Biotech Daily

Thursday November 18, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTISENSE UP 11%; SUNSHINE HEART DOWN 10%**

*** NEUREN DEVELOPS ORAL NNZ-2566 FOR PHASE II BRAIN INJURY TRIAL**

*** VALEVIA LICENCES AVEXA ANTIBACTERIAL PROGRAM FOR UP TO $66m**

*** TYRIAN 1-FOR-1 RIGHTS ISSUE TO RAISE $4m**

*** LIVING CELL DIRECTORS DUMPED, WALK AT AGM; FOUNDER IN CHAIR**

*** PATRYS RAISES FURTHER $500k**

*** STARPHARMA PLEADS SCHULTZ TO ASX 9.7% PRICE QUERY**

*** FIREBIRD GROUP SELLS 17m ANTISENSE SHARES**

*** CIRCADIAN COMPLETES UNMARKETABLE PARCELS BUY-BACK**

*** KARMELSONIX WHEEZOMETER WINS FROST & SULLIVAN GONG**

MARKET REPORT

The Australian stock market recovered 0.34 percent on Thursday November 18, 2010 with the S&P ASX 200 up 15.9 points to 4640.2 points.

Thirteen Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and six were untraded.

Antisense was best, up 0.1 cents or 11.1 percent to one cent with 2.2 million shares traded, followed by Biota and Optiscan both up 10.5 percent to $1.05 and 4.2 cents, respectively, with 1.7 million and 72,096 shares traded, respectively.

QRX climbed 8.25 percent; Genera was up five percent; Immuron and Phosphagenics were up four percent or more; Prana was up 3.6 percent; Cellestis and Pharmaxis rose more than two percent; with Cochlear, Heartware and Psivida up more than one percent.

Sunshine Heart led the falls, down 0.3 cents or 10.3 percent to 2.6 cents with 343,521 shares traded.

Cellmid and Viralytics shed more than two percent; with Alchemia, Circadian, Clinuvel, Mesoblast, Nanosonics, Resmed, Starpharma and Tissue Therapies down one percent or more.

NEUREN PHARMACEUTICALS

Neuren says it has begun development of an oral form of NNZ-2566 for mild traumatic brain injury and other conditions in which the oral route is more suitable than intravenous.

Neuren said initial experiments confirmed that the liquid micro-emulsion of NNZ-2566 previously used in an animal model of stroke was an effective formulation and based on previous pharmacokinetic studies, the oral dose required to achieve the blood level targeted in the current phase II traumatic brain injury trial would be reasonable and acceptable.

The company said that on final validation of the oral formulation, it would conduct additional pharmacokinetic studies, as well as bridging toxicology studies that would build on the data generated by the investigational new drug application-enabling toxicology studies with the intravenous form, followed by a phase I safety and pharmacokinetic trial in healthy subjects.

Neuren said that when these studies had been successfully completed, it planned to submit a clinical study protocol to the US Army, US Food and Drug Administration (FDA) and institutional review boards to conduct a phase II proof of concept trial in patients with mild traumatic brain injury.

Neuren has been collaborating on trials with the US Walter Reed Army Institute of Research on its brain protective technologies.

The company said the mild traumatic brain injury (TBI) phase II trial was being designed in coordination with an advisory committee including academic experts and regulatory advisors and including input from US Army neuroscientists.

Neuren said it expected to submit the protocol by October 2011.

The company said the majority of costs for the NNZ-2566 program were covered by funding from the US Army, including an additional $US750,000 to cover the oral NNZ-2566 preclinical program.

Neuren chief executive officer Larry Glass told Biotech Daily that the development of an oral formulation was “a major step forward for Neuren and the US Army, opening up treatment, including out-of-hospital treatment, for mild TBI and concussion not to mention use in chronic indications such as Rett Syndrome, post-transient ischaemic attack or post-stroke neuro-protection”.

“As far as we know, Neuren is the only company on the planet with a proprietary product in development for mild TBI,” Mr Glass said.

Neuren said that mild TBI was an important public health problem and therapeutic target and that there were no drugs approved to treat mild TBI.

The company said there were about 1.5 million head injuries in the US each year of which approximately 700,000 patients have mild traumatic brain injury or concussion and were treated and released from the emergency department and another 80,000 with mild traumatic brain injury were admitted to hospital.

Neuren said that among US military personnel, of the 178,876 traumatic brain injuries reported between January 2000 and May 2010, 77 percent (137,328) were categorized as mild.

The company said that many people who experience mild traumatic brain injury have problems with mood, memory and concentration months or even years after the incident.

Neuren said that mild traumatic brain injury represents a significant cause of disability, often affecting young, otherwise healthy individuals.

The company said that mild TBI was a common sports-related injury and also occurs frequently in soldiers, often association with exposure to blast.

Neuren was up 0.1 cent or 5.6 percent to 1.9 cents with 1.4 million shares traded.

AVEXA

Avexa says it has licenced its antibacterial drug program to Valevia Pharmaceuticals GmbH for up to $US65 million ($A66 million) in milestone payments and royalties.

Avexa said the Swiss-based Valevia would fund all future development of Avexa's preclinical antibacterial program, but Avexa would retain manage the intellectual property.

The company said the terms and conditions were confidential, but interim chief executive officer Dr Jonathan Coates told Biotech Daily the potential $66 million would primarily be derived from milestone payments and royalties on sales.

Dr Coates said the lead molecule AVX13616 had already shown efficacy in mice and that in anti-bacterial research mice were a good model for humans.

The Avexa announcement said the licence covered the entire Avexa antibacterial portfolio.

The company said that in the event that other compounds covered by Avexa's intellectual property were developed by Valevia, Avexa would be entitled to additional milestone and royalty payments.

Avexa controls the intellectual property covering a series of novel compounds which were active against a range of microorganisms, including strains that are resistant to the antibiotics vancomycin, methicillin and mupirocin.

Avexa said AVX13616 had "good antibacterial activity against various strains of Clostridium difficile and against mupirocin-resistant strains of Staphylococcus aureus".

Avexa said AVX13616 and others were the result of a long standing collaboration with the University of Wollongong.

"We are very excited about entering this relationship with Valevia and have high expectations for development of our well-established portfolio of potential drugs," Dr Coates said in the media release.

"It's very pleasing that our program is attractive to an antibiotic drug developer," Dr Coates said. "The achievement of development milestones for the program holds great potential for our shareholders."

"Valevia has extensive experience and understanding of developing antibacterial drugs," Dr Coates said.

"Resistance to antibiotics has become a significant clinical issue. It's a phenomenon that has continued to increase over the years, especially in hospitals," Dr Coates said.

"Any development of drugs that are active against a range of microorganisms resistant to antibiotics would be a landmark achievement," Dr Coates said.

Separately, all resolutions to Avexa's annual general meeting passed overwhelmingly.

Avexa climbed as high as 6.3 cents before closing down 0.1 cents or two percent to 4.9 cents with 34.9 million shares traded.

TYRIAN DIAGNOSTICS

Tyrian expects to raise about $4 million through a fully-underwritten, non-renounceable one-for-one share rights issue at 0.8 cents a share.

Tyrian said one free attaching option exercisable at 1.2 cents by December 20, 2013 would be issued with every five shares acquired.

Tyrian said the record date for the rights issue was November 26, 2010, the offer opens on November 29 and closes on December 13, 2010.

Tyrian said the funds would be used to fund further development of its agricultural diagnostics product portfolio and to advance development of its sputum-based diagnostics for chronic respiratory disease, using its Diagnostiq platform.

Tyrian said the rights issue was underwritten by Patersons Securities.

Tyrian fell 0.3 cents or 25 percent to 0.9 cents with 6.6 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell investors have overwhelmingly removed two directors, a third resigned at the end of the meeting and founder Prof Robert Elliott has been appointed chairman.
Shareholders removed directors Dr David Brookes by 59,598,338 proxy votes (65.4%) against, to 31,518,407 proxy votes (34.6%) in favor, with Simon O'Loughlin removed by 61,784,249 proxy votes (65.9%) against, to 31,904,407 proxy votes (34.1%) in favor.
By contrast, the usually controversial provision of options to a chief executive officer was passed with 60,828 proxy votes (90.05%) in favor of 500,000 options to Dr Ross Macdonald with 6,720,575 proxy votes (9.95%) opposed.
Living Cell appointed Labtech chairman Bob Finder and former Neurodiscovery executive director David McAuliffe as independent directors last year (BD: Sep 23, 2009).
Mr McAuliffe resigned effective from the end of the meeting.
All other resolutions including the adoption of the remuneration report, the ratification of a share issue and the approval of employee options were passed overwhelmingly.
Living Cell said the board continued with Prof Elliott, chief executive officer Dr Ross Macdonald, Mr Finder and Laurie Hunter.
Living Cell has emerged from a trading halt and last traded at 18.5 cents.

PATRYS

Patrys says it has raised a further $500,000 in the placement that raised $2.9 million in its first tranche yesterday.
Patrys said yesterday that it expected to place about 3,600,000 shares at 10 cents a share but today said it had raised about $500,000.
Patrys was unchanged at 10.5 cents.

STARPHARMA

Starpharma has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose from 72 cents on November 16, 2010 to 79 cents, a 9.72 percent increase, on November 17, 2010 and noted an increase in trading volume.
Starpharma fell one cent or 1.3 percent to 78 cents.

ANTISENSE THERAPEUTICS

The Firebird Group has reduced its substantial holding in Antisense from 101,809,329 shares (17.83%) to 84,939,444 shares (14.34%).
The substantial shareholder notice said the Cayman Island and New York based Firebird Group sold the 16,869,885 shares between November 4 and November 12, 2010 for $198,684 or an average price of 1.18 cents a shares.
Antisense was up 0.1 cents or 11.1 percent to one cent with 2.2 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian says it has completed its unmarketable parcels sale facility with a total of 212,463 shares, from 516 investors, sold on-market.
Circadian said it had a total of 2,979 shareholders with 46,396,923 shares on issue.
Circadian fell one cent or 1.5 percent to 64 cents.

KARMELSONIX

Karmelsonix says it has one the 2010 Frost & Sullivan North American “new product innovation of the year award in patient monitoring emerging markets”.

Karmelsonix said it won the award for its asthma management Wheezometer.

Karmelsonix was up 0.2 cents or 7.7 percent to 2.8 cents with 14.1 million shares traded.