Biotech Daily

Tuesday May 3, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NOVA EYE UP 12.5%;**
- UNIVERSAL BIOSENSORS DOWN 10%

*** NOVA EYE: FDA PAVES WAY FOR PIVOTAL 2RT AMD TRIAL**

*** ALBANY MEDICAL CENTER BUYS LBT APAS INDEPENDENCE**

*** FIREBRICK STARTS 2nd NASODINE FOR COMMON COLD TRIAL**

*** AUSTRALIAN PATENT FOR INOVIQ SUB-B2M PROTEIN**

*** AVECHO RECEIVES $1m FEDERAL R&D TAX INCENTIVE**

*** OSPREY TAKES 'FUNDING OPTIONS' HALT TO SUSPENSION**

*** BOTANIX REQUESTS 'DERMATOLOGY ASSET ACQUISITION' HALT**

MARKET REPORT

The Australian stock market fell 0.42 percent on Tuesday May 3, 2022, with the ASX200 down 30.8 points to 7,316.2 points.

Twelve of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and three were untraded.

Nova Eye was the best, up three cents or 12.5 percent to 27 cents, with 50,367 shares traded. Kazia climbed 5.6 percent; Cynata and Prescient improved four percent or more; Dimerix and Pro Medicus were up more than three percent; Avita and Pharmaxis rose more than two percent; Clinuvel, Mesoblast, Neuren and Proteomics were up one percent or more; with Cochlear and CSL up by less than one percent.

Universal Biosensors led the falls, down 6.5 cents or 10.1 percent to 58 cents, with 592,670 shares traded.

Alcidion, Imugene and Oncosil lost more than five percent; Amplia fell 4.2 percent; Actinogen was down 3.6 percent; Cyclopharm, Genetic Signatures, Impedimed, Micro-X, and Volpara shed two percent or more; Nanosonics, Polynovo, Resmed and Telix were down more than one percent; with Medical Developments and Paradigm down by less than one percent.

NOVA EYE MEDICAL (FORMERLY ELLEX MEDICAL LASERS)

Nova Eye says it has a defined US clinical study plan and approval pathway for retinal rejuvenation therapy (2RT) laser for intermediate age-related macular degeneration.

Nova Eye said the US Food and Drug Administration would allow the exclusion of patients with reticular pseudo-drusen for a planned up-to 800-patient, pivotal trial with two concurrent protocols, of 2RT for intermediate age-related macular degeneration (AMD).

The company said that the previous Lead study results "were confounded by a sub-group of the study population (24%) who had reticular pseudo-drusen at the time of study enrolment and did not respond well to 2RT treatment".

In 2018, the then Ellex said the trial missed its primary endpoint, but showed a reduction in progression to late-stage AMD in 76 percent of 2RT patients (BD: Sep 21, 2018).

In 2019, the company said that a four-year follow-up of 183 patients showed 2RT had a "rejuvenating" impact on the retina and potential for early intervention (BD: Jul 8, 2019).

Last year, Nova Eye says its retinal rejuvenation treatment (2RT) reduced age-related macular degeneration disease progression by up to 68 percent from baseline over five years (BD: Mar 5, 2021).

The company said at that time that the 2RT patients without reticular pseudo-drusen showed a 68 percent reduction in the rate of progression when compared to the control group ($p = 0.002$).

Today, Nova Eye said that the clinical study plan and the commercial rights would be pursued by its wholly-owned subsidiary Alpharet Pty Ltd.

Nova Eye managing-director Tom Spurling told Biotech Daily that the company was "continuing to engage with potential partners and funding sources to support the clinical study".

The company said that 2RT was a "world first nano-second laser therapy" to treat intermediate age-related macular degeneration and worked by stimulating the rejuvenation of cells in the retina to initiate a healing response that targeted the underlying causes of age-related macular degeneration.

In a media release to the ASX Mr Spurling said that the dialogue with the FDA was time consuming and complex.

"We believe that the extent of the dialogue with the FDA demonstrates the potential importance of 2RT and it is a very positive achievement to have now established a clear path forward," Mr Spurling said.

Nova Eye said patients with age-related macular degeneration had limited treatment options.

The company said that in 2021 it filed an investigational device exemption (IDE) application to the FDA for a pivotal study of 2RT for intermediate age-related macular degeneration (BD: Jul 5, 2021).

Nova Eye said that "based on the FDA feedback, approval to commence the pivotal clinical study using investigator sites in the US is contingent upon Alpharet providing additional clinical data to the FDA, which the company plans to derive through the course of the study itself which will commence at sites outside the US".

The company said Alpharet would start the confirmatory pivotal study at sites in Australia, Canada and Europe, but in accordance with the study protocol reviewed by the FDA.

Nova Eye said the principal investigator would be the Melbourne-based Centre for Eye Research Australia's Prof Robyn Guymer

The company said that the early data gathered in the study outside the US would be submitted to the FDA "to satisfy the request for certain clinical data … [and] not materially impact the overall study schedule".

Nova Eye was up three cents or 12.5 percent to 27 cents.

LBT INNOVATIONS

LBT says New York's Albany Medical Center has bought an Apas Independence with urine analysis module.

LBT said that the automated plate assessment system (Apas) Independence was sold by wholly-owned subsidiary Clever Culture Systems after a six-week "evaluation-to-buy".

Last year, LBT chief executive officer Brent Barnes told Biotech Daily that the standard retail price per unit was $US300,000 ($A420,979) with a further $US20,000 per year licence fee, but that varied with each deal (BD: May 18, 2021).

Today, the company said the Apas Independence "met all of the target performance criteria and was positively received by staff in the laboratory".

LBT said the laboratory was part of the not-for-profit Albany Medical Center, with 1,520 hospital beds in four hospitals in north-eastern New York, which provided diagnostic services to the hospital and conducted more than seven million tests every year.

Albany Medical Center microbiology laboratory director Dr Mary George said the Apas Independence would "help drive efficiencies throughout the laboratory, beyond simply our culture plate workflow".

LBT was up one cent or 13.0 percent to 8.7 cents.

FIREBRICK PHARMA

Firebrick says the first of up-to 450 adults has been recruited into its confirmatory phase III trial for Nasodine nasal spray as a treatment for the common cold.

Firebrick said that the randomized, controlled trial would recruit up to 450 subjects with early cold symptoms to achieve a target treatment population of 196 subjects, who were confirmed by a polymerase chain reaction (PCR) test, to have a viral cold.

According to Firebrick's prospectus, the endpoint for the 260-patient, phase III trial was the impact on nasal symptoms compared to a saline placebo and the Betadine-based Nasodine "achieved a positive benefit of eight percent on that endpoint, but it was not statistically significant and as a result, the phase III trial did not meet its primary endpoint".

In March, Firebrick said it would appeal against the Australian Therapeutic Goods Administration initial decision not to approve Nasodine nasal spray, based on the existing clinical data (BD: Mar 1, 2022).

Today, Firebrick executive chair Dr Peter Molloy said Nasodine "actually targets the viral cause of the common cold, where colds start - in the nose".

The company said the primary endpoint would be the impact of three sprays of Nasodine per nostril, four times daily for five days on overall cold severity in the viral-infected population, with overall cold severity would be measured using the Global Severity Score (GSS) from the Wisconsin Upper Respiratory Symptom Survey-21 cold severity survey.

"GSS is the same endpoint we used as a secondary endpoint in our first phase III trial, against which we saw a clear clinical benefit of Nasodine, especially in those who had confirmed viral infection," said Dr Molloy.

Firebrick said that the trial would be conducted in Australia and South Africa with results expected "later this year".

The company said that any subjects found by PCR testing to have severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) infection, or covid-19, would be excluded from assessment of the primary endpoint but retained for assessment of some secondary endpoints.

Last week, Firebrick said it had begun a phase II trial of Nasodine for Covid-19 in South Africa (BD: Apr 26, 2022).

Firebrick fell half a cent or 1.2 percent to 40 cents.

INOVIQ (FORMERLY BARD1 LIFE SCIENCES, SIENNA CANCER DIAGNOSTICS)

Inoviq says an Australian patent has been issued relating to its Sub-B2M protein which binds to Neu5Gc, a tumor biomarker found in multiple human cancers.

Inoviq said that the patent, titled 'Subtilase cytotoxin B subunit mutant' was issued by IP (intellectual property) Australia to Griffith University and the University of Adelaide and would provide intellectual property protection until November 9, 2037.

The company said that the patent covers the Sub-B2M technology and it held exclusive worldwide rights to the Sub-B2M intellectual property for diagnostic applications.

Inoviq chief executive officer Dr Leearne Hinch said the patent protected the Sub-B2M-based diagnostics pipeline for monitoring breast and ovarian cancers.

"This is the first patent granted for the Sub-B2M technology patent family," Dr Hinch said.

Inoviq said the patent made claims regarding modified Sub-B proteins capable of binding the N-glycolylneuraminic acid (Neu5Gc) and variants and fragments thereof, such as Sub-B2M.

In 2020, the then Sienna Diagnostics said it had licenced the B subunit of Subtilase cytotoxin (Sub-B) from the University of Adelaide (BD: Apr 20, 2020).

Inoviq was up two cents or 3.5 percent to 59 cents.

AVECHO BIOTECHNOLOGY

Avecho says it has received $1,007,990 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

The company said that the incentive payment was for the year to June 30, 2021.

Avecho fell 0.1 cents or 5.6 percent to 1.7 cents.

OSPREY

Osprey has requested a voluntary suspension to follow the trading halt requested on April 29, "as it considers its strategic and funding options" (BD: Apr 29, 2022).

Osprey last traded at 20 cents.

BOTANIX

Botanix has requested a trading halt pending "an announcement in relation to the acquisition of a dermatology asset".

Trading will resume on May 5, 2020 or on an earlier announcement.

Botanix last traded at 7.7 cents.