Biotech Daily

Wednesday October 9, 2013

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: MEDICAL DEV UP 9%, NEUREN DOWN 11.5%**

*** BURNET'S HEPSEEVAX RAISING $1.5m FOR DELTA 3 FOR HEP C**

*** UNIVERSITY OF QUEENSLAND, LEO COLLABORATE ON SKIN CANCER**

*** COGSTATE, MERCK: 'COGNIGRAM MEASURES COGNITIVE DECLINE'**

*** KAISER PERMANENTE EXPANDS IMPEDIMED L-DEX U400 ROLL-OUT**

*** QRX CLOSER TO RESUBMITTING MOXDUO APPLICATION TO FDA**

*** NOVOGEN ACQUIRES GENSCREEN'S ANTI-TROPOMYOSINS FOR CANCER**

*** UNIVERSAL BIOSENSORS J&J VERIO BACK, SIEMENS TEST DELAYED**

*** BIODIEM AGM VOTES TO DELIST FROM ASX**

*** NEUREN PLEADS SCHULTZ, GOOD NEWS TO ASX 39% QUERY**

*** ALCHEMIA AGM FOR 3m DIRECTOR, CEO, EX-CEO OPTIONS**

*** AUSTRALIAN LEADERS REDUCED, DILUTED TO 9% OF ATCOR**

MARKET REPORT

The Australian stock market edged up 0.07 percent on Wednesday October 9, 2013 with the S&P ASX 200 up 3.6 points to 5,153.0 points. Nine of the Biotech Daily Top 40 stocks were up, 16 fell, 11 traded unchanged and four were untraded.

Medical Developments was the best, up 12 cents or 9.2 percent to $1.42, with 41,000 shares traded. Benitec and Pharmaxis climbed more than four percent; Allied, Patrys and Phosphagenics were up more than three percent; Clinuvel and Universal Biosensors rose more than one percent; with Cochlear and Psivida up more than one percent.

Neuren led the falls, down 1.5 cents or 11.5 percent to 11.5 cents with 7.9 million shares traded. Antisense lost 7.7 percent; Prana was down 6.7 percent; Atcor fell 5.7 percent; Genetic Technologies and QRX fell more than four percent; Tissue Therapies was down 3.3 percent; Alchemia and Nanosonics shed more than two percent; Ellex, IDT, Mesoblast, Reva and Sirtex fell more than one percent; with Acrux, CSL, Resmed and Starpharma down by less than one percent.

THE BURNET INSTITUTE

The Burnet Institute says wholly-owned subsidiary Hepseevax Pty Ltd hopes to raise $1.5 million for a phase I trial of Delta3, a vaccine to prevent hepatitis C virus infection.
The Institute said the funds would be used to finalize the preclinical program to begin phase I trials within two years and phase II trials within four years.
The Burnet Institute said that with 200 million hepatitis C carriers worldwide the disease was the leading cause for liver transplantation in the US, Japan and other countries.
The Institute said that drug therapies were effective, but expensive and could not prevent re-infection, so there was an unmet medical need and market opportunity for a vaccine.
The Burnet Institute said that previous vaccine candidates failed to generate a protective immune response against more than one of the seven genotypes of hepatitis C, but Hepseevax used viral entry and glycoprotein biology to overcome the genotype challenge.
The Institute said that Delta3 was a recombinant protein, with no infectious material involved and had been engineered to remove highly variable regions of the key viral surface protein, to generate a universal vaccine candidate that could neutralize the most widely divergent strains of hepatitis C, by generating neutralizing antibody responses against conserved regions of the viral surface antigen E2.
The Institute said that commercially available vaccines against infectious diseases elicited neutralizing antibodies correlated with protection and that preclinical studies of Delta3 “generated the highest levels of neutralizing antibodies that prevented infection with the same and different [hepatitis C strains] ever reported in the field in-vitro”.
The Burnet Institute said its team had identified the most effective components of the vaccine formulation and a method of manufacture that would streamline the manufacturing process and reduce manufacturing costs.
The Institute said the next stage of development was the finalization of the formulation to be followed by preclinical safety, toxicity and chemistry manufacturing control programs.
The Institute said that its held three main patent families, two on method-based claims covering the candidate vaccine antigen and methods of manufacture and the third focused on the core formulation as a composition of matter.
The Institute said it provided Hepseevax with the capacity to access established cohorts of subjects with high incidence rates of hepatitis C infection, enabling streamlined clinical trials, together with infectious disease experts and facilities to conduct complex immunological monitoring in accredited facilities.
The Institute said this would allow significant cost savings and the ability to fast-track timelines to determine vaccine efficacy, with the potential for multiple value inflection and exit points throughout the development pathway over the next four years.

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says it has a three-year collaboration with Denmark’s Leo Pharma to deliver new treatments for skin cancer.
Leo said the collaboration was part of the company’s strategy to join forces with innovative universities and biotechnology companies to break important new ground in dermatology.
University of Queensland deputy vice-chancellor Prof Max Lu said the collaboration highlighted the value on research at his university.
The University of Queensland said the collaboration covered skin cancer including actinic keratosis and squamous-cell carcinoma in exploratory clinical trials, basic research, contract research and material transfer agreement activities.
In 2009, Leo paid $US287.5 million for Brisbane’s Peplin for its phase III PEP-005, later renamed Picato, for actinic keratosis, launched in 2012 (BD: Nov 12, 2009; Jan 27, 2012).

COGSTATE

Cogstate says that Merck Canada has provided study data supporting its Cognigram test to detect and monitor cognitive decline.
Cogstate said that Cognigram was a computer-based cognitive evaluation tool that helped physician decision-making for patients with cognitive impairment.
The company said it had an ongoing partnership with Merck Canada to improve disease management involving the central nervous system.
In its own media release Merck Canada said that two studies added to the evidence supporting Cognigram "as a sensitive assessment to detect and monitor cognitive decline over time, namely in healthy individuals and adults with mild cognitive impairment that are carriers of a biological marker in the brain, A-beta amyloid".
Cogstate chief science officer and study co-author Dr Paul Maruff said the test was "a true advance in the way clinicians will be able to detect and monitor the progression of cognitive disorders in older people".
"It is the first time that a computerized cognitive assessment has been associated with levels of A-beta amyloid in the brain," Dr Maruff said. "A-beta amyloid is a biomarker that signifies abnormal proteins in the brain and provides important information to indicate that the Alzheimer's disease process has begun."
"In our studies … we underscore the sensitivity of Cognigram to efficiently assess over time, up to 36 months, the decline of cognitive function in people whose brains had been scanned and showed presence of high levels of this biomarker," Dr Maruff said.
Cogstate was unchanged at 47.5 cents.

IMPEDIMED

Impedimed says Kaiser Permanente has expanded use of the L-Dex U400 lymphoedema diagnostic to Southern California.
The company said Kaiser Permanente was the largest not-for-profit health maintenance organization in the US and the expansion followed the adoption by the Northern California region, with three facilities using the L-Dex U400 since 2012.
Impedimed chief executive officer Richard Carreon said the company was "very pleased to see the expanded use of our technology by such an innovative institution renowned for their focus on patient outcomes".
Impedimed was untraded at 17.5 cents.

QRX PHARMA

QRX says the US Food and Drug Administration has encouraged it to submit its validated Moxduo dual opioid data and updated new drug application.
QRX said it met with the FDA on October 3, 2013 and the Agency provided a more complete understanding of its requirements for submission of the revised application.
The company said that the FDA reaffirmed that the safety and efficacy of Moxduo were not in question and the presentation of the totality of the respiratory safety advantages to an advisory committee of experts would help guide their final decision.
QRX said that the FDA would schedule an advisory committee meeting preceding a Prescription Drug User Fee Act (PDUFA) date six months following resubmission.
QRX chief executive officer Dr John Holaday said the company was "highly confident in the integrity of the data defining the respiratory safety advantages of Moxduo" and expected to file the documents by mid-November 2013 for a US launch in 2014.
QRX fell three cents or 4.2 percent to 69 cents.

NOVOGEN

Novogen says it has acquired a novel drug technology to be developed as a potentially major class of cancer drugs known as anti-tropomyosins.

Novogen said it acquired the technology from the Melbourne-based Genscreen Pty Ltd for a royalty payment on product sales, with no upfront or milestone fees.

The company said that Genscreen had developed extensive intellectual property in drug design targeting the Tm5NM1 protein, with laboratory and animal studies confirming the anti-cancer effect and safety of the drug target.

Novogen said that the anti-tropomyosins drugs would join its pipeline of super-benzopyran drugs and it would undertake a program to identify lead compounds, with prostate cancer, melanoma and neuroblastoma the nominal targets.

The company said that the protein Tm5NM1 was an integral part of the microfilament component of the cytoskeleton of a cell and inhibition of Tm5NM1 effectively blocked the ability of a cancer cell to function and to divide.

Novogen said that the cytoskeleton gave a cell its shape and form, also served a wide range of functions that actively contributed to the ability of a cell to survive, to move, and to divide.

The company said that drugs that targeted the cytoskeleton were highly effective anti-cancer drugs, mainly because they block the ability of the cytoskeleton to prepare the cell for division and after four decades they remained among the most commonly prescribed chemotherapeutics.

Novogen said that despite common use and relative effectiveness, negative features included non-specific activity against the cytoskeleton of non-cancer cells resulting in a range of serious side-effects, limited or no effectiveness against many types of cancer, and the rapid ability of the cancer cell to develop resistance.

Novogen said that taxanes such as paclitaxel and docetaxel, and the vinca alkaloids like vincristine, and vinblastine were off-patent and targeted the cytoskeleton's microtubules.

The company said that a second component of the cytoskeleton that, while an obvious anti-cancer drug target, the microfilament,, which had to date successfully resisted drug development.

Novogen said that the microfilament was a series of filaments made up of inter-woven strands of two proteins, actin and tropomyosin and drugs directed against the microfilaments had been too toxic to consider using because of the key role of microfilaments in muscle contraction, with muscle cells in the diaphragm and the heart being adversely affected.

The company said the roadblock had been overcome with two Australian breakthroughs: that tropomyosins were distinguishable as muscle or non-muscle varieties; and that one particular form of non-muscle tropomyosin, Tm5NM1, was restricted largely to cancer cells and was critical to the survival of the cancer cell.

Novogen chief executive officer Dr Graham Kelly said that the anti-tropomyosin drug technology "perfectly complements Novogen's super-benzopyran drug technology in our quest to deliver comprehensive anti-cancer drug therapy".

"Our super-benzopyran family of drugs are highly effective against cancer stem cells, a basic requirement of successful longer term cancer therapy," Dr Kelly said.

"But we still need to eliminate all cancer cells and that is where the potential potency of an anti-tropomyosin drug comes in," Dr Kelly said. "Rather than relying on a blend of super-benzopyran drugs and currently available standard therapy to achieve across-the-board eradication of all cancer cells, the anti-Tm drugs now give us the opportunity to own the full complement of effective drugs."

Novogen was up half a cent or 3.0 percent to 17 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says Johnson & Johnson Lifescan Verio diabetes meter fees have returned to growth but its Siemens AG coagulation test has been delayed six months.

Universal Biosensors said that its quarterly service fees for the Onetouch Verio blood sugar level meters for the three months to September 30, 2013 were up 50 percent to $833,000 compared to the previous corresponding period.

The company said that in March 2013 Lifescan recalled the Verio meters resulting in a temporary dip in quarterly service fees but the “return to strong year-on-year growth reflects the competitive strength of the Onetouch Verio system” (BD: Mar 26, 2013).

Universal Biosensors chief executive officer Paul Wright said that quarterly service fees were “a key driver of value for [the company] and a direct reflection of the success of the product in the marketplace”.

The company said Lifescan had increased its available Verio manufacturing capacity at its Inverness production facility to about 1.5 billion test strips a year taking strip manufacturing capacity to about 2.25 billion strips a year.

Universal Biosensors receives fees for the strips.

In May, Universal Biosensors said that Siemens expected to launch the Xprecia Stride coagulation analyzer prothrombin time system this year (BD: May 22, 2013).

Universal Biosensors said at that time that the Xprecia Stride was the first of a family of analyzers being developed with Siemens.

Today, Universal Biosensors said that, with Siemens, it had revised the launch timeframe for the first point-of-care coagulation testing system, with first commercial sales expected next year.

The company said the point-of-care test to monitor the use of the oral anti-coagulant warfarin was “in the late stages of development and has been undergoing extensive clinical testing over recent months”.

Universal Biosensors said the delay was caused by “the challenge of recruiting sufficient patients with high [international normalized ratio] values necessary to demonstrate performance across a wide clinical range within the expected timeframe”.

“While we are aiming for launch in the first half of 2014, [the company] is working with Siemens on a range of strategies to ensure the clinical and commercial success of this product and will update the market once further testing is completed and the revised launch strategy has been better defined,” Universal Biosensors said.

“We are planning to launch a great product in an attractive market that presents one of the largest opportunities in point-of-care diagnostics globally,” Mr Wright said.

The company said that with more than seven million warfarin users globally, the point-of-care test market was estimated at more than $500 million and growing.

Universal Biosensors climbed one cent or 1.6 percent to 65 cents.

BIODIEM

All resolutions to the Biodiem annual general meeting were passed overwhelmingly with the greatest dissent opposing the delisting of the company from the ASX.

A total of 79,930,839 votes (98.3%) supported the delisting with 1,355,567 votes (1.7%) against.

Other resolutions included the issue of 2,000,000 options to chief executive officer Julie Phillips, approval of the executive option scheme, approval of the remuneration report and the re-election of directors Donald Brooks and Prof Arthur Li.

Biodiem expects to delist from the ASX on November 9, 2013 (BD: Aug 30, 2013).

Biodiem was untraded at 3.2 cents.

NEUREN PHARMACEUTICALS

Neuren 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 9.7 cents on October 1 to 13.5 cents, a 39.2 percent increase, today, October 9, but did not note an increase in trading volumes.
Neuren said that in the last five weeks it had announced US Food and Drug Administration approval for a phase II Fragile X syndrome trial and presented mouse data showing that its compounds "were shown to normalize known Fragile X characteristics" (BD: Jul 29, Sep 9, 2013).
"This progress has been accompanied by increasing interest in Neuren from the investment community," the company said.
"The board is continuing to evaluate capital requirements with a view to accelerating the execution of Neuren's strategy," the company said.
Neuren fell 1.5 cents or 11.5 percent to 11.5 cents with 7.9 million shares traded.

ALCHEMIA

Alchemia shareholders will vote on the issue of 3,151,500 options to four directors, chief executive officer Charles Walker and former executive officer Dr Pete Smith.
Alchemia said that it proposed to issue 191,000 options, exercisable at 71.5 cent each within four years from the date of issue, to each of directors Dr Tracie Ramsdale, Nathan Drona, Dr Susan Kelley and Tim Hughes and 600,000 options to Dr Smith exercisable at the seven-day volume weighted average price to the date of issue within three years of the date of issue.
The company said it proposed to issue chief executive officer and former chief financial officer Charles Walker 71,688 shares and 1,787,500 options in four tranches with exercise prices ranging from 33.68 cents to 59.35 cents within four years of issue.
The company's notice of meeting said it would also seek shareholder approval for the re-election of Dr Ramsdale and the election of Mr Drona, Dr Kelley and Mr Hughes as well as approve the remuneration report and ratify the March placement of 34,000,000 shares at 30 cents each.
The meeting will be held at the Sofitel Wentworth Hotel, 61-101 Phillip Street, Sydney on November 8, 2013 at 9.30am (AEDT).
Alchemia fell two cents or 3.0 percent to 65 cents with 2.3 million shares traded.

ATCOR MEDICAL

The Australian Leaders Fund has reduced its substantial shareholding in Atcor and been diluted from 14,825,157 shares (10.03%) to 13,752,022 shares (9.00%).
The Australian Leaders Fund said it sold 346,300 shares for $43,317 or an average price of 12.5 cents a share on August 21, 2013 and was diluted through the exercise of 1,000,000 options on October 3, 2013.
Atcor fell one cent or 5.7 percent to 16.5 cents with 1.6 million shares traded.