Biotech Daily

Friday January 22, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: COMPUMEDICS UP 14%; PATRYS DOWN 12%**

*** FDA APPROVES COMPUMEDICS' HD-PSG GRAEL SLEEP DIAGNOSTIC**

*** ASSET REALISATION (STEM CELL SCIENCES) CHEQUE PAIN**

*** TGA APPROVES GENERA'S PAPTYPE HPV TEST**

*** ELLEX LAUNCHES 'GENTLER' OPHTHALMIC YELLOW LASER IN TOKYO**

*** HEALTHLINX EXPANDS LIVERPOOL COLLABORATION**

*** NANOSONICS PLAN RAISES FURTHER $3.6m**

*** NOVOGEN TELLS ASX RESULTS HOPES MAY HAVE PUSHED PRICE**

*** STIRLING RAISES $2m**

*** ASIA UNION REDUCES 1.5% IN ANTEO**

*** PRIMA APPOINTS ZURICH'S MATTHEW LEHMAN COO**

MARKET REPORT

The Australian stock market fell 1.6 percent on Friday January 22, 2010 with the S&P ASX 200 down 76.6 points to 4750.6 points. Six of the Biotech Daily Top 40 stocks were up, 25 fell, four traded unchanged and five were untraded. All three Big Caps were up.

Compumedics was best, up 2.5 cents or 13.51 percent to 21 cents with 1.5 million shares traded, followed by Benitec up five percent to 4.2 cents. Genera climbed as much as 13.6 percent to 87.5 cents before closing up 3.9 percent at 80 cents. Living Cell and Viralytics rose more than two percent; with Antisense and Cochlear up more than one percent.

Patrys led the falls, down 1.5 cents or 11.5 percent to 11.5 cents with 42,764 shares traded, followed by Optiscan down 10 percent to 7.2 cents.

Sirtex lost 9.2 percent; Sunshine Heart fell 7.7 percent; Mesoblast and Prana were down more than six percent; Prima was down 5.6 percent; Genetic Technologies, Phylogica and Tissue Therapies fell more than four percent; Alchemia, Chemgenex, Clinuvel, Nanosonics and Phosphagenics were down more than three percent; Avexa, QRX and Starpharma shed more than two percent; with Acrux, Cathrx, Cellestis and Pharmaxis down more than one percent.

COMPUMEDICS

Compumedics has received US Food and Drug Administration market clearance for its Grael HD-PSG sleep diagnostic amplifier system.

The company said its Grael HD PSG/EEG (polysomnography/electroencelaphography) system was the world's first high definition (HD) PSG/EEG amplifier (BD: June 3, 2009).

Compumedics said the FDA clearance allowed the introduction and sale of its most technologically advanced amplifier system into the world's largest medical devices market.

The company said Grael was "a specifications benchmark" had a 24-bit A/D converter (including sampling and storage); 77 channels; true DC-coupling; integrated light, snore, body position and respiratory inductive plethysmography sensors; and a single IP cable connection; all integrated into a compact case with a unique and convenient mounting cradle.

Compumedics chief executive officer David Burton said that with Grael, "Compumedics further enhances the sleep-diagnostics industry's broadest product range, covering all regulatory types I-IV of sleep product classifications in both wireless and wired configurations".

"As a premier product, Grael offers the features and flexibility to meet even the most demanding research applications while providing unmatched and exceptional signal quality in any clinical lab environment," Mr Burton said.

Compumedics' vice-president of US sales Phillip Moses said that being able to market the Grael HD-PSG Sleep Diagnostic Amplifier System would "significantly contribute to US revenue growth for the balance of the year and beyond".

Compumedics was up 2.5 cents or 13.5 percent to 21 cents with 1.5 million shares traded.

STEM CELL SCIENCES ASSET REALISATION CO

Four months after departing the ASX, the Asset Realisation Co, formerly Stem Cell Sciences, is still causing pain for investors (BD: Sep 16, 2009).

Liquidation distribution cheques dispatched by Computershare Investor Services Plc of the UK are being refused by Australian banks because they are denominated in Australian dollars on Royal Bank of Scotland bank cheques with no Australian reference bank.

When the Melbourne-based but London Alternative Investment Market-listed Stem Cell Sciences had its Australian initial public offer in April 2007, Biotech Daily editor David Langsam bought 1869 shares for $2000 and topped-up to 2,500 shares on-market for a further $651.49 (BD: Apr 16, 2007).

The Computershare Plc cheque for the 2,500 share holding amounted to $150.04.

The Flemington Community Branch of the Bendigo Bank was unable to accept the cheque without an Australian reference bank, saying the cheque would have to be sent back to the UK and both banks would add charges of more than $120.

The Carlton Commonwealth Bank said it did process these sorts of cheques but not for amounts below $300.

Biotech Daily understands that about 230 Australian investors are likely to have received cheques for less than $300 that are effectively worthless, unless Computershare can establish a remedy.

A Computershare Plc customer service representative told Biotech Daily last night that the company regularly dispatches this sort of foreign-denominated cheque.

Bendigo Bank and Commonwealth Bank staff were unable to resolve the issue and the Royal Bank of Scotland does not maintain any retail or personal banking facilities in Australia.

Computershare staff in Australia and the UK are following-up Biotech Daily's enquiries.

GENERA BIOSYSTEMS

Genera says the Australian Therapeutic Goods Administration has approved its Paptype human papillomavirus (HPV) test kit for the Australian Register of Therapeutic Goods.

Genera said it was permitted to supply Paptype to Australian customers, subject to the terms of the TGA licence, which chief executive officer Dr Allen Bollands told Biotech Daily related to good manufacturing practice, documentation and other regulatory matters.

Dr Bollands said his company already supplied a version of the test to Healthscope and the TGA approval related to a version that included a component with a "small amount of human DNA acting as a quality control".

Dr Bollands said the addition of the DNA component was a technical and regulatory difference.

Genera chairman Fernando Careri said the approval was "a very significant and tremendously satisfying achievement for everyone associated with our company".

"To have taken a technological concept and turned it into a product which will contribute to the health and well being of Australian women is something of which we should be extremely proud," Mr Careri said.

"Genera is already engaged in broad commercial discussions and will now also engage in discussions with women's health specialists around the country to investigate how Paptype might be incorporated into national cervical cancer screening guidelines," Mr Careri said.

Chair of the company's scientific advisory board and professor at Melbourne's Royal Women's Hospital Prof Suzanne Garland said the announcement was timely, given new data demonstrating the value of HPV testing in cervical cancer screening.

"Particularly in women over 35 years of age, it's now very clear that HPV testing detects high-grade pre-cancerous lesions more effectively than Pap smears," Prof Garland said.

"In addition, it's also likely that cervical screening methods based around HPV testing will allow longer periods between tests", Prof Garland said.

Genera said Paptype was already on sale through a pre-existing agreement with Healthscope and more widespread availability would follow "from a successful conclusion to partnering discussions.

"The notification from the TGA, whilst being extremely good news, has come somewhat earlier than we were anticipating," Dr Bollands said.

"We are focused on finalizing a commercial relationship that maximizes the value of the Paptype to our company, and naturally, we want to ensure that any commercial activities, both in Australia and elsewhere, are aligned with our eventual partner's needs," Dr Bollands said.

Genera said it had appointed has appointed the financial advisory and asset management firm Lazard to advise on its transaction alternatives.

"Appointing Lazard to support the board in these critical matters has given our company access to a first-rate, global organization with an outstanding track record in delivering creative solutions to maximize shareholder value," Mr Careri said.

Genera said it hoped to announce a partnership agreement by April 2010.

The company said it had completed the Paptype repeatability and reproducibility study with its strategic partner Sonic Healthcare.

Sonic has an option to buy the Paptype tests for use within their own company.

Genera said the study was designed to demonstrate that Paptype performed equivalently between different operators, different laboratories and at different times.

Genera said the study demonstrated that the product "comfortably exceeded its targeted study endpoints of 95 percent repeatability and reproducibility".

Genera closed up three cents or 3.9 percent at 80 cents.

ELLEX MEDICAL LASERS

Ellex says it launched its yellow laser photocoagulator, Integre Yellow, today at the meeting of the Japanese Society of Ophthalmic Surgeonsin Tokyo.

Ellex said Integre Yellow was the first system to offer high-power 561nanometre (nm) yellow in a fully-integrated design.

The company said the yellow wavelength was considered “a more gentle and patient-friendly option than other laser wavelengths used in ophthalmology to treat sight-threatening eye diseases, such as diabetic retinopathy”.

Ellex chief executive officer Simon Luscombe said that “compared to traditional 514/532nm green wavelengths, 561nm yellow creates a more gentle retinal burn and results in low scotoma or blind spot formation”.

“Most importantly, treatment can be performed at lower energy settings, thereby improving patient comfort,” Mr Luscombe said.

Ellex said the yellow wavelength was first introduced in ophthalmology in argon-pumped dye laser systems which were bulky, required high levels of energy and were expensive to maintain and service.

The company said that modern laser systems had the benefits of solid-state laser technology, but still required the use of external fibers and connectors, which degraded overall system performance.

In contrast, the fully integrated design of the Integre Yellow provides improved working distance and ergonomics in order to optimize practice efficiency, and completely eliminates the need for external adapters or fibers, “the key driver for the worldwide success of the Ellex Integre family of photocoagulators” the company said.

“With the introduction of the Integre Yellow we are confident of satisfying the need for an efficient, reliable and ergonomic yellow laser system in the Japanese market and of cementing Ellex’s position as the leading ophthalmic technology provider in Japan,” Mr Luscombe said.

Ellex will launch the laser in the US, Europe and Australia later in 2010.

Ellex was unchanged at 16 cents.

HEALTHLINX

Healthlinx says it has expanded its collaboration with the University of Liverpool to assess the utility of its proprietary biomarkers for other indications.

Healthlinx said the University of Liverpool would provide it with blood samples for specific diseases to be tested against its biomarkers to determine the potential for future pipelines.

Healthlinx managing director Nick Gatsios said the expanded collaboration with Liverpool provided the opportunity to identify additional diseases to be targeted for new diagnostics similar to its Ovplex ovarian cancer diagnostic.

Healthlinx said that under the existing agreement with the University of Liverpool, it licenced-in biomarkers that appeared to have utility in the development of the Ovplex.

The company said the University of Liverpool and the Liverpool Hospital were also trial partners for a biomarker trial that would screen 1,150 samples collected in Australia, Singapore and the UK.

Healthlinx said the multi-centre, multi-site study was designed to determine the diagnostic performance of the Ovplex panel and validate additional biomarkers for ovarian cancer.

Healthlinx said Ovplex had an efficiency of 92 percent for early stage ovarian cancer,

The company said Ovplex was available in Australia and would be launched in the UK and Ireland in February 2010 with other countries following over the next 12 months.

Healthlinx fell 0.1 cents or 1.2 percent to 8.2 cents.

NANOSONICS

Nanosonics' share plan has raised a further $3,607,176.65 through the issue of 6,558,503 shares at 55 cents each.
Last month Nanosonics raised $12 million in a placement in (BD: Dec 7, 2009).
Nanosonics fell two cents or three percent to 64 cents.

NOVOGEN

Novogen has told the ASX that expectations of trial results, not due until the April-June quarter of 2010, may have led to a share price increase.
Novogen said its US sister company Marshall Edwards was expected to unveil the results of a phase III trial of phenoxodiol in combination with carboplatin in women with advanced ovarian cancer, resistant or refractory to platinum-based drugs by July 2010.
The ASX said the company's share price rose from 63 cents on January 20, 2010 to 71.5 cents, a 13.5 percent increase, on January 21, 2010 with an increase in trading volume.
Novogen told the ASX that its operating loss for the six months year to December 31, 2010 would see an improvement of about 30 percent compared to the previous corresponding period.
Separately, Novogen said
Novogen quoted Marshall Edwards saying the analysis of tumor response data from the trial would be performed in the April-June quarter of 2010, after the database was locked and the data were subjected to independent review by the tumor response evaluation committee.
Novogen said the initial data collection had been complete and Marshall Edwards was working through routine data queries that remain to be addressed by some trial sites prior to database lock.
Consideration had been given to undertake a preliminary analysis of the primary endpoint of progression-free survival based on investigator assessments of radiological scans by site personnel prior to final data base lock.
After consideration of regulatory advice, it was decided to preserve the integrity of the study for regulatory review and not perform any endpoint analysis prior to database lock, Marshall Edwards said.
The trial protocol specifies that tumor response analysis be performed on independent tumor response evaluation committee assessment of radiological evidence, and this cannot be performed until after database was locked.
Marshall Edwards said it decided to avoid potentially compromising the data from the trial by completing an analysis of the primary efficacy endpoint of progression free survival based on assessments of radiological scans by site personnel, which have not been verified by the independent tumor response evaluation committee.
Further, there is a risk that site interpretation of radiological scans may be at variance with independent assessments, and could result in conflicting outcomes.
Novogen and Marshall Edwards group director of research Prof Alan Husband said that performing an analysis of progression free survival based on assessments of radiological scans by site personnel, that have not been verified by the independent tumor response evaluation committee could potentially compromise the integrity of the study data.
Novogen said it expected the results by July 2010.
Novogen closed up 0.5 cents or 0.72 percent at 68.5 cents.

STIRLING PRODUCTS

Stirling has raised $2,000,000 through the placement of 166,666,750 shares at 1.2 cents a share.
Stirling said the shares come with a total of 83,333,375 attaching options exercisable at 0.8 cents each up to December 31, 2015.
The company said it would issue 35.8 million shares at 1.5 cents a share in consideration of full or part fees to five consultants with 18 million shares issued to "Bob Pritchard's interests who have elected to take his fees of $270,000 for 18 months of services to be provided to the company in shares". Half of all these shares will be subject to a nine month escrow period.
Stirling said 15 of the company's executives, consultants and employees would be granted a total of 31.4 million performance rights at no cost pending performance milestones and subject to shareholder approval.
Stirling fell 0.1 cents or 6.7 percent to 1.4 cents with 28.6 million shares traded.

ANTEO DIAGNOSTICS

Asia Union has reduced its substantial holding in Anteo from 35,844,350 shares (8.56%) to 29,500,000 shares (7.05%) on January 18 and 22, 2010.
The sale of 6,344,350 shares reduced Asia Union to 7.38 percent in Anteo with Asia Union further diluted to 7.05 percent.
Anteo was up 0.1 cents or 1.7 percent to six cents with 43.9 million shares traded.

PRIMA BIOMED

Prima has appointed Matthew Lehman as the chief operating officer.
Prima said Mr Lehman had "extensive experience in clinical research, regulatory and drug development strategy, as well as operations and sourcing".
The company said Mr Lehman would be based in Zurich and would play a leading role in its research and development programs, operational oversight and manage the European clinical trials of its CVac ovarian cancer vaccine.
Prima said Mr Lehman was previously the chief operating officer for the contract research organization SPRI Clinical Trials and director of operations for the Social Psychiatry Research Institute, a CNS drug research network in New York.
In the past nine years, Mr Lehman has served in various roles for more than 100 clinical research programs, Prima said.
Mr Lehman has a Master of Science from New York's Columbia University and a Bachelor of Arts from the University of Louisville, Kentucky.
Prima fell one cent or 5.6 percent to 17 cents with 3.3 million shares traded.