Biotech Daily

Thursday September 2, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BENITEC UP 14%; PHOSPHAGENICS DOWN 6%**

*** CALZADA REBUTS AVEXA ACCUSATIONS; $23m TO STAY IN BIOTECH**

*** AVEXA NAMES 'BIOADVISORY GROUP' FOR INDEPENDENT REVIEW**

*** TISSUE THERAPIES VITROGRO CONTINUES 'OUTSTANDING RESULTS'**

*** PHOSPHAGENICS LICENCES CALZADA'S FAT-BUSTING AOD9604**

*** HELICON RIGHTS ISSUE RAISES $457k**

*** FURTHER US PATENT FOR BENITEC GRAHAM RNAI FAMILY**

*** MEDIGARD RAISES $1.1m OF HOPED FOR $4.8m**

MARKET REPORT

The Australian stock market climbed 0.82 percent on Thursday September 2, 2010 with the S&P ASX 200 up 37.0 points to 4532.7.

Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, seven traded unchanged and six were untraded. All three Big Caps were up.

Benitec was best, up 0.3 cents or 13.6 percent to 2.5 cents with 301,600 shares traded, followed by Virax up 11.5 percent to 2.9 cents with 75,000 shares traded and Phylogica up 11.1 percent to six cents with 50,000 shares traded.

Tissue Therapies climbed 8.3 percent; Antisense and Sunshine Heart were up more than seven percent; Genera and Psivida were up more than three percent; Acrux, Clinuvel, Patrys and Sirtex rose more than two percent; with Heartware, Mesoblast and Nanosonics up more than one percent.

Phosphagenics led the falls, down 0.6 cents or 6.2 percent to 9.1 cents with 477,699 shares traded.

Immuron lost 5.3 percent; Cellmid fell 4.8 percent; Starpharma was down three percent, Pharmaxis shed 2.5 percent; with Alchemia, Chemgenex and Prima down more than one percent.

CALZADA, AVEXA

Calzada's chairman David Franklyn has rebutted accusations by Avexa's board and said that he intended the company's $23 million to stay in Australian biotechnology.

At a media lunch, Mr Franklyn compared his proposed Avexa board including former Peptech and Arana executives Dr John Chiplin and Dr David Fuller along with Bruce Rathie and Dr Stewart Washer to the existing Avexa board.

Mr Franklyn said the only ASX-listed company experience on the existing board was Bell Potter private client adviser Jet Soedirdja who had worked with oil and gas companies and chairman Joe Baini who previously resigned from the Avexa board after supporting the axing of the apricitabine or ATC program for HIV. He said Avexa director Iain Kirkwood was briefly a director of Metabolic which became Calzada.

Last month, Avexa filed a notice of general meeting and made a number of claims about Caldaza and its intentions (BD: Aug 26, 2010).

Mr Franklyn said that claims by Avexa that he had not responded to or had delayed meetings were not correct and that he had made considerable efforts to engage with the new board.

"The problem that we've had is that the new board haven't engaged with us," Mr Franklyn said.

He said there were three issues facing Avexa.

Mr Franklyn said the next steps for the company which has about $23 million in cash following the closure of its apricitabine program "are going to be critical".

He said the "independent review" – announced by Avexa today (see below) – would be managed by chairman Mr Baini and acting chief executive officer Dr Jonathan Coates, both of whom had a long association with the apricitabine program.

Mr Franklyn said the third issue was how the existing board was formed after the demise of then chairman Nathan Drona and director Uri Ratner (BD: Jul 6, 2010).

Mr Franklyn said that directors Bruce Hewett and Steven Crowley were elected to the board, apparently by investors supportive of the apricitabine program and then Mr Baini, who voted to close the program, was appointed a director and chairman the next day (BD: Jul 7, 2010) followed by the appointments of Mr Soedirdja and Mr Kirkwood.

Mr Franklyn asked why Mr Baini and Mr Soedirdja did not stand for election at the July extraordinary general meeting.

Mr Franklyn said Calzada was the single largest shareholder in Avexa and did not want control of the company but did want board representation.

Mr Franklyn said the existing board had a combined holding of less than 0.1 percent of the company, while Calzada held more than 16 percent.

Mr Franklyn said Shire Pharmaceuticals of Dublin held about six percent of Avexa and Calzada had held talks with the company and had many other shareholders.

"All we want to do is what's best for shareholders and being the major shareholder, we're quite incentivized," Mr Franklyn said.

"What we need is reassurance that the independent review is independent," Mr Franklyn said.

"We're proposing a biotechnology board so our expectation is that the money would be invested in biotechnology," Mr Franklyn said.

"Biotechnology is by its nature high risk, but if you get it right, the multiples are huge," Mr Franklyn said

The meeting will be held at Computershare, 452 Johnston Street, Abbotsford, Victoria on September 28 at 10am.

Avexa was up 0.3 cents or 10.3 percent to 3.2 cents with 2.6 million shares traded.

Calzada was up 0.2 cents or 8.3 percent to 2.6 cents.

AVEXA

Avexa has appointed the Bioadvisory Group Pty Ltd for the independent review of the company's programs.

Avexa said the Bioadvisory Group was a corporate advisory firm specializing in biotechnology commercialization, with directors John Grew and his son Joshua Grew.

Mr John Grew said on the website that prior to establishing the Bioadvisory Group, he was head of business advisory services with Innovation Dynamics and holds a Masters degree in Science as well as a Masters of Business Administration.

Joshua Grew has a Bachelor of Laws and a Bachelor of Arts degree.

Avexa said the independent review would encompass existing drug development assets in its portfolio and would consider potential strategic options.

Avexa said that a plan for the company will be prepared by the board and presented to shareholders upon completion of the review.

Avexa said Mr Grew had more than 30 years experience in technology commercialization and specialized in providing advice on operational improvement, market analysis and strategic reviews for companies in the life sciences sector.

Avexa chairman Joe Baini said he expected the review would "provide the company with a clear picture of the potential value within Avexa's portfolio of assets".

The company said that in parallel with the independent review, Avexa was "exploring options for its lead asset apricitabine".

Avexa interim chief executive officer Dr Jonathan Coates said ATC "remains an important asset for Avexa and several avenues remain for the company to explore how best to extract value from the program".

The ultimate aim is to grow shareholder value," Dr Coates said. "With this goal in mind, we are in the process of arranging a meeting with regulatory authorities to discuss the potential paths forward for ATC," Dr Coates said.

The apricitabine program was closed after Avexa failed to find a partner for the drug and phase III results showed no statistically significant improvement over the existing drug 3TC (BD: May 10, 2010).

TISSUE THERAPIES

Tissue Therapies five more chronic venous ulcer patients have had "outstanding results" in its Australian human trial of Vitrogro wound healing technology.

Tissue Therapies said the Australian study had a total of 27 patients and "with only 24 days treatment with Vitrogro twice per week" the company had seen complete healing of five out of 27 patients, with an average area of ulcer healing of 41 percent with a statistical significance of $p < 0.0001$.

Tissue Therapies said the venous ulcer patients who took part in this clinical trial were "medically challenging" with an average age of 70 years, an average venous ulcer duration of 12 months and an average time during which the venous ulcers were unresponsive to compression dressings, the current state of the art treatment, prior to joining the Vitrogro trial of 10 months.

Tissue Therapies chief executive officer Dr Steven Mercer said that "compared to currently available treatments for chronic venous ulcers, these are superb results".

"This data complements the outstanding clinical outcomes achieved with Vitrogro for the extremely challenging patients in the Canadian human trial and we now have excellent clinical data from a total of 37 patients" (BD: Nov 18, 23, 2009).

Tissue Therapies was up 1.5 cents or 8.3 percent to 19.5 cents.

PHOSPHAGENICS, CALZADA

Phosphagenics has exercised its option to licence Calzada's AOD9604 for use as a cosmetic product to reduce "the appearance of cellulite and subcutaneous fat".
Calzada (formerly Metabolic) conducted a phase II trial which demonstrated that an oral version of AOD9604 had no significant weight loss effect on subjects compliant with the US Food and Drug Administration (FDA) diet and exercise regime (BD: Feb 21, 2007).
At that time Metabolic said that there did appear to be some efficacy with subjects that were not compliant with the diet and exercise regime, and more recently there have been reports that a pirated version of the drug from China reduced fat in body-builders.
Today, Calzada and Phosphagenics said that for the 12 months Phosphagenics had been developing a product based on AOD9604, a fragment of growth hormone.
The companies said the compound had been tested in extensive human clinical trials and was based on normalizing well-known hormonal and metabolic defects associated with ageing and obesity.
The companies said that collaborative research over the past year had been based on using Phosphagenics' tocopheryl phosphate mixture or TPM technology to deliver AOD9604 topically.
Phosphagenics said TPM had proven "highly effective in delivering a range of small to large molecules into and through the skin for better drug targeting" and the AOD9604 compound was well within the range of molecules delivered by the TPM technology.
Phosphagenics said its novel approach was to topically deliver the compound into the skin of problem areas directly, without having to travel through the body's stomach, digestive system or blood stream.
The commercial approach is to develop a cosmetic product to reduce the visible appearance of fat and cellulite, Phosphagenics said.
The company said that "cosmeceutical product approvals do not require large financial resources and can be launched on retail markets in a relatively short time frame".
Phosphagenics joint chief executive officer Dr Esra Ogru said that the in vitro developments "have been promising and we plan to start human testing either later this year or early in 2011".
Dr Ogru said that if work progressed as planned and subject to establishment of suitable distribution arrangements, the product would be launched by October 2011.
"Current leading commercial cosmetic creams claiming subcutaneous fat reduction are typically thin on proof of efficacy," Dr Ogru said.
"This endeavour is combining two Australian scientific innovations backed by very substantial clinical work," said Dr Ogru.
"An efficacious product should quickly command a global market," Dr Ogru said.
The two companies said they would negotiate a licence agreement based on previously agreed principles in the collaboration and option agreement (BD: Aug 13, 2009).
Phosphagenics fell 0.6 cents or 6.2 percent to 9.1 cents.

HELICON GROUP

Helicon says the non-renounceable rights issue for up to 149,514,680 shares at 1.25 cents each to raise $1,868,933 closed with acceptances for 27,139,738 shares.
Helicon said the shortfall was 122,374,942 shares with investors applying for 9,402,395 shortfall shares, raising a total of $456,777 from the rights issue.
The company said the underwriter Cunningham Peterson Sharbanne Securities would accept those applications, leaving 112,972,547 shares to be placed to raise $1,412,157.
Helicon was untraded at 1.3 cents.

BENITEC

Benitec says the US Patent and Trademark Office has allowed a further patent in the 'Control of Gene Expression' patents, part of the Graham RNAi patent family.

Benitec said it and the Commonwealth Scientific and Industrial Research Organisation received a notice of allowance from the USPTO allowing an application entitled 'Synthetic Genes and Genetic Constructs comprising the same'.

Benitec said the patent was a continuation application derived from the Graham '099 patent currently in re-examination and awaiting a decision from the USPTO following a hearing that was held on August 4, 2010.

The company said that a granted patent was typically issued by the USPTO about four to six months after allowance.

Benitec said the claims in the new patent were directed to DNA constructs and mammalian cells containing the constructs which are used in methods of silencing viral gene expression by RNA interference.

The company said the constructs had two sequences each consisting of 20 nucleotides arranged in inverted orientation to each other and separated by a stuffer fragment.

This arrangement and specific length of sequence provide some advantages for silencing of viral gene expression by DNA-delivered RNAi, Benitec said.

Certain dependent claims further define the nature of the virus that is targeted or the length of the stuffer fragment, the company said.

Benitec said it and the CSIRO were pursuing further, broader claims in several pending applications under examination at the USPTO and had the possibility of filing additional applications as the examinations progressed.

Benitec said it expected that the Graham patent family situation would continue to be clarified at the USPTO over at least the next six months.

Benitec chief executive officer Dr Peter French said his company and CSIRO were "pleased that we are seeing good progress with this family of applications in the US and consider allowance of them to be a validation of their value in the field of RNAi therapeutics".

Benitec was up 0.3 cents or 13.6 percent to 2.5 cents.

MEDIGARD

Medigard says it has raised $1,058,524 of a hoped for $4.8 million in its renounceable rights issue at 6.5 cents a share.

Medigard chief executive officer Peter Emery said it was always the company's intention to go to shareholders first to offer them the opportunity to benefit from international expansion.

"We are very pleased with the response from existing share holders, given the state of the share market during the offer," Mr Emery said.

"Medigard will now turn its attention to securing additional funds from off-market share placements," Mr Emery said.

The company said it wanted to raise up to $3.74 million in the coming three months.

Medigard fell half a cent or 7.1 percent to 6.5 cents.