Biotech Daily

Thursday November 8, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IMMUTEP UP 7%; REVA DOWN 8%**

*** IMAGION READIES FOR 1st HUMAN MAGSENSE BREAST CANCER TRIAL**

*** FEDERAL GOVERNMENT SETS 12 RESEARCH, INNOVATION PRIORITIES**

*** BARD1 TO RAISE $3.3m IN ENTITLEMENT OFFER**

*** EURO GUIDELINES 'CHALLENGE' REVA; RICHARD KIMES GOES**

*** STRIDES PAYS SUDA $1.4m FOR SUD-001H FOR MIGRAINE IN US**

*** VISIONEERING: 'LENSES SLOW CHILDREN'S MYOPIA BY 81%'**

*** OPTISCAN RECEIVES $776k R&D TAX INCENTIVE**

*** PHOSPHAGENICS RECEIVES $604k R&D TAX INCENTIVE, $200k MORE**

*** CELLMID 16% OPPOSE 33% DIRECTOR FEES POOL HIKE**

*** GENETIC TECHNOLOGIES CEO DR PAUL KASIAN $47k PAY RISE**

MARKET REPORT

The Australian stock market was up 0.51 percent on Thursday November 8, 2018 with the ASX200 up 29.8 points to 5,926.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 12 fell, seven traded unchanged and five were untraded. All three Big Caps were up.

Immutep was the best, up 0.3 cents or 6.8 percent to 4.7 cents, with 4.2 million shares traded, followed by Actinogen up 6.7 percent to 4.8 cents with 931,430 shares traded. Ellex and Neuren climbed more than five percent; Clinuvel and Impedimed improved more than four percent; Benitec, Dimerix, Nanosonics, Osprey and Telix were up more than three percent; Medical Developments and Volpara rose more than two percent; Avita, Cochlear, CSL, Pro Medicus and Resmed were up more than one percent; with Starpharma up 0.3 percent.

Reva led the falls, down two cents or 8.3 percent to 22 cents, with 22,450 shares traded. Mesoblast lost 6.3 percent; Imugene, Orthocell and Prana fell more than four percent; Bionomics and Prescient were down more than three percent; Airxpanders, Cynata, Oncosil and Opthea shed more than two percent; with Optiscan down 1.7 percent.

IMAGION BIOSYSTEMS

Imagion executive chairman Robert Proulx says the first in-human use of Magsense cancer imaging technology is expected to begin in March or April 2019.

Last year, the Albuquerque, New Mexico-based Imagion raised $12 million in an initial public offer at 20 cents a share to list on the ASX and develop its Magsense technology (BD: Jun 7, 22, 2017).

Today, Mr Proulx told Biotech Daily that the planned 20 to 30 patient ex-vivo trial would be a catalyst for a fund-raising ahead of an US Food and Drug Administration-directed pivotal trial planned for 2020.

Mr Proulx said that the pilot trial would enrol up to 30 women with HER-2 breast cancer which was expected to be metastatic and spread to lymph nodes.

Mr Proulx said that about 50 percent of breast cancers were lymph node positive and half were lymph node negative and the only way to tell was to remove the nodes.

He said that the hope for Magsense was that it could show, non-invasively, which patients were lymph node negative and spare them the unnecessary removal of their lymph nodes.

Mr Proulx said that patients would be dosed with iron oxide nanoparticles attached to HER2 antibodies that would bind to the cancer, 24 hours prior to surgery.

He said that following removal of lymph nodes, the Magsense would briefly “pulse a weak magnetic field and measure the field of particles bound to tumors”.

Mr Proulx said the magnetic field would align any non-binding particles, while the attached particles would be bound at any tumors and the nodes could be measured.

He said that only those particles attached to their target tumor were measured, with unattached nanoparticles not detected and the Magsense system did not expose the patient to ionizing radiation or radioactive tracers.

Mr Proulx said that the Magsense was like a weak version of a magnetic resonance imaging (MRI) machine but without the claustrophobic tunnel.

He said that Magsense had a 20cm field of view, able to capture a patient’s upper chest including breast and armpit.

“Iron oxide is known to be benign in humans,” Mr Proulx said, “but we will be doing toxicology and safety studies for the FDA submission”.

He said that Imagion would be blinded to the pathology and the trial was expected to take about eight to 10 weeks, with results “almost immediately” and data by July 2019.

“This is the major de-risking event for Magsense and Imagion,” Mr Proulx said.

“If this goes well, we have a true path to a pivotal study for FDA pre-market approval application and approval,” Mr Proulx said.

He said that given the FDA had no comparator device the trial would compare Magsense to pathology.

“Our goal is to get to a non-invasive way of differentiating node negative breast cancer from node positive cancer,” Mr Proulx said.

“The pivotal trial is looking for three things,” Mr Proulx said.

“Do patients tolerate the injection of particles?”

“Do the particles drain to the lymph nodes?”

“Do they attach to cancer cells in the lymph nodes?”

Mr Proulx said that if the pilot study was successful the company would need to raise about $20 million to $30 million for a pivotal study.

Last year, the company said it had spent directly and through grants about $US18 million in developing the Magsense technology and initial end-use applications.

Mr Proulx said he hoped to begin the six month, 200-to-250 patient pivotal trial by July 2020, leading to an FDA submission and response by the end of 2020.

Imagion was up 0.2 cents or 4.55 percent to 4.6 cents.

FEDERAL GOVERNMENT

The Federal Minister for Health Greg Hunt has published 12 Medical Research Future Fund “medical research and innovation priorities” for the next two years.
A media release from Mr Hunt said the focus areas were set following consultation with more than 1,200 community and industry stakeholders, taking into account “the burden of disease experienced by the Australian community and the need to enhance evidence translation in clinical practice”.
The media release said the 12 priorities included: anti-microbial resistance, global health and health security, Aboriginal and Torres Strait Islander health, ageing and aged care, digital health intelligence, comparative effectiveness research, primary care research, clinical researcher capacity, consumer-driven research, drug repurposing, public health interventions, and translational research infrastructure.

BARD1 LIFE SCIENCES

Bard1 says it plans to raise $3.3 million through the issue of 165.7 million shares at two cents a share in a one-for-five, non-renounceable entitlement offer.
Bard1 said the offer price of two cents a share was a 39.4 percent discount to the last traded price of 3.3 cents on November 7, 2018.
The company said that funds would be used to develop its auto-antibody tests for the detection of breast, ovarian and lung cancers, research and general working capital.
Bard1 said that Perth’s Merchant Corporate Advisory was the lead manager for the offer.
Bard1 fell 0.7 cents or 21.2 percent to 2.6 cents with 82.2 million shares traded.

REVA MEDICAL

Reva says that European Society of Cardiology guidelines opposing the commercial use of bio-resorbable stents has led to staff reductions.
Reva said the head of operations Richard Kimes had “departed the organization on November 6, 2018 in connection with a small reduction in workforce”.
Reva chief executive officer Dr Reggie Groves said that the reduction was due to expected slower growth in the coronary business “based on recently-published European Society of Cardiology guidelines related to the use of bioresorbable scaffolds, which was discussed in detail in our most recent earnings call.”
In the second of three third quarter reports, entitled ‘Reva Medical Reports Third Quarter 2018 Financial Results’, published on the ASX on Tuesday November 6, 2018, Dr Groves said “we continued to see growth in product shipments and new customers for Fantom in the third quarter of 2018 despite the increasing challenges in the European [bio-resorbable scaffold] market”.
“In August 2018, the European Society of Cardiology published updated clinical guidelines for percutaneous coronary intervention procedures that included a recommendation that [bio-resorbable scaffolds] should not be used outside of well-controlled clinical studies,” Dr Groves said. “As a result, we will focus on generating the clinical evidence needed to support our commercialization efforts and a modification to the [European Society of Cardiology] guidelines in the future.”
“Additionally, we are shifting resources to advance our peripheral and embolization therapy programs,” Dr Groves said.
“These markets are growing quickly and with reasonable investment, we believe we can make significant progress in the next few years,” Dr Groves said.
Reva fell two cents or 8.3 percent to 22 cents.

SUDA PHARMACEUTICALS

Suda says Strides Pharma will pay $1.0 million ($A1.4 million) to commercialize and develop its SUD-001H oral spray of sumatriptan for migraines in the US.
Suda said that the Bangalore, India-based Strides would fund product development for SUD-001H, pay $US400,000 ($A550,580) upfront, with milestone payments of $US600,000 ($A825,870) for a pilot first-in-man study, submission and approval in the US.
The company said that it would receive royalties and a handling fee, and Strides would have a right of first refusal for additional territories.
Suda said it would work with Strides through joint committees to obtain US Food and Drug Administration approval for SUD-001H.
Suda chief executive officer Stephen Carter said there was “a significant unmet medical need for a better treatment modality for patients with migraine headache, particularly patients that have rapid onset of pain and those with the co-morbidity of severe nausea and vomiting”.
“We are looking forward to working with Strides to ensure the success of SUD-001H in the world’ largest pharmaceutical market,” Mr Carter said.
Suda was up 0.1 cents or 20.0 percent to 0.6 cents with 306.7 million shares traded.

VISIONEERING TECHNOLOGIES INTERNATIONAL

Visioneering says a 32-patient prospective study has found its Naturalvue multifocal contact lenses slow near-sightedness progression in children by 81 percent each year.
Visioneering said the study found that wearing Naturalvue contact lenses reduced the progression of myopia, or short-sightedness, in children from an average rate of 1.28 dioptres (a measure of the focal length of a lens) a year to an average rate of 0.24 dioptres per year ($p < 0.01$), an 81 percent decrease in the rate of the progression of short-sightedness.
The company said that the 19 children who wore the Naturalvue multifocal contact lens for at least one year demonstrated an average axial length (a measure of eye shape) change of 0.20mm in one year compared to an estimated average of 0.43mm if they had not worn the Naturalvue contact lenses.
Visioneering said that 24 children in the study completed at least one six-month follow-up visit and that 19 children had worn the Naturalvue lenses for more than one year.
The company said the study was led by University of California Berkeley School of Optometry visiting professor Prof Thomas Aller who presented the data at the American Academy of Optometry meeting in San Antonio Texas on November 9, 2018.
Prof Aller said that “to achieve more than 1.00 dioptres of decrease in myopic refractive error change on a prospective basis after one year is quite remarkable and promising”.
“The unique design of Naturalvue multifocal offers intervention for multiple potential causes of myopic progression, and its availability as a daily disposable contact lens makes it ideal for use in children,” Dr Aller said.
Visioneering was up one cent or 5.6 percent to 19 cents.

OPTISCAN IMAGING

Optiscan says it has received $775,520 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Optiscan said that the rebate related to research and development expenditure for the year to June 30, 2018.
Optiscan fell 0.1 cents or 1.7 percent to 5.9 cents.

PHOSPHAGENICS

Phosphagenics says it has received $604,378 and expects “about $200,000” more from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Phosphagenics said that the rebate related to research and development expenditure for the year to June 30, 2018.
Phosphagenics was unchanged at 2.6 cents with 1.4 million shares traded.

CELLMID

Cellmid says its annual general meeting passed all resolutions, but with up to 16.2 percent opposition to increase the aggregate directors’ fees by 33 percent to $400,000.
Cellmid said that 4,022,147 votes (16.19%) opposed the increase in directors’ fees, with 20,631,592 votes (83.03%) in favor and 195,635 votes (0.79%) at the proxy’s discretion.
The company said that 4,668,438 votes (14.43%) opposed the issue of 500,000 incentive shares to chief executive officer Maria Halasz and the remuneration report was passed with 3,155,017 votes opposed (12.86%).
The re-election of director Dr David King and the issue of 130,000 shares to director Dennis Eck in lieu of a cash payment were passed by wider margins.
Cellmid’s most recent Appendix 3B said the company had 83,478,592 shares on issue meaning that the opposition to Ms Halasz shares, amounted to 5.6 percent of the shares on issue, sufficient to requisition extraordinary general meetings.
Cellmid was unchanged at 34 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says chief executive officer Dr Paul Kasian’s will increase from $ $153,000 to $200,000 a year.
Genetic Technologies said Dr Kasian’s salary would increase from $49,227 to $96,228 a year and his chairman and director’s fees were unchanged at $103,772 a year.
Dr Kasian’s executive salary was updated to “align his remuneration more closely with market rates and reflect the time, commitment and effort required to perform the interim [chief executive officer] role”.
Genetic Technologies was unchanged at 1.1 cents with 9.5 million shares traded.