Biotech Daily

Thursday October 15, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PROGEN UP 14%; TYRIAN DOWN 32%**

*** BECTON DICKINSON, TYRIAN PART COMPANY ON TB TEST**

*** PSIVIDA COMPLETES 24-MONTH PHASE III DME FOLLOW UP**

*** PROGEN ANTI-HEPATANASE PG545 'LIMITS SPREAD OF CANCER'**

*** PHARMAXIS' PXS25 FOR LUNG FIBROSIS BEGINS PHASE I TRAIL**

*** COMPUMEDICS LAUNCHES SOMINILIN SPAP SLEEP APNOEA DEVICE**

*** TGA APPROVES GENERA IN VITRO DEVICE MANUFACTURING**

*** BONE FILES US IND FOR CAPSITONIN FOR OSTEOARTHRITIC PAIN**

*** MEDICAL THERAPIES VOTE ON NAME, $3m RAISING, 9m OPTIONS**

*** TISSUE THERAPIES REQUESTS FINANCE TRADING HALT**

MARKET REPORT

The Australian stock market climbed 0.6 percent on Thursday October 15, 2009 with the S&P ASX 200 up 28.8 points to 4859.9 points. Seventeen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and two were untraded.

Progen was best, up eight cents or 14.04 percent to 65 cents with 23,585 shares traded, followed by Universal Biosensors up 11.6 percent to $1.64 with 130,051 shares traded.

Compumedics and Living Cell climbed more than eight percent; Uscom was up 7.2 percent; Cathrx was up five percent; Heartware climbed 4.5 percent; Nanosonics and Psivida were up more than three percent; Bone, Mesoblast and Pharmaxis rose more than two percent; with Bionomics, Biota, Starpharma and Sunshine Heart up more than one percent.

Tyrian led the falls, down 0.8 cents or 32 percent to 1.7 cents with 9.7 million shares traded followed by Labtech down 7.4 percent to 12.5 cents.

Antisense and Avexa lost more than five percent; Phylogica fell 4.8 percent; Benitec and Novogen were down more than three percent; Alchemia shed 2.8 percent; with Cellestis, Chemgenex, Phosphagenics and Sirtex down more than one percent.

TYRIAN DIAGNOSTICS

Tyrian says the collaboration with Becton Dickinson and Co to develop a point-of-care test for active tuberculosis has ended.

Tyrian chief executive officer Dr Jenny Harry told Biotech Daily that it was not a failure of Tyrian's protein biomarkers for the test, but that they could not be detected at sufficient levels in currently available point-of-care detection platform technology.

In a media release, Tyrian said that in January 2009, the company reported that its lead tuberculosis (TB) marker was detected in clinical strains of the bacteria responsible for TB as well as in clinical sputum samples, but it was unable to detect the marker at the desired levels of sensitivity and specificity.

The company said that in May 2009, it granted Becton Dickinson research and development rights to conduct further feasibility studies using its technology to achieve the desired levels of sensitivity and specificity for an effective point-of-care diagnostic product.

Tyrian said that neither company was able to consistently detect the Tyrian lead biomarkers in clinical samples at a level of detection required for a rapid test to be effective.

Dr Harry said "further advances in the available technology are required for the development of a sensitive five-minute test to detect active TB".

Dr Harry said that while Tyrian was disappointed not to be proceeding with Becton Dickinson on a protein-based point-of-care test for tuberculosis, the study "validates our decision to focus on the development of a molecular diagnostic test for active TB" and her company held "the best portfolio of biomarkers for a [point-of-care] TB test".

Dr Harry said molecular technologies were well established and "currently much more sensitive than protein-based technologies".

Dr Harry told Biotech Daily that Tyrian had both protein and molecular markers available and the Becton Dickinson collaboration used the protein markers.

She said Tyrian continued to work independently on both types of markers.

In the media release, Tyrian said it was working with the director of New Jersey's Public Health Research Institute TB Centre Dr Barry Kreiswirth to validate its lead biomarker and establish a sputum-based assay using existing molecular technology.

Tyrian said this would "pave the way for a molecular TB test to be developed in partnership with a company that offers a platform appropriate for use in TB testing".

Tyrian said molecular testing "should have the sensitivity required for detection of active TB" but it was performed in a clinical setting and there remained "an urgent requirement for a simple, rapid test which is easily deployed at point-of-care".

Dr Harry said that "among participants in this field, Tyrian arguably holds the best portfolio of biomarkers for a [point-of-care] TB test".

"We are in an excellent position to team with a new partner as an appropriate, sensitive and commercially viable technology emerges," Dr Harry said.

Tyrian fell 0.8 cents or 32 percent to 1.7 cents with 9.7 million shares traded.

PSIVIDA

Psivida says the last patient in its phase III clinical trial of Iluvien for diabetic macular oedema has completed the two-year follow up visit.

Psivida chief executive officer Dr Paul Ashton said it was an "important milestone" and top-line 24-month data from the trial was expected in mid-December, 2009.

Dr Ashton said that "assuming positive data", partner Alimera Sciences expected to file the new drug application with the US Food and Drug Administration by July 2010.

Psivida was up 13 cents or 3.75 percent to $3.60.

PROGEN PHARMACEUTICALS

Progen says preclinical data on PG545, a dual anti-angiogenic and anti-heparanase inhibitor, will be presented at an international cancer therapeutics conference.

Progen's director of preclinical development Dr Keith Dredge said that the first of two presentations at the conference focuses on the ability of PG545 to inhibit both solid tumor and metastasis in a range of different cancer models.

"Our findings are timely as scientific groups have recently reported that approved angiogenesis inhibitors can actually promote metastasis," Dr Dredge said.

"We believe that PG545's unique anti-heparanase activity can significantly limit the spread of cancer," Dr Dredge said.

"In our second presentation, we will discuss advancements in treatment schedules and provide more examples of how PG545 induces significant anti-tumor activity," he said.

"Measurement of drug levels both in blood and within the actual tumor has been used to support our current dosing schedule which should lead to greater patient compliance," Dr Dredge said.

Progen said that with its subsidiary Pharmasynth larger scale, clinical grade quantities of PG545 had been manufactured for later stage preclinical safety testing, with human clinical trials planned for 2010.

Progen chief executive officer Justus Homburg said the continuing development of PG545 was "an outstanding achievement" for the research and development team.

"The results achieved indicate that PG545 is a very promising commercial opportunity," Mr Homburg said.

"The ability of PG545 to inhibit both solid tumor growth and metastases appears to set PG545 apart from other angiogenesis inhibitors and as we move towards the clinic, we look forward to updating our shareholders about the progress of this exciting new cancer therapeutic agent," Mr Homburg said.

Progen will present the preclinical data at the 2009 Molecular Targets and Cancer Therapeutics Conference in Boston on November 16, 2009.

Progen climbed eight cents or 14.04 percent to 65 cents.

PHARMAXIS

Pharmaxis says its PXS25 compound for lung fibrosis began a phase Ia pharmacokinetic clinical trial last week.

In a quarterly report to shareholders Pharmaxis detailed its pipeline and said that it had received regulatory and ethics approval for the PXS25 trial.

Pharmaxis chief executive officer Dr Alan Robertson told Biotech Daily the trial began last week.

The report said Pharmaxis would file an application with the European Medicines Agency this month to market Bronchitol in Europe for the treatment of cystic fibrosis.

The company said that at the end of November 2009 the US Food and Drug Administration would hold an advisory committee meeting in Washington, where Pharmaxis and two clinical experts would support the application.

Pharmaxis said the meeting was open to the public and was often attended and addressed by influential patient groups and medical experts.

Pharmaxis said it had been "actively undertaking clinical awareness activities, engaging advisory boards and patient groups in both the US and Europe".

The advisory committee will make a non-binding recommendation to the FDA, which was due to announce its decision on December 27, 2009.

Pharmaxis climbed six cents or 2.6 percent to $2.36.

COMPUMEDICS

Compumedics launched its Somnilink device in the Australian market at the Australasian Sleep Association meeting in Melbourne last weekend.

Compumedics said there was strong interest in the smart positive airways pressure (SPAP) technology leading to a number of key reference site installations and distribution channel discussions.

The company said the SPAP technology evolved from a recognition that while continuous positive airway pressure (CPAP) devices proved to be the front line cure for apnoea, a number of patients still suffered from daytime sleepiness even after CPAP treatment.

Compumedics chief executive officer David Burton said "one plausible explanation of this occurrence is that the traditional CPAP treatment for sleep disordered breathing has not been adequate and that sleep disturbances persisted even after CPAP or auto-titrating airway pressure (APAP) treatment.

"As a result of some of the shortcomings of the current devices available, Compumedics commenced an examination of sleep treatment," Mr Burton said.

"The main aim was to develop a treatment that not only minimized respiratory sleep disorders but also optimized sleep quality," Mr Burton said.

"This culminated in the development of Compumedics' next generation sleep treatment device Somnilink SPAP," he said.

"Critically, the technology is no more expensive or invasive than currently available sleep treatment technologies," he said.

"The device has been validated against the best-of-class APAP devices but now incorporates technology that not only abolishes sleep breathing disorders but additionally incorporates algorithms designed to minimize arousals and improve sleep quality," he said.

Compumedics said the Australian sleep-treatment market is estimated to be more than $42 million a year with the global market at $US2.5 billion a year.

The company said it had a base of more than 4,000 beds for sleep diagnostics and an existing infrastructure would benefit from the introduction of the Somnilink SPAP device.

Compumedics climbed 1.5 cents or 8.1 percent to 20 cents.

GENERA BIOSYSTEMS

Genera has received a licence to manufacture in vitro diagnostic devices from the Australian Therapeutic Goods Administration.

Genera said the licence was "a critical milestone" to regulatory approval for its Paptype human papilloma virus (HPV) detection and genotyping assay and an essential first step for TGA approval for Paptype.

Genera chief executive officer Dr Allen Bollands said the licence was "the culmination of many months of focused endeavor ensuring that Genera has a quality system, manufacturing facility and the required processes in place that will be recognized to most of the major regulatory jurisdictions around the world".

"This is an important part of the value creation chain as it means that not only can we manufacture Paptype, but we have been certified as a recognized manufacturer of in vitro diagnostic devices and are therefore are able to develop and manufacture the products that will come after Paptype," he said.

Genera said approval "broadly mirrors CFR21 part 820 used by the US Food and Drug Administration" and future products designed and manufactured by Genera will comply with the internationally recognized standard.

Genera was unchanged at 80 cents.

BONE MEDICAL

Bone has filed an investigational new drug application with the US Food and Drug Administration for a phase II study of Capsitonin for osteoarthritic pain

Bone said Capsitonin was an oral formulation of salmon calcitonin which has been approved in injectable and nasal delivery forms for the treatment of osteoporosis for many years and Capsitonin was in development for the chronic indication.

Bone's chief scientist, Dr Roger New, said the company had broadened the potential application to include osteoarthritis.

"Salmon calcitonin has long been known to have analgesic qualities and recent published studies, both in the laboratory and in osteoarthritis patients, have also demonstrated its beneficial effects on bone structure and cartilage in osteoarthritic joints," Dr New said.

"Moving this product, particularly in our convenient oral dosage form into clinical development for osteoarthritis is a simple step to take and we shall focus initially on the control of osteoarthritic pain," he said.

The planned phase II study was designed to identify the appropriate dose of the product to take through to a phase III study.

Bone chairman Leif Jensen said the company's "existing clinical database of Capsitonin for the treatment of osteoporosis has clearly demonstrated our formulation to be safe and effective so we believe we should be able to progress straight into phase II in osteoarthritis patients".

"This widespread and chronic condition is surprisingly poorly addressed by current medications, almost all of which focus on managing its symptoms rather than physical deterioration of the affected joints," Mr Jensen said.

"With aging populations in many established pharmaceutical markets, there is a substantial and growing need for novel and effective treatments for this painful condition," he said.

Bone climbed half a cent or 2.9 percent to 17.5 cents.

MEDICAL THERAPIES

Medical Therapies will vote on a company name change to Cellmid, a $3 million capital raising and the issue of 9,000,000 options to chief executive officer Maria Halasz and director Koichiro Koike

The meeting will be asked to reelect and elect as directors Mr Koike and Robin Beaumont, respectively, as well as ratify the prior issue of 5,250,000 options to consultants, including Alison Coutts and Graeme Kaufman.

Shareholders will vote on the issue of 7,000,000 options to Ms Halasz and 2,000,000 options to Mr Koike.

The company said Ms Halasz's base salary was $350,000 and had not been increased since 2007.

Medical Therapies said the options would be issued in three tranches and were performance related.

The company Mr Koike was entitled to director's fees of $50,000 but he was paid half of this fee and he had not been previously issued any options.

The meeting will be held at Level 6, 40 King Street, Sydney on November 17, 2009 at 10am.

Medical Therapies was unchanged at 2.9 cents.

TISSUE THERAPIES

Tissue Therapies has requested a trading halt pending an announcement regarding “a capital raising”.

Trading will resume on October 19, 2009 or on an earlier announcement.

Tissue Therapies last traded at 20.5 cents.