Biotech Daily

Friday October 23, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: IMPEDIMED UP 13%; CATHRX DOWN 13%**

*** PHARMAXIS PHASE III BRONCHITOL TRIAL START; UNIFIES SUBMISSION**

*** LYMPHOEDEMA JOURNAL REVIEW BACKS IMPEDIMED TEST**

*** GENETIC TECHNOLOGIES DISTRIBUTES ROSETTA MICRO-RNA TESTS**

*** ELLEX LAUNCHES NEXT GENERATION EYE CUBED DIAGNOSTIC**

*** HEALTHLINX NAMES TRIAL COLLABORATORS**

*** SOLAGRAN CUTS ROPREN SALES PRICE**

*** STIRLING COMPLETES SHEIMAN INHALER DEAL**

*** UNILIFE CEO ALAN SHORTALL BUYS $500,000 SHARES ON MARKET**

MARKET REPORT

The Australian stock market climbed 0.97 percent on Friday October 23, 2009 with the S&P ASX 200 up 46.6 points to 4859.4 points.

Nine of the Biotech Daily Top 40 stocks were up, 16 fell, nine traded unchanged and six were untraded.

Impedimed was best, up 9 cents or 13 percent to 78 cents with 72,422 shares traded, followed by Phylogica up 8.7 percent to 12.5 cents with 30,633 shares traded.

Biota climbed 7.7 percent; Circadian was up 5.7 percent; Psivida was up 4.9 percent; Phosphagenics and Sirtex were up more than three percent; with Resmed up 1.1 percent.

Cathrx led the falls, down 13 cents or 17.8 percent to 60 cents with 66,325 shares traded, followed by Antisense down eight percent to 4.6 cents with 762,616 shares traded.

Prana lost 7.5 percent; Viralytics was down 5.9 percent; Benitec and Novogen fell four percent or more; Bionomics and Pharmaxis were down more than three percent; Chemgenex and Living Cell shed more than two percent; with Clinuvel, Cochlear, Nanosonics and Starpharma down more than one percent.

PHARMAXIS

Pharmaxis has begun screening patients in its pivotal 12 month phase III trial of Bronchitol for bronchiectasis and is unifying its global regulatory strategy for the indication.

Pharmaxis said it had voluntarily withdrawn its marketing application to the Australian Therapeutic Goods Administration for the use of Bronchitol to treat bronchiectasis.

The company said the application was submitted in September 2008 based on a three month clinical trial that used quality of life and mucus clearance as the co-primary endpoints (BD: Aug 20; Oct 1, 2008).

Pharmaxis chief executive officer Dr Alan Robertson said the first successful phase III clinical trial "remains one of the largest completed in bronchiectasis, however, the quality of life improvements may not be adequate on their own to claim other than symptomatic relief of bronchiectasis in worldwide markets".

"Bronchiectasis is a disease where there are currently no registered products, limited epidemiological data and no validated endpoints that have been accepted by the majority of regulatory authorities," Dr Robertson said.

"The reduction in antibiotic use in our first phase III trial has given us the confidence to commit to a longer trial with reduction of exacerbations as its primary endpoint," he said.

Dr Robertson said the trial had begun recruiting and based on discussions with the US Food and Drug Administration and European Medicines Agency would support a robust label claim in bronchiectasis patients "where there remains a high unmet medical need".

"As well as different clinical endpoints, the Australian submission used a product with a different dosage from that used in the current pivotal 12 month study," Dr Robertson said. "We now need to align Australia with the global bronchiectasis regulatory strategy."

Pharmaxis said it would resubmit the TGA bronchiectasis indication as soon as possible, but Bronchitol would be available in Australia through the special access scheme.

Pharmaxis said it planned to file a Bronchitol TGA marketing application for cystic fibrosis by the end of 2009 following positive results from an international phase III clinical trial.

Pharmaxis fell nine cents or 3.33 percent to $2.61.

IMPEDIMED

Impedimed says a clinical review in the Journal of Lymphoedema proposes bioimpedance spectroscopy be adopted as a reference method for the assessment of lymphoedema.

Impedimed's lymphoedema test is based on bioimpedance spectroscopy.

The company said the technology was "well positioned with respect to criteria commonly used to establish a reference method, such as specificity, accuracy, precision, repeatability, sensitivity and practicability".

Impedimed said the review was entitled "Is BIS ready for prime time as the gold standard measure?" (Ward, LC et al; Journal of Lymphoedema, 2009, Vol 4, No 2 pp52-56).

"A convincing argument can be made that on theoretical grounds, analytical and technical accuracy and precision and practicality in use, impedance technology is the method of choice when compared to competing technologies," Impedimed quoted the review.

"The case is well made for its adoption for the assessment of lymphoedema post-breast cancer treatment. It should be acknowledged that impedance ratios, in common with the other assessment modalities, should not be considered as providing the definitive diagnostic criterion," Impedimed said, quoting the review.

Impedimed quoted review author Prof Leigh Ward who said "The continued use of outmoded methods such as calculating limb volumes from tape measurements does the patient at risk of developing lymphoedema a disservice."

Impedimed climbed nine cents or 13.04 percent to 78 cents.

GENETIC TECHNOLOGIES

Genetic Technologies will be the exclusive distributor in Australia, New Zealand and Singapore for three of Rosetta Genomics microRNA-based assays.

Rosetta Genomics chief commercialisation officer Ronen Tamir said his company had made “remarkable progress in making our tests so widely available in the short time since they were launched early this year”.

“This distribution agreement marks Rosetta Genomics’ first entry into the Pacific Rim and represents the fifth continent on which our Mirview tests will be sold,” Mr Tamir said.

“In addition, distinguishing mesothelioma from other lung cancers may be a particularly important task in Australia, where the mining industry is a key component of the country’s economy,” Mr Tamir said.

Genetic Technologies chief executive officer Dr Paul MacLeman said the deal was “an important first step in Genetic Technologies’ move from predictive gene tests into advanced cancer management”.

Genetic Technologies said the Mirview mets test could “accurately identify the primary tumor site in patients presenting with metastatic cancer, as well in patients whose tumor has not been identified”; Mirview squamous differentiates squamous from non-squamous, non-small cell lung cancer patients; and Mirview meso “leverages microRNA’s high specificity as biomarkers to differentiate mesothelioma, a cancer connected to asbestos exposure, from other carcinomas in the lung”.

Genetic Technologies said microRNAs (miRNAs) were small RNAs that act as master regulators of protein synthesis and have been shown to be highly effective biomarkers.

Genetic Technologies was unchanged at 5.1 cents.

ELLEX MEDICAL LASERS

Ellex says it will introduce the latest version of the Eye Cubed diagnostic ultrasound system at this weekend’s meeting of the American Academy of Ophthalmology.

Ellex said the device was “renowned for its unparalleled sensitivity and exceptional image resolution” and offered added functionality, including an intuitive software interface with user-friendly Windows-based operation and expanded measurement options via shaped calipers as well as improved export and import functions.

Ellex said Eye Cubed was among its fastest-selling products with thousands of systems installed worldwide.

The company said that customized scan modes made the Eye Cubed suitable for both retinal sub-specialists and anterior segment surgeons and cataract surgeons would benefit from an A-scan feature which eliminated corneal compression and transmitted ultrasound waves through dense cataracts.

The company said a wide-field anterior segment B-scan gave practitioners “an unprecedented view of the lens apparatus, including zonules and ciliary muscles, areas nearly impossible to visualize with other ultrasound systems”.

The company said the system included a 24-inch wide-screen monitor that provided a larger viewing area, better color transmission and ultra-high resolution. Images are stored on a one-terabyte built-in hard drive, which included a DVD-burner.

Ellex chief executive officer Simon Luscombe said the Eye Cubed was “one of the first ultrasound systems in its genre to deliver movie mode and real-time scanning”.

“The additional enhancements to this new generation system further cement the Eye Cubed’s position as the gold standard for ophthalmic diagnosis,” Mr Luscombe said.

Ellex was up four cents or 22.2 percent to 22 cents.

HEALTHLINX

Healthlinx has confirmed its collaborators in the UK, Australia and Singapore for its second Ovplex ovarian cancer diagnostic trial.

Healthlinx said the researchers and clinicians involved in the study would be Brisbane's Mater Hospital director of gynaecological oncology Prof Lewis Perrin, the National University of Singapore's Prof Mahesh Choolani, Southend Essex Hospital's clinical director of obstetrics and gynaecology Khalil Razvi and the University of Liverpool's Dr John Green.

The company said the trial would use 1150 samples and the collaborators would contribute patient plasma samples, knowledge and clinical expertise that would enhance the development path for the Ovplex ovarian cancer test.

Healthlinx managing director Nick Gatsios said the trial would begin by April 2010 and would further evaluate the performance of the current Ovplex panel and establish the clinical utility of the HTX005 and HTX010 biomarkers.

"On the basis of studies completed to date, we believe these new markers will increase the diagnostic performance of the panel to greater than 97 percent," Mr Gatsios said.

If the second trial was successful, Healthlinx said it would have "a first in class ovarian cancer diagnostic for early stage detection".

Healthlinx was up half a cent or five percent to 10.5 cents.

SOLAGRAN

Solagran has cut the expected sale price of its over-the-counter cure-all Ropren from $US3,500 to $US6,000 a course to "between $US1,100 and $US1,250.

At the bottom of a media release discussing chief executive officer Branko Jovanovic's recent trip to Russia, Solagran said agreements had been reached "with pharmaceutical networks from Central Siberian Region, St Petersburg and Moscow, including 20 to 25 of approximately 247 pharmacies from the Moscow government network Stolichnye apteki directly linked to Moscow hospitals".

"The retail price for Ropren has been set between $US1,100 and $US1,250 per course. A course represents six grams of Bioffective R substance," Solagran said.

Solagran has said its conifer green pine needle extract compound was efficacious in a variety of liver diseases as well as alcoholism, age-related cognitive decline and neurodegenerative conditions such as Alzheimer's disease.

In March, Solagran said that at an "average retail price of $US1,000 a course, this would equate to a revenue potential of $US100 million a year" (BD: Mar 16, 2009).

But in 2007 Solagran said the price of Ropren to patients outside Russia would be "in the range $US3,500 to $US6,000 per three month course" (BD: Aug 15, 2007).

Yesterday's Solagran media release to the ASX also said it had established a manufacturing, distribution and sales entity Solagran Son, a wholly owned subsidiary of Solagran based in Tomsk, Siberia, using Sibex's infrastructure.

Solagran said Solagran Son would be the centre of its Russian operations for manufacturing, sales and promotion and the manufacturing licence for Ropren and finished products would be transferred to Solagran Son.

To begin selling Ropren, Solagran Son must first obtain a pharmaceutical wholesale licence in its own right, expected in November 2009.

Solagran was up 1.5 cents or 10.7 percent to 15.5 cents.

STIRLING PRODUCTS

Stirling says that with Zodiac Capital it has acquired the rights "to commercialize a new class of drug inhalation devices" from Sheiman Ultrasonic Research Foundation.
Stirling said Zodiac was "its joint venture partner in pharmaceutical and botanical products".
Stirling has previously said it was the distributor of the Kiev-developed Immunoxel that was efficacious against tuberculosis, HIV and the H1N1 'swine' influenza (BD: May 14, 2009).
In August, Stirling said it and Zodiac would each provide $250,000 in shares to Sheiman and the deal was conditional on the raising of $5-6 million within 12 months for research and development (BD: Aug 28, 2009).
At that time Stirling said it would retain a 35 percent interest in the device, a 35 percent interest in off-patent drugs used in the device and five percent in any products adapted from the technology, with Stirling and Zodiac sharing equally in the balance.
In yesterday's media release to the ASX, Stirling said Sheiman's high density aerosol (HDA) technology was "highly efficient and effective in delivering drugs via inhalation".
Stirling said the technology provided "the same efficacy as drugs taken orally, with far less active drug content which, subject to formal trial validation, should therefore increase drug safety and substantially lessen any side effects".
Stirling fell 0.1 cents or 7.1 percent to 1.3 cents with 46.6 million shares traded.

UNILIFE MEDICAL SOLUTIONS

Unilife says chief executive officer Alan Shortall bought 479,800 shares at an average price of $1.026 a share on October 21, 2009.
The company said Mr Shortall intended to buy more than 500,000 shares.
Mr Shortall said he bought the shares in the open market rather than participate in the recently announced private placement.
"The reason I chose to purchase these shares via the open market was to show our shareholders that I am standing by them in their belief in the company," Mr Shortall said.
"I could have simply participated in the private placement and obtained the shares at a discount to market and received the benefit of the same options that the institutions received, but I have instead chosen to show my allegiance to the company and its shareholders by purchasing additional shares in the open market," he said.
Unilife was up 2.5 cents or 2.3 percent to $1.10 with 2.3 million shares traded.