Biotech Daily

Thursday March 15, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEUREN UP 17%, PSIVIDA DOWN 9%**

*** CEO INTERVIEW: WHY DR RICHARD TREAGUS IS LEAVING ACRUX**

*** CLINUVEL, FDA 'IN-PRINCIPLE' SCENESSE PHASE III TRIAL AGREEMENT**

*** BPH'S CORTICAL DYNAMICS STARTS ANAESTHESIA TRIAL**

*** TGA APPROVES PRIMA CVAC MANUFACTURING LICENCE**

*** AETNA BEGINS BRAIN RESOURCE MYBRAINSOLUTIONS US SALES**

*** KOREAN DRUG CO SUPPLIES PHOSPHAGENICS BIOELIXIA COSMETICS**

*** VIRAX NOTEHOLDER MEETING CONDITION FOR MERGER**

*** LBT APPOINTS DR CAROLINE POPPER DIRECTOR**

*** NEURODISCOVERY APPOINTS SIMON O'LOUGHLIN DIRECTOR**

MARKET REPORT

The Australian stock market slipped 0.22 percent on Thursday March 15, 2012, with the S&P ASX 200 down 9.4 points to 4277.8 points.

Nine of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and six were untraded.

Neuren was the best on no news, up 0.4 cents or 17.4 percent to 2.7 cents, with 10.2 million shares traded.

Prima and Sunshine both climbed 7.1 percent; Antisense was up 4.35 percent; Reva rose 2.9 percent; with Clinuvel and Resmed up more than one percent.

Psivida led the falls, down 16 cents or 8.6 percent to $1.70, with 7,000 shares traded.

Genera lost 5.6 percent; Impedimed and Optiscan fell more than four percent; Anteo was down 3.7 percent; Mesoblast, Phosphagenics and Viralytics shed more than two percent; with Alchemia, Bionomics, Nanosonics, Pharmaxis and QRX down more than one percent.

ACRUX

Acrux chief executive officer Dr Richard Treagus likes a challenge.

Five years ago - in one of Biotech Daily's first CEO interviews - Dr Treagus spoke enthusiastically about the thrill of the chase and sealing the deal for Acrux's transdermal platform (BD: Apr 20, 2007).

(http://www.biotechdaily.com.au/media/ceo/Acrux_Richard_Treagus_20_April_07.pdf.)

Following a number of enquiries from readers about recent changes at Acrux, including Dr Treagus retirement on June 30, 2012, along with uninformed speculation about the company's future, Biotech Daily decided to set the record straight and end the industry gossip.

Today, Dr Treagus said that Acrux "has largely been de-risked" and that he had primarily completed the project he began in 2006.

"It's about seeking out the next personal challenge to build another company and doing it at a time when Acrux is well-positioned for the future," Dr Treagus said.

Under Dr Treagus' stewardship, Acrux has two products approved and on sale in the US, the Axiron testosterone treatment for men and the Evamist estradiol spray for women. The company has signed a major deal with Eli Lilly for Axiron and is in profit, paying dividends and expects revenues to increase significantly.

Dr Treagus said that Acrux expected $US7 million to $US8 million in Axiron royalties for the year to June 30, 2012 with additional revenue from the estradiol spray and from animal products.

But he said there would be a steep increase in Axiron royalty and milestone income as market penetration increased, with the company forecasting about $US40 million for the year to June 30, 2013, in a market growing at 24 percent a year by volume.

Dr Treagus said the reason for the dramatic increase was a combination of ageing population, greater awareness of men's health and greater accessibility of treatments.

He said that Eli Lilly had invested in 60-second television commercials screening in 10 US capital cities, marketing the Axiron product developed in the West Melbourne laboratory.

Dr Treagus said that Eli Lilly was increasing Axiron's market share by one percent a month and the revenues would increase as the US "insurance plans were kicking-in".

He said revenues would increase further when Axiron received approvals in Canada, Europe and Australia. The Australian Therapeutic Goods Administration has refused approval for the estradiol spray, despite US Food and Drug Administration approval and the product being on sale in the US for more than three years (BD: Nov 12, 2009).

Acrux decided not to conduct a TGA-required trial and concentrate on other matters.

One issue raised about the future of Acrux was the reduction in staff from 27 to 21 people in 12 months, with four science and technical staff members departing.

Dr Treagus says this was primarily due to completing the research and development work required for the company's products.

He said that the 12 staff members continuing in the science and technical division were primarily support for Eli Lilly and working on a new technology.

Another issue that Acrux has repeatedly sought to communicate with its shareholders, analysts and commentators has been the nature of the pooled development fund and how it affects shareholders.

Dr Treagus said that Acrux was an investment fund, which owned and invested in subsidiaries, which developed and commercialized products.

He said the benefits to shareholders were that dividends and share price gains were tax-free and should be treated as such on tax returns. Shareholders cannot claim tax losses from share sales.

There are some restrictions on the nature of investments, the main practical restriction on the company is that it cannot invest off-shore, but it is free to create or buy-in new technology, if it chooses to do so.

Dr Treagus said the current core technology of a combination of sun-screen esters with alcohol and a drug, acquired from Monash University, had patents running to 2017.

"We are evaluating new technology and have been for six months, but have chosen not to disclose details at this stage," Dr Treagus said.

"We have learnt a lot about US men's health and the technology is our own idea."

Dr Treagus would not discuss whether the technology was a drug or device other than if the company could demonstrate that it was technically feasible that it would have significant commercial potential.

"We will know by mid-year if it has technical and commercial viability," Dr Treagus said.

The new technology is being created in Acrux's West Melbourne laboratory.

"It's early stage, there's a lot we don't know about," Dr Treagus said.

"We worked backwards from the commercial opportunity to technical feasibility.

"We are pretty focused on this technology at the moment. It is mapped out right the way through to commercial availability and it is costed. We are looking to remove risk as much as possible and we will know by the middle of 2012 whether it's a goer.

"I am very comfortable with where the company has got to," Dr Treagus said.

Dr Treagus said he had not turned his mind to what he would do next, but confirmed that it would be biotechnology and in Melbourne.

“This is home. I like this city. I like the sector. A friend of mine described the move as ‘You are re-potting yourself’ and I think that’s right.”

Dr Treagus leaves the company in the hands of chairman, founder and former chief executive officer Ross Dobinson, along with chief financial officer Jon Pilcher and the director of technical affairs and product development Dr Clive Blower, but will remain a consultant.

With “a couple of million” Acrux shares in his portfolio he is likely to retain an ongoing interest in the company.

Dr Treagus is keen to conclude the US patent grant for the Axiron axilla applicator as well as find a European distributor for the estradiol spray.

“There are a few things keeping us busy, which is good, and we are on track for a profit at June 30, which is three years in a row, and a dividend in August.”

Acrux has increased its market capitalization from $79 million when Dr Treagus took over, to $631 million at February 29, 2012, a modest 698.7 percent increase.

Given the glacial timelines of biotechnology, from burning cash to dividends in six years is a great deal of de-risking.

Dr Richard Treagus is looking for the next big risk.

Acrux was up two cents or 0.5 percent to $3.77 with 2.1 million shares traded.

David Langsam
Editor

CLINUVEL PHARMACEUTICALS

Clinuvel has an in-principle agreement with the US Food and Drug Administration for its phase III study of Scenesse for erythropoietic protoporphyria.
Clinuvel said it was working to finalize the Scenesse (afamelanotide 16mg implant) phase III study protocol with the FDA following an end of phase-II meeting on March 12, 2012.
The company said the trial would be a nearly identical to erythropoietic protoporphyria (EPP) studies in 2011 and would complete the program.
Clinuvel said it hoped to begin the study in May 2012.
Clinuvel chief scientific officer Dr Hank Agersborg said the company was “delighted” that the FDA confirmed that the intention to treat erythropoietic protoporphyria had merit, and “recognized that this is a severe, debilitating disorder which currently lacks an effective therapy”.
“The FDA stated that it will expedite the use and availability of afamelanotide for EPP patients pending final results of this study,” Dr Agersborg said.
Clinuvel was up three cents or 1.7 percent to $1.82.

BPH ENERGY, CORTICAL DYNAMICS

BPH says its 3.6 percent subsidiary Cortical Dynamics has recruited the first of 20 patients in its anaesthesia monitoring clinical trial at Melbourne's St Vincent's Hospital.

BPH said that patients undergoing cardiopulmonary bypass surgery would be assessed by the brain anaesthesia response (BAR) monitor which combines an algorithm and electroencephalogram to indicate how deeply anaesthetised a patient is during an operation.

The company said that the primary objective of the trial was the validation of the BAR monitor in an operating room setting where the presence of multiple artifacts were known to complicate the EEG assessment of anaesthetic action.

BPH said that the principal investigator would be trial will be St Vincent's senior staff anaesthetist Dr Desmond McGlade.

BPH and Cortical chairman David Breeze said "the commencement of the validation trials … is a significant moment for Cortical Dynamics".

"The validation of the BAR monitor within the operating room is an important step in Cortical's clinical development program," Mr Breeze said.

BPH said that St Vincent's trial was the second trial of the monitor, following a study at Swinburne University in 2011 which concluded that all the signal gathering and analyzing components of the BAR monitor were functioning correctly, providing the necessary verification for the system to be used in St Vincent's clinical trial.

BPH fell 0.1 cents or 3.3 percent to 2.9 cents.

PRIMA BIOMED

Prima says the Australian Therapeutic Goods Administration has approved a manufacturing licence to produce the CVac immunotherapy ovarian cancer vaccine.

Prima said the licence was "a key component" in its development timeline to initiate the pivotal clinical trial and another step towards commercialization of the vaccine.

The company said it had manufacturing authorizations for CVac in Australia, Europe and the US.

Prima chief executive officer Martin Rogers said the approval "provides a rigorous and independent assessment of our manufacturing processes and underscores the robust manufacturing and quality processes as well as the excellent safety profile of Cvac."

Prima was up 1.5 cents or 7.1 percent to 22.5 cents with 10.2 million shares traded.

BRAIN RESOURCE

Brain Resource says the Hartford Connecticut-based Aetna has begun distribution of its Mybrainsolutions product in the US.

Brain said that the product was "an interactive brain-training website that brings together games, videos and trackers designed to improve stress management, memory and attention … designed for employers looking to improve productivity and the health and well-being of their workforce".

Brain said that Aetna provided "very significant new reach for [its] products as they are one of the leading diversified health care benefits companies in the US, serving approximately 36 million people".

The company said that sales training had been completed for about 100 sales staff.

Brain was untraded at 25 cents.

PHOSPHAGENICS

Phosphagenics says the Korean Drug Company will supply its Bioelixia cosmetics and fat buster to outlets in South Korea.

Phosphagenics said the agreement was subject to minimum volumes and Korean Drug Company clients included health and beauty salons, drugstores, and medical and dermatological clinics with more than 9,000 outlets throughout South Korea and South East Asia.

Phosphagenics said that the first sales under the agreement would be by October 2012 and would initially be for the lead product, Bodyshaper, containing AOP9604, a cosmetic version of Calzada and Metabolic's AOD9604 (BD: Mar 13, 2012).

Phosphagenics markets its cosmetics under the Elixia label in Australia and Bioelixia overseas.

Korean Drug Company chief executive officer Dr Sanghun Park said he expected "very strong consumer support for a cosmetic range based on a history of scientific supporting data".

"Considering the market growth rate for slimming products and the scarcity of high efficacy products in the Korean slimmer market, Bioelixia will be the huge potential product that customers have waited for," Dr Park said.

"Our customers want products that work," Dr Park said.

Phosphagenics fell half a cent or 2.2 percent to 22 cents with 6.7 million shares traded.

VIRAX HOLDINGS

Virax convertible note holders will vote on the company's merger with 4G Vaccines, a condition for completing the corporate transaction.

Virax said note holders would be asked to vote on two resolutions, one to amend the conditions of issue of the convertible notes – effectively seeking permission for a change from the existing company to the new company – as well as a moratorium period on note conversion.

The meeting will be held at the Quest Beaumont, 7 Studley Park Road, Kew, Victoria on March 30, 2012 at 2pm (AEDT).

A separate shareholders meeting is expected to be announced shortly.

Virax last traded at 0.9 cents.

LBT INNOVATIONS

LBT has appointed US consultant Dr Caroline Popper as a non-executive director.

LBT said that Dr Popper had more than 20 years experience in diagnostics, medical devices and drug discovery, including 10 years in management and marketing roles at Becton Dickinson & Co.

The company said that Dr Popper has worked in managerial and advisory positions at companies including Biomérieux and MDS Proteomics.

LBT said that Dr Popper was previously an attending physician at Johns Hopkins Hospital in Baltimore and was a trained pathologist.

LBT said Dr Popper ran a strategy and mergers and acquisitions advisory firm and was chair of Innovative Biosensors Inc and a director of Nanomr, Rarecyte and Pilgrim Software.

LBT was untraded at 5.4 cents.

NEURODISCOVERY

Neurodiscovery says it has appointed Simon O'Loughlin as a director, replacing directors Kyle Haynes and Neville Bassett who have resigned, effective from today.

In 2010, the Perth Western Australia-based Neurodiscovery quit drug discovery but said it owned 100 percent of the UK-based Neurosolutions electrophysiological assays specialist service business which ensured the company had sufficient funds to carry on activities without the need to raise additional capital from the markets (BD: Mar 18, 2010).

The company subsequently sold that business (BD: Jun 15, 2010) and raised $719,000 in 2010 and a further $440,000 in 2011.

The company gained and lost Harry Karelis as a chairman and lost and regained founder David McAuliffe as a director.

Today, Neurodiscovery said that Mr O'Loughlin was the founding member of O'Loughlins Lawyers, an Adelaide based medium-sized commercial law firm.

Neurodiscovery said that Mr O'Loughlin held accounting qualifications and had "extensive experience and involvement with listed public companies".

The company said that Mr O'Loughlin was the chairman of Avenue Resources and Kibaran Nickel and a director of Chesser Resources, Petratherm, Aura Energy, Probiomics, Strzelecki Metals and WCP Resources.

Neurodiscovery was up 0.7 cents or 28 percent to 3.2 cents.