Biotech Daily

Wednesday November 24, 2010

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: USCOM UP 33%; COMPUMEDICS DOWN 9%**

*** FDA ACRUX TESTOSTERONE APPROVAL REAPS $89m MILESTONE**

*** BIOGUIDE BRIEF: ACRUX JOINS THE REVENUE-POSITIVE RARE BREEDS**

*** AVEXA MEETS FDA IN 2011; LOSES CFO STEPHEN KERR**

*** PITTSBURGH'S MAGEE WOMEN'S ADOPTS IMPEDIMED'S L-DEX TEST**

*** NOVOGEN'S GLYCOTEX RECEIVES $251k OBAMACARE TAX CREDIT**

*** IMPEDIMED AGM DISSENT OVER CEO OPTIONS, US PLAN**

*** CALZADA APPOINTS DR STEWART WASHER CEO**

*** CSIRO MALCOLM MCINTOSH LECTURE UNLOCKS ALZHEIMER'S**

*** MACFARLANE BURNET 50th ORATION ON IMMUNOLOGICAL TOLERANCE**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Wednesday November 24, 2010 with the S&P ASX 200 down 4.4 points to 4584.7 points.

Ten of the Biotech Daily Top 40 stocks were up, 14 fell, 13 traded unchanged and three were untraded. All three Big Caps were up.

Uscom was best, up 10 cents or 33.3 percent to 40 cents with 15,000 shares traded, followed by Acrux up 28 cents or 9.1 percent to $3.36 with 2.2 million shares traded.

Psivida climbed 7.1 percent; Alchemia was up 4.4 percent; Circadian was up 3.2 percent; Cochlear rose 2.7 percent; with Cellestis, Chemgenex, Clinuvel, Heartware and Pharmaxis up more than one percent.

Compumedics led the falls, down one cent or 8.7 percent to 10.5 cents with 100,000 shares traded, followed by Tissues Therapies down 7.4 percent to 44 cents with 787,555 shares traded.

Bionomics lost 6.25 percent; Viralytics was down 5.6 percent; Phosphagenics fell 4.35 percent; Living Cell and Sunshine Heart were down more than three percent; Advanced Surgical shed 2.9 percent; with Nanosonics and QRX down more than one percent.

ACRUX

The US Food and Drug Administration has approved Acrux's Axiron testosterone replacement technology, triggering a $US87 million ($A88.9 million) milestone payment.

In a teleconference, Acrux chief executive officer Dr Richard Treagus said licencee Eli Lilly & Co had already paid an upfront fee of $US50 million and manufacturing transfer fees of $US3 million and Acrux would earn a further $US195 million in milestone payments.

But Dr Treagus said the royalty payments would be worth more than the combined milestones, making the deal worth more than $US670 million.

Dr Treagus said the global market for men requiring testosterone replacement was $US1.2 billion with 80 percent in the US and it was growing at 20 percent a year.

Biotech Daily asked Dr Treagus if it was a potential $1 billion deal, but he refused to be drawn on the question.

"I am not at liberty to discuss royalties," Dr Treagus said.

"But I expect they will be of greater value than the $US335 million. The royalty payments are by no means insignificant," Dr Treagus said.

Dr Treagus said the FDA approval for the armpit application of testosterone was not just a milestone for Acrux, but for the Australian biotechnology industry.

Dr Treagus told the telephone conference that Eli Lilly would be "looking for a market leadership position" in testosterone replacement and noted that the company had developed the erectile dysfunction drug Cialis.

He said Eli Lilly would distribute and market Axiron in all territories and the product would be manufactured by Finland's Orion Corp.

Dr Treagus said Eli Lilly would be responsible for gaining regulatory approval in all territories outside the US.

He said the company expected to pay dividend in 2011 and as a pooled development fund, that dividend would be tax free.

Dr Treagus said the company's estradiol spray also known as Ellavie and Evamist was being considered for market approval in Sweden and the company was reviewing its product pipeline.

Acrux has previously said that the Ellavie estradiol spray to treat the symptoms of menopause and marketed as Evamist in the US, was approved by the FDA in 2007 and has been marketed in the US since early 2008.

In August the FDA issued an note on the KV Pharmaceuticals-distributed Evamist and at the same time Acrux said negotiations with HRA-Pharma for the distribution of the estradiol spray in major European markets had been terminated (BD: Aug 10, 2010).

Acrux said at that time there had been eight adverse events relating to unintentional exposure recorded from 200,000 prescriptions and measures would be taken to make warnings more prominent.

In December 2008, Acrux said that Eli Lilly's animal health division Elanco had submitted an application to the US regulators for the first animal health product under their development and commercialization agreement for a transdermal animal health product (BD: Dec 15, 2008).

Acrux has not disclosed the nature of the product.

Dr Treagus said the company expected to have FDA market approval for its animal health product in mid-2011.

Acrux climbed 28 cents or 9.1 percent to $3.36 with 2.2 million shares traded.

MARC SINATRA'S BIOGUIDE BRIEF: ACRUX

Well, hopefully, the approval the by the US Food and Drug Administration today of Acrux's Axiron treatment for testosterone replacement therapy in men, will convince investors and the Government that the biotechnology sector is worth investing in even more, after quite a few lean years and major disappointments.

The Axiron story also seems highly likely to bring further good news with outstanding potential milestones of $US195 million still possible and a royalty rate that could be very close to 20 percent, given the stage at which Acrux licenced the product.

Axiron does appear to have very significant advantages over its competitors in terms of ease of use and safety, in terms of dosing and transference to other individuals.

With Eli Lilly, which has a strong men's health franchise focused around the blockbuster drug Cialis, behind the marketing and sales of the Axiron, it seems likely that Acrux will see most, if not all, of the $US195 million in future milestone payments possible.

Royalties, however, could really bring in the money over the coming years. Datamonitor put the US market for testosterone replacement therapy at $US828 million in 2009, with a compound average growth rate between 2005 and 2009 of 24.3 percent, while IMS Heath put 2009 growth at 20 percent.

Looking at 2012, one year post launch of Axiron and assuming market growth rates continue, the market could be worth between $US1.4 billion and $US1.6 billion.

Under this scenario, if Axiron were to grab a 10 percent market share using the 20 percent royalty rate above, Acrux would receive royalties of between $US28 million and $US32 million for 2012. Assuming a mass switch to Axiron and a 50 percent market share, those numbers become $US140 million to $US160 million.

Whatever case, even at its current market capitalization of $542 million; Acrux is looking a bit cheap and could begin to look cheaper if the typical Australian style post-positive announcement share price fall occurs.

With the promise of dividends on the way and many of the company's major risks behind it, we have another of a rare breed of biotechnology companies that will suit investors wanting exposure to the sector without the risk inherent to the vast majority of them.

Marc Sinatra
Analyst

AVEXA

Avexa says it will meet with the US Food and Drug Administration in early 2011 to discuss the company's anti-HIV drug apricitabine or ATC.

Avexa chairman Joe Baini said the meeting was "a very important opportunity for Avexa and ATC".

"We will be able to present the most recent data from our phase II/III [trials] to the Agency and discuss possible paths forward for ATC," Mr Baini said.

Separately, Avexa said chief financial officer and company secretary Stephen Kerr would resign effective from November 30, 2010.

Avexa fell 0.2 cents or 4.2 percent to 4.6 cents with 4.2 million shares traded.

IMPEDIMED

Impedimed says the Magee Women's Hospital will use its L-Dex technology in its lymphoedema screening, early detection and prevention program.

Impedimed said the Magee Women's Hospital was part of the University of Pittsburgh affiliated UPMC organization described as an "$US8 billion global health enterprise with 50,000 employees headquartered in Pittsburgh, Pennsylvania … transforming health care by integrating 20 hospitals, 400 doctors' offices and outpatient sites, a health insurance services division, and international and commercial services".

Impedimed said the L-Dex technology was an aid in the clinical assessment of breast cancer patients at risk of developing lymphoedema.

The company said the program, under the direction of the professor of surgery with the University of Pittsburgh School of Medicine and surgeon with Magee Women's Prof Atilla Soran would "incorporate a prospective model of care with pre-surgical baseline testing and quarterly surveillance of patients in order to identify early onset of lymphoedema, which is the most effective time to treat the disease".

"The progressive nature of lymphoedema mandates that we utilize emerging technologies to identify and treat the disease as early as possible," Prof Soran said.

"Since there is no cure for lymphoedema, risk identification and prevention are key," Prof Soran said.

"The bio-impedance spectroscopy technology used in L-Dex assessment has been shown to be very sensitive in detecting the fluid changes characteristic of early stage lymphoedema," Prof Soran said.

"Together with patient education and other advances in treatment, our program will provide breast cancer patients with state-of-the-art care to protect their quality of life while lowering the financial cost of treating lymphoedema," Prof Soran said.

Impedimed said Magee was an inaugural member of its US lymphoedema centers of excellence program to recognize and collaborate with academic medical institutions in establishing a pre-emptive model of lymphoedema care using its medical device.

Impedimed was unchanged at 85 cents.

NOVOGEN

Novogen's 81 percent US subsidiary Glycotex Inc has been paid $US244,479 ($A251,353) under the US Government's Healthcare reform tax credit scheme.

Novogen said the funds were awarded under the US Government's Qualifying Therapeutic Discovery Project.

The Project is a grant and tax credit scheme operated by the US Internal Revenue Service as part of the US Patient Protection and Affordable Care Act of 2010.

Novogen said Glycotex received the grant for its program to develop GLYC-101 gel for acute and chronic wounds.

The company said GLYC-101 was being developed to stimulate and modulate the natural cascade of wound healing activities of several cell populations, including wound healing following laser ablation, burn wounds, surgical wounds and venous and diabetic ulcers.

Novogen fell half a cent or 3.85 percent to 12.5 cents.

IMPEDIMED

All resolutions to Impedimed's annual general meeting were passed, with up to 11.4 percent of votes cast opposing the approval of US plan share issues.
In October 22, 2010 meeting notice, Impedimed said the 2008 US Plan was intended "to attract and retain employees, directors and consultants to the group in the US".
Impedimed said it was seeking the approval of issues under the US Plan in order to preserve its capacity to issue up to 15 percent of its issued capital without member approval by allowing it to exclude any shares, options or shares issued on the exercise of options under the US Plan from the 15 percent calculation.
A total of 31,765,912 proxy votes (88.62%) supported the exemption with 4,081,143 (11.38%) proxy votes against.
A total of 4,107,167 proxy votes (11.45%) opposed the issue of options to chief executive officer Greg Brown with 31,769,688 proxy votes (88.55%) in favor.
All other resolutions were passed overwhelmingly.

CALZADA

Calzada has appointed Dr Stewart Washer as chief executive officer.
Calzada said Dr Washer had 20 years of management and board experience in the life science sector including raising $6.3 million in venture funds as chairman of Hatchtech.
Calzada chairman David Franklyn said that he was "very pleased" with the appointment of Dr Washer.
"Calzada has progressed its technologies to a point where they are ready to be taken to the next stage of commercialization," Mr Franklyn said.
Calzada said Dr Washer was a venture partner with the Swiss Inventages Fund, a EUR1.5 billion ($A2.05 billion) life science fund, funded by Nestle and Investment Director with IB Managers based in Europe and Australia, was also the chair of Resonance Health, the founding chief executive officer of Phylogica, a senator at Murdoch University and a director of Ausbiotech.
Calzada was up 0.2 cents or eight percent to 2.7 cents.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says the 2010 Malcolm McIntosh Lecture will provide the latest insights into detecting and understanding Alzheimer's disease.
The CSIRO said Alzheimer's was one of Australia's major public health challenges and the director of the National Ageing Research Institute Prof David Ames would discuss the results of recent Australian research into early detection of Alzheimer's disease and future developments in its prevention and treatment.
The CSIRO said its biomedical imaging team leader Dr Olivier Salvado would also discuss progress made in brain imaging and findings from a clinical imaging study into how the disease works.
The CSIRO said the Malcolm McIntosh Lecture honored the memory of Dr Malcolm McIntosh, CSIRO's chief executive officer from 1996-2000.
Regarded as one of the nation's outstanding science leaders, Dr McIntosh was universally respected for his vision, energy, leadership and personal qualities, the CSIRO said.
The free public lecture at the Walter and Eliza Hall Institute of Medical Research, Building 4, 1G Royal Parade, Parkville, Melbourne will be followed by drinks and refreshments.
The lecture will be at 5pm on November 26, 2010.

THE BURNET INSTITUTE

The Burnet Institute says Prof Christopher Goodnow will deliver a commemorative oration on 50 years immunological tolerance.

The Institute said the oration was a celebration of the 50th anniversary of Prof Frank Macfarlane Burnet being awarded the Nobel prize for medicine.

A media release from the Burnet Institute said Prof Goodnow's topic would be '50 Years of Tolerance: Controversy, Validation and Evolution of Burnet's Nobel-winning Theory'.

The Institute said Prof Goodnow was the director of the immunogenomics laboratory and director of the Australian Phenomics facility at the John Curtin School of Medical Research at the Australian National University.

The media release said Prof Goodnow pioneered the use of mouse molecular genetics to reveal key mechanisms regulating the immune system.

The Institute said Prof Macfarlane's Burnet's discovery of acquired immunological tolerance was the birth of immunology as a science and Prof Goodnow would discuss this legacy and how it affected immunological research today.

The free oration will be followed by a cocktail function and will be held at the BMW Edge, Federation square, Melbourne, on December 1, 2010 from 6pm-7.30pm.

RSVP to Lisa Toone on +613 8506 2338 or email: lisa.toone@burnet.edu.au.