Biotech Daily

Tuesday April 2, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ONCOSIL UP 8%; GENETIC SIGS DOWN 8%**

*** ANATARA RE-FOCUSSES ON O-T-C BROMELAIN FOR HUMAN HEALTH**

*** IMMURON LODGES FORM F-3 TO RAISE UP TO $US100m**

*** SIENNA BUYS SEVIDENT EXOSOME CANCER TEST FOR $4m**

*** AIRXPANDERS DEBT SUSPENSION FOR REVENUE SHORTFALL**

*** IMUGENE KEY-VAXX AND B-VAXX 'REDUCE TUMOR GROWTH IN MICE'**

*** IMUGENE: HIGH DOSE HER-VAXX TUMOR 'RESPONSES, ANTIBODIES'**

*** LBT APAS INDEPENDENCE GOLDEN STAPH CONTROL STUDY**

*** CARDIEX TO BEGIN SPHYGMOCOR CARDIOVASCULAR TRIAL**

*** IMPEDIMED LAUNCHES GEN 3 SOZO, IMPROVES SECURITY**

*** EUROPEAN PATENT FOR CELLMID MONOTERPENOIDS FOR ALOPECIA**

*** JENCAY TAKES 9.5% OF UNIVERSAL BIOSENSORS**

*** OCEANIA, HCI REDUCE TO 6% OF MACH7**

*** PRO MEDICUS $150m, 10m-SHARE BUY BACK**

*** GI DYNAMICS APPOINTS DR ALLON FRIEDMAN ADVISOR**

MARKET REPORT

The Australian stock market was up 0.41 percent on Tuesday April 2, 2019, with the ASX200 up 25.4 points to 6,242.4 points. Fourteen Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and six were untraded.

Oncosil was the best, recovering 0.4 cents or 8.0 percent to 5.4 cents, with 9.7 million shares traded. Benitec and Osprey climbed more than seven percent; LBT was up 6.6 percent; Mesoblast and Patrys improved four percent or more; Antisense, Clinuvel, Cynata, Starpharma and Universal Biosensors rose more than two percent; with Actinogen, CSL and Pro Medicus up more than one percent.

Genetic Signatures led the falls, down nine cents or 7.9 percent to $1.05, with 113,403 shares traded. Imugene and Paradigm lost five percent or more; Impedimed and Optiscan fell more than four percent; Immutep and Orthocell were down more than three percent; Ellex, Opthea, Prescient and Telix shed more than two percent; with Kazia, Medical Developments and Neuren down more than one percent.

ANATARA LIFESCIENCES

Anatara chief executive officer Steve Lydeamore says the company is fully-focused on developing its bromelain-derived compounds for human health.

Last year, Anatara licenced the pineapple stem bromelain-derived Detach for livestock diarrhoea to the Florham Park New Jersey-based Zoetis in what was described as “a multi-million dollar” deal (BD: May 15, 2018).

In successive quarterly reports, the company has not disclosed large amounts of revenue separate from interest, the research and development tax incentive and other grants.

In its report for the six months to December 31, 2018, Anatara said it had received $US2.5 million ($A3.5 million) in up-front payments and was eligible for milestone payments of up to $US6.3 million.

Today in Melbourne, recently-appointed chief executive officer Steve Lydeamore told Biotech Daily that the company had developed a combination of bromelain and four unnamed compounds which individually were classified as “generally regarded as safe” (GRAS) as a treatment for the symptoms of irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD).

Mr Lydeamore said that bromelain had been shown to assist in correcting gut microbiota to restore normal microbial function and reduce inflammation, especially in the small bowel, the duodenum and jejunum, while the four unnamed components were directed at repairing the gut lining and barrier defects as well as addressing inflammation and directed at irregularities of the colon.

Mr Lydeamore said that the method of action was to prevent the bacteria associated with the diseases from embedding in the lining of the intestines.

Mr Lydeamore said that Anatara was developing the combined compounds as an over-the-counter drug and expected to begin a trial of about 100 patients by the end of 2019, with results expected by the end of 2020.

He said that the company needed to finalize patents around the combination of bromelain with the four existing compounds, as well as the delivery method which required two coatings to the tablets – one to prevent destruction by stomach acid and to reach the intestines and the second to release the ingredients over time.

Mr Lydeamore said that while preparing for the human clinical trial, to finalize label claims, the company was conducting studies to rule out negative interactions with other commonly used drugs and planning a mouse model study of irritable bowel syndrome.

He said that major pharmaceutical companies interested in gut health understood the relevance of specific mouse model studies and partnering discussions could begin once the company had the mouse data which was expected by the end of this year.

“We care hoping for a deal in 18 to 24 months,” Mr Lydeamore said.

He said the company was looking to develop other technologies for potential gastro-intestinal indications and would consider in-licencing appropriate compounds.

Anatara was unchanged at 49 cents.

IMMURON

Immuron says it has lodged a Form F-3 with the US Securities and Exchange Commission to allow it to raise up to $US100 million ($A140.7 million) until April 2022.

Immuron said it had “not resolved to raised capital at this time [but] it does consider this registration statement as important to maintain flexibility accessing the capital market in North American should the need arise.

Immuron fell one cent or 4.8 percent to 20 cents.

SIENNA CANCER DIAGNOSTICS

Sienna says it will buy the San Francisco-based Sevident for up to $US2.8 million ($A3.95 million) in cash and scrip for its biomarker capture technology.
Sienna said it would pay Sevident $US300,000 up front, provide $US1 million in shares and be eligible to receive milestone payments in cash or scrip up to $US1.5 million.
According to the US Patent and Trademark Office, the technology involved a molecular "net" which was a "three-dimensional matrix comprising capture molecules, linkers and spacers for specific and sensitive analyte capture from a sample".
Sienna said the technology would be used to develop exosome-based cancer tests.
Sienna said Sevident chief scientist and inventor of the technology Dr Stein would lead development and commercialization of the technology and Sevident chief executive officer, former Benitec chief executive officer, Dr Peter French, would join as an advisor.
Sienna was up 0.3 cents or 4.55 percent to 6.9 cents.

AIRXPANDERS

Airxpanders has requested a voluntary suspension following last week's "debt agreement" trading halt, saying it expects revenue to be below an agreed target.
Last week, Airxpanders called a trading halt to notify the lender "of the anticipated breach of certain financial covenants in its debt agreement" (BD: Mar 29, 2019).
Today, the company said it expected the lender to waive the covenant violation for the three months to March 31, 2019, with revenue expected to be $US1.65 million to $US1.75 million ($A2.3 million to $A2.5 million), but it could not be sure about future violations and the company was "currently evaluating its prospects of meeting the covenants in the coming quarters" and reviewing its operations to address its revenue shortfall.
Airxpanders said it would resume trading on commencement of a capital raise and a declaration by the US Securities and Exchange Commission on any registration statement and it expected the suspension to last until May 6, 2019.
Airxpanders last traded at 3.5 cents.

IMUGENE

Imugene says its B-Vaxx B-cell cancer vaccine improves its Key-Vaxx check-point inhibitor vaccine in reducing tumor growth in a mouse model of colon cancer.
In February, Imugene said a phase I safety, dosing and immunogenicity data trial of its B-cell vaccines in patients with solid tumors, who over expressed the human epidermal growth factor receptor 2 (HER-2) or neu receptor, showed an anti-tumor response and might "avoid therapeutic resistance" (BD: Feb 26, 2019).
Today, in a presentation to the American Association for Cancer Research meeting in Atlanta, Georgia from March 29 to April 3, 2019, the company said B-Vaxx in combination with Key-Vaxx in a mouse model of colon carcinoma was "more effective" in reducing tumor growth than the programmed cell death-1 (PD-1) Key-Vaxx alone or the control "gold standard anti-mouse PD-1 monoclonal antibody".
Imugene said the presentation, titled 'Development of a novel PD-1 vaccine and in combination with two chimeric HER-2 peptide vaccine provides synergistic inhibition of tumour growth in a syngeneic balb/c model challenged with CT26/Her-2 carcinoma cell line', showed the combination was safe and did not exhibit toxicity or autoimmunity.
The company said it had begun a phase II study of B-Vaxx in patients over expressing HER-2 at US clinical institutions.
Imugene fell 0.1 cents or 5.0 percent to 1.9 cents with 8.4 million shares traded.

IMUGENE

Imugene says new data from its 14-patient, phase Ib, open label trial of HER-Vaxx for gastric cancer shows one complete response and five partial responses.
Last year, Imugene said the trial showed the HER-Vaxx gastric cancer vaccine was safe and increased antibody response at 10 micrograms (µgm), 30µgm and 50µgm dose levels (BD: Dec 17, 2018).
Today, the company said that a presentation at the American Association for Cancer Research meeting showed that of the 11 evaluable patients, one had a complete response, five had a partial response and four had stable disease.
Imugene said that all those treated at the highest dose of 50µgm had a partial response with two demonstrating a greater than 40 percent reduction in tumor size, along with higher antibody levels.
Imugene said the presentation was titled 'A Phase Ib open label multicenter study with a HER-2/neu peptide vaccine administered with cisplatin and 5-fluorouracil or capecitabine chemotherapy shows safety, immunogenicity and clinical response in patients with HER2/Neu overexpressing advanced cancer of the stomach'.
The company said the five patients in the second cohort showed higher antibody levels following a 30-microgram dose, compared to cohort one patients who received a 10-microgram dose.
Imugene said the vaccine was well tolerated and safe at the highest 50-microgram dose, which was recommended for the phase II HER-Vaxx study it began in March 2019.
Imugene

LBT INNOVATIONS

LBT says it has begun a clinical trial to validate its automated plate assessment system (APAS) Independence to analyse methicillin-resistant Staphylococcus aureus.
LBT said the blinded trial study would be conducted with Melbourne's St Vincent's Hospital, to develop the final stage of its methicillin-resistant Staphylococcus aureus (MRSA), or "golden staph" modules.
The company said results of its APAS Independence trial would be compared with microbiologists' interpretation, similar to the approach of its 10,000-patient trial used in its de-novo submission to the US Food and Drug Administration in 2016.
LBT chief executive officer and managing director Brent Barnes said the trial would "support the continued commercialization of the APAS technology by increasing the number of customers where the APAS Independence provides clinical utility".
"It also signals LBT's transition from technology invention to a software manufacturing process for future analysis modules," Mr Barnes said.
LBT said that testing for MRSA, along with urine analysis, accounted for up to 70 percent of the culture plate volume in the target markets of Europe, the US and Australia, so the completion of MRSA modules would be "a significant milestone".
The company said it would present results of its modules' performance at the European Congress of Clinical Microbiology and Infectious Diseases meeting on April 13, 2019.
LBT said its MRSA modules would be available in Australia and the European Union by the end of 2019 following self-certification,
The company said the modules would be available in the US, following US Food and Drug Administration clearance.
LBT was up half a cent or 6.6 percent to 8.1 cents.

CARDIEX

Cardiex says it will begin a trial with subsidiary Inhealth to determine how its Sphygmocor technology can prevent and improve cardiovascular disease.
Cardiex said it would collaborate with Louisiana State University's Pennington Biomedical Research Centre and the University of South Carolina to determine how telehealth products such as its Sphygmocor central blood pressure diagnostic, could be used with "lifestyle counselling" to target cardiovascular disease.
The company said California State University Long Beach and Coastal Carolina University would collaborate on the three-year study, which was expected to cost $2.8 million with the US National Institutes of Health providing a grant worth $990,000.
Cardiex fell 0.1 cents or 2.5 percent to 3.9 cents with 3.5 million shares traded.

IMPEDIMED

Impedimed says it expects to launch the third-generation software for its Sozo bio-impedance diagnostic and comply with provisions of a US health insurance law.
Impedimed chief technology officer Shashi Tripathi said the new software would provide clinical information and analytics faster, more securely and would be easier to navigate.
The company said it would move data handling, storage and analysis of patient records to an internet "cloud"-based system and would offer additional security features for hospital administrators and clinical users.
Impedimed said it expanded security to comply with the US Health Insurance Portability and Accountability Act including security and privacy provisions, allowing it to partner with institutions to collect patient information during tests.
Impedimed fell one cent or 4.65 percent to 20.5 cents with 1.3 million shares traded.

CELLMID

Cellmid says the European Patent Office intends to grant a patent for small molecules derived from botanical extracts for its Évolis products for hair loss and alopecia.
Cellmid said the patent, titled 'Method of treatment of Alopecia with Monoterpenoids' would provide protection until December 12, 2034.
The company said the patent was under examination in the US, Japan and China.
Cellmid was up half a cent or 2.1 percent to 24 cents.

UNIVERSAL BIOSENSORS

Sydney's Jencay Capital Pty Ltd says it has increased its holding in Universal Biosensors from 14,925,509 shares (8.44%) to 16,775,962 shares (9.47%).
The notice, signed by director Brett Rock, said that between January 5 and March 26, 2019 Jencay acquired 1,850,453 shares for $399,359 or 21.6 cents a share.
Universal Biosensors was up half a cent or 2.5 percent to 20.5 cents.

MACH7 TECHNOLOGIES

Sydney's Oceania Capital and HCI say they have reduced their holding in Mach7 from 11,242,455 shares (7.62%) to 9,243,933 shares (6.26%).
Oceania, HCI Australian Operations and HCI Investments Australia said that between March 11 and 29, 2019 they sold 1,998,522 shares for 17.5 cents to 18.5 cents a share.
Mach7 was unchanged at 18.5 cents.

PRO MEDICUS

Pro Medicus says it will buy back up to 10,361,651 shares or 10 percent of shares on issue during the coming 12 months.
Pro Medicus said Goldman Sachs Australia would be the broker buying-back the shares.
Pro Medicus was up 29 cents or 1.95 percent to $15.19 with 146,094 shares traded.

GI DYNAMICS

GI Dynamics says it has appointed Dr Allon Friedman to its scientific advisory board.
GI Dynamics said Dr Friedman was currently supporting the company with obesity, type 2 diabetes and chronic kidney disease expertise.
The company said Dr Friedman was currently a professor of medicine at the Indianapolis-based Indiana University School of Medicine and a director of an affiliated dialysis unit.
GI Dynamics was unchanged at 2.1 cents.