Biotech Daily

Thursday September 28, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 14%, DIMERIX DOWN 12.5%**

*** MESOBLAST RECRUITS PHASE II END STAGE HEART FAILURE TRIAL**

*** AVITA FILES RECELL FOR BURNS FDA APPLICATION**

*** AIRXPANDERS COMPLETES COSTA RICA AEROFORM PLANT**

*** OVENTUS RELAUNCHES O2 SLEEP APNOEA, SNORING DEVICE**

*** VOLPARA SIGNS IMAGING ASSOCIATES FOR ENTERPRISE SOFTWARE**

*** ASTRAZENECA NAMES STARPHARMA DEP AZD0466 FOR TUMORS**

*** MTP CONNECT, MEDICAL ALLEY US-AUSTRALIA COLLABORATION**

*** AVIRAGEN (BIOTA) NASDAQ SHARE PRICE WARNING; FACES DELISTING**

*** AUSTRALIAN ETHICAL REDUCES TO 6.4% OF ELLEX**

*** INVITROCUE APPOINTS DR SUNNY TAN, DR RAMANUJ DASGUPTA**

MARKET REPORT

The Australian stock market edged up 0.11 percent on Thursday September 28, 2017 with the ASX200 up 6.1 points to 5,670.4 points. Twenty-two of the Biotech Daily Top 40 stocks were up, eight fell, six traded unchanged and four were untraded.

Prima was the best, up 0.3 cents or 14.3 percent to 2.4 cents with 14.5 million shares traded.

Atcor climbed 7.4 percent; Avita was up 6.9 percent; Pro Medicus improved 5.2 percent; Benitec, Cellmid and Neuren were up four percent or more; Clinuvel, Ellex, LBT, Osprey and Sirtex climbed more than three percent; Opthea and Starpharma rose more than two percent; Admedus, CSL, Cyclopharm, Medical Developments, Nanosonics, Polynovo and Prana were up more than one percent; with Airxpanders, Cochlear, Impedimed and Resmed up by less than one percent.

Dimerix led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with 2.7 million shares traded. ITL lost 7.3 percent; Oncosil fell 4.35 percent; Acrux was down 3.3 percent; Mesoblast shed 2.2 percent; Universal Biosensors and Viralytics were down more than one percent; with Factor Therapeutics down 0.9 percent.

MESOBLAST

Mesoblast says it has completed enrolment of 159 patients in its phase IIb trial of its mesenchymal precursor cells for end-stage heart failure (BD: Aug 7, 2014).

Mesoblast said the US National Institutes of Health and Canadian Institute of Health Research-funded randomized, placebo-controlled trial had a primary efficacy endpoint determining whether a dose of 150 million cells (MPC-150-IM) could strengthen heart muscle sufficiently to maintain circulation in end-stage heart failure patients weaned from a left ventricular assist device (LVAD) or heart pump.

The company said that secondary efficacy endpoints included rates of re-hospitalization, survival and other quality of life factors, measured over 12-months.

Mesoblast said that if the endpoints were met MPC-150-IM therapy “could facilitate far wider use of LVADs amongst end-stage heart failure patients”.

The company said that a 30-patient pilot study at a 25 million cell dose showed the therapy “improved native heart function, prolonged the time to first re-hospitalization following the implantation of an LVAD, and improved early survival rates”.

Mesoblast said the results were “thought to be due to the ability of the [cells] to induce a mature blood vessel network in the ailing heart and to reduce the damaging immune effects in both the native heart and in its response to the presence of the LVAD”.

The company said that positive results could support an accelerated regulatory pathway.

Mesoblast said there were about 50,000 end-stage heart failure patients in the US, with one-year mortality of more than 50 percent, but fewer than 5,000 patients received left ventricular assist devices due to the risks of increased morbidity, recurrent hospitalizations and inflammatory complications, including gastrointestinal bleeding.

Mesoblast chief executive Prof Silviu Itescu said there was “an urgent need to develop a clinical approach that could facilitate greater LVAD use in the 50,000 patients with end-stage heart failure in order to improve their dismal one-year survival rates”.

“If the native heart is strengthened sufficiently to facilitate early device explantation, this could create a bridge-to-recovery paradigm combining MPC-150-IM with temporary LVAD use,” Prof Itescu said.

Mesoblast fell three cents or 2.2 percent to $1.34.

AVITA MEDICAL

Avita says it has submitted its US Food and Drug Administration pre-market approval application for its Recell spray-on skin device for burn injuries.

Avita said the Recell autologous cell-harvesting device was intended to reduce the amount of skin required compared to conventional burn treatment and the application included data from two randomized, controlled trials with a combined enrolment of 131 patients at 12 burn centres.

The company said the first trial showed a 97.5 percent reduction in donor skin harvested for treatment of second-degree burn injuries, and the second trial demonstrated a more than 30 percent reduction in donor skin required while achieving comparable near-term healing and long-term scar outcomes for third-degree burns (BD: Sep 12, 2017).

Avita said the submission included 55 cases of compassionate use of Recell for burns.

Avita chief executive officer Dr Michael Perry said the submission was “the culmination of years of effort by our Avita team and we are thrilled to have moved a step closer to making Recell available to patients in the US”.

The company said that the application had been supported through its US Biomedical Advanced Research and Development Authority (BARDA) contract (BD: Sep 30, 2015).

Avita was up 0.4 cents or 6.9 percent to 6.2 cents with 1.5 million shares traded.

AIRXPANDERS

Airxpanders says it has completed the establishment of manufacturing plant for its Aeroform breast expansion system with a contract manufacturer in Costa Rica.
Airxpanders said that the additional production capacity would enable it to cost-effectively manufacture a higher volume of Aeroform expanders to meet increased market demand for the product, which was available at more than 100 US hospitals.
The company said that the Tempe, Arizona-based Medplast owned the Costa Rica manufacturing plant, with production capacity for up to 20,000 units a year.
Airxpanders said it would maintain its existing manufacturing facility in California with capacity of up to 4,000 units per year.
Airxpanders chief executive officer Scott Dodson said that the new manufacturing capacity supported the ability to provide access to Aeroform for every eligible patient.
“The scale of the Medplast facility gives us the ability to readily add additional manufacturing lines for added capacity,” Mr Dodson said.
Airxpanders was up 0.5 cents or 0.6 percent to 78.5 cents.

OVENTUS MEDICAL

Oventus says it will relaunch its O2Vent mouth-guard anti-snoring device with the Hong Kong-based Modern Dental Group.
In Melbourne as part of investor update roadshow, Oventus inventor, founder and executive director Dr Chris Hart told Biotech Daily that Modern Dental had exclusive distribution rights for the US and non-exclusive rights for the rest of the world.
The company first launched the O2Vent Mono system last year, prior to its $12 million initial public offer (BD: Jun 20, Jul 1, 2016).
The original design combined an airway pipe with a mouth guard to reduce snoring and sleep apnoea, with later models including an adjustment device and the potential to attach to continuous positive airways pressure (CPAP) devices via nasal prongs.
Oventus formally launched its devices last year though the 1300smiles Australian dental clinic chain (BD: Oct 28, 2016).
Today, Dr Hart said that the company had not received a great deal of revenue in the previous 12 months and the agreement with Modern Dental would take the devices to the distributor’s 345,000 customers in North America, Europe, Australia and China.
Dr Hart said that the October re-launch would target Australia and the US with the company expecting a European launch in early 2018.
Dr Hart said the sleep apnoea CPAP market was of particular interest to the company because “80 percent are out of care” primarily due to the need to use bulky face masks with noisy machinery through the night.
Dr Hart said the O2Vent CPAP connector was currently in development and would be less invasive, lighter and smaller, using nasal prongs with the ability to breathe through the mouth meant that lower volumes of air could be used, reducing the size of the generator.
He said the system could be reimbursed at the rate of $US280 per patient every three to six months and it came with a heat moisture exchange sponge to retain humidity, which needed to be replaced every two to three days.
In August, Oventus posted receipts from customers down 21.85 percent to $398,056 for the 12 months to June 30, 2017, with cash and cash equivalents of $8,648,099 and expected cash burn rate for the three months to September 30, 2017 of $2,394,000.
Dr Hart said the company expected a reduction in expenditure and with the expectation of revenue from sales, Oventus was not looking to raise further funds, at this time.
Oventus was up one cent or 2.7 percent to 38 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has a five year contract with Melbourne's Imaging Associates for its Enterprise breast-imaging quality assurance and performance monitoring system.
Volpara said that Imaging Associates was its third Australian centre, taking the total using its system to 25 centres.
The company said that Imaging Associates had two breast cancer screening centres and they would "benefit from improved image consistency and quality, as well as more accurate radiation dosage, breast compression and personalized breast density assessment for every patient".
Volpara said that Imaging Associates had 2,500 breast imaging patients a year.
Volpara chief executive officer Dr Ralph Highnam said that Imaging Associates was working with general practitioners "to educate women about the importance of knowing their own breast density and referring them for additional screening where necessary".
The company said it had also signed new clients in South Korea and Taiwan.
Volpara was up 1.5 cents or 2.4 percent to 64 cents.

STARPHARMA

Starpharma says Astrazeneca has presented the first dendrimer-enhanced product as AZD0466, a B-cell lymphoma-extra large(Bcl2/xL) inhibitor for solid and blood tumors.
Starpharma said that Astrazeneca presented AZD0466 at a symposium in Cambridge, England as "a highly-optimized nano-medicine formulation of a novel dual Bcl2/xL inhibitor" using its dendrimer-enhanced product delivery technology.
The company said that the Bcl family of proteins were important in the regulation of cell death, or apoptosis, and Bcl2 was an anti-apoptotic protein which allowed cancer cells to live indefinitely and remain resistant to many treatments.
Starpharma said that Bcl2 was a validated oncology target with the Walter and Eliza Hall co-developed venetoclax (marketed as Venclexta by Abbvie and Genentech) approved by the US Food and Drug Administration in 2016, with peak sales of venetoclax projected to be greater than $US7 billion.
The company said that despite there were gaps in the therapeutic potential of the first generation Bcl2 inhibitors and Venetoclax might not maximise the inhibition of Bcl2 proteins, with surviving cancer cells potentially able to exploit the combined Bcl2/xL pathway as a parallel survival mechanism.
Starpharma chief executive officer Dr Jackie Fairley said the company was "very excited to be able to confirm the first oncology target for our DEP licence with Astrazeneca".
"AZD0466 has the potential to be a best-in-class drug with a broad combination opportunity in solid and haematological tumors, due to its broader Bcl2/xL profile," Dr Fairley said.
"There are currently no marketed drugs which target this dual Bcl2/xL pathway and we are pleased that our DEP platform can play a part in filling this gap," Dr Fairley said.
"We look forward to Astrazeneca progressing AZD0466 into the clinic to improve the lives of cancer patients around the world," Dr Fairley said.
Starpharma said it was eligible to receive potential development, launch and sales milestones of $US124 million for AZD0466 and $US93.3 million for each subsequent qualifying product under the multi-product licence, along with tiered royalties on net sales on AZD0466 and any other resultant products, with Astrazeneca funding all development costs.
Starpharma was up three cents or 2.4 percent to $1.27 with 1.9 million shares traded.

MEDICAL TECHNOLOGIES, PHARMACEUTICALS INDUSTRY GROWTH CENTRE

MTP Connect says it has signed an agreement with the Minnesotta, Mineapolis-based Medical Alley Association to increase US-Australia collaborations.

The Federal Government-funded MTP Connect said that Medical Alley enabled health innovation and care organizations "to innovate, succeed and influence the evolution of healthcare".

The organizations said that the memorandum of understanding, signed at the Medtech Conference in San Jose, California, was intended "to increase collaboration on activities that boost the biotechnology, pharmaceutical, health and medical technology sectors of both Australia and the US".

MTP Connect said that the two organisations would provide introductions and in-market support in their respective jurisdictions, exchange information on issues and trends, support inbound and outbound missions and the delivery of joint events and projects.

AVIRAGEN THERAPEUTICS (FORMERLY BIOTA PHARMACEUTICALS)

Aviragen says it has not regained compliance with the Nasdaq $US1.00 minimum bid price requirement but is eligible for an additional 180-day period to March 26, 2018.

Aviragen said it received a compliance letter from the Nasdaq in March giving it until September 25, 2017 to regain compliance.

Today, the company said the Nasdaq had approved its application to transfer from the Nasdaq Global Select Market to the Nasdaq Capital Market, which had less stringent listing requirements, and its shares were transferred from September 21, 2017.

Aviragen said the Nasdaq granted an additional 180-day grace period based on it meeting listing requirements for market value and all other requirements, except the minimum bid price and its intention to comply through a share consolidation, if necessary.

The then Biota conducted an eight-to-one consolidation in its move from the ASX to the Nasdaq when it merged with Nabi Pharmaceuticals, renamed Biota Pharmaceuticals and then renamed Aviragen (BD: Apr 23, Sep 18, Oct 26, 30, Nov 2012).

Today, Aviragen said that if its closing share price was $US1.00 or more for 10 consecutive business days any time during the second 180-day grace period the matter would be closed, but the Nasdaq could require 20 business days and if it had a share consolidation, it must be completed 10 business days prior to March 26, 2018.

Aviragen said if it did not comply, it would be delisted, but that could be appealed.

Last night on the Nasdaq, Aviragen was up 0.011 US cents or 0.17 percent to 64.8 US cents (82.7 Australian cents, equivalent to 10.3 cents prior to the Biota-Nabi merger, when it was trading around $A1.00), with 70,565 shares traded.

ELLEX MEDICAL LASERS

Australian Ethical Investment says it has reduced its holding in Ellex from 8,977,413 shares (7.41%) to 7,736,389 shares (6.39%).

Australian Ethical previously reduced its holding in Ellex selling shares at prices from 75 cents to $1.16 each having acquired 5,000,000 shares at 26 cents and 30 cents each (BD: Oct 3, 2013; Oct 10, 2016).

Today, Australian Ethical said it sold shares between August 1 and September 27, 2017 and bought shares between May 11 and June 14, 2017, with the largest purchase 100,000 shares for $101,222 or $1.01 a share and the largest sale 245,440 shares for $237,798 or 96.9 cents a share.

Ellex was up four cents or 3.8 percent to $1.09.

INVITROCUE

Invitrocue says it has appointed Dr Sunny Tan as head of scientific affairs and corporate development and Dr Ramanuj Dasgupta as chief scientific officer.

Invitrocue said Dr Tan would begin immediately leading the company's engagement with scientific and commercial partners.

The company said that Dr Tan had experience commercializing biomedical technologies as head of Exploit Technologies, the commercialization company for Singapore's Agency for Science, Technology and Research and investment in early stage biomedical companies at Singapore government investment holding company Temasek.

Invitrocue said Dr Tan held a Bachelor of Science from the University of New South Wales and a Doctorate of Philosophy from the Australian National University.

The company said that Dr Dasgupta had been a scientific adviser since 2016 and as chief scientific officer would oversee the development of the service pipeline for the oncology patient-derived organoid (Onco-PDO) business.

Invitrocue said Dr Dasgupta trained as a development and cancer biologist and was a co-founder of the Onco-PDO technology, used to grow micro-tumor models and test the models against a range of drug candidates to determine targeted treatment.

The company said that Dr Dasgupta was currently with the Singapore Agency for Science, Technology and Research Genome Institute as a senior investigator and group leader in cancer therapeutics and stratified oncology and a New York University School of Medicine professor.

Invitrocue said Dr Dasgupta held a Bachelor of Arts from Cambridge University, a Bachelor of Science from Delhi University and a Doctorate of Philosophy from the University of Chicago.

Invitrocue was untraded at 8.5 cents.