Biotech Daily

Monday July 31, 2017

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: DIMERIX UP 9%, ONCOSIL DOWN 14%**

*** HAEMALOGIX BUYS RIGHTS TO MULTIPLE MYELOMA AGENT**

*** SIENNA IPO RAISES $4.6m TO LIST ON THURSDAY**

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*** ZELDA, COMPLUTENSE CANNABINOID BREAST CANCER RESEARCH**

*** COCHLEAR 2-YR CEO CHRIS SMITH GOES, DIG HOWITT STARTS ON $1.6m**

*** ALCIDION APPOINTS GEOFF ROHRSHEIM, REBECCA WILSON DIRECTORS**

MARKET REPORT

The Australian stock market was up 0.31 percent on Monday July 31, 2017 with the ASX200 up 17.8 points to 5,720.6 points. Twelve of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and eight were untraded.

Dimerix was the best, up 0.1 cents or 9.1 percent to 1.2 cents, with 15.6 million shares traded. ITL climbed 5.4 percent; Bionomics and Clinuvel were up more than four percent; Pharmaxis was up 3.9 percent; Atcor, Impedimed, Polynovo and Pro Medicus rose more than two percent; Orthocell was up 1.6 percent; with CSL, Ellex, Resmed and Sirtex up by less than one percent.

Oncosil led the falls, down 1.45 cents or 14.15 percent to 8.8 cents with 2.5 million shares traded. Viralytics lost 6.9 percent; Acrux, Admedus, Benitec and Medical Developments were down more than three percent; Compumedics and Osprey shed more than two percent; Avita and Cochlear were down more than one percent; with Mesoblast and Starpharma down by less than one percent.

HAEMALOGIX PTY LTD

The Sydney-based Haemalogix says it has acquired the research commercialization rights to an immuno-oncology agent for multiple myeloma.

Haemalogix executive chairman Bryce Carmine told Biotech Daily that his company owned two antibodies to surface antigens only found on malignant cells and the research institutes had developed a chimeric antigen receptor T-cell from one of the antibodies.

Mr Carmine said that Haemalogix had acquired the rights to the collaboration research undertaken by Sydney's Westmead Institute for Medical Research, Western Sydney Local Health District, Children's Medical Research Institute and the University of Sydney.

Mr Carmine said that cappa myeloma antigen was found only on malignant cells and the resultant immuno-oncology technology was designed to specifically target malignant cancer cells present in the bone marrow of multiple myeloma patients.

In a media release Haemalogix that myeloma was a blood cancer caused by malignant plasma cells that developed and multiplied in bone marrow.

The company said that the bone marrow was invaded by the malignant plasma cells in multiple areas of the body, hence the disease was "often called multiple myeloma" and about 1,500 Australians were diagnosed with the disease each year.

Haemalogix said that multiple myeloma accounted for 15 percent of blood cancers and one percent of all cancers and despite the recent introduction of new agents to treat multiple myeloma "almost all patients will develop drug resistance and the disease will eventually recur".

"This collaboration positions Haemalogix to be a strong competitor in the rapidly developing global immuno-oncology field and among a few companies that have an agent selectively targeting only the malignant myeloma cells, and not healthy cells," Mr Carmine said.

Mr Carmine said the technology was similar to other promising chimeric antigen receptor T-cell therapies developed by other companies to treat non-myeloma blood cancers.

Haemalogix said that the research was funded by a Cancer Council of New South Wales project grant.

The company said that its antibody had been tested in patients with multiple myeloma and further clinical trials were ongoing, with the Westmead research team preparing to test the promising chimeric antigen receptor (CAR) T-cell therapy in myeloma patients in 2018.

University of Sydney professor of haematology Prof David Gottlieb said that "if the clinical trial proves successful this agent may provide an additional option for patients with drug-resistant myeloma".

"Remarkable clinical results have been achieved in forms of leukaemia and lymphoma in patients who had exhausted all treatment options," Prof Gottlieb said.

Haemalogix is a private company.

SIENNA CANCER DIAGNOSTICS

Sienna says it has raised $4.6 million in its initial public offer at 20 cents a share and it expects to list on the ASX under the code SDX on Thursday, August 3 (BD: Jun 8, 2017).

Sienna said it had developed a US, Europe and Australia approved in-vitro diagnostic to detect telomerase, to be used as an adjunct to urine cytology for bladder cancer.

Sienna chief executive officer Matthew Hoskin said the company was "delighted to commence trading on the ASX as a publicly listed company".

"Commercial sales of the product have commenced, substantially reducing the risk profile of Sienna for investors," Mr Hoskin said.

SIRTEX MEDICAL

Law firms William Roberts and Maurice Blackburn say they intends to take legal action against Sirtex relating to its share price and a forecast of double-digit dose sales growth.

The Sydney-based William Roberts Lawyers said it would allege breaches of disclosure obligations and misleading or deceptive conduct regarding the dose sales guidance.

The website of William Roberts Lawyers said the proposed class action was funded by Litigation Lending Services and said it expected to take the matter to the Federal Court "subject to sufficient interest" on behalf of shareholders who bought shares in the company between August 24 and December 9, 2016.

William Roberts' Sydney-based principal Bill Petrovski told Biotech Daily that the proposed class action was separate from action initiated by Melbourne's Todd Hayward through Portfolio Law (BD: Feb 1, 13, May 29, 2017).

Mr Petrovski said that his firm was representing primarily institutional investors.

In a media release William Roberts said that the dose sales of SIR-Spheres radiation therapy accounted for almost all Sirtex's revenues and the proposed claim would allege that Sirtex "engaged in misleading and deceptive conduct and breached its continuous disclosure obligations when it forecast double-digit growth in SIR dose sales for [the year to June 30, 2017] on August 24, 2016 and then reaffirmed this guidance later in the year, despite lacking reasonable grounds for doing so".

William Roberts said it was not until December 9, 2016 that Sirtex "issued a downward revision of dose sales forecasts to the market, triggering a 37 percent slump in its share price to $16.00 at the day's close".

The law firm said that in its results for the half-year to December 31, 2016 the company reported dose sales growth of 5.6 percent.

Mr Petrovski said that Sirtex shareholders who bought shares after August 24 and held some of or all those shares on December 9, 2016 "had every right to feel aggrieved at their losses".

"We contend that Sirtex never had any reasonable basis for leading investors to believe that it would record double-digit growth in sales of its primary revenue-earner in [the year to June 30, 2017]," Mr Petrovski said.

"The company's own communications to the market following December 9, 2016 confirm that it had a very short window of visibility over sales," Mr Petrovski said.

"How could it then reasonably predict double-digit sales growth over a six-month or 12-month period?" Petrovski said.

"It is our view that Sirtex's share price was artificially inflated based on misleading disclosures to the market," Petrovski said.

"Shareholders who suffered losses as a result may seek compensation for their losses from the company," Mr Petrovski said.

Separately, IMF Bentham told the ASX today that it proposed "to fund on a conditional basis claims of certain current and former shareholders of Sirtex … against Sirtex".

IMF said that the claims related to alleged breaches by Sirtex of its continuous disclosure obligations and it was proposed that the proceedings would be conducted by the Melbourne-based Maurice Blackburn Lawyers.

A Sirtex executive told Biotech Daily that the company had nothing to add to its previous response to the Todd Hayward and Portfolio Law claim.

In January, Sirtex said it would "vigorously defend the proceeding" (BD: Jan 31, 2017).

Sirtex was up one cent or 0.06 percent to $16.09 with 411,202 shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says that receipts from customers for the 12 months to June 30, 2017 were up 391.3 percent to $17,924,000 reflecting “the expanding roll-out of … Scenesse”.
Clinuvel said that it had an increase in its cash balance from $13,845,000 at July 1 2016 to $23,752,000 at June 30, 2017.
Clinuvel was up 30 cents or 4.9 percent to $6.43.

RHINOMED

Rhinomed says that receipts from customers for the 12 months to June 30, 2017 were up 140.4 percent to $2,024,000.
Rhinomed said its net operating cash burn for the three months to June 30, 2017 was $1,123,000 with cash at the end of the quarter of $1,667,000 and it had a credit standby facility for $2,000,000.
Rhinomed was unchanged at 23.5 cents.

ELLEX MEDICAL LASERS

Ellex says it has installed its Itrack minimally invasive glaucoma surgery system at 50 government hospitals in China for clinical evaluation.
Ellex said the installation was “a significant milestone in its efforts to drive greater market penetration … in China” and the Itrack was the only minimally invasive glaucoma surgery device for the treatment of glaucoma approved by China.
Ellex was up one cent or 0.9 percent to $1.08.

SUDA

Suda says it has achieved International Standards Organisation ISO 9001:2015 accreditation for its quality management system.
Suda said that ISO 9001 demonstrated a company’s “ability to consistently provide products and services that meet customer and regulatory requirements”.
The company said that the standard included development services for formulating active pharmaceutical ingredients into proprietary oro-mucosal sprays.
Suda said it was one of the first Australian pharmaceutical companies to be certified under the more rigorous requirements of the latest version of ISO 9001:2015.
Suda chief executive officer Stephen Carter said the certification “helped to attract Pfizer … and other prospective pharma partners to work with Suda in the knowledge that we have a quality management system that meets the highest international standards”.
Suda fell 0.1 cents or 5.6 percent to 1.7 cents.

NUHEARA

Nuheara says its net operating cash burn for the three months to June 30, 2017 was $2,595,000 with cash at the end of the quarter of $3,405,000.
Nuheara said that it had invoiced sales for the three months to June 30, 2017 of $1.7 million, but recorded receipts from customers for the three month period of $415,000 and $1,899,000 for the 12 months to June 30, 2017.
The company said it expected to spend $5,800,000 in the next three months.
Earlier this month, the company raised $9 million at 9.2 cents a share (BD: Jul 20, 2017).
Nuheara fell 0.4 cents or 4.5 percent to 8.5 cents with 7.3 million shares traded.

RESAPP

Resapp has requested a trading halt “pending the release of an announcement regarding an update on its Smartcough-C study”.
Trading will resume on August 2, 2017 or on an earlier announcement.
Resapp last traded at 31 cents.

ATCOR MEDICAL

Atcor says it has a two-year agreement to provide Sphygmocor hyper-tension management systems to with New York University centres and affiliated practices.
Atcor said it had an initial order for five Sphygmocor central blood pressure and arterial stiffness diagnostic systems with up to 30 systems expected to be placed in the first 15 months of the agreement.
The company said that the New York University Langone Health network included five hospitals, affiliated hospitals and more than 175 outpatient and ambulatory care locations in the greater New York City area.
Atcor said that the Langone Medical Centre was a local integrated delivery networks and contracts with the networks provided “substantial economies of scale in sales investment” and was a catalyst for other local networks to contract and adopt.
Atcor chief executive officer Duncan Ross said that New York University was the third network contracted within the past five months “and provides a strong catalyst for accelerated penetration in Atcor’s largest targeted metropolitan market”.
Atcor was up 0.1 cents or 2.4 percent to 4.3 cents.

ONCOSIL MEDICAL

Oncosil says it has recruited 13 of 20 patients required for Conformité Européenne (CE) mark approval with recruitment “much slower … than planned”.
Oncosil said that recruitment “for a study of this nature is a complex and challenging process … [and it would] need to accelerate operational performance if it expects to submit data in sufficient time for the notified body [the British Standards Institute] to make a decision by end of [2017]”.
The company said that four patients had been implanted at Melbourne’s Monash Health and a compassionate access patient was implanted at Sydney’s St Vincent’s Hospital, with 10 centres in Australia, the UK and US active and recruiting subjects, and further five centres had received ethics approval, with discussions on-going at three more centres (BD: Apr 26, 2017).
Oncosil said that the US Food and Drug Administration patient data restriction had been lifted.
The company said it intended to conduct a “full-scale trial” in the US, with 20-patient data a pre-requisite.
“Until recently, the FDA indicated that all 20 patients were required to be US based [but] on July 11, the FDA confirmed that data from 10 patients in recognized non-US centres would be eligible for inclusion,” Oncosil said.
The company said that the FDA change meant it could meet the requirements in a quicker timeframe, with greater flexibility and at a lower cost, recognizing the centres it was working with outside the US.
Oncosil fell 1.45 cents or 14.15 percent to 8.8 cents with 2.5 million shares traded.

RECCE

Recce says that further pre-clinical work for its Recce 327 antibiotic confirms that administration through an intravenous drip is the preferred mode of delivery.
Recce said that trials in rats and dogs showed that Recce 327 remained in the animals systems long enough to kill pathogenic bacteria and cleared within a few hours.
The company said that for the main targets of Staphylococcus aureus and Escherichia coli, the maximum tolerated dose that could be administered without observing excessive toxicity was 17-fold and seven-fold overdose, respectively.
Recce said it was “on-track” to file its investigational new drug application to the US Food and Drug Administration by the end of this year.
Recce was up one cent or 5.9 percent to 18 cents.

ZELDA THERAPEUTICS

Zelda says it has expanded its breast cancer cannabinoid research collaboration with Madrid’s Complutense University to 2019.
In June, Zelda said that in-vitro pre-clinical research supported the use of cannabinoids as anti-cancer agents (BD: Jun 2, 2017).
Today, the company said it would continue pre-clinical studies to investigate the effect of cannabinoids on cancer stem cell-like cells that were self-renewing, causing tumor re-growths, which was “a common concern for women following treatment of breast cancer”.
Zelda was up 0.2 cents or 2.9 percent to seven cents.

COCHLEAR

Cochlear says that chief executive officer Chris Smith will be replaced by chief operating officer Dig Howitt on January 2, 2018.
Mr Smith was appointed chief executive officer from September 1, 2015 on a base salary of $1,450,000 and according to Cochlear’s annual report, in the year to June 30, 2016, Mr Smith received total remuneration of $3,754,906. (BD: May 26, Aug 31, 2015).
A Cochlear executive told Biotech Daily that the company had “returned to our traditional pattern of having an Australia-based CEO”.
Biotech Daily believes that Mr Smith needed to retain closer ties to the US than expected.
Cochlear said that within 14 days of his retirement Mr Smith would be paid $1,452,589 in lieu of notice as well as accrued but unused annual leave and any unpaid base salary, along with a half year short term cash incentive for the period from July 1, 2017 to December 31, 2017, but no long term incentive options and/or performance rights for the year to June 30, 2018.
The company said it would grant deferred rights to Mr Smith in August 2017 for the year to June 30, 2017, vesting in August 2019.
Cochlear said Mr Howitt was appointed company president from today and would work with Mr Smith as responsibilities and relationships were transferred by January 2, 2018.
The company said that Mr Howitt had been with the company since 2000 and was appointed chief operating officer in July 2016 and was previously the head of its Asia Pacific division and head of manufacturing and logistics.
Cochlear said that from July 31, 2017, Mr Howitt would be paid a base salary of $1,644,664 including superannuation, with a short term incentive of $1,600,000 of which $1,230,743 would be in cash and $369,258 in deferred performance rights, along with a long term incentive of a further $1,600,000 in options and equity rights.
Cochlear fell $2.32 or 1.6 percent to $142.85 with 402,031 shares traded.

ALCIDION GROUP

Alcidion says it has appointed Geoff Rohrsheim and Rebecca Wilson as non-executive directors, replacing Brian Leedman and Nathan Buzza.

Alcidion said that Mr Buzza had been a director of the company for four years and would continue as an executive until December2017 to assist in transitioning his roles and responsibilities and Mr Leedman had been a director for one year.

The company said that Mr Rohrsheim was a software, services and technology entrepreneur and Ms Wilson was an experienced investor relations and corporate advisor with Buchan Consulting.

Alcidion said that Mr Rohrsheim had founded three start-ups including Kloud Solutions and held a Bachelor of Engineering from the Australian Defence Force Academy and a Master of Engineering for the University of Adelaide.

The company said that Ms Wilson was currently the chief executive officer of WE Buchan with 18 years in the health and technology sectors.

Alcidion said that Ms Wilson held a Bachelor of Arts from Deakin University.

Alcidion fell 0.3 cents or 4.55 percent to 6.3 cents.