
- * OVENTUS REQUESTS 'CAPITAL RAISING' TRADING HALT
- * HONG KONG APPROVES ONCOSIL PANCREATIC CANCER DEVICE
- * MEMPHASYS: NEW IVF PRODUCTS INCLUDE STALLION SPERM TEST
- * NEUROTECH STARTS PHASE I/II MARIJUANA FOR AUTISM TRIAL
- * EMYRIA ECSTASY PROGRAM FOR PTSD
- * NEUROSCIENTIFIC: EMTINB DOSE FOUND IN RABBIT EYES TO 14 DAYS
- * NYRADA: NEW COMPOUNDS IMPROVE NYX-PCSK9I, IN-VITRO
- * REGENEUS GRANTS CEO KAROLIS ROSICKAS 25m INCENTIVE OPTIONS
- * AVECHO LOSES DIRECTOR DAVID SEGAL

MARKET REPORT

The Australian stock market was up 0.39 percent on Wednesday May 5, 2021, with the ASX200 up 27.9 points to 7,095.8 points. Just five of the Biotech Daily Top 40 stocks were up, 27 fell and eight traded unchanged.

Imugene was the best of the few, up 4.5 cents or 22.5 percent to 24.5 cents, with 48.6 million shares traded. CSL climbed 2.4 percent; Dimerix, Universal Biosensors and Volpara were up more than one percent; with Cochlear and Cyclopharm up by less than one percent.

Actinogen led the falls, down 0.6 cents or 10.3 percent to 5.2 cents, with 25.4 million shares traded. Genetic Signatures, Impedimed and Patrys lost more than seven percent; Osprey and Polynovo were down more than five percent; Nova and Starpharma fell more than four percent; Alterity, Neuren and Oncosil were down more than three percent; Antisense, Immutep, LBT, Medical Developments, Next Science, Paradigm and Proteomics shed two percent or more; Mesoblast, Opthea, Optiscan, Pro Medicus and Resmed were down more than one percent; with Avita, Clinuvel, Kazia, Nanosonics and Telix down by less than one percent.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says it expects sales for the 12 months to June 30, 2021 to increase by 18 percent to \$79.6 million, compared to the corresponding period last year of \$67.4 million.

SDI said that sales growth was driven by the continued increase in aesthetic and whitening products, partially offset by the decline in amalgam products.

The company said that most countries were showing "strong recovery from the Covid-19 pandemic, returning to normal operating conditions, however, SDI continues to experience product supply challenges into many overseas markets, due to shipping backlogs".

SDI said it expected after-tax profit for the 12 months to be in the range of \$7.5 million to \$8.5 million, an increase of 77 percent to 101 percent, compared to the previous corresponding period.

SDI was up 3.5 cents or 4.4 percent to 83 cents.

ALCIDION GROUP

Alcidion says it has raised \$3 million in an "oversubscribed" share plan at 32 cents a share taking the total raised to \$18.4 million.

Last month, Alcidion says it had raised \$15.4 million at 32 cents a share to buy Extramed, a UK provider of patient flow management software, and hoped to raise a further \$2.5 million in a share plan (BD: Apr 15, 2021).

Today, the company said the share plan had received \$30 million of applications, with most applicants receiving the basic entitlement of \$1,000 worth shares, or 3,125 shares, with the remaining applications being scaled back on a pro-rata basis based on the size of the applicant's shareholding at the record date.

Alcidion said that applicants who sold shares between the record date and the share plan closing date, or who held less than a marketable parcel of 1,471 shares as at the record date would receive zero allocation.

The company said Henslow Pty Ltd was the lead manager to the capital raising. Alcidion was up 0.5 cents or 1.35 percent to 37.5 cents with 2.4 million shares traded.

RACE ONCOLOGY

Race says its "over-subscribed" placement has raised \$5.4 million at \$3.00 a share, with existing shareholders to receive one free option for every 20 shares purchased.

Race said the share price was a 2.3 percent discount to the last traded price and a 7.8 percent discount to the 10-day volume weighted average price.

The company said that the free attaching options were exercisable at \$4.50 by May 16, 2022.

Race said the funds would be used to manufacture Bisantrene and conduct clinical trials for cancer.

The company said that Merchant Capital Partners Pty Ltd and MST Financial Services Pty Ltd were the joint lead managers and bookrunners to the placement.

Race was up 10 cents or 3.3 percent to \$3.17 with 636,585 shares traded.

OVENTUS MEDICAL

Oventus has requested a trading halt pending an announcement "in relation to a capital raising".

Trading will resume on May 7, 2021 or on an earlier announcement.

Oventus last traded down 0.5 cents or 2.9 percent to 16.5 cents.

ONCOSIL MEDICAL

Oncosil says it has received regulatory approval in Hong Kong to market and sell its radiation device for locally-advanced pancreatic cancer.

Oncosil said that locally-advanced pancreatic cancer treatment in Hong Kong was concentrated within a relatively small number of hospitals and healthcare spending per capita was relatively high compared to other Asian markets.

The company said the approval from the Hong Kong Department of Health's Medical Device Division was a "key step" in its commercialization strategy in Asia, following the approvals in Singapore and Malaysia last year (BD: Jun 1, Aug 28, 2020).

Oncosil fell 0.3 cents or 3.1 percent to 9.5 cents with 1.5 million shares traded.

MEMPHASYS

Memphasys says it is developing a portfolio of assisted reproductive products including a stallion sperm test with Prof John Aitken's team at the University of Newcastle. Memphasys said that with research assistance from the New South Wales-based University of Newcastle it was expanding its focus from sperm separation to reproductive technologies for humans and animals and included prospective medical devices, in-vitro diagnostics and proprietary media.

The company said that the first developmental product would be a stallion fertility test called the Stallion Dismount Diagnostic.

Memphasys executive chair Alison Coutts told Ag & Vet Weekly that the test sampled the remnant of "dismount" semen left on a horse's penis after natural mating with a mare and a chemical test could determine the activity level of the stallion's sperm.

Ms Coutts said that the test detected the probability of the stallion being able to fertilize a mare based on the level of mitochondrial activity in the sperm, with the result known almost instantly.

Ms Coutts said that the test was based on equine sperm being highly dependent on their mitochondria to generate the energy needed for motility and fertilization of the egg. In a media release, the company said that a prototype was currently being developed, with field testing during the Australian race-horse breeding season starting in September 2021. Memphasys said that since the spermatozoa of other ungulate species, including cattle, pigs and sheep, had a similar pattern of metabolism, Prof Aitken and his research team were "confident that this diagnostic system ... [would] permit the rapid assessment of semen quality in other commercially valuable domestic species".

The company said that the Australian thoroughbred industry had more than 20,000 matings in Australia each season, resulting in some 13,000 foals, with all required to be natural and not through artificial insemination.

Memphasys said that breeders wanted conceptions and viable pregnancies as close as possible to the start of the breeding season on September 1, with each additional "day of age" costing more than \$US163 to the owner, with an overall difference of \$US23,000 between the oldest early season conception and youngest late season conception, and "service fees" from \$3,000 to \$250,000 not payable until the pregnancy was confirmed. Ms Coutts said she was "extremely encouraged by the progress both Memphasys and Newcastle University have made in relation to all the products under development, but especially the stallion dismount diagnostic".

"Importantly, it highlights that while bringing our Felix device for humans into commercialization is priority, we are not a one product company reliant on a single revenue stream," Ms Coutts said.

Memphasys was unchanged at 6.2 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has begun a 20-subject. phase I/II study of NTI-Dolce medical marijuana for children aged five to 17 years old with autism spectrum disorder. Neurotech said the open-label study, led by the Monash Children's Hospital head of paediatric neurology Prof Michael Fahey, would assess full-spectrum marijuana strains with less than 0.3 percent tetrahydrocannabinol (THC), including the NTI-Dolce FEN-164. The company said the 16-week trial included a four-week washout, or no treatment period, with daily dosing of FEN-164 delivered in a neutral tasting oil in the treatment period. Neurotech said the trial would assess behavior, agitation, irritability and quality of life. Neurotech was up 0.5 cents or 7.8 percent to 6.9 cents with 7.6 million shares traded.

EMYRIA

Emyria says it has launched its 'EMDMA-001' psychedelic-assisted therapy program for treatment-resistant post-traumatic stress disorder with Mind Medicine Australia. Emyria said the program would start with a phase II, open-label trial of 2,3-methylene-dioxy-meth-amphetamine (MDMA)-assisted psychotherapy at Emyria's Melbourne clinic before expanding to other sites, with the trial of MDMA, also known as 'Ecstasy', to begin pending ethics review and the finalization of logistics.

The company said the program would use specially-trained psychotherapists graduating from Melbourne's Mind Medicine Australia Certificate in Psychedelic-Assisted Therapy (CPAT) training program at the "end of this month".

Emyria said that a priority of the program was to help "evaluate the long-term safety, efficacy and cost benefits of MDMA-assisted psychotherapy".

Emyria fell one cent or 3.85 percent to 25 cents with 1.5 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says that a single dose of its Emtinb penetrates eye tissue for up-to six days and was active in rabbit ocular fluid for up-to 14 days.

Neuroscientific said Emtinb was a therapeutic peptide designed to mimic the neuro-protective and neuro-regenerative ability of the metallothionein-II protein, targeting Alzheimer's disease and glaucoma, as well as other Emtin peptides.

Last year, the company that Emtinb indicated a neuroprotective effect for glaucoma-like damage in pigs (BD: Mar 11, 2020).

Today, Neuroscientific said that a trial by Perth's Lion's Eye Institute showed that a single dose of Emtinb in a range of ocular tissue samples, including the retina and the optic nerve, could be detected for up-to six days, and a study of multiple doses of Emtinb in the ocular fluid of rabbits conducted by the Bedford, Massachusetts-based Toxikon showed that all doses of Emtinb were bioavailable for between four to 14 days in ocular fluid, with "minimal leakage of Emtinb from ocular tissue into systemic blood flow".

Neuroscientific said the studies verified the bioavailability of intra-vitreally delivered Emtinb and indicated the potential for a patient dosing regimen of four to six-week intervals. The company said Emtinb could be administered by a less invasive method, such as an eye drop formulation and the Lion's Eye Institute would begin studies this year, with a three-month safety study of Emtinb in non-human primates to begin "later in 2021". Neuroscientific managing-director Matt Liddelow said the impressive [pharmacokinetic] data means we have flexibility with patient dosing in clinical studies and the tissue distribution data gives us confidence in investigating non-invasive methods of delivery". Neuroscientific fell one cent or 3.8 percent to 25.5 cents with 3.1 million shares traded.

NYRADA INC

Nyrada says it has two "more potent candidates" NYX-PCSK9I-211 and NYX-PCSK9I-212 improve the cholesterol lowering qualities of NYX-PCSK9I, in-vitro.

Last year, Nyrada said NYX-PCSK9I reduced total cholesterol by 57 percent in mice, with 30mg/kg and 50mg/kg doses showing a dose-related response (BD: Jan 17, 2021). Today, the company said that in-vitro testing showed that NYX-PCSK9I-211 and NYX-PCSK9I-212 had improved potency and bioavailability compared to NYX-PCSK9I and might be less prone to interactions with drugs prescribed to patients with high cholesterol. Nyrada said it would add the NYX-PCSK9I-211 and NYX-PCSK9I-212 to its mouse studies to determine the efficacy of NYX-PCSK9I in combination with a statin, which help to lower the level of low-density lipoprotein (LDL) cholesterol in the blood.

The company said the trial aimed to determine whether NYX-PCSK9I, NYX-PCSK9I-211 and NYX-PCSK9I-212 improved the efficacy of statins when co-administered. Nyrada was unchanged at 32 cents.

REGENEUS

Regeneus says it will grant up-to 25,000,000 long term incentive options exercisable at 10 cents each, to chief executive officer Karolis Rosickas.

Last year, Regeneus said it appointed Mr Rosickas chief executive officer, starting on \$250,000 a year with short-term incentives of up to 150 percent of his remuneration and a long-term incentive of up to 6,000,000 options (BD: Nov 2, 3, 2020).

Today, the company said Mr Rosickas' 25,000,000 options were in lieu of the previous long term incentive options, with had not been issued.

Regeneus said the options would vest in three tranches based on conditions, expiring in five years from the grant date.

Regeneus was unchanged at 12 cents.

AVECHO (FORMERLY PHOSPHAGENICS)

Avecho says director David Segal has resigned as a director, effective from the company's annual general meeting on May 31, 2021.

In 2016, Avecho, then Phosphagenics, said that former company investor relations manager Mr Segal was elected as a director at company's annual general meeting, despite lacking board endorsement (BD: Apr 15, May 19, 2016).

Today, the company said that Mr Segal had been "a valuable asset ... and has contributed to the company's growth".

"The remaining directors wish to thank Mr Segal all the best in his future endeavors," Avecho said.

The company said it had withdrawn two resolutions from the annual general meeting relating to Mr Segal's re-election and the proposed grant of options.

Avecho fell 0.1 cents or five percent to 1.9 cents with 2.2 million shares traded.