Biotech Daily

Friday February 21, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 42%, BENITEC UP 26%, MEDICAL DEVELOP DOWN 9%**

*** ASCEND PREPARES FOR SKIN, BREAST CANCER IMMUNOTHERAPY TRIALS**

*** PRIMA SEALS ISRAEL-PALESTINE DEAL**

*** BENITEC PLEADS GOOD NEWS TO ASX 23% QUERY; JUMPS 56% IN US**

*** INVION PLACEMENT RAISES $5m, RIGHTS ISSUE FOR $2m MORE**

*** IMMUNEXPRESS $1m COMMERCIALISATION AUSTRALIA SEPSIS TEST GRANT**

*** NSW $15.5m FOR 26 CANCER PROJECTS**

*** 'NEUROSURGERY' ARTICLES BACK OPTISCAN MICROSCOPES**

*** ATCOR H1 REVENUE DOWN 51% TO $2.7m, PROFIT TO $1m LOSS**

*** LBT H1 REVENUE UP 426% to $2.4m, LOSS DOWN 5.5% TO $866k**

*** IDT H1 REVENUE UP 28.5% TO $6.5m, LOSS UP 125% TO $2m**

*** MEDICAL DEVELOPMENTS H1 REVENUE DOWN 2%, PROFIT DOWN 17%**

*** PERPETUAL TAKES PROFIT, DOWN TO 9% OF SIRTEX**

*** CIRCADIAN PROMOTES DR MEGAN BALDWIN TO CEO, M-D**

MARKET REPORT

The Australian stock market climbed 0.49 percent on Friday February 21, 2014 with the S&P ASX 200 up 26.4 points to 5,438.7 points. Nineteen Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and one was untraded. All Big Caps rose.

Optiscan was the best, up 2.5 cents or 41.7 percent to 8.5 cents with 590,047 shares traded, while Benitec closed up 26.2 percent at $1.59 with 2.6 million shares traded. Oncosil climbed eight percent; Antisense was up 7.1 percent; Alchemia and Prima were up more than six percent; QRX and Tissue Therapies were up more than five percent; Admedus and Cellmid were up more than three percent; Acrux and Patrys rose more than two percent; with Bionomics, Cochlear, Living Cell, Nanosonics, Psivida and Resmed up one more than one percent.

Medical Developments led the falls, down 11.5 cents or 9.4 percent to $1.105, with 96,886 shares traded. Prana fell eight percent; IDT and Viralytics lost more than seven percent; Osprey and Uscom were down more than five percent; Impedimed fell 4.35 percent; Atcor, GI Dynamics, Genetic Technologies and Universal Biosensors were down three percent or more; Avita shed 1.9 percent; with Clinuvel down 0.6 percent.

ASCEND BIOPHARMACEUTICALS

Ascend says it has developed two mucin-1 targetting immunotherapy drugs, initially for breast cancer and basal cell carcinoma, but with potential for a broad range of cancers.

Speaking at an investor and media briefing at the office of Melbourne lawyers K&L Gates, Seattle, Washington-based director and former Amgen and Immunex executive Dr Richard Stead said that immune therapies had been developed over more that 20 years, with significant work conducted in Melbourne at the Austin Hospital by Prof Ian McKenzie and by the Walter and Eliza Hall Institute's Prof Don Metcalf.

Dr Stead said that immunotherapies worked through amplification of immune responses and had a "memory" to allow them to continue stimulating the response and that by targeting mucin-1, immunotherapies could generate responses with no recurrence.

He said that while Ascend's ASN-002 for basal cell carcinoma and ASN-004 for breast cancer shared "a common pedigree [with Prima's CVac] the technology is fundamentally different".

"Our product [ASN-004] is in a vile and directly injected sub-cutaneously," Dr Stead said.

Dr Stead said that the Ascend products did not require cancer tissue samples or blood to be taken from the patient like some other immunotherapies, but was an off-the-shelf product.

"ASN-002 makes interferon in the cancer and one injection lasts for two weeks," Dr Stead said. "ASN-004 is targeting mucin-1, fused to oxidized mannan to target mucin-1 cancers."

Dr Stead said that initially the company would target difficult late stage breast cancers, but 90 percent of all breast cancers carried the mucin-1 glyco-protein.

In a media release last week Ascend said that 15-year follow-up data of a 1998 trial of the breast cancer vaccine OM-MUC-1, a prototype of its ASN-004, showed evidence of efficacy and substantially reduced rates of breast cancer recurrence.

The company said that OM-MUC-1 was developed at Melbourne's Austin Research Institute and licenced to Ascend in 2006.

Ascend chief executive officer Dr Clement Leong said the results of the 15-year follow up study were among the most favorable reported for cancer vaccines in preventing cancer recurrence.

"The results have been compelling to this point," Dr Leong said.

"This study showed OM-MUC-1 was found to reduce a patient's cancer returning from 60 percent to 12.5 percent chance, which clearly are much better odds for any patient," Dr Leong said.

The study found that of 16 patients treated with OM-MUC-1, only two have experienced a recurrence of stage II breast cancer (12.5%), while among those who received the placebo, nine of 15 experienced a recurrence (60%), consistent with the historical recurrence rate with stage II breast cancer.

Ascend said that the time of recurrence in the placebo group ranged from seven to 180 months (mean: 65.8 months) while in the two patients of the vaccine group, the recurrence appeared at 95 and 141 months (mean: 118 months) after surgery.

The study, entitled 'Up to 15-year clinical follow-up of a pilot phase III immunotherapy study in stage II breast cancer patients using oxidized mannan-MUC1' was published in Future Medicine. An abstract is at: http://www.ncbi.nlm.nih.gov/pubmed/24188672.

The company said that OM-MUC-1 had been studied in 100 patients in a number of clinical trials demonstrating that targeting the mannose receptor on macrophages and dendritic cells led to both a strong cellular and antibody immune response.

Ascend said it hoped to begin a phase Ib trial of ASN-004 for breast cancer in 2015, with a phase II trial of ASN-002 for basal cell carcinoma to begin by the end of 2014.

Ascend is a public unlisted company.

PRIMA BIOMED

Prima says it has finalized its agreement with Neopharm Group to market and sell CVac for epithelial ovarian cancer in Israel and the Palestinian Authority (BD: Nov 7, 2013).
Prima said that CVac was intended to stimulate the immune system to target and destroy tumors with the treatment custom manufactured for each patient.
The company said that CVac consisted of each patient's own dendritic cells, a type of white blood cell, treated with mucin-1 fused to mannan, which was a carrier facilitating the uptake of mucin-1 into the dendritic cells.
Prima's said the manufacturing process was intended to provide for a one year course of CVac from one blood collection from the patient.
The company said Neopharm would reimburse Prima for CVac manufacturing costs of and the two companies would split net profits from sales.
Prima said it would also receive small up-front and development milestone payments.
Prima chief executive officer Matthew Lehman said the Neopharm licence was the company's first corporate partnership for CVac
Neopharm executive chairman David Fuhrer said his company was "obligated to provide innovative superior solutions to improve health and quality of life [and] we are constantly seeking to extend our portfolio in breakthrough technologies, in particular in the oncology field".
"We see CVac as an excellent addition to our group's growing portfolio," Mr Fuhrer said.
Prima said that CVac was in phase II trials for epithelial ovarian cancer patients in remission and a pilot trial to evaluate CVac for resected pancreatic cancer was expected to begin soon.
Prima was up 0.3 cents or 6.5 percent to 4.9 cents with 4.1 million shares traded.

BENITEC BIOPHARMA

Benitec has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price climbed from 99 cents on February 19 to $1.26, a 27.3 percent increase, on February 20, 2014 and noted an increase in trading volumes.
Benitec said that on February 18 it provided an update on its phase I/II trial of its DNA-directed RNA-interference (ddRNAi) drug TT-034 for hepatitis C with the first patient expected to be dosed in March 2014 (BD: Feb 18, 2014).
The company said that "another potential explanation relates to increased interest in the sector".
"The company has observed announcements made and stock movements in the past 48 hours by other companies operating in the broader field of RNAi therapeutics," Benitec said.
"These activities suggest increased investor interest in companies active in the field of RNAi therapeutics," the company said.
Last year, Benitec raised $10.7 million at 1.1 cents a share, followed by a 25-to-one consolidation valuing those shares at 27.5 cents each (BD: Jun 6, Jul 19, 31, 2013).
On the Nasdaq last night, Benitec over-the-counter shares jumped as much as 52 US cents or 55.9 percent to $US1.45 ($A1.61) before closing up 39 US cents or 41.94 percent at $US1.32 with 878,031 shares traded.
Today on the ASX, Benitec climbed as much as 49.5 cents or 39.3 percent to $1.755 before closing up 33 cents or 26.2 percent at $1.59 with 2.6 million shares traded.

INVION

Invion says it has raised $5.0 million in a private placement at 7.5 cents a share to institutional and sophisticated investors.

Invion said it expected to offer a 20-for-one non-renounceable rights issue to raise a further $2 million, providing existing shareholders with the opportunity to participate in the capital raising on the same terms as the placement.

The company said the placement was at a 20 percent discount to the five-day volume weighted average price to February 18, 2014.

Invion managing-director Dr Greg Collier said the placement was heavily oversubscribed and applications needed to be scaled back.

Dr Collier said the funds meant Invion was “well positioned to achieve milestones in both clinical development and partnering in the coming year that should drive significant value creation”.

Invion said that the funds would be “applied to the collaboration with 3M Drug Delivery Systems to develop Invion’s inhaled respiratory drugs franchise and continuing development of Invion’s three drug assets” INV102 or nadolol, INV103 or chaperonin-10 and INV104 or zafirulkast.

Invion said that Patersons Securities and Morgans Corporate were joint lead managers to the capital raise.

Invion fell half a cent or 5.3 percent to 8.9 cents.

IMMUNEXPRESS GROUP

Immunexpress says it has received a $982,707 Commercialisation Australia grant to bring its whole blood Septicyte Plus qRT-PCR sepsis diagnostic assay to market.

Immunexpress said that the Septicyte Plus test was designed to diagnose sepsis accurately within a clinically relevant timeframe.

The company said that the grant funding, along with existing cash resources, would be used to develop the Septicyte Plus prototype through to a laboratory developed test and make it available to hospital laboratories at two large health systems in the US along with an academic hospital in Germany.

Immunexpress said that the prospective data collected through these centers was expected to inform the regulatory pathway and future medical device application for Septicyte Plus in the US.

The company said that new technologies that allowed for the earlier detection and personalized management of people with, or at risk of, sepsis could significantly reduce the financial burden on health care systems through reduced patient mortality and morbidity, reduced stays in hospital and intensive care units, more targeted use of antibiotics and anti-inflammatories and reduced antimicrobial resistance.

Immunexpress chief executive officer Dr Roslyn Brandon said that the Commercialisation Australia grant was “an important step forward in the development of Septicyte Plus and our efforts to bring novel sepsis assays to health care centers and patients around the world”.

“Based on the results to date, Septicyte Plus has the potential to make an important impact on the health care community and improve patient outcomes by allowing for earlier diagnosis and targeted antimicrobial treatment within a clinically relevant time frame of under three hours,” Dr Brandon said.

Immunexpress is a private company, founded in Brisbane as Athlomics and based in Seattle, Washington.

NEW SOUTH WALES GOVERNMENT

New South Wales Minister for Health and Medical Research Jillian Skinner says her Government will provide $15.5 million to 26 cancer researchers.

Ms Skinner said the Cancer Institute New South Wales Fellowship Grant Program was one of the largest in the state's history and would support the 26 researchers to continue their work over the next three to five years.

"As the nation's first Minister for Medical Research, I am absolutely committed to supporting research in the laboratory and, importantly, as it translates into new therapies and treatments," Ms Skinner said.

"These fellowships, funded by the [New South Wales] SW Government through the Cancer Institute NSW are absolutely vital to ensuring we attract and retain the best and brightest cancer researchers," Ms Skinner said.

"Cancer is not one disease but over 100 different diseases," Ms Skinner said.

"One in two men and one in three women will be diagnosed with one form of cancer or another in their lifetime," Ms Skinner said. "Those of us who do not experience it ourselves will have loved ones, friends or colleagues who do."

"These 26 recipients will have the opportunity to make discoveries once thought impossible," Ms Skinner said. "I wish them well in the important work that lies ahead."

A State Government media release said that The Cancer Institute NSW was one of the six pillar agencies of NSW Health and distributed the annual fellowship grants.

Cancer Institute NSW chief executive and State chief cancer officer Prof David Currow said that strong cancer research added value to every health system.

"Giving cancer researchers the opportunity to investigate emerging therapies in an environment that is truly independent is crucial," Prof Currow said.

"The work of these 26 researchers spans the full spectrum of cancer research," Prof Currow said.

"They will be looking at how to better treat melanoma with novel therapies, investigate new therapies for leukemia and pancreatic cancer, as well as investigate brain cancer recurrence," Prof Currow said.

"They will be investigating methods to detect ovarian cancer, identify predictive biomarkers for lung cancer patients to enable more effective treatments and exploring Vitamin D's role in breast cancer progression," Prof Currow said.

"As our population ages, the incidence of cancer in our community increases," Prof Currow said.

"It has never been more important to support our cancer researchers who are working at the cutting edge of science to end cancers as we know them," Prof Currow said.

The media release said that the successful grant recipients would be awarded fellowships in one of three categories: early career fellowship; career development fellowship; or future research leader fellowship.

The media release said that the recipients were from New South Wales' leading universities and research institutions, including the Centenary Institute, the Garvan Institute of Medical Research, the University of New South Wales, Macquarie University, University of Newcastle, ANZAC Research Institute, University of Sydney and University of Western Sydney.

The State Government said that its investment in health and medical research was more than $200 million a year.

The full list of Cancer Institute NSW Fellowship Grant Program recipients is available at: http://www.cancerinstitute.org.au/news/i/bright-minds-unlocking-cancers-secrets.

OPTISCAN

Optiscan says its confocal microscope was key to three articles on fluorescence imaging for improving brain tumor resection surgery in the US journal Neurosurgery.
Optiscan said the Neurosurgery supplement papers released data from the use of its endomicroscopy technology in both human and animal studies entitled:
'Laser scanning confocal endomicroscopy in the neurosurgical operating room: a review and discussion of future applications';
'Potential application of a handheld confocal endomicroscope imaging system using a variety of fluorophores in experimental gliomas and normal brain'; and
'In vivo visualization of GL261-luc2 mouse glioma cells by use of Alexa Fluor– labeled TRP-2 antibodies'.
Abstracts for all three articles are available at: http://thejns.org/toc/foc/36/2.
Optiscan said the first paper reported that "the application of confocal imaging into a handheld endomicroscope with in vivo utility has spurred the exploration of this technology in the management of brain tumors intraoperatively [and] when combined with intravenous and topical fluorophores, real-time information about brain neoplasms at the cellular level can be gathered in the operating room".
The company said the second paper reported that "handheld confocal microscopy can distinguish between normal brain and neoplastic tissue intraoperatively, which is important for instrument capability if fully implemented to help ensure completeness of glioma resection".
Optiscan said that in these two papers, the authors reviewed extensive data collected using Optiscan's devices from both humans and animals and reviewed the five previous human clinical reports of neurosurgical endomicroscopy as well as animal studies.
The company said that the third paper was a longer view using its Five-1 research instrument to explore the potential of imaging novel molecular markers that would enable specific identification of tumor cells when combined with microscopic imaging.
Optiscan said there was "a solid range of published works that establish the utility of these devices … in the fields of neurosurgery and neuroscience".
Optiscan was up 2.5 cents or 41.7 percent to 8.5 cents.

ATCOR MEDICAL

Atcor says its revenue for the six months to December 31, 2013 fell 51 percent to $2,680,356 taking the previous $2,268,297 net profit after tax to a loss of $958,858.
Atcor sales fell 51 percent from $5,429,353 in the six months to December 31, 2012 to $2,674,161 for the six months to December 31, 2013.
Atcor said that US sales were down 64 percent due to delays in pharmaceutical contracts, while the clinical practice market increased 77 percent.
The company said that one-off sales to researchers in the previous period was not repeated in the six months to December 31, 2013.
Atcor said that Asia-Pacific sales were up 13 percent and European sales were "marginally down"
Atcor said that its net tangible asset backing per share was up 3.4 percent from 2.9 cents at December 31, 2012 to 3.0 cents at December 31, 2013.
The company said that said that diluted loss per share was 0.63 cents compared to the previous corresponding period's diluted earnings per share of 1.51 cents.
The company said it held cash and cash equivalents of $4,102,453 at December 31, 2013 compared to $2,874,209 at June 30, 2013.
Atcor fell half a cent or 3.6 percent to 13.5 cents.

LBT INNOVATIONS

LBT says that revenue for the six months to December 31, 2013, was up 425.9 percent to $2,370,352 reducing net loss after tax 5.5 percent to $865,960.
LBT said that the increase “was largely attributable to two milestone payments from Clever Culture Systems according to the joint venture agreement between LBT innovations and Hettich AG Switzerland” and royalty revenue was in line with minimum royalty arrangements in place with Biomérieux (BD: Feb 13, 2102; Jun 25, 2013).
LBT said that diluted loss per share decreased 5.4 percent from 0.92 cents in the previous year to 0.87 cents for the six months to December 31, 2013.
The company said it had cash and cash equivalents of $2,080,040 at December 31, 2013, compared to $876,000 at June 30, 2013.
LBT said that net tangible assets per share was up 351.2 percent to 1.85 cents at December 31, 2013 compared to 0.41 cents at December 31, 2012.
LBT was untraded at 8.6 cents.

IDT AUSTRALIA

IDT says that revenue for the six months to December 31, 2013, was up 28.5 percent to $6,539,000 with net loss after tax up 125.0 percent to $2,176,000.
IDT said that the increased revenue “was largely a result of a strong first half from [its] clinical trial business at CMax”.
The company said that it was pursuing “a changed business model with investment in both the in-house development and acquisition of an IDT-owned generic drug portfolio”.
IDT said that diluted loss per share increased 40.9 percent from 2.2 cents in the previous year to 3.1 cents for the six months to December 31, 2013.
The company said it had cash and cash equivalents of $4,039,000 at December 31, 2013, compared to $578,000 at June 30, 2013.
IDT said that net tangible assets per share fell 34.5 percent to 36 cents at December 31, 2013 compared to 0.41 cents at December 31, 2012.
IDT fell three cents or 7.9 percent to 35 cents.

MEDICAL DEVELOPMENTS

Medical Developments says its revenue for the six months to December 31, 2012 fell 30.0 percent to $4,538,000 taking net profit after tax down 70.5 percent to $426,000.
Medical Developments said that the six months to December 31, 2013 “were challenging in that our respiratory division suffered three independent negative impacts”.
“These were Glaxosmithkline cancelling its contract to buy Space Chambers, the deferral of a very significant order to our New Zealand partner and the merger of two of our important trading partners, EBOS and Symbion, in Australia,” the company said.
“As a result, we took immediate action to reduce costs and develop alternative channels to market [and] we expect the second half year to show a significant improvement,” Medical Developments said.
The company said it paid a fully-franked two cent per share dividend for the year to June 30, 2013 on October 11, 2013.
Medical Developments said diluted earnings per share fell 73.1 percent from 2.6 cents in the previous corresponding period to 0.7 cents for the six months to December 31, 2013.
The company said it held cash and cash equivalents of $1,088,000 at December 31, 2013 compared to $2,129,000 at December 31, 2012.
Medical Developments fell 11.5 cents or 9.4 percent to $1.105.

SIRTEX MEDICAL

Perpetual and its subsidiaries have reduced their substantial shareholding in Sirtex from 5,631,175 shares (10.04%) to 5,049,609 shares (9.00%).
Perpetual said it sold the 581,566 shares on February 18 and 19, 2014 at prices ranging from $15.04 to $15.13 (BD: Feb 18, 19, 2014).
Sirtex was up two cents or 0.1 percent to $14.81 with 187,394 shares traded.

CIRCADIAN TECHNOLOGIES

Circadian says that Dr Megan Baldwin has been appointed as chief executive officer and managing-director, effective from February 24, 2014.
Circadian said that Dr Baldwin joined the company in 2008 and was previously the head of preclinical research and development and chief executive officer of the Opthea subsidiary
The company said that Dr Baldwin had more than 18 years experience in angiogenesis and therapeutic strategies for cancer and ophthalmic indications.
Circadian said that as Opthea chief executive officer Dr Baldwin led the capital management, investor engagement and advancement of Opthea's program for eye disease.
The company said that Dr Baldwin previously held research and commercial roles at Roche (formerly Genentech) in San Francisco.
Circadian said that Dr Baldwin held a Bachelor of Science from the University of Melbourne and Doctorate of Philosophy in medicine from the Ludwig Institute for Cancer Research, affiliated with the University of Melbourne.
Circadian said that chairman Dominique Fisher would resume her role as non-executive chairman.
Circadian was unchanged at 21 cents.