Biotech Daily

Friday October 18, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NANOSONICS UP 17%, PSIVIDA DOWN 12%**

*** AVITA INVESTIGATOR RECELL TRIAL 'EXCELLENT' REPIGMENTATION**

*** US 'FAST-TRACK' FOR NEUREN FRAGILE X TRIAL, TRADING HALT**

*** CELLMID, PACIFIC EDGE CXBLADDER TEST SIGNS US DEAL**

*** JAPAN PATENT FOR CELLMID'S MIDKINE**

*** US PATENT FOR ONCOSIL PANCREATIC CANCER TREATMENT**

*** PSIVIDA REQUESTS FDA PDUFA ILUVIEN DME REVIEW TRADING HALT**

*** FEDERAL GOVERNMENT BOOSTS SUDA WESTCOAST RECORD REVENUE**

*** STARPHARMA AGM FOR 950k CEO 'PERFORMANCE RIGHTS'**

*** PATRYS LOSES DIRECTOR DR ALAN ROBERTSON**

*** CANARY NETWORKS BIOTECHNOLOGY SYDNEY, MELBOURNE SHOWS**

MARKET REPORT

The Australian stock market was up 0.73 percent on Friday October 18, 2013 with the S&P ASX 200 up 38.4 points to 5,321.5 points. Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, nine traded unchanged and four were untraded.

Nanosonics was the best, on Trophon sales up 327 percent to $5,067,000 for the three months to September 30, 2013, up 13 cents or 16.9 percent to 90 cents with 1.4 million shares traded.

Benitec climbed 9.8 percent; Antisense and Phosphagenics were up more than eight percent; Anteo was up 7.3 percent; both Prima and Phylogica were up 5.9 percent; Mesoblast, Patrys and QRX were up more than three percent; Genetic Technologies rose 2.7 percent; Acrux, CSL, GI Dynamics, Medical Developments, Universal Biosensors and Viralytics were up more than one percent; with Sirtex up 0.65 percent.

Psivida led the falls, down 52 cents or 11.9 percent to $3.84 with 11,069 shares traded. Allied lost 9.1 percent; Impedimed and Reva fell more than five percent; Atcor was down 4.8 percent; Alchemia and Living Cell shed more than two percent; with Bionomics, Clinuvel, Ellex and Resmed down by more than one percent.

AVITA MEDICAL

Avita says that interim results from a 20-patient, investigator-led German trial has shown "excellent" Recell repigmentation in patients with hypo-pigmented burn scars

Avita said the Cologne, Germany Malteser Hospital's plastic and cosmetic surgery specialist and principal investigator Dr Matthias Aust presented the Recell Spray-On Skin

The company said the presentation "highlighted excellent repigmentation outcomes from the randomized, within-patient controlled pilot study of 20 participants with hypo-pigmented burn scar".

Avita said that the study compared Recell to both positive controls with medical needling and negative controls with no treatment, using objective measurements of melanin or pigmentation, self-reported satisfaction ratings of participants and evaluations by a physician blinded to treatment.

The company said that a separate presentation by the Paris, France-based University Hospital Henri Mondor's head of the department of plastic surgery Prof Jean- Paul Meningaud showed "positive results achieved using Recell in combination with mechanical dermabrasion, lipofilling and platelet-rich-plasma in the remodeling of burn scars".

Avita chief executive officer Dr William Dolphin said that the fields of aesthetics and reconstructive surgery "are large and important markets for Avita".

"A growing body of clinical data, such as included in the presentations by Dr Aust and Prof Meningaud, clearly demonstrate the efficacy and applicability of Recell in the restoration of pigmentation and improved scar remodeling," Dr Dolphin said.

"These data, in combination with results from other pigmentation studies currently underway on the treatment of vitiligo and dyspigmented scars, will form the basis for the submission of a pivotal phase III investigational device exemption trial with the US FDA in 2014," Dr Dolphin said.

Avita said that Recell was undergoing clinical investigations for indications in plastics, aesthetics, chronic wounds and burns.

Avita was unchanged at 11.5 cents.

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has granted fast track designation for its NNZ-2566 for Fragile X syndrome program.

Neuren said that fast track designation was designed to expedite the development and review of medicines intended to treat serious diseases with unmet medical needs.

Neuren said it intended to begin a double-blind, placebo-controlled phase II trial to assess the safety, tolerability and efficacy of NNZ-2566 in treating symptoms of Fragile X syndrome by the end of 2013, with enrolment completed by the end of 2014 and top-line results by July 2015.

Neuren's head of clinical development and medical affairs Dr Joe Horrigan said the FDA decision was "important and timely … [and] recognizes the critical unmet needs of individuals with Fragile X syndrome".

Neuren said the FDA had granted fast track designation to all three of its NNZ-2566 clinical development programs for Fragile X Syndrome, Rett Syndrome and traumatic brain injury.

Separately, Neuren requested a trading halt pending the release of an announcement "regarding a capital raising".

Trading will resume on October 22, 2013 or on an earlier announcement.

Neuren last traded at 12.5 cents.

CELLMID

Cellmid says that midkine licencee, the Dunedin New Zealand-based Pacific Edge Diagnostics, has signed its first US provider network agreement for Cxbladder.

In 2010, Cellmid licenced its midkine technology to Pacific Edge for its bladder cancer test in return for upfront and milestone payments in addition to royalties on product sales (BD: May 19, 2010).

Earlier this year, Cellmid said it had been issued 1,084,622 milestone shares, worth $566,913, by Pacific Edge for the use of midkine as one of the biomarkers in the Cxbladder cancer test (BD: Aug 2, 2013).

In a media release, Pacific Edge said it had signed an agreement with the US national preferred provider network Fedmed to make Cxbladder available to 40 million Americans.

Pacific Edge said the agreement provided Fedmed's contracted insurance carriers, third party administrators, health and welfare funds and self-insured health plans with access to Cxbladder.

Pacific Edge chief executive officer David Darling said the agreement was "further recognition for Cxbladder and its ability to enable clinicians to detect urothelial carcinomas, including cancers of the bladder, from a small urine sample".

The company said negotiations were underway with other provider networks and insurers as well as integrated health systems, Medicare and Medicaid.

Cellmid was unchanged at 3.3 cents with 2.8 million shares traded.

CELLMID

Cellmid says the Japanese Patent Office has granted a further patent as part of the key patent family in its anti-midkine antibody patent portfolio.

Cellmid said the patent, entitled 'Method for Treatment or Prevention of Diseases Associated with a Functional Disorder of Regulatory T Cells', covered the use of midkine antibodies to increase the number of regulatory T-cells.

The company said that regulatory T-cells were central controllers of autoimmune responses and when their numbers were too low, the body's immune system could attack its own tissues, leaving subjects vulnerable to autoimmune diseases, and increasing the number of regulatory T-cells could mitigate such autoimmune attack.

The company said that published studies showed that midkine suppressed regulatory T-cell numbers, but they could be boosted by the use of midkine antibodies.

Cellmid said that in animal models of autoimmunity, inhibiting midkine using its midkine antibodies alleviated disease.

The company said the US patent was granted last year, with similar claims allowed and expiring in 2027.

ONCOSIL MEDICAL

Oncosil says the US Patent and Trademark Office has allowed a patent entitled 'Devices and Methods for the Treatment of Cancer'.

Oncosil said it was a key patent and provided patent coverage in the US for the company's nuclear medical device in development for treatment of locally advanced pancreatic cancer until 2022.

The company said that the Oncosil technology provided a localized radiation therapy for tumors, avoiding the systemic side effects of external radiation treatment.

Oncosil said it would begin a pivotal study by April 2014.

Oncosil was up 1.5 cents or 11.1 percent to 15 cents with 8.5 million shares traded.

PSIVIDA

Psivida has requested a trading halt pending an announcement “in respect to the FDA decision on … Iluvien for the treatment of chronic diabetic macular oedema”.
Psivida said the results of the Prescription Drug User Fee Act review by the US Food and Drug Administration were expected during the day of October 18, 2013 (US EST).
The original PDUFA date was set for October 17, 2013.
Trading will resume on October 22,, 2013 or on an earlier announcement.
Psivida fell 52 cents or 11.9 percent to $3.84 prior to the trading halt.

SUDA, WESTCOAST SURGICAL AND MEDICAL SUPPLIES

Suda says wholly-owned subsidiary Westcoast posted record revenue for the three months to September 2013 up more than 200 percent to $3.3 million
Suda said Westcoast recorded net profit after tax for the three months of $720,000 compared to a loss in the previous corresponding period.
The company said that Westcoast was a Perth, Western Australia-based sales and logistics operation for medical devices and consumables and in August secured preferred supplier status for an organization funded by the Federal Government (BD: Aug 15, 2013).
Suda said that revenue from the Federal Government-funded organization “played a significant part in the jump in Westcoast’s sales”.
Suda chief executive officer Stephen Carter said that although revenues from the organization “may have seasonal variation, we believe that Westcoast has entered a new era in its operations”.
Suda was up 0.3 cents or 11.1 percent to three cents with 10.2 million shares traded.

STARPHARMA

Starpharma shareholders will vote to issue 950,000 conditional ‘performance rights’ to chief executive officer Dr Jackie Fairley.
Starpharma said the rights would be vested in three tranches between September 30, 2014 and November 22, 2016, each with conditions relating to share price and/or development milestones, including advancing Vivagel for bacterial vaginosis and as a condom coating, as well as taking dendrimer-docetaxel into clinical trials..
The company said shareholders would also vote on the remuneration report and the re-election of directors Peter Bartels and Richard Hazleton.
Last year, a resolution granting 960,000 conditional performance rights to Dr Fairley was supported by 147,642,859 votes (92.8%) and opposed by 12,501,125 votes (7.8%).
Director Ross Dobinson resigned prior to the meeting but had he stayed he would have faced 124,963,300 votes (79.3%) against his re-election and 32,633,056 votes (20.7%) in favor (BD: Nov 29, 30, 2012).
All other resolutions to the annual general meeting were passed overwhelmingly.
At the time Starpharma had 283,640,060 shares on issue, meaning that the opposition to Dr Fairley’s performance rights came from 4.4 percent of all shares on issue, not sufficient to requisition extraordinary general meetings.
The opposition to Mr Dobinson came from 44.1 percent of all Starpharma shares on offer.
The meeting will be held at Norton Rose Fulbright, Level 15, RACV Tower, 485 Bourke Street, Melbourne, on November 22, 2013 at 4pm (AEDT).
Starpharma was unchanged at 92 cents.

PATRYS

Patrys says that founding non-executive director Dr Alan Robertson will retire at the annual general meeting on October 23, 2013.
Patrys said that Dr Robertson was resigning “due to the growing demands of his new ventures”.
Dr Robertson was the founding chief executive officer of Pharmaxis and resigned from the position earlier this year (BD: Mar 12, 2013).
Patrys said that as a founding director, Dr Robertson “played a significant role in the establishment and early development of the company”.
Patrys was up 0.1 cents or 3.7 percent to 2.8 cents with 1.9 million shares traded.

CANARY NETWORKS

Canary Networks is holding its first ‘Biotech and Healthcare Investor Roadshow’ in Sydney and Melbourne next week.
Canary said that speakers included Cellmid chief executive officer Maria Halasz, Impedimed chair Dr Cherrell Hirst, Biotron chief executive officer Dr Michelle Miller and Antisense managing director Mark Diamond.
The Sydney seminar will have recently-appointed Baillieu Holst analyst Stuart Roberts as keynote speaker with Biotech Daily editor David Langsam the keynote speaker in Melbourne.
The Sydney event will be held at the Swissotel, Market Street, Sydney, on October 23, 2013 from 1pm to 4pm.
The Melbourne event will be at The Rydges Hotel, Exhibition Street, Melbourne on October 24, 2013, from 1pm to 4pm.
Canary Networks director Brendan Sullivan told Biotech Daily that registration was free and the presentation included lunch and a networking drinks reception.
More information is at: http://www.canarynetworks.com.au/upcomingforums.php.