

Biotech Daily

Tuesday February 19, 2013

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: PATRYS UP 7%, USCOM DOWN 9%
- * NOVOGEN CS-6 'KILLS OVARIAN CANCER STEM CELLS IN-VITRO'
- * POLYACTIVA RAISES \$9.2m FOR DRUG-POLYMER DRUG DELIVERY
- * ANTEO PARTNERS WITH ONE WORLD LAB FOR MIX&GO SALES
- * ADVANCED SURGICAL PLACES \$594k; RIGHTS ISSUE FOR \$1.5m MORE
- * CIRCADIAN H1 REVENUE DOWN 22% TO \$600k, LOSS UP 125% TO \$4m
- * PHARMAUST H1 REVENUE UP 32% TO \$1m, LOSS DOWN 52% TO \$324k
- * ALLIED HEALTH TELLS ASX PRICE QUERY 'NEWS NOT MATERIAL'
- * GI DYNAMICS RELEASES 48.6m ESCROW CDIs
- * FISHER FUNDS TAKE 6% OF NANOSONICS
- * DIRECTOR, CSO DR ANDREW HEATON TAKES 6.5% OF NOVOGEN
- * JARROD WHITE REPLACES BIOXYNE CFO, CO SEC ASHOK JARAITH

MARKET REPORT

The Australian stock market climbed 0.37 percent on Tuesday February 19, 2013 with the S&P ASX 200 up 18.5 points to 5,081.9 points. Seven of the Biotech Daily Top 40 stocks were up, 20 fell, 10 traded unchanged and three were untraded. All Big Caps were up.

Patrys was best, up 0.2 cents or 6.7 percent to 3.2 cents with 2.3 million shares traded. Cellmid and Impedimed climbed four percent or more; Genetic Technologies and Viralytics were up more than three percent; Prana rose 2.5 percent; CSL was up 1.8 percent; with Cochlear, GI Dynamics and Resmed up by less than one percent.

Uscom led the falls, down two cents or 9.1 percent to 20 cents with 25,000 shares traded. Ellex and Phosphagenics lost more than six percent; Sirtex fell five percent; Allied Health, Avita and Phylogica were down more than three percent; Acrux, Anteo, Bionomics and Medical Developments shed more than two percent; with Circadian, Heartware, Pharmaxis, Reva, Tissue Therapies and Universal Bio down more than one percent.

<u>NOVOGEN</u>

Novogen says an in-vitro study of CS-6 has shown anti-cancer activity against cancer cells representative of malignancies, including ovarian cancer and glioma.

Novogen said that the study was conducted by Yale University spin-off, Mazor Oncology, and was designed to test the ability of CS-6 to kill ovarian cancer stem cells.

The company said that cancer stem cells had been identified in a range of cancers including gut, skin, ovarian and brain cancers and leukaemia and cancer stem cells were almost completely resistant to radiotherapy and standard anti-cancer drugs.

Novogen said that although representing less than about one percent of all cells present in these cancers, stem cells were thought to be the cause of cancer relapse following radiotherapy and chemotherapy where the bulk of the tumor was replaced with new highly-resistant cells derived from the cancer stem cells.

The company said that CS-6 had shown potent anti-cancer activity against cancer cells representative of a broad range of malignancies including ovarian cancer and glioma cancer, but it was important to extend this to see whether the drug also would be effective against cancer stem cells.

Novogen said that such dual activity, unknown in all currently approved drugs and very rare among experimental drugs, would mark CS-6 as having significant potential as a comprehensive chemotherapy, targeting both the minority cancer stem cell as well as the majority non-stem cells.

The company said that studies performed by Dr Gil Mor at Yale University identified and characterized ovarian cancer stem cells as the source of ovarian cancer recurrence. Novogen said that targeting the cells was a critical approach to prevent recurrence, the main cause of mortality in patients with ovarian cancer and in laboratory tests conducted since it acquired the Triaxial drug technology, CS-6 had proved highly effective at stopping the growth of these cancer stem cells, eventually causing them to die.

Dr Mor said that ovarian cancer stem cells were "among the toughest cancer cells to kill". "Standard chemotherapies have no effect on them, so finding a compound such as CS-6 with the capacity to target these highly chemo-resistant cells is very exiting," Dr Mor said. Novogen said that the Mazor Oncology study showed a highly effective cytotoxic effect on ovarian cancer stem cells, at low concentrations and within a short period of time.

Novogen chief scientific officer Dr Andrew Heaton said that when Triaxial designed CS-6, "we built into it years of experience in benzopyran anti-cancer drug design".

"We expected it to be a highly potent drug across almost all forms of cancer, but seeing its anti-cancer activity extended beyond the regular cancer cell to the originating cancer stem cells has exceeded my expectations as a drug designer," Dr Heaton said.

Novogen chief executive officer Prof Graham Kelly said the company's primary goal was to develop CS-6 as a treatment for glioblastoma multiforme, the main form of brain cancer. Prof Kelly said the study results showed that CS-6 could be developed for ovarian cancer, which like glioblastoma multiforme was a deadly disease for which there was no effective long-term therapy and there was "the hope that CS-6 might also be effective against the cancer stem cells that we know exist in brain cancer".

"It is important to point out that this is early days and we have some way to go before we will have clinical evidence, but there is no doubt that this news elevates CS-6 and the super-benzopyran family of drugs to which it belongs into an entirely new clinical dimension where we hope it will be possible to provide a comprehensive cancer treatment," Prof Kelly said.

Novogen fell 3.5 cents or 14 percent to 21.5 cents with 6.3 million shares traded.

POLYACTIVA, BRANDON CAPITAL

Polyactiva says it has raised \$9.2 million to develop its sustained release, site-specific drug-polymer conjugate delivery technology.

Polyactiva said the funds were raised from the Medical Research Commercialisation Fund, Brandon Biosciences Fund 1, Yuuwa Capital and angel investors.

Polyactiva chairman and Brandon Capital managing director Dr Chris Nave said the raising was "a significant achievement in the current financial environment for an early stage company to have attracted this level of funding from new investors and it reflects the confidence the investors have in the quality of Polyactiva's technology and the commercial potential of its products".

Both the Medical Research Commercialisation Fund and Brandon Biosciences Fund 1 are managed by Brandon Capital.

Polyactiva said the funds would be used for preclinical and clinical development of its products, including intra-ocular implants to treat glaucoma and severe eye infections and an intra-articular product for osteoarthritis.

Polyactiva chief executive officer Dr Russell Tait said the funding "significantly transforms our business by providing sufficient funds to take each of our planned development programs to clinical proof-of-concept".

"Once we have demonstrated significant clinical outcomes, we will seek commercial partners for these products," Dr Tait said. "We are also open to any companies looking to adopt our technology for the delivery of their own drugs."

Polyactiva said that its drug-polymer conjugate technology enabled sustained release, site-specific drug delivery from products with different physical forms, including rods, films, fibers and gels, substantially broadening its potential applications.

The company said that the conjugates were able to carry high drug loads, which allowed therapeutic quantities of drug to be delivered over extended periods from a small implant. Polyactiva said that at the end of therapy, the polymer was designed to erode completely leaving no residue, which facilitated its chronic use and repeat administration.

The company said it had proven the technology in validated animal models for delivery of drugs to the posterior region of the eye and the portfolio included low-risk products that delivered established drugs to a proven site, abbreviating the product registration process, and high-value products that delivered novel drugs to treat clinically unmet needs. Polyactiva is a private company.

ANTEO DIAGNOSTICS

Anteo says it has a sales partnership program with One World Lab to provide its Mix&Go surface chemistry products to academic and industry researchers.

Anteo said that One World Lab was a San Diego-based company supplying small quantities of antibodies and complimentary reagents to researchers.

Anteo said it would provide One World Lab with Mix&Go products for use in different areas and applications, focusing initially on coating micron-sized beads, nano-beads and a formulation optimized for use with biosensor surfaces and then adding additional Mix&Go products based on customer requests.

The company said the sales partnership would take Mix&Go to academic and industry scientists, describing the product as "double-sided molecular Velcro".

One World Lab chief executive officer Michael Simson said the company was "happy to be working with Anteo Diagnostics and offering their Mix&Go surface chemistry to our growing customer base".

Anteo fell 0.2 cents or 2.9 percent to 6.8 cents with 1.4 million shares traded.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says it has raised \$594,808 through a placement at 11 cents a share and hopes to raise a further \$1,500,000 in a non-renounceable one-for-three rights issue. Advanced Surgical said the proceeds would be directed to working capital and sales. Advanced Surgical was untraded at 12 cents.

CIRCADIAN TECHNOLOGIES

Circadian says revenue for the six months to December 31, 2012 was down 22 percent to \$600,233, with a net loss after tax up 125 percent to \$3,803,792.

Circadian chief executive officer Robert Klupacs told Biotech Daily that the majority of the revenue "about \$350,000" came from royalties.

Circadian said the revenue reflected programs for cancer with VGX-100 and eye disease with VGX-300 as well as licences to Imclone and Healthscope.

Circadian said its net tangible assets per share fell 24.4 percent to 31 cents and diluted loss per share was up 115.4 percent to 7.84 cents, with cash and cash equivalents of \$13,804,654 at December 31, 2012 compared to \$18,169,732 at June 30, 2012. Circadian fell half a cent or 1.75 percent to 28 cents.

PHARMAUST

Pharmaust says revenue for the six months to December 31, 2012 was up 32 percent to \$972,027 with a net loss after tax down 52 percent to \$324,139.

Pharmaust director told Biotech Daily that all of the revenue was from the company's wholly-owned subsidiary Epichem, which provided contract research services.

Pharmaust said that Epichem was awarded a 12-month extension to its Drugs for Neglected Diseases Initiative contract to provide synthetic and medicinal chemistry for the Initiative's drug discovery projects until December 31, 2013.

The company said its diluted loss per share fell 62.5 percent to 0.06 cents at December 31, 2012, with cash and cash equivalents of \$500,456 at December 31, 2012. Pharmaust was unchanged at 0.9 cents.

ALLIED HEALTHCARE GROUP

Allied Health has told the ASX that its share price rose 13.0 percent as it was preparing a non-material announcement about its Cardiocel patch.

The ASX said the share price climbed from 2.3 cents on February 4, to 2.6 cents, a 13.0 percent increase, on February 5, 2013, but did not note an increase in trading volumes. The ASX said the company announced results of a study of its Cardiocel tissue patch on February 6 (BD: Feb 6, 2013).

Allied said it did not consider the study results to be material and said it became aware of the results on the morning of February 4, and the data was reviewed by management with a draft media release circulated to directors and its partner, the Commonwealth Scientific and Industrial Research Organisation, in the afternoon of February 5.

Allied said that following approval of the media release it was lodged with the ASX in the evening of February 5 for pre-market release on February 6.

The company said the results were not material because they were preliminary in-vitro data and the project was at a very early stage and supportive of previously announced results in a previous study.

Allied fell 0.1 cents or 3.7 percent to 2.6 cents with 3.9 million shares traded.

GI DYNAMICS

GI Dynamics says 9,722,004 shares of common stock, equivalent to 48,610,020 Chess depositary interests (CDIs), will be released from voluntary escrow on March 5, 2013. The company said that 649,570 options over shares of common stock, (equivalent to 3,247,850 CDIs) would also be released from voluntary escrow.

Following the release GI Dynamics will have 286,805,155 CDIs if all shares of common stock were held as CDIs.

GI Dynamics was up half a cent or 0.6 percent to 80 cents.

NANOSONICS

Fisher Funds Management and associates have increased their substantial shareholding in Nanosonics from 13,350,565 shares (5.12%) to 16,095,763 shares (6.16%). Nanosonics was unchanged at 48 cents.

NOVOGEN

Director Dr Andrew Heaton has become a substantial shareholder in Novogen with the issue of 7,600,400 shares (6.47%) for his Triaxial holding (BD: Nov 12, 2012). Dr Heaton is a director of Novogen and the company's chief scientific officer. Novogen chief executive officer Prof Graham Kelly told Biotech Daily that the share issue to all six Triaxial shareholders was the first of four tranches that were milestone dependent.

BIOXYNE (FORMERLY HUNTER IMMUNOLOGY)

Bioxyne says that Ashok Jaraith has relinquished his role as chief financial officer and company secretary, effective immediately and will be replaced by Jarrod White. Bioxyne said Mr White was previously a joint company secretary and had been with the company since the Hunter Immunology backdoor listing into the then Probiomics in 2011 and 2012 (BD: Oct 11, Dec 14, 2011; Apr 3, 2012)

Mr Jaraith was Probiomics company secretary since 2007, and today Bioxyne said he would continue to manage the probiotic sales and distribution business. Bioxyne was untraded at 2.5 cents.