Biotech Daily

Monday December 10, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PRESCIENT UP 5.5%; TELIX DOWN 10%**

*** PRESCIENT: 'BREAST CANCER RESPONDERS PROGRESSION-FREE'**

*** PRO MEDICUS EXTENDS UNNAMED GERMAN HOSPITAL CONTRACT**

*** CE MARK APPROVAL FOR SPEEDX GONORRHOEA TEST**

*** IMPEDIMED: 'STUDY BACKS L-DEX FOR BREAST CANCER LYMPHOEDEMA'**

*** MEDIBIO NOTES RAISE $2.5m; RIGHTS OFFER FOR $4m MORE**

*** PHOSPHAGENICS REQUESTS 'MYLAN NEGOTIATIONS' TRADING HALT**

*** ALLAN GRAY DILUTED TO 15% OF OSPREY**

*** ONCOSIL APPOINTS MICHAEL BASSETT DIRECTOR**

*** PAINCHEK, BLAMEY SAUNDERS WIN UK 'ROCKETSHIP' TRAVEL GRANTS**

MARKET REPORT

The Australian stock market followed the US down, falling 2.27 percent on Monday December 10, 2018, with the ASX200 down 129.0 points to 5,552.5 points.

Six of the Biotech Daily Top 40 stocks were up, 25 fell, six traded unchanged and three were untraded. All three Big Caps fell.

Prescient was the best, up 0.4 cents or 5.5 percent to 7.7 cents, with 7.9 million shares traded. Paradigm climbed 5.2 percent; Patrys was up 3.85 percent; Actinogen and Impedimed rose more than two percent; with Kazia up 1.3 percent.

Telix led the falls, down 6.5 cents or 10.3 percent to 56.5 cents, with 527,318 shares traded, followed by Uscom down 10 percent to 13.5 cents, with 56,135 shares traded.

Antisense lost 9.1 percent; Volpara fell 7.5 percent; Compumedics, Medical Developments and Nanosonics were down more than six percent; Cochlear, Clinuvel, Immutep and Prana fell five percent or more; Imugene and Oncosil were down more than four percent; Airxpanders, CSL, Cynata, Osprey and Pro Medicus lost three percent or more; LBT, Neuren, Proteomics, Resmed, Starpharma and Universal Biosensors shed more than two percent; Pharmaxis was down 1.85 percent; with Genetic Signatures, Opthea and Polynovo down by less than one percent.

PRESCIENT THERAPEUTICS

Prescient says that the five breast cancer patients of 10 in its trial of PTX-200 for HER2 negative, locally advanced breast cancer have been progression free since treatment.
Prescient said that follow-up studies determined that none of the five responders in the phase II component of the trial have had disease progression to date, ranging from 22.8 months to 30.4 months so far, with an average of 27 months.
In April, Prescient said that of the 10 evaluable patients in its 28-patient, phase Ib trial of PTX-200 for breast cancer five (50%) had an overall response rate, twice the expected rate (BD: Apr 10, 2018).
Prescient said at that time that the trial dosed 28 patients, 16 patients in the dose escalation stage, while the expansion cohort comprised a further 12 patients with locally advanced or metastatic human epidermal growth factor receptor 2 (HER2)-negative breast cancer, who received 35mg/m2 of PTX-200, with 80mg/m2 per week of paclitaxel, followed by standard doxorubicin-cyclophosphamide and surgery for locally advanced disease.
The company said that 10 of the 12 expansion patients were evaluable for clinical response, of which five had locally advanced disease and five had metastatic disease.
Prescient said that in patients with locally advanced disease, two patients had pathologic complete responses meaning a complete eradication of cancer.
Today, the company said that not only did patients with pathological complete responses remain free of disease progression, interestingly all patients that had partial responses also remained free of disease progression after more than two years.
Prescient chief medical officer Dr Terrence Chew said that “typically, women with locally advanced breast cancer will have disease recurrence five years after successful treatment, but many of these women will progress within the first two years”.
“The observation that our patients have not experienced any cancer progression beyond two years on average is therefore encouraging and supports the response rates we have seen so far,” Dr Chew said.
Prescient said that while progression-free survival and overall survival were not study endpoints, their analysis “fortifies the body of evidence for the study’s endpoint of pathological complete response rates” which the US Food and Drug Administration “recognizes as an endpoint to accelerated approval”.
Prescient chief executive officer Steven Yatomi-Clarke said that Roche’s phase III Akt inhibitor ipatasertib was being tested in a different subset of breast cancer, metastatic triple negative disease and it showed three things “very relevant” to Prescient.
“Firstly, the Akt pathway is activated in response to chemotherapy in breast cancer patients,” Mr Yatomi-Clarke said.
“Secondly, Akt inhibitors enhance the killing of breast cancer cells [and] thirdly and most significantly, this Akt inhibition results in clinical benefit for breast cancer patients,” Mr Yatomi-Clarke said.
“This demonstrates that Akt inhibition can make a clinical difference to breast cancer patients, which is what Prescient is seeking to demonstrate in these studies,” Mr Yatomi-Clarke said.
“Further, we believe that PTX-200’s unique mechanism of action as a PH domain inhibitor may have advantages over other Akt inhibitors,” Mr Yatomi-Clarke said.
Mr Yatomi-Clarke said that two of the people involved in the discovery and development of ipatasertib at Array Biopharma were Prescient’s head of chemistry, manufacturing and controls, Dr Mike Preigh and our head of business development Dr Jim Winkler.
Prescient was up 0.4 cents or 5.5 percent to 7.7 cents, with 7.9 million shares traded.

PRO MEDICUS

Pro Medicus says it has a more than $3 million extension to the contract with an unnamed German Government hospital network.

Pro Medicus said the contract was through its European subsidiary Visage Imaging GmbH and included additional licences for the existing site, and would see its Visage 7 and Visage Open Archive serve as the central component of “a next generation imaging infrastructure at two additional hospitals within the network”.

The company said the Visage client-server architecture and streaming technology would allow cross-regional diagnostic image access from other government sites in northern and southern Germany to facilitate better image sharing.

Pro Medicus said the product was scheduled to go live by the end of this year.

The company said the capital purchase would see Visage provide software and services with revenue of more than $3 million, excluding ongoing service contracts.

Pro Medicus chief executive officer Dr Sam Hupert said the German hospital market was “difficult to penetrate so we see this as a solid step forward”.

“We initially implemented Visage at one facility within this government hospital network,” Dr Hupert said.

“With this contract we will now extend our reach to most of the enterprise,” Dr Hupert said.

“This will provide us with our first large, multi-facility reference site in Europe which we see as instrumental to building the base for further sales in the region,” Dr Hupert said.

Pro Medicus fell 36 cents or 3.4 percent to $10.21.

SPEEDX

Speedx says it has Conformité Européenne approval for its Resistanceplus GC assay for gonorrhoea and susceptibility to the antibiotic ciprofloxacin.

The Sydney-based Speedx said the test detected both the sexually-transmitted gonorrhoea and sequences in the gyrA gene of the bacteria associated with susceptibility to ciprofloxacin, a front-line antibiotic treatment.

The company said that ceftriaxone was “a painful intramuscular injection” and was one of the last remaining antibiotics for multi-drug resistant infections.

Speedx said that up to 70 percent of infections could be treated with a single oral dose of ciprofloxacin if the susceptibility status was established prior to prescribing.

Westmead Clinical School sexual health clinician Prof David Lewis said the new test would help improve current clinical practice.

“The assay will allow us to treat and reduce transmission of antimicrobial resistant gonorrhoea at the earliest opportunity,” Prof Lewis said. “For the first time, it will provide clinicians with treatment options other than ceftriaxone for treating gonorrhoea, and in doing so will make better use of currently-available antibiotics such as ciprofloxacin.”

Speedx said that susceptibility to ciprofloxacin was as high as 70 percent in some regions.

Speedx chief executive officer Colin Denver said that “Resistanceplus GC is an important next step in our portfolio and is a welcome addition in managing the extensive antibiotic resistance in [Neisseria] gonorrhoeae infections”.

The company said that Resistanceplus GC was “the first commercially available molecular test providing ciprofloxacin antibiotic susceptibility information and is well placed to support current laboratory molecular testing workflows”.

Speedx said Australian cases were up 113 percent in the past 10 years and the infections were often asymptomatic, enabling it to spread unnoticed, but left untreated it could cause complications from infertility and ectopic pregnancies, to premature births and blindness.

Speedx is a private company.

IMPEDIMED

Impedimed says a Macquarie University study of the retrospective data on 753 women who underwent bioimpedance spectroscopy (BIS) supports its L-Dex technology.

The journal article, titled 'Early Surveillance Is Associated With Less Incidence and Severity of Breast Cancer-Related Lymphedema Compared With a Traditional Referral Model of Care' was published in Cancer and an abstract is available at: https://onlinelibrary.wiley.com/doi/epdf/10.1002/cncr.31873.

The abstract concluded: "The current findings support the adoption of an early prospective surveillance model of care using BIS for the early detection and management of breast cancer-related lymphedema."

Last year, Impedimed says that four abstracts on its L-Dex lymphoedema diagnostic would be presented at the San Antonio, Texas Breast Cancer Symposium, including the Macquarie University study, by lead author Louise Koelmeyer (BD: Nov 8, 2017).

Today, the company said the analysis examined the outcomes of patients who were followed in either an early surveillance group or a traditional referral group.

The study said the early surveillance group of 188 patients prospectively followed with L-Dex included 121 women from a pre-operative baseline and 67 women within 90 days of their surgery, while the traditional referral group of 285 patients consisted of women who were referred to the practice more than 90 days from the time of surgery.

Impedimed said that women who underwent early surveillance "received lymphoedema care almost two years earlier than women in the traditional referral group".

"The early surveillance group had a significantly lower incidence of clinical lymphoedema than the traditional referral group, and those who were diagnosed in the early surveillance group had significantly less severe lymphoedema," the company said.

Impedimed chief executive officer Richard Carreon said the study "adds to the growing body of clinical evidence and will significantly strengthen our case to the [US National Comprehensive Cancer Network] and private payors".

Impedimed was up half a cent or 2.2 percent to 23.5 cents.

MEDIBIO

Medibio says it has commitments to raise $2.5 million through the issue of convertible notes at two cents each and will offer a one-for-one rights issue to raise $4.01 million.

Medibio said it had commitments from sophisticated and professional investors for about 125,000,000 convertible notes, to be issued in two tranches at the lower of two cents each or the offer price of any subsequent share issue undertaken during the term of the note, which was 18 months from the date of issue.

The company said that unless converted earlier, all notes must be converted on their maturity date and would be convertible on the last business day of each quarter from March 31, 2019.

Medibio said that tranche 1 would comprise 30,394,240 notes to raise $607,885 under the existing placement capacity with tranche 2 expected raise a further $1.9 million, subject to shareholder approval.

The company said that fund would be used to advance its US Food and Drug Administration 510(k) regulatory approval, progress its de novo submission, technology development, product commercialization and for working capital.

Medibio said that the entitlement offer, at two cents a share, would have a record date of December 13, open on December 18, 2018 and close on February 7, 2019.

Medibio fell 1.6 cents or 40.0 percent to 2.4 cents with 1.7 million shares traded.

PHOSPHAGENICS

Phosphagenics has requested a trading halt “pending an announcement … in relation to advanced negotiations with Mylan”.
Phosphagenics said the negotiations related to “the quantum of costs that might be payable under the arbitration and future arrangements for commercialization of the intellectual property that has been under dispute”.
Last month, the company said it lost its $US300 million ($A415.5 million) case against Mylan Laboratories over injected tocopheryl phosphate mixture (TPM) daptomycin for skin infections (BD: Nov 12, 2018).
Phosphagenics said at that time that the Singapore International Arbitration Centre Arbitration Centre issued a partial final award that it was “unsuccessful in all of its claims”.
Last year, Phosphagenics said it has filed its expert reports in the arbitration, including the $US300 million damages claim over Mylan’s licence of its tocopheryl phosphate mixture (TPM) daptomycin for skin infections and staphylococcus aureus bloodstream infections originally licenced to Strides Arcolab subsidiary, the India-based Agila Specialties, acquired by Mylan in 2013 (BD: Oct 30, 2012; Mar 3, May 29, 2017; Oct 23, 2018).
In September, the company said that the Mylan on-line product catalogue included a generic daptomycin injectable product (BD: Sep 10, 2018).
Today, Phosphagenics said “the parties will make submissions on costs, on a date to be set, which are reserved to a final award on costs”.
“Phosphagenics has spent approximately $5.6 million on arbitration and legal fees to date,” the company said.
Trading will resume on December 12, 2018 or on an earlier announcement.
Phosphagenics last traded at 0.25 cents.

OSPREY MEDICAL

Allan Gray Australia says that its holding in Osprey of 64,516,130 Chess depository instruments (CDIs) has been diluted from 15.97 percent to 14.94 percent.
Allan Gray said that it became a substantial shareholder in October when it acquired the shares for $10 million at 15.5 cents a share (BD: Oct 30, 2018).
The company said it was diluted in the following entitlement offer which raised $4.3 million at the same price (BD: Nov 29, 2018).
Osprey fell half a cent or 3.85 percent to 12.5 cents.

ONCOSIL MEDICAL

Oncosil says it has appointed Michael Bassett as a non-executive director, effective from today.
Oncosil said that Mr Bassett had more than 25 years’ experience in capital markets and held management roles at Australian fund management and investment banking firms.
The company said that Mr Bassett had experience in analyzing, advising and investing in small-cap ASX-listed companies and previously worked as a portfolio manager for Regal Australian Small Companies Fund with a focus on life science companies.
Regal holds or has held shares in Oncosil, Adherium, Airxpanders, Avita, IDT, Impedimed, Medibio, Opthea, Prescient, Suda and Visioneering.
Oncosil said that prior to Regal, Mr Bassett held management positions within Credit Suisse’s institutional equities business, Deutsche Asset Management and Merrill Lynch.
The company said Mr Bassett held a Bachelor of Economics from Macquarie University.
Oncosil fell one cent or 4.9 percent to 19.5 cents with 1.2 million shares traded.

PAINCHEK, BLAMEY SAUNDERS HEARS

Blamey Saunders and Painchek have won UK Tech Rocketship Awards to travel to the UK in February 2019 to promote their businesses.

A media release from the British Consulate-General said that the nine winning companies "beat a competitive field of 197 entries to secure a highly sought-after place on the Tech Rocketship program".

The Consulate-General said that each winner would receive a paid trip to the UK in February 2019 to participate in "a series of meetings, networking events and workshops aimed at supercharging their expansion plans".

The Consulate-General said the Tech Rocketship Award categories aimed to support the UK's innovation priorities, including technologies to tackle the first four 'Grand Challenges' in the UK's Industrial Strategy: artificial intelligence and data; an ageing society; clean growth; and the future of mobility.

In a media release, Painchek chief executive officer Philip Daffas said "the Rocketship Award is a significant recognition of the Painchek technology, the successful market introduction in Australia and the large overseas market potential".

"The award will provide Painchek with financial support as well as the key contacts and processes to fast track our UK and European commercialization in early 2019," Mr Daffas said.

Painchek has developed facial recognition software to assess pain, designed for those who cannot describe their pain including the elderly and infants (BD: Jun 7, 2018).

In March, Blamey Saunders Hears launched its locally-developed Facett "modular self-fit hearing aid" costing about half the price of standard hearing aids (BD: Mar 5, 2018)

British Consul General and Department for International Trade, Australia and New Zealand, director-general Michael Ward said the awards were "an invaluable opportunity to gain access to the fifth largest economy in the world and a thriving tech community and we are excited to welcome them to the UK in the New Year".

"I am absolutely delighted at the response to our Tech Rocketship Awards and the exceptionally high calibre of entries," Mr Ward said.

"It is fantastic to see so many innovative Australian and New Zealand companies delivering leading-edge technologies," Mr Ward said.

Painchek fell 0.2 cents or 4.65 percent to 4.1 cents.

Blamey Saunders is a private company.