Biotech Daily

Monday September 20, 2010

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: PSIVIDA UP 12%, PATRYS DOWN 5%**

*** ADVANCED SURGICAL PAD DEAL FALLS; ORTHOPAEDICS RE-FOCUS**

*** US FDA DESIGNATES PRIMA'S CVAC 'ORPHAN'**

*** QUEENSLAND APPROVES NANOSONICS TROPHON DISINFECTOR**

*** RELINQUISH, RESALE OF LEGGETT LEGACY SAVES AGENIX $900k**

*** NOVOGEN APPOINTS THREE NEW DIRECTORS**

*** BIOPROSPECT FINDS CHEAPER VERSION OF SOLAGRAN TECHNOLOGY**

*** STIRLING, UNNAMED US GOVERNMENT INSTITUTE STUDY IMMUNOXEL**

MARKET REPORT

The Australian stock market slipped 0.16 percent on Monday September 20, 2010, with the ASX200 down 7.6 points to 4631.3 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and nine were untraded. All three Big Caps fell by less than one percent.

Psivida was best, up 45 cents or 11.5 percent to $4.35 with 3,979 shares traded, followed by Prima up 0.9 cents or 9.4 percent to 10.5 cents with 23.7 million shares traded.

Novogen climbed eight percent; Antisense and Cathrx were up more than seven percent; Bionomics, Circadian and Nanosonics were up more than three percent; Biota and Chemgenex rose more than two percent; with Alchemia, Impedimed and Sirtex up more than one percent.

Patrys led the falls, down 0.4 cents or 4.9 percent to 7.8 cents with 565,066 shares traded.

Viralytics lost 3.1 percent; Genera, Living Cell, Optiscan, Pharmaxis and QRX shed more than two percent; with Acrux Phylogica and Universal Biosensors down more than one percent.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says the agreement to commercialize the peripheral access device to prevent amputations has unraveled and the company is reviewing its projects.

In an announcement entitled 'Major new revenue opportunities' Advanced Surgical said that to increase sales and profitability, it would "dramatically extend its product offerings" which would compliment its core product, the active total knee replacement.

The company said that a number of existing research and development projects including the peripheral access device (PAD) "have been returned to manufacturing only, in accordance with our exclusive manufacturing agreement, whilst the review is completed".

Advanced Surgical chief financial officer Tom Milicevic told Biotech Daily that discussions with the peripheral access device inventor Prof Rodney Lane to acquire full rights to the device had not been fruitful.

In July, Advanced Surgical said it had signed a deal with Allvascular and its principal Prof Lane to commercialize the device which Prof Lane invented (BD: Jul 6, 2010).

The device returns the patient's own blood under pressure to perfuse gangrenous legs and save them from amputation.

Advanced Surgical chief executive officer Dr Greg Roger told Biotech Daily at that time that Prof Lane owned the intellectual property, Advanced Surgical had developed and manufactured the device and his company would pay Prof Lane "a single-digit royalty" of sales of the device.

Advanced Surgical was to have taken control of all the aspects of commercialization of the peripheral access device with a view to accelerating the speed to market of the treatment and the device.

Prof Lane said at the time the company had been "key in proving up this technology and is now the ideal partner to take the device and treatment to market".

In its media release, Advanced Surgical said it would begin "a number of new and significant initiatives in growing revenue and bottom line profits" and the company's primary product, the active total knee replacement was kernel to increasing sales and profitability over the past few years.

Advanced Surgical said "new and highly profitable product offerings" would be marketed directly through the company's sales team to its growing network of orthopaedic relationships.

The company said that new implantable orthopaedic medical device offerings would leverage its existing cost base and offer new and innovative products to the market.

"With immediate effect, the company is undertaking a strategic review of its research and development projects," Advanced Surgical said.

"The particular focus of this review will be to grow the long term prospects of the company and to deliver major, longer term opportunities for shareholder return," the company said.

Advanced Surgical said director Michael Spooner had been engaged as a consultant to assist with immediate sales growth initiatives and to undertake a strategic review of the company's long-term research and development strategy.

"ASDM has a great and proven product in its artificial knee," Mr Spooner said.

"We've built an experienced, national sales team and we're ideally positioned to dramatically expand sales and profitability," Mr Spooner said.

"We have the reputation, resource and market reach," Mr Spooner said. "I'm particularly excited with the prospect of working closely with Dr Roger and the team to comprehensively review ASDM's long term R&D strategy".

The company said it intended "to establish a number of new initiatives specifically focused on market and investor relations".

Advanced Surgical fell 11 cents or 23.4 percent to 36 cents.

PRIMA BIOMED

Prima says CVac has been granted orphan medicinal product designation with the US Food and Drug Administration for use in ovarian cancer.

The company said the approval was given under the generic name 'Autologous Dendritic Cells Pulsed With Recombinant Human Fusion Protein (Mucin1- Glutathione S Transferase) Coupled To Oxidized Polymannose for treatment of ovarian cancer'.

Prima said the designation provided benefits during the commercialization process including exclusive rights to the cure or treatment for a specific condition for a period of seven years after the approval to commercially market CVac along with priority review within the FDA, waiving of FDA fees, grant eligibility and the provision of tax reductions.

Prima said the approval was "another significant milestone" following orphan drug designation in Europe (BD: Jun 3, 2010).

The company said it had recently begun its phase IIb clinical trial for CVac in the US and Australia and it plans to start phase III trials in Europe in 2011.

Prima was up 0.9 cents or 9.4 percent to 10.5 cents with 23.7 million shares traded.

NANOSONICS

Nanosonics says that Queensland Health has approved its Trophon EPR for inclusion on the Health Supply Panel to provide equipment to the State's public hospitals.

Nanosonics said the inclusion on the panel "as the only approved transducer reprocessing unit provides further endorsement of the Trophon as providing the accepted best practice in quality assurance for the high level disinfection of ultrasound transducers".

The company said the panel arrangement runs for five years from September 15, 2010, with a further option to extend for two years.

Nanosonics said that purchasing through the public panel was mandatory for all new public hospitals and replacement disinfection equipment for existing public hospitals in Queensland.

Nanosonics was up two cents or 3.1 percent to 67 cents.

AGENIX

Agenix says the relinquishing and resale of unused Queensland properties has saved the company more than $900,000.

Agenix said that in June 2006, a previous board and then chief executive officer Neil Leggett sold and leased back the company's head office properties at 1602 Beaudesert Street, which was vacant land, 7 Durbell Street and 11 Durbell Street in Acacia Ridge Queensland, an arrangement that bound the company for six years to June 30, 2012.

Agenix said the premises have been surplus to the company's requirements for a number of years.

Earlier this year Mr Leggett was gaoled for nine years for the theft of more than $4 million from Agenix (BD: Feb 18, 2010).

The company said that in 2008, it surrendered 11 Durbell Street providing a total saving of more than $700,000 and the release of an associated bank guarantee of $94,600 and in 2009 the landlord sold 1602 Beaudesert Street saving more than $50,000.

On September 17, 2010, Australian Investment Trust said it had an unconditional contract of sale for 7 Durbell Street, which would save about $170,000.

The combined savings achieved by the board with regard to the Leggett legacy was more than $900,000, Agenix said.

Agenix was up 0.7 cents or 20.6 percent to 4.1 cents with 2.1 million shares traded.

NOVOGEN

Novogen has appointed three directors, with backgrounds in investment and corporate finance, one based in Australia and two in the US.

Novogen chairman Philip Johnston said the appointments were “in line with a commitment to broaden contributions at board level to provide fresh perspectives on developing the company’s direction”.

Earlier this month Novogen agreed to sell its intellectual property in the isoflavone cancer technology to its 71.3 percent US subsidiary Marshall Edwards (BD: Sep 9, 2010).

“We feel our new board appointments will bring together a variety of commercial expertise that will have a positive influence on the evolution of Novogen’s strategy,” Mr Johnston said.

Novogen said the appointments were Ross Youngman, Peter White and major shareholder Josiah T Austin.

Novogen said Mr Youngman was the chief executive officer of Five Oceans Asset Management and had more than 25 years experience in the finance industry covering stockbroking, financial planning and asset management.

Mr Youngman has a Masters of Business administration from Columbia Business School, New York and a Bachelor of Commerce from the University of Tasmania.

Novogen said the US-based Mr White was a corporate finance professional with more than 30 years experience and has broad industry experience including technology, media and communications, business services and energy distribution.

The company said the US-based Mr Austin was the largest shareholder in Novogen and was the managing member of El Coronado Holdings, a privately owned investment holding company, which invests in public and private companies.

Novogen said the appointments were effective from September 20, 2010, with the directors standing for re-election at the annual general meeting in October 2010.

Novogen was up one cent or eight percent to 13.5 cents.

BIOPROSPECT, SOLAGRAN

Bioprospect says it has signed a terms sheet with an alternative supplier of conifer green needle complex, marketed by Solagran as Bioeffective A.

Bioprospect and former director Leo Khouri are involved in two separate legal disputes with Solagran (BD: Sep 17, 2010).

Bioprospect said the conifer green needle complex (CGNC) from the alternative source had been tested and verified by a laboratory in Australia and found to be chemically comparable to the product previously supplied by Solagran.

Bioprospect’s managing director Charles Pellegrino, a former Solagran employee, said the company was pleased with the new agreement, which offered certainty of supply along with superior pricing for the rollout of the Company’s planned horse treatments.

“Bioprospect has been seeking to identify alternative supply sources of CGNC, and after extensive market research is very pleased to have secured this agreement,” Mr Pellegrino said.

Bioprospect said the new supplier of conifer green needle complex was able to provide other products previously supplied by Solagran under the 2007 development agreement, as well as certain highly refined pine needle extract products not previously included in the agreement.

Bioprospect has been investigating the compound’s efficacy in horse digestive illnesses.

Bioprospect was up 0.2 cents or 18.2 percent to 1.3 cents with 2.7 million shares traded.

Solagran fell half a cent or 3.3 percent to 14.5 cents.

STIRLING PRODUCTS

Stirling says pre-clinical studies of Immunoxel will be conducted with an unnamed “major US Government research institute”.

Stirling says Immunoxel is a “botanical immunomodulator” and refers to the over-the-counter cure-all compound as its own.

Stirling has previously told Biotech Daily it does not hold the intellectual property to Immunoxel which it distributes for the Kiev-based owners, Ekomed (BD: Apr 16, 2009).

Stirling has said that a 12-patient trial showed Immunoxel had “100 percent efficacy in treating drug-resistant tuberculosis patients” and the company has also made claims that it was also good for AIDS, H1N1 ‘swine’ influenza and kidney health.

Today, the company said the pre-clinical study would be “a significant further investigation of an initial study that the Institute conducted independently”.

The company said it was the same unnamed major US institute that had conducted ”in vitro and in vivo laboratory studies commenced in 2009 … [which] have resulted in a positive determination of certain mechanisms of action of Immunoxel and opened up potentially new opportunities for its clinical use” (BD: Jul 5, 2010).

Today the company said that several published clinical studies showed that Immunoxel decreased the elevated liver enzymes and increases CD4 T-cell counts in HIV infected patients co-infected with TB or having viral hepatitis.

These clinical studies have indicated that Immunoxel can decrease viral load as well as help to achieve better clinical response when combined with standard antiretroviral and anti-tuberculosis therapy, the company said.

Stirling said that “variable degrees of success have been reported with Immunoxel, likely due to the lack of standardization of the dose, types of combined treatments, timing of initiation, and the duration of therapy”.

“A large, controlled, randomized, multicentre trial has not been performed to formally evaluate the efficacy of this treatment,” the company said.

Stirling said the institute proposed collaborative studies to investigate: the mechanism of the action of Immunoxel in-vitro on simian immunodeficiency virus-infected and uninfected cells; immunomodulatory activity of Immunoxel during simian immunodeficiency virus infection and the effect of Immunoxel on viral load, CD4 T-cell count and immune activation in chronically simian immunodeficiency virus-infected antiretroviral therapy naïve animals; and if warranted, the efficacy of Immunoxel in combination with antiretroviral therapy to improve immune reconstitution during simian immunodeficiency virus infection will then be evaluated.

Stirling managing director, Peter Boonen said the “proposed collaborative study with the US government agency [is] a significant step forward for Stirling to be able to validate and better understand the findings of all the early trials that have demonstrated the extraordinary properties of Immunoxel”.

Stirling fell 0.1 cents or 10 percent to 0.9 cents with 5.3 million shares traded.