Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: LBT UP 31%; IMMUTEP DOWN 43%**

*** PREVATEX, BARWON: 'MUM'S P COPRI PREVENTS FOOD ALLERGIES'**

*** COCHLEAR PLACEMENT, SHARE PLAN FOR $850m; $150m LOAN**

*** IMMUTEP: 'IMP321 IMPROVES PACLITAXEL FOR BREAST CANCER'**

*** AMPLIA: FDA ORPHAN STATUS FOR AMP945 FOR PANCREATIC CANCER**

*** BOTANIX BTX1204 FOR ECZEMA FAILS ENDPOINTS**

*** ZUCERO INVESTIGATES ZU545 COVID-19 EFFICACY**

*** IMPRESSION PLANS PHASE IIb IHL-42X FOR SLEEP APNOEA TRIAL**

*** SOMNOMED $15.5m RIGHTS OFFER FOR COVID-19 IMPACT, WORKING CAPITAL**

*** IMAGION $2m RIGHTS ISSUE, DIRECTOR BRONWYN LE GRICE GOES**

*** CARDIEX $1.5m MITCHELL R&D LOAN**

*** DORSAVI: COVID-19 CUTS STAFF HOURS 30%, EXPENSES 20%**

*** MEDIBIO, DXC PARTNER FOR ILUMEN OPPORTUNITIES**

*** LIFESPOT ADAPTS BODYTEL FOR (COVID-19) TEMPERATURE**

*** MGC EXTENDS MARIJUANA COVID-19 J-V SUSPENSION, AGAIN**

*** VANGUARD GROUP TAKES 5% OF AVITA**

*** TALI APPOINTS 3 EXECUTIVES; COVID-19 BENEFIT**

*** JERRY KANELLOS REPLACES IMMURON CEO GARY JACOB - COVID-19**

MARKET REPORT

The Australian stock market was up 5.54 percent on Wednesday March 25, 2020, with the ASX200 up 262.4 points to 4,998.1 points. For the second day in a row, 27 of the Biotech Daily Top 40 stocks were up, nine fell and four traded unchanged.

LBT was the best, up 2.5 cents or 31.25 percent to 10.5 cents, with 1.1 million shares traded. Uscom climbed 17.4 percent; Resonance and Starpharma were up more than 13 percent; Avita was up 12.5 percent; Clinuvel and Optiscan were up more than 11 percent; both Antisense and Osprey improved 9.1 percent; Dimerix and Pharmaxis were up more than eight percent; Compumedics, Cynata, Oncosil and Volpara were up more than seven percent; Actinogen was up 6.7 percent; Amplia, Kazia and Nanosonics were up more than five percent; Cyclopharm and Orthocell climbed more than four percent; Mesoblast was up 3.5 percent; Neuren and Opthea rose more than two percent; with Genetic Signatures, Polynovo and Resmed up by more than one percent.

Immutep led the falls, down 13 cents or 43.3 percent to 17 cents with 14.5 million shares traded. Ellex lost 12.4 percent; Universal Biosensors was down 7.1 percent; Medical Developments retreated 6.5 percent; Paradigm fell 5.2 percent; Impedimed, Pro Medicus, Proteomics and Telix shed more than two percent; with CSL down 0.35 percent.

PREVATEX PTY LTD, BARWON HEALTH, DEAKIN UNIVERSITY

A multi-institutional study says the maternal microbiome is impacted by family size and the presence of Prevotella copri is associated with a reduced food allergy risk in infants.

The Barwon Infant Health Study, which began in 2010, is led by Geelong's Barwon Health and Deakin University, with contributions from 10 universities and institutes.

The research paper's lead author, Prof Peter Vuillermin is a professor at Barwon Health and Deakin University and cites an interest in Prevatex Pty Ltd, with the findings subject of a Prevatex licenced patent, whose executive chairman is Dr Greg Collier.

The paper, titled 'Maternal carriage of Prevotella during pregnancy associates with protection against food allergy in the offspring' was published in Nature Communications and is at: https://www.nature.com/articles/s41467-020-14552-1.

A media release from Springer Nature said that "the presence of the bacterium Prevotella copri in mothers' microbiome during pregnancy is associated with a decreased risk of their children developing food allergies during the first year of life".

The media release said the maternal gut microbiome had a role in stimulating foetal immune development and "the absence of specific bacterial species may be associated with an increased risk of immune-related diseases".

"Prof Peter Vuillermin and colleagues analyzed the microbiome of 1,064 mothers in an Australian cohort during pregnancy and reviewed their children every three months until one year of age" and found that children of mothers who carried the gut bacterium Prevotella copri (P copri) were less likely to develop food allergies and the protective association was greatest among women whose diet was high in fat and fibre.

The media release said that larger households and lack of exposure to antibiotics in the third trimester of pregnancy correlated with increased maternal carriage of P copri.

The research article said Prevotella was a commensal bacterial genus that produced short chain fatty acids and endotoxins, each of which might promote the development of foetal immune tolerance, and faecal analyses showed that maternal carriage of P copri during pregnancy "strongly predicts the absence of food allergy in the offspring".

The paper said Prevotella was substantially less abundant in westernized populations than in traditional communities.

The research paper said that Prevotella metabolized dietary fiber and fat to produce succinate, which stimulated innate immune cell development, migration and function and Prevotella produced endotoxins, which influenced foetal immune development and allergic outcomes via Toll-like receptor 4- dependent pathways.

"Thus, it is plausible that low maternal carriage of Prevotella during pregnancy may be causally related to dysregulated immune development and high rates of allergic disease among children in westernized populations," the paper said.

The paper said it was possible that P copri might be a biomarker of other mechanisms underlying susceptibility to allergy; and promoting maternal carriage of P copri might have adverse effects including for rheumatoid arthritis, colitis in mice and might "either exacerbate or improve insulin resistance".

"Our findings have clear implications for public health, given the burden of allergic disease … the magnitude of effect was substantial and P copri was undetected in about 80 percent of mothers … [and] if we assume causality, the estimated population attributable risk of absence of maternal carriage of P copri for food allergy is greater than 50 percent," the research paper said.

Dr Collier said that publication of the Barwon Infant Study results in Nature Communications "adds support to our intellectual property portfolio and commercial strategy for Prevotella copri".

Prevatex is a private company, in which Biotech Daily editor David Langsam owns shares.

COCHLEAR

Cochlear says it hopes to raise $800 million through a placement at $140 a share, $50 million through a share purchase plan and borrow $150 million.
Cochlear said the placement price was a 16.7 percent discount to the March 24, 2020 closing price of $168 and it was fully underwritten by J P Morgan Securities Australia.
The company said that shareholders would be able to apply for up to $30,000 of new shares at the lesser of the placement price or a two percent discount to the five-day volume weighted average price to April 23, 2020.
Cochlear said the share plan record date was March 24, it would open on April 1 and close on April 23, 2020.
The company said it had a $150 million bank facility from an existing lender and would suspend its dividend until trading conditions improved following payment of its dividend for the six months to December 31, 2019 on April 17, 2020.
The company said the funds would be used to enhance its balance sheet and financial flexibility, to “support the business during the current macro-economic uncertainty” due to the Covid-19 outbreak and to materially increase liquidity and reduce net debt.
Cochlear requested a trading halt pending an announcement about completion of the placement, with trading to resume on March 27, 2020 or on an earlier announcement.
Cochlear last traded at $168.00.

IMMUTEP

Immutep says patients in its 227-patient, phase IIb trial receiving IMP321 with paclitaxel for metastatic breast cancer had better outcomes than those on paclitaxel alone.
The company said that 63 percent of patients receiving eftilagimod alpha, or IMP321, with paclitaxel were progression-free at six months, compared to 54 percent in the cohort receiving paclitaxel and placebo.
Last year, Immutep said it had enrolled 226 patients in the phase IIb active immune-therapy paclitaxel with IMP321 (Aipac) trial for human epidermal receptor 2 (HER2) negative and hormone receptor positive metastatic breast cancer (BD: Jun 25, 2019).
Today, the company said the Aipac study was a multi-centre, placebo-controlled, double-blind, randomized study to evaluate IMP321 with paclitaxel, which aimed to boost the T-cell immune response against tumors.
Immutep said patients received paclitaxel at days one, eight and 15 and either IMP321 or a placebo on days two and 16 in six four-week cycles.
The company said that the overall response rate for patients receiving the combination therapy was 48.3 percent compared to 38.4 percent for paclitaxel and placebo.
Immutep said that patients with a low monocyte count at baseline treated with the combination had a median progression free survival of 7.29 months compared to 5.45 months for paclitaxel and placebo, the same progression free survival difference for patients with more aggressive, immunogenic luminal B type cancer.
The company said that patients receiving IMP321 and paclitaxel with lower general performance status at baseline had median 7.13 months progression free survival compared to 6.67 months for paclitaxel and placebo.
The company said the combination treatment of paclitaxel and IMP321 was safe and well tolerated.
Immutep said that with overall survival and immune-monitoring data expected later this year, the results would allow it to build a platform to begin planning a phase III clinical trial of IMP321 for metastatic breast carcinoma.
Immutep fell 13 cents or 43.3 percent to 17 cents with 14.5 million shares traded.

AMPLIA THERAPEUTICS

Amplia says the US Food and Drug Administration has awarded its focal adhesion kinase inhibitor AMP945 orphan drug designation for pancreatic cancer.
Amplia said it would qualify for waived FDA fees, clinical trial protocol assistance and other incentives.
The company said that if approved by the FDA, AMP945 would qualify for seven years' market exclusivity for pancreatic cancer in FDA-administered markets.
Amplia said it aimed to start a phase I trial later this year to confirm that AMP945 was well-tolerated and if successful, begin its first phase II clinical study in cancer patients in 2021.
The company said that AMP945 had multiple modes of action that made it an appealing candidate for treatment regimes for hard-to-treat solid cancers, including pancreatic, ovarian, breast and lung cancers.
Amplia scientific advisory board member Prof Paul Timpson said pancreatic cancer was "a seriously unmet medical need and [the] FDA's designation of AMP945 as an orphan-drug underlines global regulatory agencies' interest in supporting novel treatments for this deadly disease".
Amplia was up 0.3 cents or 5.3 percent to six cents with 1.2 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says its 200-patient, phase II trial of synthetic cannabinoid BTX1204 for atopic dermatitis, or eczema, did not meet its primary or secondary endpoints.
Last year, Botanix said its 368-patient, phase II trial of BTX1503 for acne did not meet its primary endpoint for reduction of inflammatory lesions at 12 weeks (BD: Oct 23, 2019).
Today, the company said the randomized, blinded, controlled study evaluated the safety and efficacy of BTX1204 in patients aged 12 to 70 years with moderate atopic dermatitis, treated for 12 weeks, at 29 dermatology sites in Australia, New Zealand and the US and "did not achieve statistical significance in the primary and secondary endpoints".
Botanix began the trial last year and said that a 37-patient, four-week, phase I trial had shown safety and efficacy (BD: Jun 6, Dec 18, 2018; Jan 25, 2019).
The company said the primary endpoint was the proportion of patients achieving Investigator's Global Assessment success after 12 weeks of treatment, defined as "clear" or "almost clear" and at least a two-grade improvement from baseline at week-12.
Botanix said the secondary endpoints included changes to the signs of atopic dermatitis, the percent of body surface area affected and the itch-numeric rating scale.
The company said that for the primary endpoint, there was no statistical difference, with 12.1 percent of the BTX1204 group achieving success, compared to 18.9 percent in the vehicle group.
Botanix said there was "a small, but statistically non-significant improvement" in the signs, reduction in body surface area affected and a reduction in itch compared to vehicle, with BTX1204 safe and well-tolerated, adverse events primarily mild or moderate in severity, and no treatment-related serious adverse events reported.
Botanix executive chairman Vince Ippolito said the company was "disappointed" by the results and the company would undertake a thorough review of the complete 1204 study data set and provide an update on the wider dermatology platform.
The company said it did not expect further analysis to change the study results.
Botanix said that it had $27.2 million in cash at December 31, 2019, not including the $7.6 million Federal Research and Development Tax Incentive received in January 2020, and a further Tax Incentive claim million expected to be lodged for the year ended 30 June 2020.
Botanix fell 4.1 cents or 61.2 percent to 2.6 cents with 68.5 million shares traded.

ZUCERO THERAPEUTICS

Zucero says it is investigating the efficacy of its lead clinical candidate ZU545 against Covid-19.

In 2016, TBG (formerly Progen Pharmaceuticals) said it had sold its PG500 assets, including PG545, to Zucero for $5,999,000, payable over three years (BD: Aug 22, 2016).

Last year, Zucero executive chairman Chris Burrell said the company was conducting an open-label, phase Ib study of the safety and tolerability of intra-venously infused pixatimod or PG545, in combination with nivolumab, for patients with advanced solid tumors and an expansion cohort of metastatic pancreatic cancer patients (BD: May 7, 2019).

Today, the company said ZU545, previously PG545, had shown anti-viral activity against several viruses, including respiratory syncytial virus, herpes simplex virus, HIV and Ross River fever, by blocking the binding of virus particles to the surface of a host cell, had viricidal activity and the potential to inactivate certain viruses.

The company said it could progress ZU545 quickly to the clinic for Covid-19 cases and it could be reformulated for delivery as a spray in the longer term.

Zucero said it had submitted applications to the US Biomedical Advanced Research and Development Authority and the Commonwealth Scientific and Industrial Research Organisation to test ZU545 against Covid-19.

Zucero is a public unlisted company.

IMPRESSION HEALTHCARE

Impression says its IHL-42X is a potential candidate for obstructive sleep apnoea and it hopes to go direct to a phase IIb trial and an animal toxicology bridging study.

Impression said preclinical and phase I trials were not required due to “extensive existing publicly available clinical information … on the primary constituents of IHL-42X”.

Impression executive director and chief medical officer Dr Sud Agarwal told Biotech Daily that IHL-42X was a combination of two approved drugs, but the company was concluding intellectual property protection measures before releasing further details.

The company said it was developing marijuana-based drugs for a range of indications.

Impression said it expected sales following the phase IIb trial and before US Food and Drug Administration registration, through special access schemes and had commissioned Camargo Pharmaceutical Services to advise on the FDA approval pathway.

Impression was up 0.2 cents or 6.9 percent to 3.1 cents with 7.9 million shares traded.

SOMNOMED

Somnomed says it hopes to raise $15.5 million through an underwritten, one-for-3.24 pro-rata non-renounceable institutional and retail rights offer at 80 cents a share.

Somnomed said the price was a 60 percent discount to the $2.00 closing price on March 17 and the offer was fully underwritten by Wilsons Corporate Finance.

Somnomed said the record date would be March 27, 2020, the institutional offer would open from today, the retail offer would open on April 1 and close on April 15, 2020.

The company said the funds would be used for working capital, the short-term impact of the Covid-19 pandemic through the lockdown of countries in which it operates, and on its Somnodent oral device for obstructive sleep apnoea.

Somnomed said it would reduce its chief executive officer Neil Verdal-Austin’s $480,000 salary by 50 percent, staff salary costs by at least 30 percent, directors would forgo fees until further notice and it would downsize manufacturing.

Somnomed was in a suspension and last traded at $2.00.

IMAGION BIOSYSTEMS

Imagion says it hopes to raise up to $2,040,000 through a two-for-five pro-rata renounceable rights issue at 1.0 cent a share.
Separately, the company said director Bronwyn Le Grice would resign, effective from March 31, 2020.
Imagion said each new share would have an attaching option, exercisable at 3.0 cents each withing three years.
The company said the record date would be March 30, the offer would open on April 1 and close on April 21, 2020.
The company said the funds would be used to complete manufacturing of nanoparticle material, initiate a first-in-human study and for general working capital.
Imagion said Ms Le Grice had been a non-executive director since April 2018 and had resigned due to “professional commitments” as chief executive officer of Andhealth.
Imagion fell 0.6 cents or 37.5 percent to one cent with 16.0 million shares traded.

CARDIEX

Cardiex says it has a $1,500,000 loan facility with Mitchell Asset Management against two years of expected Federal Research and Development Tax Incentives.
Cardiex said the loan was a pre-payment for the expected Incentives for the years to June 30, 2020 and June 30, 2021.
The company said it would be able to draw down $1,420,125 after initial establishment costs and prepaid interest for the first quarter, at a fixed rate of 1.25 percent a month.
The company said the funds would be used to continue research and development programs, for working capital and to fully commit to its previously announced product development initiatives without further equity capital.
Cardiex said the agreement would terminate on October 31, 2021.
Cardiex fell 0.2 cents or 12.5 percent to 1.4 cents with 5.5 million shares traded.

DORSAVI

Dorsavi says that as a result of the Covid-19 outbreak, staff have agreed to reduce working hours by 30 percent and it has reduced operational expenses by 20 percent.
Dorsavi said that there would be no travel or discretionary spending.
The company said the extent of the impact of Covid-19 on its recurring revenue stream over a prolonged period was difficult to assess stage but it would be closely monitored.
The company said that it was aware it needed to protect its $1.83 million cash reserves and ensure its business was sustainable through this period, as it was anticipated that there would be an impact on new sales.
Dorsavi was untraded at 0.8 cents.

MEDIBIO

Medibio says it has an agreement with the Tysons, Virginia-based DXC Technology to identify opportunities for its Ilumen mental health corporate screening product.
Medibio said the memorandum of understanding would target mining, oil and gas clients with fly-in fly-out workforces, who were more likely to suffer from anxiety and depression.
The company said its Ilumen biometric data and subjective assessments provided users with a well-being snapshot to monitor and improve mental health and well-being.
Medibio was unchanged at 0.6 cents with 1.9 million shares traded.

LIFESPOT HEALTH

Lifespot says it will adapt its existing Bodytel smartphone application and platform to include temperature monitoring in response to fever as a symptom of Covid-19.
Lifespot said Bodytel had the capability to track blood sugar, electrocardiogram (ECG), blood pressure and weight.
The company said it was in negotiations with an Australian pharmacy distributor to begin an Australian and Asia Pacific regional rollout.
Lifespot was up 2.7 cents or 122.7 percent to 4.9 cents with 3.3 million shares traded.

MGC PHARMACEUTICALS

MGC has requested a further extension to its voluntary suspension to follow the trading halt requested on March 19, 2020 for a Covid-19-related joint venture.
Last week, MGC requested a trading halt pending an announcement on “a material agreement regarding a strategic joint venture with a Swiss company in relation to Covid-19” (BD: Mar 19, 2020).
On Monday, the company requested a voluntary suspension, which it expected to last until March 24 and yesterday requested an extension which it expected to last until today (BD: Mar 23, Mar 24, 2020).
Today, MGC said it expected the suspension to last until March 26, 2020.
MGC last traded at 1.7 cents.

AVITA MEDICAL

Vanguard Group says it has become a substantial shareholder in Avita with 111,991,869 shares or 5.252 percent of the company.
The Valley Forge, Pennsylvania-based Vanguard said that it bought and sold shares between November 22, 2019 and March 20, 2020, at prices ranging from 34 cents to 84 cents, with the single largest purchase of 3,788,357 shares at 36 cents a share on March 19, 2020.
Avita was up 4.5 cents or 12.5 percent to 40.5 cents with 29.4 million shares traded.

TALI DIGITAL (FORMERLY NOVITA HEALTHCARE, AVEXA)

Tali says it has appointed three executives for sales, marketing and operations and expects Covid-19 encouraged remote learning will benefit its attention products.
Tali said that it had appointed David Turnbull as national sales manager, Lee Simpson as marketing manager and Pete Saunders as chief operations officer.
Tali said Mr Turnbull had held senior positions in the education, training and employment sector and in sales leadership, Mr Simpson had recently held marketing positions with CSG and other organizations and Mr Saunders had worked with state and federal governments, hospitals and private organizations and previously co-founded a health technology company.
Tali said the accelerated shift by the education sector to remote learning, due to the Covid-19 outbreak, would benefit the company due to its attention deficit product suite business model, which was built for digital remote delivery globally.
Tali was up 0.2 cents or 13.3 percent to 1.7 cents with 5.8 million shares traded.

IMMURON

Immuron says Dr Jerry Kanellos will replace chief executive officer Dr Gary Jacob to allow the company to cut costs.

Immuron said this was the first step of a strategy to combat the expected reduction in sales of Travelan for Traveller's diarrhoea, as a result of the Covid-19 outbreak.

The company said it would reduce or remove all external consultant costs and would establish a remuneration model to pay board fees other than by monetary compensation, reducing costs by more than $2 million a year.

Immuron said it would attempt to increase overall revenue by promoting Travelan and Protectyn for their gut health benefits.

Immuron fell 1.1 cents or 14.7 percent to 6.4 cents.