

Biotech Daily

Monday September 13, 2010

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: ANTISENSE UP 21%, BIOTA UP 17% - PHOSPHAGENICS, PHYLOGICA DOWN 7%
- * BIOTA, DAIICHI SANKYO 'INAVIR' APPROVED FOR JAPAN'S 'FLU SEASON
- * BIOGUIDE BRIEF: BIOTA, DAIICHI & A NEW GENERATION 'FLU DRUG
- * BIOGUIDE BRIEF: BROADVECTOR'S 'VERY REASONABLE' IPO
- * COURT ALLOWS US EMBRYONIC STEM CELL RESEARCH FUNDING
- * SELECT LICENCES TECHNOLOGY TO ARTES, BURNET; RAISES \$115k
- * CSL VOTES ON \$16m 'PERFORMANCE RIGHTS', DIRECTORS' PAY
- * MIKE HIRSHORN, COLIN ADAMS REPLACE CATHRX'S ANDREW DENVER
- * ADVANCED SURGICAL APPOINTS MICHAEL SPOONER DIRECTOR
- * NEW PAINT WINS 2010 VICTORIA PRIZE, BIOTECH TAKES 3 FELLOWSHIPS

* VICTORIA TO PROVIDE \$400,000 CANCER RESEARCH FELLOWSHIP

MARKET REPORT

The Australian stock market climbed 1.2 percent on Monday September 13, 2010, with the ASX200 up 54.6 points to 4614.9 points. Fourteen of the Biotech Daily Top 40 stocks were up, seven fell, 10 traded unchanged and nine were untraded.

Antisense was best, up 0.3 cents or 21.4 percent to 1.7 cents with 1.7 million shares traded, followed by Biota up 17.4 percent to \$1.045 with 5.4 million shares traded.

Prana and Sunshine Heart both climbed 15.4 percent; Chemgenex was up six percent; Benitec was up 4.6 percent; Nanosonics was up 3.3 percent; Tissue Therapies rose 2.2 percent; with Acrux, Cochlear, Pharmaxis, Sirtex and Universal Biosensors up one percent or more.

Phosphagenics and Phylogica both fell 7.14 percent to 9.1 cents and 5.6 cents respectively on modest volumes. Optiscan lost seven percent to four cents; Bionomics and Viralytics were down more than three percent; with Alchemia and Patrys down more than one percent.

BIOTA

Biota's second influenza drug laninamivir octanoate has been approved for sale in Japan, is expected to be on the shelves next week and could earn up to \$3 million in its first year. Biota said its Japanese partner Daiichi Sankyo would market laninamivir octanoate, previously known as CS-8958, under the name Inavir.

Biota chief executive officer Peter Cook told Biotech Daily that Daichi Sankyo had the capacity to manufacture up to three million courses in the first year and would "look to increase the capacity to 10 million courses".

Mr Cook said that courses of his company's Relenza and its competitor Tamiflu typically sold for about \$US20 a course and Biota would receive "a single digit royalty" from Daiichi Sankyo. Using a five percent royalty figure, Biota would be entitled to about \$US1 (\$A1.075) per course.

Mr Cook said the patents on the drug ran until 2017 and 2021, but the inhaler was protected until 2027 and laninamivir needed to be inhaled as it only became activated in lung tissue.

Mr Cook said that although laninamivir was Biota's second influenza drug to go to market the company previously had incomes of up to \$1 million a year from two diagnostic tests. Mr Cook said that with the Northern Hemisphere winter approaching, Daiichi Sankyo was expected to have Inavir "on the shelves within the next week or two".

He said the regulatory and marketing approval was for its use as a therapy meaning that patients with influenza symptoms would be prescribed the drug which was expected to reduce symptoms in about 24 hours.

Biota said neuraminidase inhibitors were antiviral agents effective against influenza, providing both for the treatment of an established influenza infection or for the prevention of influenza prior to exposure.

Biota said the opportunity to medicate patients on a one dose basis and offered several potential benefits, including greater patient compliance and a reduced cost of storage and transport per course, where the product was intended to be stockpiled.

Biota said it would receive a royalty on all sales in Japan, could qualify for certain milestone payments on sales and that with Daiichi Sankyo it was in ongoing discussions "with a number of suitable companies for the licencing of laninamivir in the rest of world". Biota climbed 15.5 cents or 17.4 percent to \$1.045 with 5.4 million shares traded.

MARC SINATRA'S BIOGUIDE BRIEF: BIOTA

Biota shareholders got some good news today when Biota announced that their Japanese partner, Daiichi Sankyo, had successfully gained regulatory approval to market their next generation 'flu drug, Inavir in Japan. Biota will receive royalties on Inavir's sales.

Both companies are now looking to licence the drug in the rest of the world.

Anti-flu drugs have historically sold well in Japan, but not in the rest of the world, except for stockpiling for pandemic 'flu prevention.

It will be interesting to see what sort of response Biota and Daiichi Sankyo get while shopping Inavir around.

The general lesson from the swine flu outbreak seems to be that no matter what we do, we won't be able to stop or control similar future outbreaks.

Consequently, interest is now focused on developing treatments for those who get lifethreateningly sick from the 'flu, not the general public.

Still, some company may be willing to take a punt that stockpiling will continue or that Inavir will work well enough to improve its take up in the US and EU to make it a successful product. Only time will tell.

MARC SINATRA'S BIOGUIDE BRIEF: BROADVECTOR

Broadvector is a Melbourne-based biotechnology company focused on conditions of the aging. Their two internal projects use local administration of an enzyme in the form of a gene, via a viral vector into the target tissue.

This is followed by the systemic delivery of a pro-drug, which is turned into the active form of the drug via the enzyme enabling tissue-specific targeting of the drug at comparably high concentrations. The technology is termed "gene directed enzyme pro-drug therapy".

Offer Details

Price: \$0.20; Funds Sought: \$8.5 million; Market Cap at Offer Price: \$24.5 million.

Directors & Management

Chairman Dr Wayne Millen; managing director & chief executive officer Dr Andrew Bray; non-executive directors Dr Roland Toder, Iain Kirkwood; chief scientific officer Dr Gerald Both; chief financial officer Malcolm Booth; company secretary Lee Mitchell,.

Broadvector has a solid board and management. One or two significant additions to the team will be warranted as the company progresses its products.

Products in Development

1. Aseptic loosening of prosthetic implants: Aimed at removing spongy tissue that can develop around prosthetic implants, causing them to become loose. An enzyme and prodrug combination destroys this tissue. Bone cement is then injected into the space once occupied by the tissue, effectively re-anchoring the prostheses. A phase IIa trial is scheduled to begin next year

2. Early-stage prostate cancer: The enzyme-containing vector is injected directly into the cancer. A regulatory element in the vector means that the enzyme is only produced in prostate cancer cells. The pro-drug is given systemically where it travels to the cancer, is turned into the active drug and attacks the prostate cancer. A phase I trial is expected to commence soon.

3. Vaccine platform: This product is based on the enzyme containing vector used in the prostate cancer product. Used as a vaccine, the vector would be engineered to encode antigens specific to the pathogen the vaccine is aiming to immunize against. Broadvector considers this project an out-licencing opportunity.

Comment

Broadvector's products are well protected by the patents and licenses they hold and the technology is well supported in the scientific literature. The aseptic loosening product may find orphan niches, although I am not 100 percent sure it will meet the criteria that the problem be life-threatening.

The amount of capital being sought, the prospective market capitalization and plans for deployment of the capital raised, all fall into the "very reasonable" category.

Broadvector appears to have recognized that many past offerings have left little on the table for new investors; so this may be the first successful biotech IPO for a long time.

US APPEALS COURT, STEM CELL RESEARCH

The US Court of Appeals in the District of Columbia has granted a stay on an earlier decision to prevent Federal funding of human embryonic stem cell research.

The September 9, 2010 decision by the appeal court granted "the emergency motion for stay pending appeal and for immediate administrative stay [and] ... ordered that the district court's August 23, 2010 order be stayed pending further order of the court". The Court said the purpose of the administrative stay was to give the court sufficient opportunity to consider the merits of the emergency motion for stay and should not be construed in any way as a ruling on the merits of that motion.

In the District Court of Washington DC on August 23, 2010, Judge Royce Lamberth granted a preliminary injunction in favor of the plaintiffs in the case of Dr James Sherley et al versus defendants Kathleen Sebelius et al, preventing the use of Federal funds for human embryonic stem cell research (BD: Aug 26, 2010).

Ms Sebelius is named in the case in her official capacity as Secretary of the Department of Health and Human Services.

Dr Sherley is described on the Massachusetts Institute of Technology Pro-Life website as a senior scientist at the Boston Biomedical Research Institute working on adult stem cells.

SELECT VACCINES

Select Vaccines says the Germany-based Artes Biotechnology GmbH will acquire its Anavax virus-like-particle technology and the Burnet Institute will acquire rights to the remaining technologies.

Select Vaccines had hoped to acquire "an attractive opportunity in the medical device sector" (BD: Aug 12, 2010) but told the ASX on September 6, 2010 that it had "mot been able to reach agreement on the potential acquisition".

Today Select Vaccines said Artes would offer the Anavax technology to clients primarily in conjunction with its proprietary yeast-based expression systems and Select would receive an upfront payment and double-digit royalties on sales revenues obtained by Artes. The company said Artes was a profitable, private company based in Langenfeld, 20km north of Köln (Cologne) focused on production cell line and process development for pharmaceutical and chemical industry.

Select said Artes held exclusive rights to the patented yeast Hansenula polymorpha protein expression system, approved globally for the production of hepatitis B vaccines. The company said the Anavax technology was developed by scientists at Melbourne's Burnet Institute and the Burnet Institute would receive a royalty-free, non-exclusive licence from Artes to use the Anavax technology to develop vaccines against malaria and HIV. Select Vaccines said it had a binding agreement for the Burnet Institute to acquire the rights to commercialize the company's portfolio of diagnostic and antiviral therapy technologies for indications such as hepatitis C and picornaviruses.

The company said the technologies were invented by Burnet Institute scientists and had been developed by Select Vaccines in collaboration with the Burnet Institute and the Howard Florey Institute in Melbourne.

Select Vaccines said it would receive a share of the future proceeds of commercialization earned by the Burnet Institute from the development of these technologies.

Select Vaccines director Dr Ian Cooke told Biotech Daily the deals effectively left the company as "a shell ... looking for other business opportunities".

Separately, Select Vaccines said it raised \$114,908 through the placement of 38,302,567 shares to professional and sophisticated investors at 0.3 cents a share.

Select Vaccines last traded at 0.4 cents.

<u>CSL</u>

CSL's annual general meeting will vote on the grant of up to 500,000 "performance rights" to chief executive officer Dr Brian McNamee and chief operating officer Peter Turner. CSL's performance rights are granted free of charge and convert into shares at no cost. The company said the 500,000 performance rights were to be granted over a three year period and were dependent on achieving specified targets.

At today's share price of \$32.20 they would be worth \$16.1 million.

CSL shareholders will also be asked to increase directors' remuneration from \$2,000,000 to \$2,500,000 and vote on the re-election of directors Peter Turner, John Akehurst, David Anstice and Ian Renard.

The meeting will be held at the National Tennis Centre, Melbourne Park, Batman Avenue, Melbourne on October 13, 2010 at 10am.

CSL fell 30 cents or 0.9 percent to \$32.20 with 2.6 million shares traded.

CATHRX

Cathrx has appointed Dr Michael Hirshorn and Dr Colin Adam as directors to replace Andrew Denver who has retired to focus on Universal Biosensors (BD: Sep 9, 2010). Cathrx said Dr Hirshorn had qualifications in medicine, business and finance with more than 30 years experience in "founding, building, managing and investing in international technology companies".

Dr Hirshorn has 10 years experience in venture capital and private equity and is a founder and director of Four Hats Capital and a director of Biotron, TGR and Dynamic Hearing and a member of Australian Private Equity and Venture Capital Association (AVCAL). Cathrx said Dr Hirshorn "played a major role in the commercial development of Cochlear, including a period as chief executive officer and was a founding director of Resmed". Cathrx said Dr Adam had management experience in the commercialization of technologies and research and development in the life sciences industry and worked as program manager in advanced alloy development for Pratt & Whitney Aircraft. Cathrx said that Dr Adam was deputy chief executive of the Commonwealth Scientific and Industrial Research Organisation responsible for all commercial activity. Cathrx said Dr Adam was a director and founder of PFM Cornerstone. Cathrx was untraded at 18 cents.

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ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical Design and Manufacture has appointed Michael Spooner as a director. Advanced Surgical said Mr Spooner was a respected business leader with an extensive network of relationships with investment firms and business communities.

The company said Mr Spooner consulted to listed and unlisted companies in Australia and the US and was a non-executive director of Mesoblast, chairman of artificial heart company Bivacor and a non-executive director of vaccine developer Hawaii Biotech. Advanced Surgical said Mr Spooner was a director of Peplin until the company was sold in 2009 for more than \$300 million.

The company said Mr Spooner was the executive chairman of Hunter Immunology from 2007 to 2008.

Advanced Surgical said he had served as chairman of Mesoblast and managing director and chief executive officer of Ventracor until 2003 and was a principal partner and director of consulting services with Pricewaterhousecoopers Hong Kong.

Advanced Surgical was untraded at 47 cents.

VICTORIA PRIZE, FELLOWSHIPS

Biotechnology researchers have won three of six \$18,000 Victoria Fellowships with the \$50,000 Victoria prize going to Prof Wojciech Gutowski for reducing paint waste. Announcing the prizes, Victorian Innovation Minister Gavin Jennings said Prof Gutowski had solved difficult technology problems by inventing "the world's first zero waste technology for the plastics and car industry".

Dr Gutowski's work addressed the waste problem faced by the car industry which uses 9.68 million litres of paints a year in manufacturing, with all solvents used in the process becoming airborne and 2.5 million litres of solids going to landfill.

"Dr Gutowski has developed a coating technology that uses solvent-less powder resins that enables powder coatings, paints and inks to adhere to plastics," Mr Jennings said. Dr Gutowski is the Commonwealth Scientific and Industrial Research Organisation's chief research scientist of the Materials Science and Engineering Division and the division will receive the \$100,000 Anne & Eric Smorgon memorial award.

The Victoria Fellowship winners receive an \$18,000 travel grant for a short-term study mission, to receive specialist training, or to develop commercial ideas.

Dr Michelle Ma won a Fellowship to test molecular compounds developed for use in detecting early stage cancer.

Denise Miles's Fellowship is to continue investigating the cause of testis cancer, which has doubled worldwide since 1982.

Dr Sant-Rayn Pasricha has won a Victoria Fellowship to work with the World Health Organisation on global policy development for iron deficiency anaemia which affects one billion people.

Suzanne Ftouni's Fellowship is for the detection and prevention of drowsiness in drivers. Dr Matthew Hill will research materials to store carbon dioxide.

Dr Baohua Jia is researching develop solar cells that efficiently convert solar energy into electricity.

VICTORIAN GOVERNMENT

Victoria's Health Minister Daniel Andrews said the State Government would provide a \$400,000 fellowship for skin cancer research to honor campaigner Clare Oliver.

"Two in three people are diagnosed with skin cancer before the age of 70, yet it is one of the most preventable cancers," Mr Andrews said in a media release.

The media release said Clare Oliver was 26 years old when she died from an aggressive melanoma after using solariums frequently.

"We believe the new Clare Oliver Memorial Fellowship is a fitting tribute to a woman who left a lasting legacy," Mr Andrews said.

The media release said the fellowship would be funded through the Victorian Cancer Agency, established to facilitate cancer research in Victoria.

A media officer for the Victorian Government said details for applications for the fellowship were expected to be released in the next few weeks and the two-year fellowship would be announced in early 2011.

Biotech Daily can be contacted at: PO Box 5000, Carlton, Victoria, Australia, 3053 email: <u>editor@biotechdaily.com.au</u> <u>www.biotechdaily.com.au</u>