Biotech Daily

Tuesday October 5, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: CYCLOPHARM UP 4%; PRESCIENT DOWN 8%**

*** CSIRO ELIMINATES DENGUE, YELLOW FEVER, ZIKA MOSQUITO**

*** REDHILL SUB-GROUP DATA BACKS OPAGANIB FOR COVID-19**

*** VOLPARA: $3m US BREAST SOFTWARE CONTRACT**

*** RHYTHM RECEIVES $2.4m FEDERAL R&D TAX INCENTIVE**

*** PHARMAXIS APPROVED FOR PHASE II PXS-5505 MYELOFIBROSIS TRIALS**

*** OPTHEA STARTS EURO ENROLMENT FOR OPT-302 WET AMD TRIALS**

*** CLINUVEL READY FOR SCENESSE XERODERMA PIGMENTOSUM TRIAL**

*** ANTERIS DURAVR HEART VALVE 'FULLY-FUNCTIONING' IN SHEEP**

*** ATOMO, ACCESS REPLACE RAPID SARS-COV-2 SELF-TEST DEAL**

*** CRESO $809k MARIJUANA ORDERS**

*** GOODBYE LIFESPOT HEALTH, HELLO INHALERX**

*** PAUL SHERMAN REPLACES PALLA CFO BRENDAN MIDDLETON**

MARKET REPORT

The Australian stock market fell 0.41 percent on Tuesday October 5, 2021, with the ASX200 down 30.1 points to 7,248.4 points. Five of the Biotech Daily Top 40 stocks were up, 30 fell and five traded unchanged. All three Big Caps fell.

Cyclopharm was the best, up seven cents or 4.4 percent to $1.66, with 35,024 shares traded. Pharmaxis and Uscom climbed more than three percent; with Medical Developments and Next Science up by more than one percent.

Prescient led the falls, down two cents or 8.0 percent to 23 cents, with 14.25 million shares traded. Dimerix lost 6.9 percent; Imugene was down 5.6 percent; Amplia, Genetic Signatures, Kazia, LBT, Mesoblast, Nanosonics, Optiscan, Osprey, Patrys and Starpharma fell four percent or more; Alterity, Opthea, Telix and Volpara were down more than three percent; Antisense, Avita, Clinuvel, Cochlear, Orthocell, Paradigm, Polynovo, Resmed and Universal Biosensors shed two percent or more; Compumedics, Cynata, Immutep, Nova Eye and Pro Medicus were down by more than one percent; with CSL and Proteomics down by less than one percent.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says the Wolbachia pipientis bacteria sterilizes male Aedes aegypti mosquitoes preventing reproduction.

The CSIRO said that its researchers showed that Wolbachia sterilized and eradicated “the invasive, disease carrying Aedes aegypti mosquito … responsible for spreading dengue, yellow fever and Zika”.

The Organisation said that the breakthrough could support the suppression and potential eradication of Aedes aegypti worldwide.

The research article, titled ‘Releasing incompatible males drives strong suppression across populations of wild and Wolbachia-carrying Aedes aegypti in Australia’ was published in the US Proceedings of the National Academy of Sciences (PNAS) and is available at: https://www.pnas.org/content/118/41/e2106828118.

The CSIRO said that the trial released three million male Aedes aegypti mosquitoes in Northern Queensland, sterilized with Wolbachia, across three trial sites over a 20-week period during the summer of 2018.

The Organisation said that the sterile male insects mated with wild females, preventing the production of offspring.

The CSIRO said that scientists returned the following year and found one of the trial sites, Mourilyan in Queensland, was almost devoid of mosquitoes.

The Organisation said the trial was a collaboration with the University of Queensland, the Google-Alphabet subsidiary Verily Life Sciences, the Queensland Institute for Medical Research (Berghofer) and the Townsville, Queensland-based James Cook University.

CSIRO chief executive Dr Larry Marshall said that more than 40 percent of humans “suffer from mosquito-spread diseases”.

“It’s an opportunity for Australia to develop environmentally-friendly mosquito control tools to tackle current and future mosquito incursions,” Dr Marshall said.

The Organisation said that the three million male Aedes aegypti mosquitoes needed for the trial were reared in the insectary at James Cook University in Cairns.

CSIRO scientist Prof Nigel Beebe said the trial showed the technique was robust and capable of effectively suppressing mosquito populations.

“During the trial, we saw over 80 percent of the mosquito population suppressed across our three trial sites,” Prof Beebe said.

“When we surveyed the sites the following year, we were very encouraged to see the suppression still in effect, with one of our most productive towns for Aedes aegypti almost devoid of this mosquito with a 97 percent reduction across the following season,” Prof Beebe said.

“One year on, the mosquito population at the second trial site remained substantially suppressed, while the population fully recovered at the third site,” Prof Beebe said.

“We are currently investigating the differences observed in the following mosquito season as they are incredibly informative in further developing this technology and in modelling how we could remove this exotic virus-transmitting pest in other locations worldwide,” Prof Beebe said.

The CSIRO said that the technique could be used to remove the virus-transmitting Asian tiger mosquito, Aedes albopictus, that had established in the Torres Strait Islands.

The Organisation said that techniques from the trial were being used to support its mosquito suppression programs in French Polynesia and the Hunter region in New South Wales.

REDHILL BIOPHARMA

Redhill says sub-group data from its phase II/III trial of oral opaganib for Covid-19 pneumonia showed a 62 percent reduction in mortality and other improved outcomes.

In September, Redhill said that top-line data from its 475-patient trial of opaganib for Covid-19 showed “consistent trends … [but] the study endpoints did not achieve statistical significance” (BD: Sep 15, 2021)

The company fell $US2.41 or 32.66 percent to $US4.97 on the news.

Today, Redhill said that a sub-group of 251 hospitalized, moderately severe Covid-19 patients, 53 percent of the 475 participants, had a 62 percent “statistically significant reduction in mortality as well as statistically significant improved outcomes in time to room air and median time to hospital discharge”.

The company said the sub-group required a “fraction of inspired oxygen up to 60 percent at baseline … considered to be severely affected and typically require oxygen supplementation via a nasal cannula or face mask”.

Redhill said that there were seven deaths in the 117-patient opaganib arm compared to 21 deaths in the 134-patient placebo arm ($p = 0.019$).

The company said there was a 21 percent statistically significant efficacy benefit with opaganib in reaching room air by day-14, the study primary endpoint, with 77 percent of opaganib patients compared with 63.5 percent on placebo ($p = 0.033$).

Redhill said that opaganib-treated patients had a median four days earlier hospital discharge compared with the placebo arm, a cumulative saving of 524 days of hospitalization across the group by day-42 ($p = 0.0195$).

Redhill medical director Dr Mark Levitt said that the new findings “support the potential for opaganib’s use in hospitalized, moderately severe Covid-19 patients, a key group of patients that are at high risk of disease progression, morbidity and mortality, and who may benefit from opaganib’s combined antiviral and anti-inflammatory activities”.

“The results provide a strong rationale for opaganib’s potential efficacy in hospitalized patients in need of oxygen supplementation up to 60 percent [fraction of inspired oxygen] a large proportion of hospitalized Covid-19 patients,” Dr Levitt said.

“The phase II/III study results are also consistent with opaganib’s earlier US phase II study results and the demonstrated potent antiviral inhibition of [severe acute respiratory syndrome coronavirus-2] variants in human bronchial epithelial cells, providing further support for its potential in earlier stages of disease where viral load is higher,” Dr Levitt said.

Redhill said that “given the post-hoc characteristics of this subset, statistical inferences of significance cannot be formally attributed” so p-values are “nominal”.

The company said that a detailed analysis of baseline risk factors and their potential impact on the mortality outcome in the sensitivity analysis group had been undertaken, showing that the benefit was “robustly maintained irrespective of the subgroups/risk factors, confirming that the positive outcome observed is due to opaganib”.

Redhill said that the overall adverse events were balanced between the opaganib and placebo groups, suggesting good safety, with no new safety signals emerging, further supporting potential use in the patient population and earlier stage populations.

The company said that Opaganib had “a unique dual anti-viral and anti-inflammatory mechanism of action that acts on the viral cause and inflammatory effect of Covid-19”.

“It is believed to exert its antiviral effect by selectively inhibiting SK2, a key enzyme produced in human cells that may be recruited by the virus to support its replication and is expected to be effective against emerging viral variants,” Redhill said.

On the Nasdaq, Redhill climbed 51 US cents or 11.67 percent to $US4.88 ($A6.71) with 8,813,782 shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has a $US2.15 million ($A2.96 million) five-year contract with an unnamed Florida-based company for its breast mammography tracking and diagnostics software.
Volpara said that under the agreement its Patient Hub would replace multiple patient tracking systems and include Risk and Scorecard breast health platform technologies.
The company said the new software would be installed across the US company's imaging centres in 11 states "to provide a standardized patient tracking platform" incorporating the breast density software Risk and Scorecard to enable "the customer to accurately triage each patient into the appropriate personalized breast cancer screening pathway".
Volpara chief executive officer Dr Ralph Highnam said the company "would not normally announce individual deals, [but] this is Volpara's highest-value contract signed to date".
"We are experiencing tremendous momentum for our platform in the market," Dr Highnam said.
Volpara said that the contract translated to $US430,000 ($A591,600) in annual recurring revenue.
Volpara fell 4.5 cents or 3.8 percent to $1.135.

RHYTHM BIOSCIENCES

Rhythm says it has received $2,412,406 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Rhythm said the rebate related to expenditure for the year to June 30, 2021.
Rhythm fell half a cent or 0.4 percent to $1.18.

PHARMAXIS

Pharmaxis says it has been approved to progress to a phase II trial of its PXS-5505 treatment for bone marrow cancer myelofibrosis.
In August, Pharmaxis said it had dosed the third and final cohort of its phase Ic trial of PXS-5505, and that the preceding cohort had showed "predictable increase in drug blood levels in patients… and good tolerability".
Today, the company said that the phase Ic trials had shown "inhibition of the target enzymes, LOX and LOXL2, at greater than 90 percent over a 25-hour period at day-7 and day 28".
Pharmaxis said the study would progress to the phase II dose expansion phase, in which 24 patients would be treated twice a day with the highest dose for six months.
According to the trial listing on the clinicaltrials.gov website, the dose escalation started at 100mg twice daily for four weeks, but did not specify the second and third cohort doses.
Pharmaxis chief executive officer Gary Phillips said the company was "very pleased to have completed the dose escalation phase of this study with such clear and positive findings".
"We will now immediately progress to the phase II dose expansion study where we aim to show PXS-5505 is safe to be taken longer term with the disease-modifying effects that we have seen in the pre-clinical models," Mr Phillips said.
"The trial infrastructure and funding is in place and we are on track to complete the study by the end of 2022," Mr Phillips said.
Pharmaxis was up half a cent or 3.85 percent to 13.5 cents.

OPTHEA

Opthea says it has begun European enrolment for its phase III trials of OPT-302 with ranibizumab and aflibercept for wet age-related macular degeneration (AMD).
In March, Opthea said it had treated the first of about 1,980 patients in the US and Canada, for its two randomized, double-blinded, controlled trials, evaluating the efficacy and safety of OPT-302 in combination with ranibizumab (Lucentis) or OPT-302 with aflibercept (Eylea), compared to ranibizumab or aflibercept alone (BD: Mar 15, 2021).
Today, the company said that the two studies would be conducted in up to 20 countries around Europe, and that enrolment was now open for up to 990 treatment naïve patients in each study.
Opthea chief executive officer Dr Megan Baldwin said that the start of European trials was “an important step in our continued commitment to improve the lives of patients around the world suffering from retinal diseases”.
Opthea said enrolment was ongoing in the US and Canada and would be expanded to the rest of the world.
Opthea fell five cents or 3.7 percent to $1.30.

CLINUVEL PHARMACEUTICALS

Clinuvel will begin a nine-month six-patient phase II study of Scenesse, or afamelanotide 16mg, for treatment of xeroderma pigmentosum group C.
Clinuvel has previously had US, Australian and European approvals for Scenesse for erythropoietic protoporphyria (BD: May 18, 2016; Oct 9, 2019; Oct 27, 2021).
Today, the company said the phase II study would enrol six xeroderma pigmentosum patients to evaluate the safety of Scenesse administered every two weeks, as well as its efficacy in assisting the reparative processes following ultra-violet light-provoked DNA damage of the skin.
Clinuvel said the study, named CUV156, would take place at a specialized xeroderma pigmentosum clinic in Europe for up to nine months, with the first patients to be screened by the end of this month.
Clinuvel fell $1.08 or 2.6 percent to $40.85 with 94,740 shares traded.

ANTERIS TECHNOLOGIES

Anteris says a sheep study of its Duravr transcatheter heart valve shows fully functioning leaflets and haemo-dynamics resulting in zero mortalities.
Anteris said the three-month, six sheep study showed that the Duravr “functioned well” terms of healing characteristics, effect of post-implantation changes in shape and structural components, haemolysis, thrombus formation, embolization of material from the implant site, delivery device or heart valve substitute, migration or embolization of the heart valve substitute; the biological response, interaction with surrounding anatomical structures and structural valve deterioration and/or non-structural valve dysfunction.
The company said that the completed study was required for US Food and Drug Administration early feasibility approval for a human clinical trial.
Anteris said that formal histopathology results would be available in about four weeks and once the data had been formally analyzed it would be submitted to the FDA to supports its application for a human trial.
Anteris was up nine cents or 1.1 percent to $8.30.

ATOMO DIAGNOSTICS

Atomo says it and Access Bio have ended last year's agreement with Access paying Atomo a one-off fee and supplying up to 20 million Sars-Cov-2 rapid antigen tests.
Atomo chief executive officer John Kelly told Biotech Daily that the fee was material but not disclosed, in-line with last year's announcement, and his company had the right to buy up to 20 million severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) rapid tests but his company was "not obliged" to buy the tests.
Last year, Atomo said it had a binding agreement with the Somerset, New Jersey-based Access Bio to supply two million of its rapid diagnostic tests for their Covid-19 antibody test, with Access obliged to sell a minimum of two million products by September 30, 2021, and Atomo would receive a percentage of the gross revenue (BD: Jul 28, 2020).
In September last year, Atomo said that, pending approvals, it would sell Access Bio's Sars-Cov-2 test in Australia, New Zealand and India (BD: Sep 29, 2020)
Today, Atomo said the fee would be in lieu of any payments due from Access Bio under last year's agreement, and that Atomo's obligations to provide Access Bio with its Galileo lateral flow assay devices, as well as the original equipment manufacturer agreement between the two companies, would be terminated.
The company said that the new agreement afforded it the right to buy 10 million Atomo-branded rapid antigen tests at a fixed price per unit from Access Bio, for use in professional settings in Australia and New Zealand, between now and the end of 2022.
Atomo said the rapid Sars-Cov-2 test was listed on the Australian Register of Therapeutic Goods for use in professional settings.
The company said that it also allowed it to buy 10 million Atomo-branded rapid antigen self-tests from Access Bio during 2022, for sale in Australia only.
Mr Kelly said that the Access Bio self-test had US Food and Drug Administration emergency use authorization.
Atomo said it intended to apply to the Therapeutic Goods Administration for the self-test to be authorized for use in Australia.
Atomo fell 3.5 cents or 10.45 percent to 30 cents with six million shares traded.

CRESO PHARMA

Creso says its Canadian subsidiary Mernova Medicinal Inc has received $C742,572 ($A808,572) in purchase orders for its marijuana products.
Creso said $583,261 of purchase orders had been generated from sales by its Canadian provincial partners, which had shown "strong interest in its dried flower and pre-roll joint range, Ritual Sticks".
Creso fell half a cent or 4.8 percent to 10 cents with 35.6 million shares traded.

LIFESPOT HEALTH (TO BE INHALERX)

Lifespot Health says its name will formally change to Inhalerx from tomorrow October 6, 2021 and its ASX code will change to IRX.
Lifespot Health said that the name change was "a combination of inhale and Rx, the common shorthand for prescription, which better reflects the company's focus on medical inhalation devices for the delivery of prescribed medicines".
The company previously said it would specialize in marijuana vaping and acquired Seng Vital for its marijuana vaporizing assets (BD: Sep 18, 2018; Aug 18, 2021).
Lifespot Health last traded at 9.5 cents.

PALLA PHARMA

Palla has appointed Paul Sherman as chief financial officer replacing Brendan Middleton effective from October 19, 2021.

Palla said Mr Sherman was a chartered accountant with 25 years' experience in finance roles, most recently at Clover Corp.

The company said that Mr Sherman had worked for Fosters Group and Nylex.

Palla said that it thanked Mr Middleton for his four years as chief financial officer and as acting chief executive officer this year.

Palla fell six cents or 15.6 percent to 32.5 cents.