Biotech Daily

Monday December 13, 2010

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: QRX UP 7%; BENITEC DOWN 10%**

*** NICTA DEVELOPS SMART-CHIP FOR PAIN**

*** COMMITTEE BACKS PHARMAXIS BRONCHITOL FOR CYSTIC FIBROSIS**

*** AVEXA RENAISSANCE ROADSHOW**

*** EVADO TRIAL SOFTWARE IN CHINESE; TAIWAN DISTRIBUTOR**

*** EUROPEAN HEPATITIS C PATENT FOR BENITEC**

*** ACTINOGEN RIGHTS ISSUE RAISES $525k OF HOPED-FOR $3.2m**

*** PSIVIDA DISSENT ON DIRECTORS' OPTIONS, RE-ELECTION**

*** ROBERT, SUSAN MARTIN TAKE 12% OF ACUVAX**

*** SOLAGRAN CUTS PRICE, SELLS 84 COURSES, EARNS $42k IN NOVEMBER**

MARKET REPORT

The Australian stock market was up 0.24 percent on Monday December 13, 2010 with the S&P ASX 200 up 11.2 points to 4757.1 points.

Eleven of the Biotech Daily Top 40 stocks were up, 11 fell, 13 traded unchanged and five were untraded.

QRX was best, up eight cents or 6.9 percent to $1.24 with 66,786 shares traded.

Bionomics, Clinuvel and Optiscan climbed more than six percent; Heartware was up 4.3 percent; Mesoblast and Sunshine Heart were up more than three percent; with Biota, Immuron and Starpharma up more than one percent.

Benitec led the falls, down 0.3 cents or 10.3 percent to 2.6 cents with 3.1 million shares traded, followed by Genetic Technologies down 8.1 percent to 3.4 cents with 95,000 shares traded.

Circadian lost 6.15 percent; Tissue Therapies fell 4.1 percent; Phosphagenics was down 3.85 percent; Patrys and Universal Biosensors shed more than two percent; with Sirtex down 1.3 percent.

NATIONAL INFORMATION AND COMMUNICATIONS TECHNOLOGY AUSTRALIA

The New South Wales Government says Sydney trials are being prepared for the first smart-chip to treat chronic pain by implanting it near the spinal cord.

The New South Wales Treasurer and Minister for State and Regional Development Eric Roozendaal said the miniature technology was called INS2 (implantable neuro-sensing and stimulation) and measured pain signals then blocked the signals from traveling to the brain.

Mr Roozendaal said "the world-first revolutionary technology" had been designed in Sydney by the National Information and Communications Technology Australia (NICTA) and was developed at its Australian Technology Park laboratory.

The State Government media release said the project was led by NICTA chief technology officer Dr John Parker, the former chief technology officer at Cochlear.

Mr Roozendaal said the technology had "the potential to be the next Cochlear, only larger" and had "the potential to deliver a revolution in the management of chronic pain and bring relief to many thousands of sufferers worldwide".

Mr Roozendaal said the device would be used to treat chronic pain and had the potential to treat other neurological disorders such as Parkinson's disease tremors and epileptic seizures.

The media release said the INS2 was a smart-chip is built into a biocompatible device slightly smaller than the size of a match head.

PHARMAXIS

Pharmaxis says the Australian Advisory Committee on Prescription Medicines has recommended marketing approval for Bronchitol (inhaled mannitol) for cystic fibrosis.

Pharmaxis chief executive officer Dr Alan Robertson said the company was "delighted to have received this recommendation from the Advisory Committee on Prescription Medicines and look forward to the prospect of making Bronchitol available to people with cystic fibrosis".

"For all concerned, this is a difficult disease, so we are excited to be another step closer to making this new treatment alternative available," Dr Robertson said.

"We are working with the Therapeutics Goods Administration to complete the review process early in 2011," Dr Robertson said.

Pharmaxis said the Advisory Committee on Prescription Medicines was appointed by the Federal Minister for Health and Ageing to advise on the suitability of drugs for marketing in Australia.

The company said the committee included physicians, pharmacologists, toxicologists and pharmacists and provided independent, scientific advice on new drugs to the Australian Therapeutic Goods Administration (TGA).

Pharmaxis said the review and recommendation by the committee at its most recent meeting followed the TGA evaluation of clinical, pharmacological quality and safety data submitted by Pharmaxis in December 2009, in addition to consultation between the company and the TGA.

The company said Bronchitol was the subject of two pivotal clinical trials in cystic fibrosis in more than 600 people and in April 2009 it was awarded orphan drug designation in Australia for the treatment of patients with cystic fibrosis to improve lung function and reduce exacerbations.

Pharmaxis fell two cents or 0.7 percent to $2.89.

AVEXA

Avexa's chairman Joe Baini and chief executive officer Dr Jonathan Coates are on a roadshow to reposition the company following the closure of its lead HIV program.

Avexa had been developing apricitabine or ATC for HIV until poor phase III trial results led to the closure of the program, a successful board spill by investors supportive of the ATC program and an unsuccessful board spill by the then 16 percent shareholder Calzada (BD: May 10, Jul 6, Sep 28, 2010).

While Avexa has been able to demonstrate that apricitabine has efficacy and that of the 36 patients who successfully completed the phase II study, "94 percent [34 patients] maintained undetectable viral loads up to week 144", the 24-week data from its phase III HIV trial showed a non-significant positive clinical benefit for apricitabine compared to the standard of care, 3TC (BD: Feb 4, 5 and 15, 2010).

Today, Mr Baini and Dr Coates told Biotech Daily that Avexa would be an anti-viral focused company with two main assets, a second generation HIV integrase program and a stake in Allied Medical which controls Coridon Vaccines which is developing a treatment for herpes simplex virus-2 (HSV-2).

Mr Baini said that Avexa had licenced its anti-biotic programs to Valevia for a potential $66 million.

Mr Baini said there was no up-front fee with the licence but there were significant milestone payments.

He said the company had also licenced its first generation HIV integrase program to the Shanghai Institute of Organic Chemistry in July, again, without any up front-fee.

"They pay for the development," Mr Baini said. "And if it works we get 50 percent".

Mr Baini said the Institute had the right to market any developed drug in China, with Avexa holding the rights to other jurisdictions.

Dr Coates said there were broad similarities among the first generation HIV integrase drugs developed by Avexa, Glaxosmithkline, Merck Inc and Gilead.

Dr Coates said Avexa would continue to develop a second generation HIV integrase drug.

Dr Coates said that the aim of integrase drugs was to prevent HIV forcing its DNA into humans and said the second generation drug so far had no cross-resistance with the first generation integrase drugs, which work through a different mechanism of action to the nucleoside reverse transcriptase inhibitor class of drugs, which includes ATC and the drug it hoped to replace, 3TC, which was invented by Dr Coates.

Mr Baini said the independent review by the Bioadvisory Group of John Grew and his son Joshua Grew had recommended that ATC retained some potential and said a meeting would be held with the US Food and Drug Administration early in 2011 to discuss regulatory options.

Dr Coates said that the investment in Allied Medical was 'hedged' because the company had revenue positive medical device assets, as well as attempting to develop a vaccine for HSV-2.

Dr Coates said the work already done by Coridon was "good science" but needed further development and Avexa would work with Coridon to develop the drug.

If Avexa takes up the option to fully invest in Allied Medical it would hold 24 percent of the company. It currently holds 14 percent of Allied Medical.

"We're getting Avexa back on-track as a drug discovery and development organization," Mr Baini said.

He said the company retained about $20 million of the $23 million leftover from its capital raising for the closed phase III apricitabine trial.

Avexa was unchanged at four cents.

EVADO

Evado says it has a partnership with Taiwan's clinical research organization, Fuga Biotechnology which will have exclusive distribution rights in Taiwan.
Evado said it would develop a Chinese version of the Evado clinical trials software system with Fuga in 2011.
Evado chief executive officer Jennie Anderson said that the agreement extended to the localization of the software for the Taiwanese regulatory environment.
"This is a great opportunity to work with a world class contract research organization that is extremely well respected in Taiwan," Ms Anderson said.
Evado said Fuga would sell and implement the Evado clinical trial software for their clients and for members of the Taiwan Biotechnology Service and Business Trade Association.
Evado said its applications would be available in Taiwan as stand-alone versions and as software-as-a-service.
Evado is a private company.

BENITEC

Benitec says the European Patent Office intends to grant a patent entitled 'Multiple promoter expression cassettes for simultaneous delivery of RNAi agents'.
Benitec said the claims covered the use of an RNA interference construct with multiple promoters to inhibit the level of hepatitis C virus in cells, tissues and organs.
The company said additional related applications were pending, to extend the scope of protection, including constructs having single promoters.
Benitec said it had licenced the rights to use the patent for hepatitis C exclusively to Tacere Therapeutics, which was working with Pfizer to further develop and commercialize Tacere's hepatitis C virus compounds.
Benitec quoted Tacere's chief executive officer Sara Hall Renison saying the company was "very pleased with the news from the EPO"
"Benitec has been a strong ally in developing this and other patent families and Tacere and Pfizer look forward to continuing clinical development of this first-in-class drug," Ms Renison said.
Benitec fell 0.3 cents or 10.3 percent to 2.6 cents with 3.1 million shares traded.

ACTINOGEN

Actinogen's one-for-one rights issue has raised $524,900 from the issue of 6,561,253 shares at eight cents a share.
Actinogen said in October that it hoped to raise up to $3,189,600.
The company said that each new share came with a free attaching option exercisable at 20 cents by September 30, 2015.
The company said the funds would be used for a new method to produce Anacardic acid in pure form from an actinomycete; an actinomycete/bacterial system for the rapid digestion of papers and organic based plastics both aerobically and anaerobically; an antifungal bioactive molecule that is active against a brown rot of stone-fruit and a curly leaf fungus of stone fruit trees; an active program in the discovery and isolation of soil actinomycetes from Western Australian soils producing new bacterial antibiotics, in particular against the methicillin resistant staphylococcus aureus (MRSA) and anti cancer agents; and working capital.
Actinogen fell 1.5 cents or 17.7 percent to seven cents.

PSIVIDA

Several resolutions at the Psivida annual general meeting were won against significant opposition with director options the most controversial.

The closest vote was on the issue of options to director Paul Hopper which was won with 4,139,367 proxy votes (60.4%) in favor and 2,713,697 proxy votes (39.6%) against.

Options for director Peter Savas were passed by a slightly wider margin of 64.0 percent in favor and 36.0 percent against, but Mr Savas also faced significant opposition for reelection as a director, winning that resolution by 4,925,087 proxy votes (71.0%) to 2,008,489 (29.0%) proxy votes 'withheld'.

Psivida's head of investor relations Brian Leedman told Biotech Daily that for the vote on the election of directors the US expression 'withheld' effectively meant voted against.

Paul Hopper's reelection was opposed by 905,239 proxy votes (13.1%), with 6,028,337 proxy votes (86.9%) in favor.

The issue of options for chief executive officer Dr Paul Ashton and directors Michael Rogers and David Mazzo also faced significant opposition.

Psivida's most recent Appendix 3B share issue announcement said there were 18,531,392 shares on issue, meaning that the strongest opposition came from 14.6 percent of all shares on issue.

Psivida was unchanged at $5.35.

ACUVAX

Funds associated with Robert and Susan Martin have become substantial shareholders in Acuvax with the acquisition of 187,500,000 shares or 12.15 percent of the company.

The initial substantial shareholder notice said that RPM Super, RP Martin and SP Martin and Accord Investment Corp of 8 Alvan Street, Subiaco, Western Australia, acquired the shares for $375,000 or 0.2 cents a share.

Acuvax was unchanged at 0.4 cents with 19.3 million shares traded.

SOLAGRAN

Solagran has cut the price of its over-the-counter, cure-all Ropren from $US1,150 per course of six bottles to $US600.

Solagran said that refinements in technology and significant changes to two stages of our extraction processes had increased the general yield of Bioeffective R substance by nearly 100 percent.

Solagran said the refinements enabled it "to reduce the price to the end user of the product to $US600 per course".

The company said that in November 2010, a total of 502 bottles of Ropren or 83.7 courses were sold in Russia across 11 regions.

Last month Solagran said it sold 2,021 bottles or 336.8 courses of Ropren in Russia of the 78,000 bottles it had hoped to sell by the end of November (BD: Nov 16, 2010).

In March, Solagran said it was "confident of achieving the forecast previously provided of selling in excess of 13,000 courses [78,000 bottles] of Ropren by December 2010" (BD: Mar 12, 2010).

Solagran was up half a cent or 3.85 percent to 13.5 cents.