Biotech Daily

Wednesday March 4, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEUREN UP 10%, PATRYS DOWN 17%, ACRUX 12%**

*** FEDERAL R&D TAX CREDIT STANDS AT 45%, $100m CAP; COMMENT**

*** ACRUX: 'FDA TIGHTENS TESTOSTERONE LABELLING'**

*** BIOTA BEGINS 150-PATIENT VAPENDAVIR ASTHMA HRV (COLD) TRIAL**

*** NSW GRANTS $14.2m FOR CANCER RESEARCH**

*** NOVOGEN: 'TRXE-009 CAN KILL BRAIN CANCER CELLS'**

*** NARHEX READY FOR RESPIRATORY 'PHONE DIAGNOSTIC TRIAL**

*** RHINOMED APPOINTS CHRISTIAN JOHNSON FOR US SALES**

*** BIO-MELBOURNE LAUNCHES WOMEN IN LEADERSHIP AWARDS**

MARKET REPORT

The Australian stock market fell 0.54 percent on Wednesday March 4, 2015 with the S&P ASX 200 down 32.3 points to 5,901.6 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and one was untraded.

Neuren was the best, recovering one cent or 10.0 percent to 11 cents with 23.5 million shares traded.

Prana climbed 7.1 percent; Circadian and Clinuvel were up more than six percent; Pharmaxis was up 4.4 percent; IDT, Sirtex and Universal Biosensors were up more than three percent; Anteo rose 2.2 percent; Alchemia, GI Dynamics, Living Cell, Medical Developments and Optiscan were up one percent or more; with Cochlear, CSL, Impedimed and Mesoblast up by less than one percent.

Patrys led the falls, down 0.2 cents or 16.7 percent to one cent with 70 shares traded, followed by Acrux, down 11.8 percent to 90 cents with 3.7 million shares traded.

Genetic Technologies lost 8.5 percent; Admedus, Analytica, Benitec, Phosphagenics, Tissue Therapies and Viralytics fell more than four percent; Antisense, Biotron and Osprey were down three percent or more; Avita, Bionomics, Oncosil, Prima and Uscom shed two percent or more; with Psivida and Resmed down by less than one percent.

FEDERAL GOVERNMENT

The 45 percent Research and Development Tax Incentive will not be reduced by 1.5 percent as foreshadowed in the 2014 Federal Budget (BD: May 14, 2014).

A spokesman for Treasurer Joe Hockey told Biotech Daily that the measure would not proceed.

Biotech Daily was told earlier by an Officer of the Federal Parliament that the Senate removed the amendment from the "Tax and Superannuation Laws Amendment (2014 Measures No. 5) Bill 2014" and the House of Representatives agreed to its removal.

A spokesman for the Treasurer told Biotech Daily: "The 1.5 percent reduction was removed to ensure quick passage of the other measures in that Bill".

"The Government remains committed to the 2014 Budget measure," the Treasurer's spokesman said.

In August 2011, The Tax Laws Amendment (Research and Development) Act 2010 and the companion Act, relating to Australian Taxation Office payment provisions, the Income Tax Rates Amendment (Research and Development) Act 2010 were passed by the House of Representatives and Senate following protracted opposition from the then Coalition Opposition (BD: Aug 11, Nov 25, 2010; Jun 15, Aug 26, 2011).

The tax credit provides a 45 percent refundable tax credit for companies with revenue less than $20 million a year and a 40 percent non-refundable tax credit to all other companies.

Grant Thornton Australia

Accounting and advisory firm Grant Thornton Australia welcomed the news and said that "mid-size businesses, especially those in the technology, life sciences and manufacturing sectors, today welcome the news from the Senate that will see the rate for research and development incentives unchanged, allowing these businesses to continue to receive tax incentives to innovate and remain competitive".

Grant Thornton Head of Research & Development Tax Sukvinder Heyer said that it was "positive news for many mid-size businesses for whom the reduction in the rate would have meant an actual cash decrease".

"With the resolution of this proposal and the passing of the $100 million cap on expenditure, from a legislative perspective there are no other matters relating to R&D outstanding," Ms Heyer said. "What remains to be seen is the impact of the introduction of the cap on expenditure."

"This measure has the potential to push R&D offshore because the margin provided by the R&D tax offset to large companies is diminished," Ms Heyer said.

Ausbiotech

Ausbiotech chief executive officer Dr Anna Lavelle said that "the abandonment of plans to cut the R&D Tax Incentive by a further 1.5 percent in line with a corporate tax rate cut, which has not eventuated, is welcomed as the right thing to do".

"The unrelenting threat to the R&D Tax Incentive and efforts to trim and cap it is unsettling for an industry that takes many years to develop each treatment, diagnostic, cure and medical device," Dr Lavelle said. "Transitional arrangements are also needed to assist companies that were blindsided by the sudden, recent amendment to place a $100 million cap on claims and apply it retrospectively."

"Companies have made commitments based on the program's provisions and allowed for the 2013 Bill's original intent before the amendment sent plans awry," Dr Lavelle said.

"The backdating of this latest amendment will cause havoc with planning, create even greater uncertainty and discourage the industry from investing, which needs to be counter balanced," Dr Lavelle said.

ACRUX

Acrux reports that the US Food and Drug Administration will require tighter labeling of testosterone products precluding age related low testosterone.

Acrux chief executive officer Michael Kotsanis told a teleconference that the FDA would be requiring two tests prior to prescription of testosterone replacement therapy and the sponsors would be required to run large population long term safety studies.

Mr Kotsanis said that US partner Eli Lilly would be responsible for any further trials.

Mr Kotsanis said it was not possible to determine how it would affect market share and sales as the company did not have data on how many prescriptions were for the indication allowed by the FDA compared to age-related low testosterone.

Mr Kotsanis said that the FDA had factored findings from other studies published after the September 2014 joint meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

He said that studies by the European Medicines Agency and one published in the Mayo Clinic Proceedings were positive for testosterone for cardiovascular risk.

In a media release Acrux said that the FDA statement was entitled 'FDA Cautions About Using Testosterone Products for Low Testosterone Due to Aging; Requires Labeling Change to Inform of Possible Increased Risk of Heart Attack And Stroke'.

The FDA said that testosterone was approved as replacement therapy "only for men who have low testosterone levels due to disorders of the testicles, pituitary gland, or brain that cause a condition called hypogonadism".

"Examples of these disorders include failure of the testicles to produce testosterone because of genetic problems, or damage from chemotherapy or infection," the FDA said.

"However, FDA has become aware that testosterone is being used extensively in attempts to relieve symptoms in men who have low testosterone for no apparent reason other than aging," the Agency said.

"The benefits and safety of this use have not been established," the FDA said.

The FDA said that "based on the available evidence from published studies and expert input from an advisory committee meeting, FDA has concluded that there is a possible increased cardiovascular risk associated with testosterone use".

"Some studies reported an increased risk of heart attack, stroke, or death associated with testosterone treatment, while others did not," the FDA said.

"Based on our findings, we are requiring labelling changes for all prescription testosterone products to reflect the possible increased risk of heart attacks and strokes associated with testosterone use," the FDA said.

"We are also requiring manufacturers of approved testosterone products to conduct a well-designed clinical trial to more clearly address the question of whether an increased risk of heart attack or stroke exists among users of these products," the FDA said.

"We are encouraging these manufacturers to work together on a clinical trial, but they are allowed to work separately if they so choose," the FDA said.

The FDA said it reviewed five observational studies and two meta-analyses of placebo-controlled trials to examine the risk of cardiovascular events associated with testosterone replacement therapy and the five retrospective cohort studies reported conflicting results.

The Agency said that two studies found statistically significant cardiovascular harm, two studies found a statistically significant mortality benefit and one was inconclusive.

"The advisory committee members were in general agreement that the signal of cardiovascular risk is weak and that only a prospective, well-controlled clinical trial could determine whether testosterone causes cardiovascular harm," the FDA said.

Acrux said that Eli Lilly was liaising with the FDA and had several trials underway.

Acrux fell 12 cents or 11.8 percent to 90 cents with 3.7 million shares traded.

BIOTA PHARMACEUTICALS

Biota said it has begun dosing of about 150 asthmatic patients with laboratory-confirmed human rhinovirus in its phase IIb Spiritus trial of vapendavir.

Biota said the study would enroll patients with moderate-to-severe asthma from the US and Europe over the next 12 months and report top-line data in mid-2016.

Principal investigator stated Dr Jonathan Matz said that there were no anti-virals currently approved for the treatment of human rhinovirus infection, which was a major cause of disease exacerbation among patients with asthma and chronic obstructive pulmonary disease.

The company has previously said that the human rhinovirus infection was the cause of most incidents of the common cold.

“The initiation of this important trial of vapendavir in moderate-to-severe asthmatics is truly exciting and based on the positive outcome from the phase II study in mild asthmatics, I am looking forward to the data from this trial next year,” Dr Matz said.

Biota head of clinical development Anna Novotney-Barry said that the beginning of dosing was “a significant achievement in our ongoing effort to further define the efficacy and safety profile of vapendavir in patient populations with respiratory disease, whose disease control is at risk due to viral respiratory infection”.

Biota said that the primary endpoint of the multi-center, randomized, double-blind, placebo-controlled dose-ranging study was the change from baseline to study day-14 measured by an asthma control questionnaire score.

The company said that the secondary endpoints were safety and tolerability, with lung function assessments such as forced expiratory volume in one second (FEV1), incidence of asthma exacerbations, assessments of the severity and duration of cold symptoms and virological assessments such as changes in viral load.

Last night on the Nasdaq, Biota closed down two US cents or 0.78 percent to $US2.55 ($A3.26 - equivalent to 40.75 cents prior to the Nabi merger, when it was trading around $A1.00), with 52,023 shares traded.

NEW SOUTH WALES GOVERNMENT

The New South Wales Government says that four teams of researchers will share $14.2 million in grants to target new cancer treatments.

The Minister for Health and Medical Research Jillian Skinner said that the Cancer Institute NSW grants would support the teams investigating individualized treatments for ovarian cancer, new therapeutic approaches to childhood cancers, better management of cancer-related anxiety and depression and the prevention and treatment of chemotherapy-induced nerve damage.

“The grants I announce today will support translational work which allows great ideas to move from the laboratory bench top to the patient’s bedside,” Ms Skinner said.

A media release from Ms Skinner’s office said that the University of Sydney’s Prof Phyllis Butow would receive $3.64 million for “a sustainable and supported clinical pathway for managing anxiety and depression in cancer patients, developing and evaluating components and testing implementation strategies” ; the University of New South Wales’ Prof David Goldstein would receive $3.04 million to study chemotherapy-induced peripheral neuropathy, assessment strategies, treatments and risk factors; the University of Sydney’s Prof Anna DeFazio would receive $3.75 million for individualized ovarian cancer treatment through integration of genomic pathology in to multidisciplinary care; and the University of New South Wales’ Prof Glenn Marshall would receive $3.75 million for experimental therapeutics for the Myc regulator gene-driven childhood cancer.

NOVOGEN

Novogen says that US studies have confirmed that TRXE-009 shows the potential to kill a library of patient-derived cell cultures from subjects with glioblastoma multiform.
Novogen said that the cells were cultured to promote cancer stem cells believed to be responsible for chemotherapy resistance and tumor recurrence.
The company said that killing the resistant glioblastoma multiform cancer stem cells was considered to be a fundamental requirement to successfully treating the disease.
Novogen said that all patient-derived cancer cells in the library responded to TRXE-009 at clinically relevant doses, suggesting a strong therapeutic potential.
The company said that the studies were conducted at the New York-based Feinstein Institute for Medical Research by Dr John Boockvar and Dr Marc Symons and the findings joined recently announced pre-clinical studies showing that TRXE-009 was highly cytotoxic of chemo-resistant pediatric brain cancers such as diffuse intrinsic pontine glioma, as well as other pediatric neural and neural crest-derived tumors.
Novogen said that the next step was to confirm the ability of TRXE-009 to cross the blood-brain barrier and as the formulated drug candidate Trilexium would begin a phase I study in early-2016.
The company said that with the Feinstein Institute, alternative means of delivering TRXE-009 to the brain were under investigation including direct injection into the brain cancer and the use of lipid brain-targeting particles injected intravenously.
Novogen chief executive officer Dr Graham Kelly said that TRXE-009 started with the discovery of a compound that was highly cytotoxic against glioblastoma multiform (GBM) brain cells that came from patients who had failed to respond to temozolomide, the only standard of care chemotherapy for glioblastoma multiform.
“It then showed itself to be an equally effective killer of GBM cancer stem cells,” Dr Kelly said.
“It also is highly active in vitro against a range of pediatric brain cancer cells that are notoriously resistant o chemotherapy [and] ... has been designed to cross the blood-brain barrier,” Dr Kelly said.
“It shows little toxicity against normal human brain cells, astrocytes, in vitro [and] in its parenteral delivery form, the Trilexium drug-product is highly active in animal models of xenografted human tumors, including GBM, and is reasonably well tolerated,” Dr Kelly said.
Novogen was up five cents or 38.5 percent to 18 cents with 56.2 million shares traded.

NARHEX LIFE SCIENCES

Narhex says it has ethics approval to begin a 150-patient trial of its Resapp mobile telephone respiratory illness diagnostic licenced from the University of Queensland.
Narhex said that a trial was expected to begin within two weeks, with preliminary results expected within three months.
The company said the patients would have a variety of respiratory conditions and the aim of the trial was to optimize the Resapp algorithms for pneumonia and asthma as well as broaden the validation to other common respiratory conditions such as bronchitis, bronchiolitis and upper respiratory tract conditions.
Narhex said it was in discussions with a second hospital to increase the speed in which patient data could be acquired.
The company said that Resapp was in negotiations to fund a collaborative trial in developing countries.
Narhex climbed 0.1 cents or 14.3 percent to 0.8 cents with 5.7 million shares traded.

RHINOMED

Rhinomed says it has appointed Christian Johnson as its North America vice-president.
Rhinomed said that Mr Johnson was a sports industry executive and previously the head of sales for the Berkeley, California-based sports nutrition company GU Energy Labs.
Rhinomed chief executive officer Michael Johnson (no relation) said that Christian Johnson had “a track record of growing sales, establishing markets for new products and driving distribution into new territories”.
“His knowledge of the North American market will provide us with the traction to build our foothold in the American market,” Michael Johnson said.
Rhinomed said that the distribution agreements signed for Australia, Israel, the Asia Pacific; Central and South America and Europe had minimum orders worth $500,000 in the first year and $1.5 million in the second year.
Rhinomed was up 0.1 cents or 5.3 percent to two cents with 2.3 million shares traded.

THE BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will launch the Women in Leadership awards, to honor outstanding women in the biotechnology and healthcare technology sector.
The Network said the awards were designed to celebrate women who demonstrated leadership in their fields of expertise and had made outstanding contributions to advancing the industry.
The Bio-Melbourne Network said it was looking to profile remarkable women who serve as role models and mentors and who have given-back to the industry.
The Network said it would present two awards that recognized established and emerging leaders who take strategic risks, tenaciously pursue goals and were a driving force in the progress of industry here in Victoria.
The Network said that applications would close on March 31, 2015, with the awards to be presented at the Connecting Women in Biotechnology Lunch on May 22, 2015.
For more information go to: http://www.biomelbourne.org/news_items/view/709.