Biotech Daily

Tuesday December 13, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: COMPUMEDICS UP 12.5%, VIRALYTICS DOWN 6%**

*** FDA APPROVES CYCLOPHARM PHASE III TECHNEGAS TRIAL**

*** PHARMAXIS BRONCHIECTASIS ENROLMENT, $80m RAISE COMPLETE**

*** COMPUMEDICS $1m YALE NEUROLOGY CONTRACT**

*** M&G GROUP BUYS 1m MORE STARPHARMA SHARES**

*** IMPEDIMED $1.5m SUPPORTS STANFORD BREAST CANCER REGISTRY**

*** CBIO APPOINTS DR DAINA VANAGS CSO; REVIEW; CEO HUNT**

MARKET REPORT

The Australian stock market fell 1.4 percent on Tuesday December 13, 2011 with the S&P ASX 200 down 59.4 points to 4,193.4 points.

Ten of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and seven were untraded. All three Big Caps fell.

Compumedics was the best, up one cent or 12.5 percent to nine cents with 22,498 shares traded.

Genetic Technologies and Sirtex climbed more than four percent; Antisense, Clinuvel and Prana were up more than three percent; Universal Biosensors rose 2.1 percent; Circadian and Heartware were up more than one percent; with QRX up 0.7 percent.

Viralytics led the falls, down two cents or 5.6 percent to 34 cents, with 202,651 shares traded.

Avita lost 4.55 percent; Cochlear, Mesoblast, Neuren, Starpharma and Tissue Therapies were down three percent or more; Acrux, Allied Health, Resmed, Reva and Sunshine Heart shed more than two percent; Alchemia, Biota, CSL, Nanosonics and Optiscan fell more than one percent; with Bionomics and Pharmaxis down by less than one percent.

CYCLOPHARM

Cyclopharm says the US Food and Drug Administration has approved the 750-patient phase III clinical trial of its Technegas imaging agent.

Cyclopharm said the FDA approval was based on a successful review of its investigational new drug application submitted last month.

The company said Technegas was a lung ventilation imaging agent used primarily to detect pulmonary embolism and was already distributed in more than 50 countries.

Cyclopharm managing director James McBrayer told Biotech Daily that he expected the trial to take more than one year to complete and pending patient recruitment marketing approval could be granted by 2014.

Mr McBrayer said the company had targeted about 10 centres for the trial with George Washington University in St Louis the first of two signed-up

Cyclopharm's media release said the US was the world's largest nuclear medicine market and based on the Canadian market, the company expected to "more than double its current size" within five years of US marketing authorization approval.

Mr McBrayer said the application to the FDA was for both a drug and a diagnostic and he was delighted by the speed with which the FDA had approved the trial.

Cyclopharm said the trial was expected to cost up to $4 million.

Cyclopharm was up 0.7 cents or 18.4 percent to 4.5 cents.

PHARMAXIS

Pharmaxis says it has recruited all 474 patients in its European and US regulatory phase III study of inhaled Bronchitol for bronchiectasis.

In October, Bronchitol was approved for European use of cystic fibrosis and the company expected to file its new drug application to the US Food and Drug Administration for that indication by July 2012 (BD: Oct 24, 2011).

Today, Pharmaxis said the randomized, controlled, double blind study would investigate the safety and efficacy of Bronchitol (inhaled mannitol) twice daily over 12 months and collect data on quality of life, lung function and other aspects of the condition.

Pharmaxis said the trial was being conducted at 83 hospitals throughout the world.

Pharmaxis chief executive officer Dr Alan Robertson said that "reaching the enrollment target has involved a great deal of effort by many people and we are delighted to have come to this point in the trial".

Pharmaxis said there had been no new therapeutic advances for this patient group in the last 20 years and bronchiectasis was an incurable, degenerative and chronic lung condition affecting more than 200,000 people in Europe alone.

The company said that in the US more than 110,000 people were receiving treatment for bronchiectasis, medical-care expenditure was more than $US630 million a year and patients spent between $US6,000 and $US13,000 on treatment.

The company said the trial results would be available early in 2013.

Separately the company said that it received applications for 13,815,725 in its share rights offer at $1.05 a share, about 47 percent of eligible applicants, raising $14.5 million.

Pharmaxis raised $50 million in a placement at the same price last month and the underwriters Merrill Lynch International and Wilson HTM agreed to convert their exposure from 50 percent of the total $80 million to all of the subsequent rights issue (BD: Nov 16, 18, 2011).

Today, Pharmaxis said the placement raised $49 million and the underwriters would place the remaining $16.5 million in shares.

Pharmaxis fell one cent or 0.9 percent to $1.05.

COMPUMEDICS

Compumedics says it has been awarded a contract worth more than $1 million to supply equipment to the Neurology Department at Yale School of Medicine

Compumedics said it would supply electroencephalogram (EEG) products comprising the Neuvo long-term EEG monitoring (Neuvo-LTEM) system, GraelHD, Profusion EEG 4 and Curry NS7 software for routine clinical EEG and surgical monitoring.

The company said the purchase was “another major milestone in Compumedics’ strategic entry into the global $250 million per annum LTEM neurology market”.

Compumedics said the order followed several other significant EEG orders in the US in the past six months.

The company said that Neuvo-LTEM systems could record a minimum 64 individual channels of high-density EEG data on a single patient for days or weeks at a time.

Compumedics said the GraelHD provided high definition EEG signals while the Siesta802 was the industry’s most compact wireless EEG recording device.

Compumedics said that its digital amplifier technology and breadth of EEG diagnostic products was state-of-the-art providing higher quality brain recordings and more precise brain analysis than alternatives, helping to improve patient outcomes.

The company said that the Department of Neurology was “a major part of the Yale University School of Medicine and has several active clinical programs at local medical establishments”.

Compumedics said its equipment would help the Department of Neurology provide the highest level of patient care through state-of-the-art clinical programs, educating future leaders in the field of neurology and being at the forefront of neuroscience research within one of the world’s most prestigious universities.

The company said the Department had a long history of being a pioneer in Neurology, such as establishing one of the first epilepsy monitoring units and creating one of the first stroke centres.

Compumedics chairman and chief executive officer Dr David Burton said his company had made “significant investments in product development, targeting the neuro-diagnostics market to leverage its expertise in high-end amplifier design and physiological signal processing”.

“This project further underpins our strategy to grow our business across this important, but relatively new, market sector for Compumedics,” Dr Burton said.

“In particular, this prestigious sale to one of the world’s pre-eminent epilepsy monitoring centres validates our key growth strategy to penetrate the global LTEM market,” Dr Burton said.

“The LTEM market alone is more than twice the size of our existing core sleep diagnostic business,” Dr Burton said.

Compumedics was up one cent or 12.5 percent to nine cents.

STARPHARMA

M&G Investment Funds has increased its substantial shareholding in Starpharma from 18,604,651 shares (6.70%) to 19,490,077 shares (7.01%).

The London-based M&G companies first acquired shares last month for $19,999,999 or an average price of $1.075 a share (BD: Nov 24, 2011).

Today the M&G Group said it acquired shares on every trading day between November 29 and December 9, with the largest parcel 129,082 shares for $154,099 or an average price of $1.194 a share.

Starpharma fell 4.5 cents or 3.6 percent to $1.21.

IMPEDIMED

Impedimed says it is supporting Stanford University Medical Center's breast cancer lymphoedema registry to collect and analyze data from breast centres across the US.
Impedimed chief executive officer Greg Brown told Biotech Daily that the company would provide $1.5 million over five years for the project, which had funding from other sources.
Impedimed said the unrestricted educational grant would go to the University and the registry's principal investigator and lymphoedema expert, Dr Stanley Rockson.
The company said the registry would collect health and demographic information on patients with the data held in a central database to be mined by investigators to gain insight into the natural history and optimal treatment of the condition.
Impedimed said the Stanford registry was designed to investigate the impact of lymphoedema surveillance on breast cancer survivors, with one arm of the registry collecting information on patients being monitored using its L-Dex U400 device.
Dr Rockson said the registry was "a major step forward for breast cancer therapeutics and breast cancer survivorship".
"Within a year, we expect to have gained further substantial insights into the value of systematic early surveillance to prevent and minimize the lymphoedema risk in women treated for breast cancer," Dr Rockson said.
Impedimed was untraded at 56 cents.

CBIO

CBio says Dr Daina Vanags has been appointed chief scientific officer.
CBio said that Dr Vanags graduated with a Bachelor of Science and Ph D in pharmacology from the University of Adelaide before undertaking postdoctoral appointments at Oxford University, UK and the Karolinska Institute, Sweden.
CBio said Dr Vanags had more than 20 years experience in clinical and experimental pharmacology, with 15 publications in peer-reviewed journals on inflammation.
CBio said Dr Vanags joined the company in 2004, working on clinical biomarker development and the management of early phase IIa clinical studies in rheumatoid arthritis, psoriasis and multiple sclerosis.
The company said that as chief scientific officer Dr Vanags would be responsible for the management and coordination of research and development.
In a shareholder update, CBio said it was considering "many opportunities" and when it confirmed activities next year it would begin a search for a new chief executive officer.
CBio said it had a number of potential candidates which was "very encouraging".
CBio said the option agreement with Novo Nordisk was under consideration and the company was awaiting notice regarding negotiations over a licencing agreement for the further development of XToll for rheumatoid arthritis.
Non-significant phase IIa trial results for XToll led to the board spill and change of management (BD: Aug 1, Sep 5, Nov 4, 2011)
The company said the board was "positioning CBio to take advantage of opportunities being presented to us to participate in the development of new drugs" and that XToll or one of its variants could be beneficial in the treatment of Lupus.
CBio was unchanged at 16.5 cents.