Biotech Daily

Monday November 13, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MESOBLAST UP 11%; LIVING CELL DOWN 25%**

*** OPTISCAN CLAIMS 1st CHINA MICROSCOPE SALE**

*** JAPAN APPROVES VOLPARA ENTERPRISE**

*** MACH 7 RAISES $2m FROM OCEANIA CAPITAL PARTNERS**

*** GI DYNAMICS ENDOBARRIER CONFORMITY CERTIFICATE WITHDRAWN**

*** ITL LAUNCHES CLINICAL BRAND**

*** USCOM WINS US GOVERNMENT LISTING**

*** MESOBLAST: STEM CELLS 'DURABLE' FOR RA AT 52-WEEKS**

*** COURT ORDERS GORDAGEN WIND-UP, CREDITORS MEETING**

*** BOTH RESMED, FISHER & PAYKEL CLAIM UK PATENT WIN**

*** G MEDICAL REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** NOVOGEN LICENCES TRILEXIUM TO HEATON-BROWN; CHINA ADVISOR**

*** CRESO WELCOMES CANADA $1/gm RECREATIONAL MARIJUANA TAX**

*** CONSONANCE TAKES LOSS ON 5% OF AIRXPANDERS**

*** CREDIT SUISSE BORROWS, BUYS TO 7% OF MESOBLAST**

*** AUCKLAND'S MILFORD REDUCES TO 5.3% OF LIVING CELL**

MARKET REPORT

The Australian stock market fell 0.13 percent on Monday November 13, 2017 with the ASX200 down 7.6 points to 6,021.8 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, with eight trading unchanged.

Mesoblast was the best, up 13.5 cents or 10.9 percent to $1.37 with 3.4 million shares traded. Impedimed climbed 10.3 percent; Neuren was up 9.1 percent; Oncosil rose 7.4 percent; Prana improved 4.6 percent; Uscom, Viralytics and Volpara were up three percent or more; Admedus, Airxpanders and Compumedics rose more than two percent; Orthocell was up 1.4 percent; with Clinuvel, Opthea, Resmed and Starpharma up less than one percent.

Living Cell continued to lead the falls, down one cent or 25 percent to three cents with 31.1 million shares traded. Prima lost 7.4 percent; Cyclopharm shed five percent; Dimerix fell 4.8 percent; Acrux and Osprey were down more than three percent; Actinogen, Avita, Bionomics, Genetic Signatures, Nanosonics, Polynovo, Reva and Universal Biosensors shed more than one percent; with Cochlear, CSL, Pro Medicus, Psivida and Sirtex down by less than one percent.

OPTISCAN IMAGING LIMITED

Optiscan says it has sold two of its Viewnvivo confocal research microscope systems to the Shanghai, China-based Fudan University, its first sales in China.

Optiscan said that the Viewnvivo was an endo-microscope system for pre-clinical research that allowed researchers to obtain cellular and sub-cellular images from living tissue in a living animal, in-vivo, in real time.

The company said the system provided “greater control and flexibility and [provided] images of higher resolution compared to other existing endo-microscope technologies”.

Optiscan said the first China sales “underlines Optiscan’s solid progress with commercialization of Viewnvivo”.

The company said that Fudan University had agreed to work with it as a reference site for the pre-clinical research community.

Optiscan said it secured the Fudan University sales through a competitive public tender process and shipment of the product was expected in about four weeks.

Optiscan chief executive officer Archie Fraser said the sale “shows our solid progress with commercializing this unique platform technology”.

“A number of leading Chinese research institutes [are] expecting to finalize their purchase agreements over the near term … [and] our direct activity with distributors and potential customers in China indicates that we should receive more orders in 2017 and beyond,” Mr Fraser said.

Optiscan fell 0.2 cents or 2.1 percent to 9.3 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says Japan has approved its Enterprise breast-screening software as a Class II medical device and it would launch the products through distributor Breast Healthcare.

Volpara said it had installed its Volpara Density software at Hokkaido Cancer Centre, Niigata Cancer Centre, Hokuto Hospital and Showa University School of Medicine and launched the Enterprise software at the Japanese Association of Breast Cancer Screening meeting held in Tokushima, last week.

The company said that Japan had 65 million women, screening about five million each year for breast cancer using mammography, and was a potential major market.

The company said that Japan had about 3,200 mammography machines, making it one of the world’s largest users of mammography outside the US.

Volpara said that breast cancer incidence was increasing in Japan, accounting for 20.4 percent of all new cancers, so breast cancer screening and increasing screening compliance was an area of focus for the Government of Japan.

Volpara chief executive officer Dr Ralph Highnam said that Japan was “an extremely important market due to its size and density notification discussions, and our track record with leading research institutes”.

“We also know it has a higher proportion of women with dense breasts compared to the West,” Dr Highnam said.

Volpara was up two cents or three percent to 69 cents.

MACH7 TECHNOLOGIES

Mach7 says it has raised $2 million in a placement at 17.5 cents to the Sydney-based Oceania Capital Partners.

Mach7 said the funds were for US sales, marketing and new product development.

Mach 7 fell five cents or 22.2 percent to 17.5 cents with one million shares traded.

GI DYNAMICS

GI Dynamics says that its European notified body SGS United Kingdom will withdraw Endobarrier's certificate of conformity from November 12, 2017.

GI Dynamics said that it received notification from SGS in May that the Endobarrier duodenal liner for obesity and type 2 diabetes certificate of conformity was being suspended pending resolution of non-conformances related to ISO 13485 compliance (BD: May 18, 2017).

The company said it had "been working diligently to address the issues raised by SGS".

GI Dynamics said it was "evaluating its options including grounds for appeal of the decision, consulting with its advisors and has initiated communications with SGS to clarify certain procedural and substantive matters relating to the notice".

GI Dynamics said that withdrawal of the certificate of conformity meant it was not able to affix the Conformité Européenne (CE) mark and sell Endobarrier in European Union countries until another certificate of conformity was issued or any appeal was successful.

GI Dynamics fell 0.8 cents or 16.7 percent to four cents with 1.6 million shares traded.

ITL HEALTH GROUP

ITL says it has launched ITL Clinical as a new brand to distribute products to hospitals and clinical markets.

ITL Health said that ITL Clinical would focus on the design and manufacture of easy-to-use medical and surgical products for hospital and clinical use, including ITL Essentials medical devices for storage, transfer and disposal products.

ITL executive chairman Bill Mobbs said that ITL Clinical would "provide our clients, stake-holders and internal teams with a more defined focus and ITL Essentials is the first product suite to reflect this new strategy".

The company said that ITL Essentials included the Quiver surgical tool storage devices for secure instrument holding and protection from heated instruments, a sharps passing tray for commonly used sharps up to a 30mL syringe and a needle mat for secure needle placement, retention and post-surgery count featuring a magnetic service and foam numbered counters for visual confirmation".

ITL was unchanged at 41 cents.

USCOM

Uscom says it has a US General Services Administration Schedule listing allowing it to supply the $US45 billion a year US Federal Government and agencies market.

Uscom said that the listing allowed it to sell to the Department of Veterans Affairs and some state and local governments.

The company said that its ultra-sonic cardiac output monitor the Uscom 1A was being loaded onto the General Services Administration (GSA) Advantage website, the Government shopping site and when its BP+ central blood pressure monitor and Spirosonic respiratory devices received US Food and Drug Administration approval they would be admitted under Uscom GSA listing.

Uscom executive chairman Prof Rob Phillips said that "GSA listing is more important than FDA for revenue".

"FDA is the US regulatory permission to sell, while GSA listing effectively puts our products on the supermarket shelves of most US medical device buyers, and this is a real path to volume sales," Prof Phillips said.

Uscom was up half a cent or three percent to 17 cents.

MESOBLAST

Mesoblast says that 52-week data from its 48-patient, phase II rheumatoid arthritis trial shows its stem cells provide “early and durable effects”.

In February, Mesoblast said that the 39-week data from the trial was “compelling” despite non-significance on the secondary efficacy endpoints (BD: Feb 16, 2017).

Today, the company said that comparing 1,000,000 mesenchymal precursor cells (MPCs) per kilogram of body weight, 2,000,000 MPCs/kg and placebo “at 12, 39 and 52 weeks: the MPC 2,000,000/kg group significantly outperformed placebo at every time point for ACR-N area under the curve ($p = 0.05$ at 12 weeks, $p = 0.004$ at 39 weeks and $p = 0.008$ at 52 weeks), indicating a robust, durable and consistent clinical effect of this MPC dose”.

Mesoblast said that ACR-N measured “the mean or median magnitude of benefit using an ACR composite for a typical patient”.

In February, the company said the American College of Rheumatology criteria measured changes in swollen joints, a pain scale and disability rating with ACR20 a 20 percent improvement, ACR50 a 50 percent improvement and ACR70 a 70 percent improvement.

Last year, when the company presented the 12-week data, Mesoblast chief executive Prof Silviu Itescu said ACR20 was a very low bar, but ACR70 was a high bar, which was not met by any of the control patients, which was the same result in February’s 39-week data for both the whole group and the sub-group (BD: Aug 9, 2016).

The company said the 39-week data showed a clear trend for the treated groups compared to the controls, but none reached significance on the three ACR measures.

Today, Mesoblast said the data was presented at the American College of Rheumatology meeting in San Diego California from November 4 to 8, 2017.

Lead investigator Dr Suzanne Kafaja said that the “clinical responses in this phase II trial, together with the safety profile, position MPC-300-IV to become an early treatment option in rheumatoid arthritis patients who are resistant to or intolerant of anti-[tumor necrosis factor] or other biologic agents”.

Mesoblast said that infusions of MPCs were well-tolerated with no treatment-related serious adverse events reported, the safety profile was comparable among the placebo and two MPC treatment groups, with dose-related improvements in clinical symptoms, function, disease activity and patient-reported outcomes and the higher dose showed the greatest overall treatment response with greatest benefit for patients who had failed fewer than three biologic treatments, “a potentially optimal target population”.

Mesoblast was up 13.5 cents or 10.9 percent to $1.37 with 3.4 million shares traded.

GORDAGEN PHARMACEUTICALS

Gordagen says the Supreme Court of Victoria has issued it a winding-up order.

Gordagen chief executive officer Dr Glenn Tong told Biotech Daily that a creditors meeting had been convened for November 22, 2017 as a result of more than 77 percent of creditors by value requesting the meeting.

Dr Tong said the group of creditors “representing the majority in both number and value of debt are strongly supportive of the former management and directors of Gordagen in their efforts to preserve and realise the value of Gordagen’s intellectual property assets”.

In June, Supreme Court of Victoria documents disclosed legal action between Gordagen and former chief operating officer Dr Ric DeGaris (BD: Jun 27, 2017).

In 2014, Gordagen said it had raised $6 million for the first stage of its over-the-counter and regulatory-directed trials of vitamin E-derived tocotrienols, with a further $4 million in non-dilutive funding between November 2012 and August 2017 (BD: Feb 4, 2014).

Gordagen is a private company.

FISHER AND PAYKEL HEALTHCARE CORP, RESMED

Fisher and Paykel says a UK court has ruled that a patent asserted against it by Resmed is invalid.
Fisher and Paykel said that in 2016, it sought a declaration from the UK High Court of Justice, Chancery Division, Patents Court that three of Resmed's European patents were invalid in the UK and should be revoked.
The company said that Resmed counterclaimed for infringement.
Fisher and Paykel said that "just before the trial was to start, Resmed conceded to revocation of two of its patents in the UK, leaving only one, EP 2 708 258 B1, for consideration by the court" with Resmed arguing that EP 2 708 258 B1 was infringed by two Fisher and Paykel sleep apnoea masks, the Eson and Simplus masks.
Fisher and Paykel said that had the patent been valid it would have been infringed, "however, the court found that the patent was invalid in its entirety".
The company said that, subject to any appeal, this European patent would be revoked in the UK and it was entitled to recover its legal costs from Resmed in an amount to be determined by the court.
Fisher and Paykel said that people could continue to buy its masks.
The company said that infringement proceedings brought by Resmed in Germany in relation to the same three European patents were "stayed pending the outcome of opposition proceedings before the European Patent Office".
Fisher and Paykel said that all three opposition proceedings would continue as it sought to invalidate the Resmed patents throughout Europe, with other patent litigation actions in progress in the US and New Zealand.
Fisher and Paykel chief executive officer Lewis Gradon said that while the UK ruling was "just one more step on the journey, it reinforces our confidence in our position and we are satisfied with progress so far".
In a separate announcement Resmed general counsel and chief administrative officer David Pendarvis said the company was "disappointed the English Patents Court has ruled that Resmed's patent EP 2 708 258 is invalid in the UK [but] we are pleased by the court's unambiguous statement regarding our assertion that Fisher and Paykel's Simplus and Eson masks infringe Resmed's patent.
Resmed reported that the English Patents Court said: "Had it been valid it would have been infringed."
"We appreciate the court's attention to this matter and we are considering an appeal," Mr Pendarvis said.
"The ruling has no impact on Resmed's commercial operations in the UK," Mr Pendarvis said. "All of our products will continue to be available there with customer service support."
"Likewise, the ruling is limited only to the UK and has no impact on Resmed's pending cases against Fisher and Paykel in the US, New Zealand or Germany," Mr Pendarvis said.
"We are confident that when the courts in those countries apply their different evidentiary rules and validity procedures, we will prevail," Mr Pendarvis said.
Resmed was up three cents or 0.3 percent to $10.81 with 1.7 million shares traded.
Fisher and Paykel fell 12 cents or one percent to $11.82 with 329,538 shares traded.

G (GEVA) MEDICAL INNOVATIONS

G Medical has requested a trading halt "pending an announcement regarding a capital raising".
Trading will resume on November 15, 2017 or on an earlier announcement.
G Medical last traded at 52.5 cents.

NOVOGEN

Novogen says it will licence Trilexium (TRX-E-009-1) and other “super-benzopyran” molecules to Heaton-Brown Life Sciences LLC.

Novogen said that the private company was formed by former Novogen North America chief executive officer Dr Andrew Heaton and former chief scientific officer Dr David Brown.

The company said it would retain worldwide rights to Cantrixil (TRX-E-002-1), which was in a phase I trial for ovarian cancer.

Novogen said it would receive 10 percent of the equity in Heaton-Brown, along with milestone and royalty payments linked to successful development of the intellectual property

The company said that Dr Heaton and Dr Brown were co-founders of the Triaxial technology that was integral to the discovery and early development of the super-benzopyran and “ad-het” programs, both Cantrixil and Trilexium deriving from the super-benzopyran program.

Novogen said it owned “considerable intellectual property that may ultimately provide drug candidates of significant value to patients”.

“Given that the company’s primary focus is now on the acquisition, development, and partnering of clinical stage assets, the agreement … allows for these earlier-stage, high-quality assets to continue their development at no cost to Novogen,” the company said.

The company said that costs for maintenance of the super-benzopyran patents would be shared, with Heaton-Brown paying for costs associated with the ad-het program.

Novogen said the agreement precluded the development of Trilexium as a therapy for ovarian cancer.

Separately, Novogen said it had a letter of intent with Cedrus Investments for advisory services to establish a corporate structure focused on expansion into China.

Novogen said that the new corporate entity would enable it to interact directly with the China Food and Drug Administration for clinical trials and would facilitate potential partnering and investing opportunities for the company.

Novogen was up 0.1 cents or 2.6 percent to four cents with 2.2 million shares traded.

CRESO PHARMA

Creso says it welcomes a proposed Canadian Government tax of $C1 ($A1.03) a gram for recreational marijuana.

Creso said it was “well positioned in Canada with the recent purchase of Mernova Medical, based in Nova Scotia”.

The company said it had begun construction of a 20,000 square foot (1,858 square metres) cannabis growing facility expected to be completed by October 2018.

Creso said the Canadian Government “stated that the tax should not exceed $C1 per gram or 10 percent of the producer’s price, whichever is higher”.

The company said that Canada had a “progressive stance in leading the world as a medical and recreational marijuana jurisdiction …. [and] this low level of tax is designed to quash the black market for recreational marijuana and lure customers away from that market”.

Creso said the total tax revenue from the initiative was expected to be as much a $C1 billion a year.

Creso was up 10 cents or 14.7 percent to 78 cents with 1.4 million shares traded.

AIRXPANDERS

Consonance Capital Management says it has reduced its shareholding in Airxpanders from 14,899,767 shares (5.18%) to.

In September, the New York-based Consonance Capital Management said it had become substantial in Airxpanders buying the shares between July 27 and September 14, 2017 with the single largest acquisition 6,931,401 shares for $4,926,216 or 71.1 cents a share (BD: Sep 15, 2017).

Today, the company said it sold all of its shares for $10,121,918 or 67.9 cents a share.

Consonance said that Goldman Sachs was a registered holder of the shares with Mitchell Blutt, Kevin Livingston and Benny Soffer as associated holders.

MESOBLAST

Credit Suisse says it has become a substantial shareholder in Mesoblast with 34,783,057 shares (7.39%).

Credit Suisse said the shares were held under “lending agreements” as well as under an underwriting agreement and between July 13 and October 31, 2017 it mainly borrowed and returned shares as well as buying shares.

The company said that on November 10, 2017 it acquired 22,597,159 shares owned by Cephalon (Teva Pharmaceuticals) under an underwriting agreement.

Last month, Mesoblast said that Teva sold 29,000,000 shares reducing its holding from 52,395,656 shares (11.14%) to 23,395,656 shares (4.75%) (BD: Oct 25, 2017).

LIVING CELL TECHNOLOGIES

Milford Asset Management says it has reduced its substantial holding in Living Cell from 36,078,640 shares (6.32%) to 30,154,580 shares (5.28%).

The Auckland, New Zealand-based Milford said that it sold shares between October 9 and November 8, with three purchases on October 13 and 19, 2017, with the single largest sale, on October 31, of 684,467 shares for $141,885 or 21.9 cents a share.

Last week, Living Cell fell as much 88.8 percent to 2.3 cents on the news of no efficacy statistical significance of its NTCell for Parkinson’s disease (BD: Nov 10, 2017).

Living Cell fell one cent or 25 percent to three cents with 31.1 million shares traded.