Biotech Daily

Wednesday June 10, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ATCOR UP 11%, VIRALYTICS DOWN 10%**

*** RESONANCE STUDY BACKS MRI TEST FOR LIVER FIBROSIS**

*** WEHI: 'DENDRITIC CELL CONTROL AIDS IMMUNE SYSTEM'**

*** AIRXPANDERS IPO RAISES $36.5m FOR BREAST IMPLANT DEVICE**

*** RHINOMED DISPUTES, WON'T CHALLENGE ASIC $33k FINE**

*** ALCHEMIA WINDING UP TO PAY FONDAPARINUX DIVIDENDS**

*** FIL TAKES 5% OF STARPHARMA**

*** FDA RE-ACTIVATES PRESCIENT PTX-100 IND**

*** ANATARA $61k FEDERAL R&D TAX INCENTIVE, PIG TRIALS CONTINUE**

*** OPTISCAN TAKES FUNDRAISING TRADING HALT TO SUSPENSION**

*** IDT APPOINTS ALAN FISHER DIRECTOR**

MARKET REPORT

The Australian stock market rose 0.13 percent on Wednesday June 10, 2015 with the S&P ASX 200 up 7.3 points to 5,478.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and three were untraded.

Atcor was the best, up two cents or 11.1 percent to 20 cents with 174,500 shares traded.

GI Dynamics climbed 7.1 percent; Neuren was up 6.2 percent; Bionomics rose 5.6 percent; Biotron, Compumedics, Mesoblast, Prima and Universal Biosensors were up more than three percent; Genetic Technologies, Medical Developments and Starpharma rose more than two percent; Acrux, Benitec, Clinuvel and Impedimed were up more than one percent; with Cochlear, Resmed and Sirtex up by less than one percent.

Viralytics led the falls, retreating nine cents or 10.1 percent to 80 cents with 1.4 million shares traded.

Analytica lost 8.3 percent; both Antisense and Cellmid fell 4.35 percent; Anteo, Ellex, Psivida and Reva were down three percent or more; IDT and Tissue Therapies shed more than two percent; with Actinogen, CSL and Living Cell down more than one percent.

RESONANCE HEALTH

Resonance says it has “promising results” from a 30-patient study of a liver fibrosis diagnostic distinguishing between low and high fibrosis scores in hepatitis C patients.

Resonance said that chief scientific officer Prof Tim St Pierre has submitted an abstract to the American Association for the Study of Liver Disease and if accepted, the abstract would be published on Oct 1, 2015 and presented at the meeting in San Francisco, California from November 13 to 17, 2015.

Resonance general manager Sander Bangma told Biotech Daily that detailed results were under embargo with the abstract submission, which the company did not want to jeopardise, while meeting its obligations as an ASX-listed company.

“It is an important development for Resonance,” Mr Bangma said.

“I can say that we believe the results are promising as they show potential clinical utility of the test,” Mr Bangma said.

According to the Australian New Zealand Clinical Trials Registry the trial was entitled ‘A pilot study to assess the utility of magnetic resonance imaging in the staging of liver fibrosis’ with the primary outcome of assessing the utility of magnetic resonance imaging (MRI) in the assessment and staging of liver fibrosis

The Registry said that secondary outcomes included the assessment of the within-patient reproducibility of MRI-derived fibrosis measurements and to explore the correlation between MRI-derived fibrosis measurements and a five other measures, as well as to explore the sensitivity of MRI-derived fibrosis measurements to differentiate between fibrosis stages 3 and 4.

Resonance said that the study conducted at Melbourne’s Austin Hospital was funded by Pfizer Inc to assist development of a non-invasive MRI-based detection and measurement of liver fibrosis.

The company said that a standardized, accurate test to non-invasively measure liver fibrosis would offer clinicians vital information on their patients’ liver condition and could be used either in isolation or in conjunction with its Hepafat-Scan to measure liver fat and Ferriscan to measure liver iron.

Resonance said that the most widely used method for measuring liver fibrosis was through liver biopsy which was invasive, painful and could be inaccurate, and a non-invasive triple test of fibrosis, iron and fat would be “a significant opportunity”.

The company said that liver fibrosis was caused by a number of factors including chronic liver disease resulting from hepatitis C, non-alcoholic fatty liver disease, high alcohol intake or a compromised immune system and could lead to liver cancer.

Resonance said that there were about 2.7 million chronically infected hepatitis C patients in the US, most of whom require biopsy in the course of their treatment.

Mr Bangma said that “reaching this stage of development for a fibrosis measurement is an exciting achievement and we are currently working to obtain new data to test the technology in a variety of clinical scenarios”.

“We are also exploring other avenues to perform validation studies of the technology, including partnership with [pharmaceutical] companies developing therapies to treat this increasingly prevalent condition,” Mr Bangma said.

“We are undertaking to turn this prototype model into a clinical tool,” Mr Bangma said.

Resonance said it intended to begin validation studies as soon as possible and further research would be required to confirm the utility of the test across different disease states, such as non-alcoholic fatty liver disease.

The company said its Ferriscan non-invasive measure of liver iron overload was used globally and was widely regarded as the gold standard for liver iron measurement.

Resonance was untraded at 4.7 cents.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the development of immune cell 'spies', provides information on how the immune system could better fight disease.

The Institute said that dendritic cells were intelligence-gathering immune cells, using information on viruses, bacteria, cancer and fungi to aid the immune system in fighting disease.

The Institute said that understanding how dendritic cells developed would assist scientists in finding ways to boost the immune response to infections or dampen it in autoimmune diseases such as lupus and rheumatoid arthritis.

WEHI said Dr Shalin Naik and Jaring Schreuder collaborated with the Singapore Immunology Network's Dr Florent Ginhoux, Dr Andreas Schlitzer and colleagues to discover that each sub-type of dendritic cell had its own, unique parent cell.

The research study entitled, 'Identification of cDC1- and cDC2-committed DC progenitors reveals early lineage priming at the common DC progenitor stage in the bone marrow' was published in the journal Nature Immunology and an abstract is available at: http://www.nature.com/ni/journal/vaop/ncurrent/full/ni.3200.html.

Dr Naik said dendritic cells were the James Bond of the immune system gathering intelligence to educate the immune system and "tell the infection-fighting T-cells and [natural killer] cells what a virus, bacterium, fungus or cancer looks like so they know what they're looking for when fighting disease".

"If we learn how to control dendritic cells, we could strengthen our immune response to infection when needed, or weaken the action of certain immune cells that attack the body's own tissues in autoimmune disease," Dr Naik said.

WEHI said its researchers had made "significant contributions to understanding dendritic cell biology for more than 40 years" with previous research showing different sub-types of dendritic cells, each primed to recognize certain types of infections and uncovering the parents, or progenitors, that produce dendritic cells.

Dr Ginhoux said that previous research had examined thousands of cells at once but this study "examined individual immune cells and their daughter cells, revealing there isn't one single parent cell for all subtypes of dendritic cells, but instead a unique progenitor for each individual subtype".

"Targeting progenitor cells could make treatments more efficient," Dr Ginhoux said.

"One progenitor cell can produce multiple daughter cells," he said.

"Suppressing a progenitor from creating the sub-type of dendritic cells implicated in causing lupus, for example, could be an efficient way of treating autoimmune diseases while minimising the impact on the rest of the immune system," Dr Ginhoux said.

"Similarly, triggering extra production of particular dendritic cells could improve the immune response to infections or vaccines," Dr Ginhoux said.

"This discovery will enable scientists to find ways of tweaking our immune response with much greater accuracy and precision than ever before," Dr Ginhoux said.

"Mapping the blood cell family tree would help to understand what goes wrong when disease occurs, Dr Naik said. "Every blood and immune cell in our body descends from blood stem cells."

"We and others have been following this family tree from one daughter cell to the next to discover how each cell type is created and how the parent cell decides if it should make more of itself or create the next cell type," Dr Naik said.

"By dissecting the heritage of these cells, we can find new targets to tackle a range of conditions including infectious diseases, cancers and immune disorders, and even make vaccines more effective," Dr Naik said.

AIRXPANDERS INC

Canaccord Genuity says the Airxpanders initial public offer has raised $36.5 million at 50 cents per Chess depositary interest and will list on the ASX on June 22, 2015.
Canaccord senior analyst Dr Matthijs Smith told Biotech Daily that his company had fully-underwritten the offer and the company would list on the ASX under the code AXP.
The Delaware-incorporated and Paolo Alto, California-based Airxpanders previously said that following the offer, it would have a market capitalization of about $113 million and have the equivalent of 225,176,142 CDIs on offer (BD: May 25, 2015).
The company said its Aeroform tissue expander was used in breast reconstruction procedures following mastectomy to expand and stretch the skin and underlying muscle prior to the placement of a permanent breast implant.
Airxpanders said that tissue expansion through traditional saline-based expanders was unpleasant, painful and time-consuming procedure, while its Aeroform tissue expander was needle-free and activated by a patient-controlled wireless remote control unit.
The company said Aeroform had been used in more than 350 patients, providing needle-free, faster and less painful tissue expansion with a reduced need for surgeon office visits.
Airxpanders said that Aeroform had Australian and European regulatory approval and it expected US Food and Drug Administration clearance by the end of 2015.

RHINOMED, AUSTRALIAN SECURITIES AND INVESTMENTS COMMISSION

The Australian Securities and Investments Commission (ASIC) has fined Rhinomed $33,000 for non-disclosure, which the company disputes, but says it will pay the fine.
ASIC said that “following an … investigation” Rhinomed had paid a penalty of $33,000 for allegedly failing to comply with its continuous disclosure obligations.
ASIC said that on July 9, 2014 Rhinomed told the ASX that it would partner with the Fitness First health clubs to promote its Turbine technology throughout July and described the deal as an "outstanding commercial opportunity" and "a real coup" for the company.
ASIC said that Rhinomed and Fitness First entered into the agreement on June 6, 2014 and by failing to inform the ASX of the agreement on that day, Rhinomed was in breach of its continuous disclosure obligations.
ASIC said it issued the company with an infringement notice and Rhinomed complied with the infringement notice and paid the penalty on June 9, 2015.
ASIC said its action followed a referral from the ASX and that Section 674(2) of the Corporations Act and ASX Listing Rule 3.1 detailed listed companies’ continuous disclosure obligations; the Corporations Act provided that compliance with infringement notices was not an admission of guilt or liability and Rhinomed was not, by reason of its compliance with the notice, regarded as having contravened section 674(2) of the Act.
Rhinomed said ASIC had characterised the agreement as price sensitive information warranting immediate disclosure, but it “strongly denies the alleged contravention”.
Rhinomed said that an independent expert presented a comprehensive case on behalf to ASIC outlining why this information was not price sensitive and did not warrant immediate disclosure.
Rhinomed said it “fundamentally disagrees with ASIC’s position regarding the issue of the infringement notice in the present circumstances”.
“Nevertheless, given the relatively immaterial $33,000 penalty, when compared with the likely cost and distraction of challenging the matter further, the board considers it in the best interests of the company’s shareholders simply to pay the penalty and focus its energies and efforts on continuing to develop and commercialise its technology platform”.
Rhinomed was unchanged at 3.7 cents with 4.05 million shares traded.

ALCHEMIA

Alchemia says two directors have resigned, all assets other than Fondaparinux will be sold and it will end analysis of its hyaluronic acid–irinotecan phase III cancer trial.

Alchemia said that chairman Santo Costa and director Dr Susan Kelley had resigned effective immediately, with Tim Hughes assuming the role of chairman and Dr Tracie Ramsdale and Nathan Drona continuing as directors, with "significant pay cuts" reducing total board remuneration by 59 percent.

The company said that analysis of the phase III study data did not provide a definitive explanation for the observed anomalous Russian patient results and it did not intend to continue the analysis or pursue discussions with the US Food and Drug Administration about the outcome of the phase III trial.

Last year, Alchemia fell as much as 86 percent on news that its 415-patient, phase III, randomized, double-blinded, controlled study comparing its Hyact hyaluronic acid-irinotecan, HA-irinotecan, to irinotecan as components of the standard combination of folinic acid, fluorouracil and irinotecan (Folfiri) for second or third-line metastatic colorectal cancer failed to meet its III primary endpoint (BD: Oct 10, 27, 2014).

Today the company said it was in active negotiations to sell the Hyact technology and it would not commit any further funding to Hyact beyond September 12, 2015.

Alchemia said it was also in active negotiations to divest the versatile assembly on stable templates (VAST) drug discovery platform and would not commit further funding to VAST beyond June 30, 2015 (BD: Dec 9, 2014).

The company said that it was "committed to returning excess cash reserves, expected R&D Tax [Incentive] refunds and future fondaparinux revenues to shareholders as a priority".

Alchemia said it expected to have about $5.0 million in cash at June 30, 2015 with about $3.0 million required for leases that run until July 2016, restructuring costs and the final activities related to closing the phase III trial, leaving about $2.0 million.

The company said that it expects to claim $5.3 million to $5.6 million for research and development tax credits for the year to June 30, 2015 and if accepted by Ausindustry, expected to receive the cash refund by November 30, 2015.

Alchemia said that cash burn, excluding committed amounts above, was forecast to be about $185,000 a month to September 30, 2015 quarter and about $70,000 a month for the three months to December 31, 2015

The company said it expected to have five employees either on notice or who have indicated their intention to leave upon completion of key activities and from September 30, 2015, it would have one part-time executive and one part-time contractor.

Alchemia said that revenues from Fondaparinux were "increasingly uncertain" due to a sharper than expected market decline and negotiations with partner Dr Reddy's regarding changes to methodologies used in calculating the Alchemia net profit share.

The company said its primary focus was to secure its fair share of future Fondaparinux revenues, which was critical to the company's value and share price.

Alchemia fell 0.4 cents or 10 percent to 3.6 cents with 9.5 million shares traded.

STARPHARMA

The Sydney and Hong Kong-based FIL Limited, formerly Fidelity Investments, says it has become a substantial shareholder in Starpharma with 16,106,957 shares (5.05%).

FIL said it acquired the shares between February 9 and June 5, 2015 at prices ranging from 54 cents to 80 cents.

Starpharma was up 1.5 cents or 2.05 percent to 74.5 cents.

PRESCIENT THERAPEUTICS (FORMERLY VIRAX HOLDINGS)

Prescient says the US Food and Drug Administration has reactivated its investigational new drug application for PTX-100 for a phase Ib trial for metastatic breast cancer.
Prescient said that last year it acquired PTX-100, formerly known as GGTI-2418, from Pathway Oncology (BD: May 30, Jun 23, Sep 9, 2014).
The company said it had submitted to the FDA a detailed and complete protocol for the proposed study in patients with stage IV metastatic breast cancer.
Prescient said that the study objective would be to determine the optimal dosing schedule and dose of PTX-100 in combination with chemotherapy drug docetaxel, which was approved for the treatment of patients with metastatic breast cancer.
Prescient managing-director Dr Rob Crombie said that "despite decades of research and use of chemotherapy regimens, resistance to cancer chemotherapy is a common phenomenon, resulting in rapid disease progression and treatment failure in up to 90 percent of metastatic breast cancer patients …one of the leading causes of cancer mortality, accounting for more than 400,000 deaths annually worldwide".
"The reactivation of the [FDA application] for PTX-100 is an important development for Prescient and opens the way to commence additional clinical trials at some of the world's leading cancer centres," Dr Crombie said.
"Prescient's lead drug candidate PTX-200 has already commenced phase Ib/II trials with a breast cancer trial underway at Albert Einstein University in New York and an ovarian cancer trial underway at the Moffitt Cancer Center in Florida," Dr Crombie said.
"Very few ASX companies have two open INDs with the FDA that cover two novel approaches to treating cancer," Dr Crombie said.
Prescient was up 0.4 cents or 4.9 percent to 8.6 cents with three million shares traded.

ANATARA LIFESCIENCES

Anatara says it has received its first Federal Government R&D Tax Incentive of $61,000 for the year to June 30, 2013 and is ready for its second trial of Detach for pig diarrhoea.
In February, Anatara said the first field trial of the pineapple stem-derived non-antibiotic Detach reduced piglet mortality by 47.8 percent, reduced severe morbidity and increased weight gain (BD: Feb 18, 2015).
The company has previously said it intended to develop Detach for human use.
Anatara said that the third trial site had been agreed and planning was on-track.
The company said that the US Food and Drug Administration had granted a sponsor fee waiver, so that the company could begin its application for field studies in the US without having to pay the $US100,000 a year sponsor user fee.
Anatara said it had appointed former Intervet Schering Plough Animal Health director of pharmacovigilence Dr Kevin Woodward as its international regulatory affairs advisor.
Anatara chairman Dr Mel Bridges said that the company was formalizing an agreement with the Cooperative Research Centre for High Integrity Australian Pork.
Anatara fell 2.5 cents or 3.4 percent to 70.5 cents.

OPTISCAN

Optiscan has requested a voluntary suspension following its fundraising trading halt requested last week (BD: Jun 5, 2015).
Optiscan last traded at 5.2 cents.

IDT AUSTRALIA

IDT says Alan Fisher has been appointed as a director for his business and corporate experience and expertise in financial and operational restructuring.

IDT said that Mr Fisher was currently the managing-director of DMC Corporate, a business which specialized in restoring and enhancing shareholder value.

The company said that Mr Fisher was previously Pental's chief executive officer and was instrumental in its restructure and prior to that was a Coopers & Lybrand corporate finance partner.

IDT said that Mr Fisher held a Bachelor of Commerce from the University of Melbourne.

IDT fell half a cent or 2.1 percent to 23 cents.