Biotech Daily

Tuesday April 4, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRANA UP 18%, CELLMID DOWN 8%**

*** REVA FANTOM BIO-RESORBABLE STENT WINS CE MARK**

*** CSIRO BACKS MTP CONNECT '$18b, 28k JOBS, 10 YEAR PLAN'**

*** BIONIC VISION RAISES $23.5m FOR BIONIC EYE**

*** INVITROCUE VALIDATING 10-DAY, PATIENT-SPECIFIC CANCER TEST**

*** FDA APPROVES AIRXPANDERS ENHANCED CO2 FILM**

*** VIRALYTICS CAVATAK, KEYTRUDA MELANOMA RESULTS EXPANDS TRIAL**

*** MESOBLAST, HARVARD HLHS STEM CELL TRIAL**

*** ONCOSIL: 'UK ETHICS APPROVAL FOR PANCREATIC CANCER TRIAL'**

*** NEUREN RECEIVES $982k FEDERAL R&D TAX INCENTIVE**

*** LIFESPOT BODYTEL TO MONITOR MEDICAL MARIJUANA**

*** OBJ MULTIPLE UNNAMED PARTNER LICENCING DEALS UNDERWAY**

*** PRESCIENT REQUESTS BREAST CANCER TRIAL RESULTS TRADING HALT**

*** BOTANIX TAKES CAPITAL RAISING TRADING HALT TO SUSPENSION**

*** BVF PARTNERS, MARK LAMPERT TAKE 13% OF PHARMAXIS**

*** AUSTRALIAN ETHICAL TAKES 10% OF PHARMAXIS**

*** CRESO APPOINTS DAVID RUSSELL COO**

MARKET REPORT

The Australian stock market fell 0.27 percent on Tuesday April 4, 2017 with the ASX200 down 16.1 points to 5,856.6 points. Nine of the Biotech Daily Top 40 stocks were up, 17 fell, 12 traded unchanged and two were untraded.

Prana is the new daytraders' delight, up 1.1 cents or 17.7 percent to 7.3 cents with 1.4 million shares traded, followed by Neuren up 14.5 percent to 7.9 cents with 2.7 million shares traded. Benitec and Oncosil climbed more than 11 percent; Airxpanders and Mesoblast were up more than five percent; Cyclopharm improved 3.7 percent; Medical Developments rose 2.2 percent; Ellex was up 1.85 percent; with CSL up 0.2 percent.

Cellmid led the falls, down 0.3 cents or 7.9 percent to 3.5 cents with three million shares traded. Uscom lost five percent; Compumedics fell 4.7 percent; Avita, IDT, Living Cell and Viralytics were down more than three percent; Impedimed shed two percent; Osprey, Polynovo, Pro Medicus, Psivida, Reva and Universal Biosensors were down more than one percent; with Clinuvel, Cochlear, Resmed, Sirtex and Starpharma down by less than one percent.

REVA MEDICAL

Reva says it has received Conformité Européenne (CE) mark approval for its Fantom drug-eluting bio-resorbable coronary scaffold.

Reva chief executive officer Dr Reggie Groves told Biotech Daily the company needed to complete labelling and packaging details for the Fantom stent which would first be sold in Germany, followed by the rest of Europe, with first sales expected by July 2017.

In a media release, Reva said that the Fantom stent had "multiple and substantial performance advantages over first-generation scaffolds".

The company said that initial quantities of the product had been manufactured and were available to support commercialization.

Dr Groves said that "CE Mark approval for Fantom is a major milestone for the company".

"It is the culmination of years of effort," Dr Groves said.

"As the patient population becomes increasingly acquainted with the appeal of bio-resorbable scaffolds in general, versus metal stents, we believe they will come to ask for Fantom by name, based on our positive data and the increasing preference for Fantom that we expect leading clinicians will develop over time," Dr Groves said.

Reva said that data from patients enrolled in its Fantom II clinical trial were used to support the CE mark application.

The company said the trial enrolled 240 patients between March 2015 and March 2016 and the major adverse cardiac event (Mace) rate at six months for all 240 patients was 2.1 percent, which compared favorably to commercial bio-resorbable scaffolds.

Reva said it continued to follow and evaluate patients and planned additional data releases at major industry conferences in May and October of this year.

The company said it was pursuing a private financing to support its Fantom launch, working capital, follow-on trials and product feasibility work, expected to close this month.

Reva fell one cent or 1.1 percent to 90 cents.

CSIRO, MTP CONNECT

The Commonwealth Scientific and Industrial Research Organisation says it supports the MTP Connect 10-year sector competitiveness plan.

CSIRO said that the Medical Technologies and Pharmaceuticals Roadmap, set out a path for Australia to become an important player in the medical technologies and pharmaceuticals sector, which was expected to grow to $US3 trillion globally by 2025.

CSIRO chief executive Dr Larry Marshall said the roadmap "was written in collaboration with industry, government and researchers".

"The … Roadmap is part of that vision and the guidepost that will help the … sector to become a key pillar of our economy, creating jobs and growth," Dr Marshall said.

In January, MTP Connect, or the Medical Technologies and Pharmaceuticals Industry Growth Centre, said its 10-year competitiveness plan would increase the sector's value by $3.2 billion a year value and increase jobs by 28,000 over 10 years (BD: Jan 22, 2017).

MTP Connect said in January that with Federal Government funding of $40 million over four years it would achieve an additional $3.2 billion in industry gross value added a year, an increase of 75 percent compared to 2015, resulting in an additional cumulative gross value added of $18 billion over the 10-year period from 2015 to 2025 and an additional 28,000 jobs compared to 2015, of which 14,000 jobs would be in universities and medical research institutes, reflecting "the substantial increase in research funding being delivered by the Medical Research Future Fund".

The proposed $20 billion Medical Research Future Fund is yet to release any funds.

The plan is available at www.mtpconnect.org.au/SCP.

BIONIC VISION TECHNOLOGIES

Bionic Vision says it has raised US18 million ($A23.5 million) from two Hong Kong-companies to develop and commercialize devices to restore vision to the blind.

Bionic Vision said it was a private consortium comprising the University of Melbourne, the University of New South Wales, the Bionics Institute, the Centre for Eye Research Australia, Commonwealth Scientific and Industrial Research Organisation's Data 61, the Royal Victorian Eye & Ear Hospital, Western Sydney University and the Australian College of Optometry.

The company said the two Hong Kong companies, China Huarong International Holdings and State Path Capital, made the investment based on its work in developing bionic vision technologies including a successful clinical trial of a prototype device in three patients.

Bionic Vision said that its bionic eye had "significant advantages over competitors, including a superior surgical approach, stability of the device and unique vision processing software that potentially improves the patient's experience".

The company said the financing "formally launches the company as it transitions to a commercialization stage business".

Bionic Vision said the development of Australia's bionic eye had been funded through a five-year, $50 million Australian Research Council grant (BD: Jul 9, 2013).

The company said it would use the funds raised to manufacture devices and begin a human clinical trial of its bionic eye implant in patients with the inherited degenerative eye condition retinitis pigmentosa, the most common cause of inherited blindness, which affected more than 1.5 million people worldwide.

State Path chairman Alastair Lam said that given Bionic Vision's "commitment to developing and delivering a revolutionary solution for vision loss, we believe its bionic eye technology has the potential to transform the lives of millions of people".

"Our investment support will help move the current product closer to market and the communities who will benefit," Mr Lam said. "Our investment … aligns with our strategy of backing transformative new technology with significant global potential."

Bionic Vision executive chairman Robert Klupacs said the investment was "an important milestone for our unique Australian technology and an endorsement of our approach to making a positive impact on global health".

"These new funds will help create an innovative, solution to potentially help improve the lives of blind people," Mr Klupacs said.

"The funding will propel this Australian technology into clinical trials in coming months as we work towards securing regulatory approval and a commercial launch in key markets where loss of vision is a significant medical burden," Mr Klupacs said.

"There is currently no treatment for conditions such as retinitis pigmentosa and our new investors recognise [Bionic Vision] has developed a world-leading solution with potential to make a significant impact patient's sight and lifestyle," Mr Klupacs said.

Bionic Vision said that one in 4,000 people had retinitis pigmentosa worldwide with a higher number of cases in China and India.

The company said the retinal implant was placed at the back of the eye where it stimulated the surviving nerve cells in the retina with electrical signals created from images collected by an externally worn camera.

Bionic Vision said that the next stage clinical trials were scheduled to start in the coming months in Melbourne and patients would be recruited and monitored for up to two years.

Bionic Vision said that patients would be surgically implanted with a permanent device to wear in their everyday activities, compared to the early trials which monitored patients in the clinic, with researchers measuring mobility and independence.

INVITROCUE

Invitrocue executive director Dr Steven Fang says he expects validation trial results for his company's patient-specific 10-day oncology test by the end of this year.

Dr Fang said that the ability to grow specific patient cancer cells in the company's scaffold, meant that the individual's cancer could be tested against an array of drugs to determine which was the most efficacious and/or cost-effective.

In Melbourne, for an Australian investor roadshow, the Singapore-based Dr Fang said that the metal mesh scaffold was invented by National University of Singapore and Massachusetts Institute of Technology professor Prof Henry Yu, who was a co-founder of the company as well as a shareholder and director.

Dr Fang said that initially the company grew liver cells for testing against drug treatments, but diversified when it became aware of the ease of obtaining cancer tissue samples and the need for patient-specific treatments.

He said that having grown the cancer they could use a multi-well plate to test an array of drugs to see which worked best with a particular patient's cancer.

Dr Fang said that Invitrocue had contracts with Johnson & Johnson, Roche, Novatis, Mundipharma and Qiagen for use of the technology and the company posted revenue of $300,839 ($A284,097) for the six months to December 31, 2016.

"Invitrocue offers a personalized service," Dr Fang said.

"We can report on what works for each specific patient's cancer," Dr Fang said.

He said the technology was currently in a collaborative trial at the Genome Institute of Singapore which was examining 194 patients' head, neck, shoulder and throat cancers "to see which drug works best with which patient".

Dr Fang said the Institute was expected to report on the 197 samples by the end of 2017 and the collaboration was preparing trials of up to 200 patients' ovarian cancers and up to 200 patients' colorectal cancers.

In February, the company announced a trial to validate the technology at Sydney's Garvan Institute and St Vincent's Hospital and Dr Fang said that he had been in discussions with "leading Melbourne research institutes" (BD: Feb 23, 2017).

Dr Fang said that "the phenotype driven precision oncology was patient specific" and Invitrocue intended to roll-out the technology to centres in Australia, Singapore, China and the UK, and then the rest of the world.

"We can grow and harvest cancers in 72 hours and conduct the test in 72 hours and report in 10 days with models predicting the clinical response," Dr Fang said.

"Then it is up to the oncologist to select the most effective treatment," Dr Fang said.

Invitrocue fell 0.2 cents or 2.35 percent to 8.3 cents.

AIRXPANDERS

Airxpanders says the US Food and Drug Administration has granted 510(k) clearance for an enhanced film material used to contain carbon dioxide in its Aeroform device.

Airxpanders said the Aeroform tissue expander system for reconstructive breast surgery following mastectomy was activated by a handheld wireless controller that administered small amounts of carbon dioxide, to stretch the tissue to prepare for a breast implant.

Airxpanders chief executive officer Scott Dodson said the company was "very excited about the FDA's decision which is consistent with the CE Mark and the TGA approval that we have already received".

"Plastic surgeons and their patients in the United States are very excited to finally have access to this game changing product for breast reconstruction," Mr Dodson said.

Airxpanders was up five cents or 5.7 percent to 93 cents.

VIRALYTICS

Viralytics says that 15-patient data from its Cavatak with Keytruda melanoma trial shows an overall response rate of 60 percent and stable disease in 27 percent of patients.

Viralytics said that the data from the30-patient, phase Ib Cavatak and pembrolizumab (Keytruda) in advanced melanoma (Capra) trial, entitled 'Phase Ib study of intratumoral oncolytic Coxsackievirus A21 (CVA21) and systemic pembrolizumab in subjects with advanced melanoma: Interim results of the Capra clinical trial' was presented by the New Jersey-based Rutgers Cancer Institute Prof Ann Silk at the American Association for Cancer Research meeting in Washington, DC and is available at: https://viralytics.com/wp-content/uploads/2017/04/170404-AACR-CAPRA-FINAL.pdf.

The company previously reported a 100 percent disease control rate among the first 10 patients, of which seven showed an objective response or the shrinking of tumors, while three were stable (BD: Nov 14, 2016).

Viralytics said that the phase Ib study had 20 patients enrolled and was designed to evaluate the tolerability and anti-cancer activity of intra-lesion injected Cavatak in combination with the systemic administration of Keytruda in patients with unresectable melanoma.

"I am encouraged and impressed by this initial data from the Capra study in the first 15 evaluable patients which include a best overall response rate of 60 percent and stable disease in 27 percent of patients," Prof Silk said.

"I am pleased with the patient's tolerability to the combination Cavatak [and] Keytruda treatment," Prof Silk said.

"We saw no dose limiting toxicities and no grade 3 or higher treatment-related adverse events," Prof Silk said.

"We are focused on looking for new combination therapies that will increase the proportion of patients that will benefit from checkpoint agents such as Keytruda," Prof Silk said.

"The Capra results compare favorably to other combination studies and I look forward to expanding the study to enroll up to 50 patients, including patients that have failed prior checkpoint therapies," Prof Silk said.

Viralytics said that the best overall response rate was 60 percent with nine of 15 patients in the evaluable patients, which compared favorably to published trial data where a best overall response rate of 33 percent was achieved in patients with advanced melanoma who received Keytruda alone.

The company said that tumor responses were ongoing in all nine patients who responded to the combination, with one patient's response lasting for one year after the initiation of therapy.

Viralytics said that to date two patients had demonstrated complete responses in the target lesions.

The company said that in the sub-group of patients with the most advanced stage IV metastatic disease the best overall response rate was 83 percent or five of six patients.

Viralytics said there were no grade 3 or higher treatment-related adverse events, which compares favorably to Keytruda monotherapy in advanced melanoma patients where the reported rate of grade 3 or higher treatment related adverse events was 10.1 percent.

Viralytics chief executive officer Dr Malcolm McColl said the company was "very pleased with the ongoing results from the Capra study suggesting that Cavatak may be able to enhance activity and reduce adverse events compared to Keytruda alone".

"Based on these results, and with strong support from leading oncologists, we are delighted to continue exploring the potential of this combination therapy in an expanded cohort of patients," Dr McColl said.

Viralytics fell five cents or 3.9 percent to $1.22 with 911,142 shares traded.

MESOBLAST

Mesoblast says the US Food and Drug Administration has cleared a 24-patient trial of its stem cells with corrective surgery for children with hypo-plastic left heart syndrome.
Mesoblast said that the trial of children under the age of five years would be enrolled in the trial at Boston Children's Hospital, the paediatric teaching hospital of Harvard University.
The company said that children with hypo-plastic left heart syndrome (HLHS) had a functioning right ventricle, but a small left ventricle that was incapable of supporting the systemic circulation and if left untreated the congenital condition was "uniformly fatal".
Mesoblast said that the current treatment, ventricle palliation, used the right ventricle to support the entire circulation through a series of surgeries, but the right ventricle eventually tired out, leading to nearly 50 percent mortality by adolescence.
Boston Children's complex biventricular repair program director and Harvard Medical surgery professor Prof Sitaram Emani, the trial's principal investigator said that injecting Mesoblast's mesenchymal precursor cells into the hypo-plastic left ventricle as an adjunct to surgical rehabilitation of the left heart had "the potential to promote growth and regeneration of that ventricle and recruit it back into the circulation, so that the patient has a chance to regain a normal two-ventricle circulation with improved quality of life and longevity".
Mesoblast said that Prof Emani and his colleagues had been developing strategies to rehabilitate the left ventricle and perform biventricular conversion, which would give the patient a normal circulation and prevent complications associated with single ventricle circulation including renal failure, arrhythmias, and the need for a heart transplant, but only one third of patients were able to undergo biventricular conversion.
The company said that the key to successful ventricular recruitment and biventricular conversion was cardiac muscle growth and regeneration and in the randomized controlled trial, its MPC-150-IM would be injected into the left ventricle of children with hypo-plastic left heart syndrome during surgical recruitment procedures of the small ventricle with the intent of improving ventricular mass and function leading to higher likelihood of biventricular conversion.
Mesoblast climbed 13 cents or 5.6 percent to $2.46 with 687,293 shares traded.

ONCOSIL MEDICAL

Oncosil says it has been granted UK central ethics approval for its clinical study program for pancreatic cancer.
Oncosil said the approval initially covered London's Guys and St Thomas' Hospital and would facilitate ethics approval for all five UK centres, helping expedite recruitment.
The company said the other centres included the University of Leicester, the Royal Liverpool Hospital, London's Hammersmith Hospital and the Cambridge-based Addenbrookes Hospital and Sydney's Westmead Hospital had granted ethics approval.
Oncosil was up 1.1 cents or 11.7 percent to 10.5 cents with 1.7 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has received $981,507 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Neuren said the rebate related to research and development expenditure for the year to December 31, 2016.
Neuren was up one cent or 14.5 percent to 7.9 cents with 2.7 million shares traded.

LIFESPOT HEALTH

Lifespot says it is in “advanced negotiations” with unnamed European companies to integrate its Bodytel monitoring platform with medical marijuana opportunities.
Lifespot said that with Melbourne-based corporate advisor Peak Asset Management it had “reviewed several opportunities in the medicinal cannabis sector to integrate its Bodytel platform in the monitoring, measuring and administrating of cannabis, for both medicinal and the growing leisure markets”.
In January, Lifespot raised $8,000,000 at 20 cents a share to list on the ASX to develop and commercialize its digital health medical diagnostic and monitoring technology.
Lifespot said its systems and applications aimed “to bring efficiencies in the medical system to clients and end users, saving time and money … [by integrating] software to combine enhanced sensor technology with self-learning algorithms, allowing patients to monitor chronic diseases and critical conditions with their smartphones”.
The company said that its Bodytel system was software that facilitated the management of chronic diseases and assisted with the measurement of key vital functions and indicators of these diseases, including but not limited to blood glucose, blood pressure and weight levels, as well as assisting with the monitoring of prescribed therapies for chronic diseases, including medication dosages, diets and levels of physical activity.
In February, Lifespot said that its wholly-owned subsidiary, Bodytel GmbH and Roche Diagnostics Deutschland GmbH signed an agreement to integrate the Roche Bluetooth enabled Coaguchek Inrange blood coagulation test with the Bodytel platform.
Lifespot fell 2.5 cents or 7.6 percent to 30.5 cents with 1.3 million shares traded.

OBJ

OBJ says it has additional licencing term sheets for two new collaboratively developed products with an unnamed partner for its third and fourth products.
OBJ has previously announced licencing agreements for multiple products with Proctor & Gamble (BD: Apr 28, 2014; Sep 8, 2015; May 27, Sep 2, 2016).
The company said that it could not name the partner for confidentiality reasons.
OBJ said the new products would extend the use of its technology within the partner’s pipeline and was expected to result in application across multiple brands and categories.
Separately, OBJ said that it was in negotiations for the licence of a second technology platform with a separate unnamed company.
OBJ was up 0.1 cents or 1.45 percent to seven cents with 1.35 million shares traded.

PRESCIENT THERAPEUTICS

Prescient has requested a trading halt “pending the release of an announcement … in relation to results from [its] phase Ib breast cancer trial”.
Trading will resume on April 6, 2017 or on an earlier announcement.
Prescient fell 0.2 cents or two percent to 9.8 cents before the trading halt.

BOTANIX

Botanix has requested a voluntary suspension to follow the trading halt requested on March 31 pending “an announcement regarding a capital raising” (BD: Mar 31, 2017).
Botanix last traded at 6.8 cents.

PHARMAXIS

BVF Partners and Mark Lampert say they have increased their substantial holding in Pharmaxis from 41,209,253 shares (12.99%) to 60,423,669 shares (18.94%).
The San Francisco, California-based BVF Partners and Mr Lampert said they acquired the shares in 128 trades between October 6, 2015 and March 31, 2017, buying 16,920,547 shares on March 31 for $4,483,945 or 26.5 cents a share.
Pharmaxis was unchanged at 28 cents.

PHARMAXIS

Australian Ethical Investment says it has increased its substantial shareholding in Pharmaxis, from 28,424,427 shares (8.91%) to 32,424,427 shares (10.16%).
Australian Ethical said that it bought the 4,000,000 shares on March 31, 2017 for $1,062,332 or 26.6 cents a share.

CRESO PHARMA

Creso says it has appointed the Sydney-based David Russell as its chief operating officer responsible for overall business and corporate strategy.
Creso said that Mr Russell would be responsible for developing the Australian marijuana-derived food additives business and commercial strategy.
The company said that Mr Russell had more than 25 years' experience in the pharmaceutical and biotechnology industry including with Roche, Actelion Pharmaceuticals, Celgene and Novogen and held sales and marketing roles at Roche Australia.
Creso fell 0.5 cents or 0.7 percent to 75 cents.