Biotech Daily

Thursday October 8, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OSPREY UP 8%; LBT DOWN 8%**

*** FEDERAL $1.7b FOR CSL-UQ, ASTRA ZENECA COVID-19 VACCINES**

*** FEDERAL $17m FOR DOHERTY RESEARCH**

*** VOLPARA H1 REVENUE UP 27% TO RECORD $18m**

*** AMPLIA DOSES 1st PHASE I AMP945 CANCER FIBROSIS TRIAL SUBJECTS**

*** REDHILL PASSES 2nd US REVIEW OF OPAGANIB FOR COVID-19**

*** HERAMED HERABEAT 'COMPARABLE TO HOSPITAL CTG MACHINES'**

*** WEHI SLOWS MOTOR NEURON DISEASE, IN-VITRO**

*** SIMAVITA REVENUE DOWN 76% TO $43k; ASX SUSPENSION LIFTED**

*** ATOMO TO RELEASE 19.8m VOLUNTARY ESCROW SHARES**

*** M&G REDUCES TO 10% OF STARPHARMA**

*** ALLIANZ SE TAKES 7% OF STARPHARMA**

*** AUCKLAND TRUST, LANG WALKER TAKE 42% OF NEXT SCIENCE**

*** MARK LAMPERT, BVF TAKE 17% OF BIONOMICS**

*** PYXIS INCREASES, DILUTED TO 7% OF LIFESPOT**

MARKET REPORT

The Australian stock market was up 1.09 percent on Thursday October 8, 2020, with the ASX200 up 65.6 points to 6,102.0 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 11 fell and eight traded unchanged. All three Big Caps were up.

Osprey was the best, up 0.2 cents or eight percent to 2.7 cents, with 6.3 million shares traded. Avita, Cochlear, Patrys and Universal Biosensors climbed five percent or more; Antisense, Polynovo and Volpara improved more than four percent; Actinogen, Nanosonics, Paradigm and Prescient were up more than three percent; CSL, Immutep, Pro Medicus, Proteomics and Resmed rose more than two percent; Genetic Signatures and Medical Developments were up more than one percent; with Clinuvel, Cynata, Kazia, Neuren and Next Science up by less than one percent.

LBT led the falls, down one cent or 7.7 percent to 12 cents, with 1.95 million shares traded. Uscom fell five percent. Nova Eye was down 3.1 percent; Compumedics and Orthocell shed more than two percent; Dimerix, Impedimed, Imugene, Pharmaxis and Starpharma down one percent or more; with Mesoblast down by 0.3 percent.

FEDERAL GOVERNMENT, CSL, UNIVERSITY OF QUEENSLAND

The Federal Government says it will provide $1.7 billion to CSL to supply 84.5 million vaccine doses to protect people from acquiring Covid-19.

A media release from Federal Health Minister Greg Hunt said the Government was investing $1.7 billion to pre-order 84.8 million doses of vaccine from CSL's Seqirus vaccine division and UK-based Astra Zeneca to prevent severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) infection leading to the Covid-19 disease.

The Federal Government said that "should promising trials prove successful" for the University of Oxford and Astra Zeneca AZD1222 and the University of Queensland-CSL V451 vaccine candidates, it would provide more than 80 million doses of the two potential vaccines (BD: Sep 7, 2020).

Today, Mr Hunt said that the vaccines would be "almost entirely manufactured in Melbourne" including 51 million doses of the University of Queensland-CSL V451 vaccine candidate and 33.5 million doses of the University of Oxford and Astra Zeneca AZD1222 candidate.

The Government said it had a final supply agreement with CSL Seqirus to supply 51 million doses, including key terms to support clinical and technical development activities for the vaccine candidate.

The media release said that phase IIb/III trials of the University of Queensland-CSL vaccine candidate to evaluate efficacy, immunogenicity and safety in adults aged 18 years and above, scheduled to begin in early December 2020.

The Federal Government said it had paid $123.2 million to join the Covax facility, "providing access to a large portfolio of Covid-19 vaccine candidates and manufacturers" and guaranteeing Australia received offers to purchase a number of vaccine candidates from around the world as they become available, meeting safety and effectiveness standards.

Mr Hunt said that in August, the Government donated $80 million to the Covax Advance Market Commitment "a collaborative effort to provide doses to developing countries, enabling more countries to protect their most vulnerable groups".

"Australia's contribution supports a global coordination effort to ensure equitable and affordable access to Covid-19 vaccines, which is essential to reinvigorate the global economy," Mr Hunt said.

Separately, CSL said it has an agreement with the Federal Government to supply 51 million doses of the University of Queensland-CSL Covid-19 vaccine candidate, V451.

In February, CSL said it had partnered with Brisbane's University of Queensland for its coronavirus disease-19 (Covid-19) vaccine program to combine with its influenza subsidiary Seqirus's MF59 adjuvant (BD: Feb 12, 2020).

Last month, the company said that through Seqirus it had an agreement with the Federal Government to supply 51 million doses of the V451 vaccine, based on a two dose per person regime, subject to successful trials (BD: Sep 7, 2020).

Today, CSL said the agreement included "an up-front financial commitment from the Government to support the clinical and technical development activities" to progress V451, but did not disclose the amount.

The company said that if clinical trials were successful it would produce and supply the vaccine "onshore" for Australia.

CSL said the phase I V451 study was underway and enrolment for a multi-site, randomized, blinded, placebo-controlled phase IIb/III study of V451 in adults for efficacy, immunogenicity and safety would begin enrolment, subject to the phase I results, in December 2020, with enrolment expected to be completed by March 2021.

CSL was up $7.08 or 2.4 percent to $298.94 with 896,891 shares traded.

PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY

The Peter Doherty Institute says the Federal Government has provided $17 million for infectious disease management and diagnostics research programs.

The Doherty Institute said $10 million was granted to its 'Precision Public Health in Australia through Integrated Pathogen Genomics' project for rapid and coordinated responses to infectious disease, with $7 million for its 'Meta-GP' meta-genomic program to develop and implement clinical meta-genomic diagnostics for infectious diseases in Australia.

Doherty Institute director Prof Sharon Lewin said that "as evidenced by the Covid-19 pandemic, infectious diseases represent one of the greatest threats to human health and socioeconomic prosperity".

"Pathogen genomics, [or] the deployment of rapid, precise and accurate identification and characterization of infectious diseases pathogens such as viruses and bacteria, has revolutionized the diagnosis, surveillance and control of infectious diseases globally," Prof Lewin said.

VOLPARA HEALTH TECHNOLOGIES

Volpara says annual recurring revenue for the six months to September 30, 2020 was up 26.75 percent to $NZ19.9 million ($A18.3 million).

Volpara said the increase in sales "came from a mix of significant upsells and major new deals" including contract renewals and extensions for its Volpara Breast Heath software-as-a-service platform for personalizing breast screening and optimizing clinical decisions support.

The company said furthers sales increases came from manufacturing partners Fuji Medical and GE Healthcare selling Volpara software with their x-ray machines.

Volpara said the average revenue per user for the three months to September 30, 2020 rose 26.1 percent to $US1.16 ($A1.625), with the average revenue per user within the period ranging from $US1.75 to $US4.30.

Volpara chief executive officer Dr Ralph Highnam said "Covid-19 has been challenging for many companies, so I'm very pleased with how we've adapted to the 'new normal'".

"We now intend to accelerate our plans around upselling the installed base to migrate our customers to [software-as-a-service] contracts and the powerful new integrated breast care platform we've now formally released," Dr Highnam said.

"That platform is a game-changer for radiology practices," Dr Highnam said.

Volpara was up six cents or 4.4 percent to $1.43 with 1.6 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it has dosed the first of 64 patients in its phase I trial of focal adhesion kinase inhibitor AMP945 for cancer and fibrotic diseases.

Last month, Amplia said Melbourne's Alfred Hospital had approved the double blind, placebo-controlled, safety trial of AMP945 in healthy volunteers (BD: Sep 8, 2020).

Today, Amplia chief executive officer Dr John Lambert said "dosing the first human subject with AMP945 is a transformative milestone for Amplia and one that has been the key focus for the company".

"We expect that this trial will provide the foundation upon which we can build parallel clinical programs in cancer and fibrosis," Dr Lambert said.

Amplia was unchanged at 17 cents with 1.1 million shares traded.

REDHILL BIOPHARMA

Redhill says its 40-patient, US phase II trial of opaganib, or Yeliva, for severe Covid-19 pneumonia has passed the second US safety monitoring committee review.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

In August, the company said its phase II opaganib trial had passed the first US safety monitoring committee review, which evaluated unblinded safety data from the first 12 patients treated for at least seven days and recommended the study “continue with no changes” (BD: Aug 28, 2020).

Today, Redhill said the US safety monitoring committee reviewed an unblinded analysis of safety data from the first 24 patients treated in the study for at least seven days and unanimously recommended “continuation without change” for the study.

The company said the trial was 75 percent enrolled, and was expected to be fully enrolled this month with data expected by the end of 2020.

Redhill said that the phase II trial was not powered for efficacy and was focussed on safety evaluation and “identifying a signal of efficacy”.

The company said that the US trial was in parallel to a phase II/III, randomized, double-blind, parallel-arm, placebo-controlled efficacy study in Italy, the UK, Russia, Mexico, Brazil and Israel, which was on track to enrol up-to 270 patients by the end of the year (BD: Apr 7, 2020).

Redhill medical director Dr Mark Levitt said that “passing this second pre-scheduled independent safety review, involving data from 60 percent of the patients in the study, is an important milestone in the ongoing development of opaganib as a potential therapy for patients with severe Covid-19”.

“We are rapidly building more data and experience with opaganib, with the safety database from opaganib studies now numbering close to 200 patients,” Dr Levitt said.

Redhill said it was in discussions with US Government agencies regarding “potential funding to support the rapid advancement of opaganib toward potential emergency use approval and manufacturing scale-up”.

On the Nasdaq, Redhill was up 12 US cents or 1.27 percent to $US9.57 ($A13.41) with 405,997 shares traded.

HERAMED

Heramed says study results show the accuracy of its Herabeat foetal and maternal heartrate monitor to be comparable to hospital-grade cardiotocography machines

Last month, Heramed said it had completed the 81-patient study of its Herabeat foetal heart rate monitor at Perth’s Joondalup Health Campus (BD: Sep 3, 2020).

Today, the company said the results showed a 100 percent foetal heart rate detection by both expectant mothers as well as clinicians.

Heramed said the results showed a “very high level of accuracy with a 0.3 beats per minute mean difference and a total accuracy rate with minimal deviation of between [0.9 and negative 1.5 beats] per minute … from the industry standard benchmark”.

The company said the Herabeat had “exceptional user satisfaction and usability” scores of 96 percent to 100 percent.

Heramed chief executive officer David Groberman said the results were “an important milestone in Heramed’s history as they represent the first comprehensive, independent clinical validation of the accuracy and usability of our technology which can now be leveraged in to all existing and future commercialization opportunities.”

Heramed was unchanged at 14 cents with 6.8 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it is working with the University of Melbourne and Melbourne's Hudson Institute on a potential treatment to slow motor neuron disease.
The Institute said the research team discovered how inflammation in motor neuron disease was triggered and identifying the molecules involved in the pathway "could be a first step towards a new treatment".
WEHI said that blocking the STING immune sensor could "dramatically prevent inflammation from [motor neuron disease] patient cells, paving the way for a new class of drugs to be developed for people with neurodegenerative disorders".
The research article, titled 'TDP-43 Triggers Mitochondrial DNA Release via mPTP to Activate cGAS/STING in ALS' was published in Cell, and is available at: https://www.cell.com/cell/fulltext/S0092-8674(20)31161-2.
The Institute said that the primary immune pathway was activated by the TDP-43 protein that accumulated in the central nervous system of patients with motor neuron disease and by blocking the STING immune sensor, researchers were able to prevent inflammation from patient motor neurons, and thus promote motor neuron survival.
WEHI said that motor neuron disease was "an incurable condition in which the nerve cells controlling the muscles that enable us to move, speak, swallow and breathe, fail to work" with one in 10,000 Australians diagnosed with motor neuron disease and the average life expectancy from diagnosis was two years.
WEHI's Prof Seth Masters said the researchers were investigating how inflammation was triggered in motor neuron disease (MND) which "unexpectedly identified that an immune sensor called STING is activated downstream of TDP-43".
"Fortuitously, our team had already studied the role of STING in other inflammatory diseases and are now working out how to block it," Prof Masters said. "The team then used new inhibitors … to block different components of this inflammatory pathway."
"Using cells from patients with MND that we can turn into motor neurons in a dish, we showed that blocking STING dramatically prevented inflammation and kept the cells alive longer," Prof Masters said. "We are now aiming to validate a biomarker of the pathway earlier in the disease progression … once this neuro-inflammatory biomarker is validated, we will better understand which patients will benefit the most from treatments targeting the pathway [and] … there is the potential to develop a treatment for patients with MND."
"Our pre-clinical models suggest that although the anti-inflammatory drugs that inhibit STING did not prevent disease onset, they did slow the degenerative progression of disease," Prof Masters said. "While it isn't a cure, we hope it might extend life expectancy and dramatically improve the quality of life for people diagnosed with MND."

SIMAVITA

Simavita says its revenue for the year to June 30, 2020 was down 76.45 percent to $43,469 and its ASX suspension has been lifted.
Last week, the ASX suspended Simavita "for failure to lodge the relevant periodic report by the due date" (BD: Oct 1, 2020).
Today, Simavita said net loss after tax was up 3.4 percent to $4,066,679.
The company said revenue came from its Smartz wearable and disposable nappy technology and smartphone application alert system for adults and infants.
Simavita said its diluted loss per share was the same as the previous year at 0.01 cents a share with cash and cash equivalents of $2,062,844 at June 30, 2020 compared to $689,462 at June 30, 2019.
Simavita was untraded at 1.9 cents.

ATOMO DIAGNOSTICS

Atomo says it will release 19,775,112 shares from voluntary escrow on October 16, 2020.
According to Atomo's most recent Appendix 2A, the company had 406,040,337 shares on issue, with 156,307,470 shares restricted in ASX escrow.
Atomo was up half a cent or 1.4 percent to 36.5 cents with 1.05 million shares traded.

STARPHARMA

M&G Investment Management says it has reduced its substantial holding in Starpharma from 45,186,512 shares (12.15%) to 41,674,452 shares (10.35%).
The London-based M&G said it sold shares between April 20 and October 6, 2020 with the single largest sale on May 29 of 905,266 shares for $995,792 or $1.10 a share.
Starpharma fell 1.5 cents or one percent to $1.485.

STARPHARMA HOLDINGS

Allianz SE says it has increased its substantial shareholding in Starpharma from 18,648,131 shares (5.01%) to 28,632,065 shares (7.11%).
The Munich, Germany-based Allianz said it bought and sold shares between June 18 and October 6, 2020 at prices ranging from $1.07 to $1.51 a share.

NEXT SCIENCE

Next Science says Walker Group has amended the substantial shareholder notice filed last year as part of Next Science's initial public offering (BD: Apr 18, 2019).
The Auckland and Sydney-based Auckland Trust Company, Walker Group Holdings Pty Ltd, and Lang Walker said they held 75,510,500 shares or 42.15 percent of Next Science.
Next Science was up half a cent or 0.4 percent to $1.205.

BIONOMICS

Mark Lampert and BVF Partners say they have increased their substantial holding in Bionomics from 108,537,206 shares (15.94%) to 119,401,557 shares (16.98%).
The San Francisco-based Mr Lampert said that on October 6 he and BVF bought 10,864,351 at four cents a share in Bionomics' $893,235 rights offer (BD: Sep 28, 2020).
Bionomics fell half a cent or 3.7 percent to 13 cents.

LIFESPOT HEALTH

Perth's Pyxis Holdings says it, has increased but been diluted in Lifespot from 8,600,015 shares (8.80%) to 8,909,441 shares (7.32%).
Pyxis said that between August 21 and September 3, 2020 it bought 309,426 shares for $11,028 or 3.6 cents a share and was diluted on October 2, 2020 following a $960,000 private placement to Cannvalate Pty Ltd (BD: Oct 2, 2020).
Lifespot fell 0.1 cents or 1.96 percent to five cents.