# Biotech Daily

Tuesday October 6, 2009

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: CYTOPIA UP 14%; VIRALYTICS DOWN 13%**

*** TORONTO'S YM BIOSCIENCES BUYS CYTOPIA FOR $14m**

*** BIOTRON'S HIGH DOSE BIT225 REDUCES HEPATITIS C VIRAL LOADS**

*** PROF ELIZABETH BLACKBURN'S NOBEL PRIZE GOOD FOR SIENNA**

*** COGSTATE SEALS $4m DEALS IN THREE MONTHS**

*** SCICLONE HALTS ACUVAX RP101 PANCREATIC CANCER TRIAL**

*** FDA APPROVES HEARTWARE TRIAL SITE INCREASE**

*** LABTECH RECEIVES FIRST $111k MICROSTREAK ROYALTY**

*** PATRYS BUYS GASTRIC CANCER ANTIBODY SC1**

*** BENITEC TAKES OPTION ON 5 T-CELL PROGRAM PATENTS**

*** MEDICAL THERAPIES COLLABORATES WITH KUMAMOTO UNIVERSITY**

*** AVITA'S FUNHALER WINS JAPANESE PATENT**

*** RESONANCE APPOINTS SIMON PANTON DIRECTOR**

## MARKET REPORT

The Australian stock market climbed 0.4 percent on Tuesday October 6, 2009 with the S&P ASX 200 up 18.3 points to 4591.6 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and three were untraded.

Cytopia was best, up 1.5 cents or 14.3 percent to 12 cents with 760,441 shares traded, followed by Psivida up 11.8 percent to $3.80. Benitec climbed six percent; Universal Biosensors was up five percent; Avexa, Heartware and Living Cell were up more than four percent; Bionomics was up 3.5 percent; Biota rose 2.9 percent; Chemgenex and Pharmaxis were up more than one percent; with Cochlear up 0.6 percent.

Viralytics led the falls, down 0.4 cents or 13.3 percent to 2.6 cents with 1.2 million shares traded. Antisense lost 7.8 percent; Phosphagenics fell 6.5 percent; Clinuvel, Optiscan and Tyrian fell more than four percent; Cellestis and Labtech fell more than three percent; Compumedics, Novogen, Prana, Resmed, Sunshine Heart, Starpharma and Tissue Therapies shed more than two percent; with CSL, Genetic Technologies, Mesoblast and Nanosonics down more than one percent.

CYTOPIA

Cytopia says it will be acquired by the Toronto-based YM Biosciences for 16.59 cents a share or $14 million.

At its 10.5 cents a share close last night, Cytopia's maket capitalization was $8.9 million.

Cytopia said YM would acquire its shares and options through schemes of arrangement, at one YM share for 11.737 Cytopia shares, with options at an equivalent ratio.

The company said the offer of 16.59 cents per Cytopia share was a 58 percent premium to the trading price of Cytopia shares immediately prior to signing the agreement.

The payment is subject to an arrangement providing for adjustments to the share exchange ratio where there are significant movements in the trading price of YM shares.

Cytopia chief executive officer Andrew Macdonald told Biotech Daily that nothing would change at Cytopia's Melbourne establishment, other than the ownership.

He said Cytopia would become a wholly-owned subsidiary of YM Biosciences and existing Cytopia shareholders would become investors in the Canadian company.

"The operations and staff remain the same," Mr Macdonald said.

"This still remains an operation with a lot of upside," Mr Macdonald said.

"Investors will have access to a broader program and there will be more investment in CYT997, without further dilution," he said.

Cytopia said YM had a market capitalization of $C87 million ($A93 million), with 58.2 million shares on issue.

Cytopia said YM reported cash and cash equivalents of $C41 million at June 30, 2009.

On implementation of the schemes, Cytopia shareholders would own 11 percent of YM and Cytopia's chairman Bob Watson would be appointed to the YM board.

Cytopia said YM was a cancer-focused company with lead drug candidate nimotuzumab in several phase II and III clinical trials and marketing approval in 21 countries.

YM has offices in Canada, the US, United Kingdom and Cuba and is listed on the Toronto Stock Exchange (YM) and the New York Stock Exchange (YMI).

Cytopia said the resultant entity would develop four clinical stage assets: Cytopia's vascular disrupting agent for solid tumors CYT997 and CYT387, a JAK2/JAK1 kinase inhibitor, for myeloproliferative disorders and cancer; along with YM's Nimotuzumab an EGFR-targeting antibody being developed for multiple tumor types in combination with radiation and chemoradiation and AeroLEF, an inhaled version of fentanyl for pain.

The merged companies would manage other Cytopia collaborations, including the partnership with the Cancer Therapeutics CRC to develop FAK inhibitors for cancer.

Cytopia said it had more than 4,000 tyrosine kinase inhibitors and other small molecule compounds for further development and was reviewing similar out-licencing opportunities.

Cytopia directors unanimously recommended that the acquisition was in the best interests of Cytopia investors in the absence of a superior offer.

"With their broad international reach and strong cancer focused clinical development expertise, we believe YM is an excellent partner for Cytopia," Mr Macdonald said.

"This merger provides the best opportunity available for the continued development and expansion of our lead programs and also provides our shareholders with exposure to a broader portfolio of potential cancer therapies and geographic diversification," he said.

YM chairman and chief executive officer David Allan said the transaction was "a significant step in developing a wide portfolio of cancer related products to maximize success and to better manage risk".

The merger is subject to investor, court and regulatory approval and both companies have agreed to a $A500,000 break fee.

Marc Sinatra's Bioguide Brief on the merger will appear in tomorrow's edition.

Cytopia was up 1.5 cents or 14.3 percent to 12 cents.

## BIOTRON

Biotron' trial of BIT225 for hepatitis C virus has shown the drug is safe and tolerable, with several subjects on the highest dose recording significant reductions in viral loads.
Biotron said the phase Ib/IIa proof-of-concept clinical trial showed that BIT225 met its primary end point of safety and tolerability in subjects dosed twice daily for seven days.
BIT225 was well tolerated with no serious adverse events reported and no discontinuations from the study.
The company said the secondary objectives were to assess the pharmacokinetics of BIT225 and the antiviral efficacy of BIT225 in the patients.
Biotron said that a preliminary analysis of the pharmacokinetic profile of BIT225 demonstrated sustained plasma levels of BIT225 that were within the potential therapeutic range and were consistent with the potential for once or twice daily oral dosing.
BIT225 has also met the objective of antiviral efficacy, which was assessed by measurement of viral load in the plasma of the subjects, the company said.
Preliminary statistical analysis of viral load reductions, as measured by the mean change in virus levels from baseline at Day 0 through to the end of the study at Day 21, indicated that the effect of BIT225 treatment on the 200mg cohort as a group was modest but highly significant compared to placebo controls.
Three of six subjects receiving 200mg of BIT225 had significant reductions in viral loads.
Biotron said the load reductions were modest (a maximum of 0.5 log10) but were significant and showed that reported in vitro activity translated to in vivo efficacy.
Chief executive officer Dr Michelle Miller said the data was encouraging, "with 50 percent of subjects receiving 200mg of BIT225 showing significant reduction in viral loads".
"We know from previous preclinical studies that BIT225's potency is significantly enhanced in combination with interferon-alpha and ribavirin, so we would expect greater efficacy levels in future combination studies," Dr Miller said.
"This current result demonstrates proof-of-concept … that BIT225 is able to target and reduce [hepatitis C virus] replication in a clinical setting," Dr Miller said.
Biotron said the study was the first demonstration of efficacy with a new class of anti-hepatitis C drug, targeting the p7 protein of hepatitis C virus (HCV).
The company said there was a demand for new classes of antiviral drugs in hepatitis C treatment and the standard of care of interferon-alpha and ribavirin was ineffective in 50 percent of cases and was often associated with severe side effects.
Biotron said the use of new classes of HCV drugs in development known as protease and polymerase inhibitors lead to rapid resistance when used on their own.
Future HCV treatment was likely to involve cocktails of several specific antiviral drugs and BIT225 had the potential to be included in these combinations as it had shown high degrees of synergism with other treatments in cell culture models.
Biotron said it planned to take BIT225 to a 14-day dose-ranging study in combination with interferon-alpha and ribavirin.
Biotron was up two cents or 14.3 percent to 16 cents.

## COGSTATE

Cogstate has signed sales contracts worth $US3.68 million ($A4.31 million) since July 1, 2009.
Cogstate said that in the three months to September 30, 2009 a total of 11 sales contracts were signed with a combined value of $US3.18 million an improvement of 26 percent over the September 2008 quarter and an 11 percent improvement over the June 2009 quarter.
Cogstate was up one cent or 4.2 percent to 25 cents.

## SIENNA CANCER DIAGNOSTICS

Sienna managing director Dr Kerry Hegarty says the Nobel Prize awarded to Prof Elizabeth Blackburn will increase interest in telomerase enzymes.

Dr Hegarty said that the Nobel Prize for Medicine presented to the discoverers of telomerase Prof Blackburn, Prof Carol Greider and Prof Jack Szostak would help highlight the work of her Melbourne-based company which develops “novel diagnostic technologies to measure with exquisite sensitivity for telomerase, or more precisely telomerase activity”.

Dr Hegarty said telomerase was the enzyme responsible for the maintenance of the ends of chromosomes.

Dr Hegarty said Australia's first woman Nobel laureate, Dr Blackburn, and her colleagues proposed 25 years ago that a particular protein had the role of keeping chromosomes forever young, but “the flip-side of eternal youth … is uncontrolled growth and cancer”.

Dr Hegarty said it was recognized that telomerase was related to tumor-building events, due to its function of maintaining the length of the ends of chromosomes.

She said that measuring telomerase activity allowed for a more reliable method to monitor the stage of cancer and identify appropriate treatments.

She said Sienna’s first telomerase test targeted the surveillance of bladder cancer, which was conventionally assessed every four months by invasive means whereas her company’s test required “only a urine sample”.

Dr Hegarty said the test could also lead to earlier detection of cancer and related enzymatic activity was detectable at an earlier stage than revealed at later stages by blood in the urine or faeces with bladder or colorectal cancer, or a lump in breast cancer.

Dr Hegarty said Sienna third clinical trial would be completed before the end of 2009.

She said major shareholder, California’s Geron Corp, provided exclusive rights to telomerase allowing the company to bring its oncology diagnostic products to market.

Sienna is a private company.

## ACUVAX

Acuvax says that trials of its RP101 pancreatic cancer drug being developed by Sciclone Pharmaceuticals have been halted following a data monitoring safety committee report.

Acuvax said it owned 43 percent of Avantogen Oncology Inc, which was in a licencing partnership with Sciclone.

Acuvax said it took a cash gain by selling all assets related to rest of world rights to RP101 earlier this year (BD: April 15, 2009).

The company said RP101 drug was in phase II trials paid for by Sciclone but the Avantogen Acuvax group decided to share the development risks of the RP101 for treatment, in combination with chemotherapy drug gemcitabine, for pancreatic cancer.

Acuvax said the group received significant upfront cash and milestone payments with Sciclone paying $4 million and agreeing to pay for the full costs of initiation and completion of a phase II clinical trial.

In March 2009 Sciclone said it had invested heavily to accelerate enrolment completion ahead of schedule of the RP101 phase II trial of 167 patients and in September 2009 provided guidance that top line results were expected in early to mid-2010.

Acuvax chief executive officer Dr William Ardrey said news of the trial's suspension was disappointing, but remained hopeful the pancreatic trial program may resume.

The company said Sciclone was evaluating next steps, pending a detailed review and analysis of safety and efficacy once data were unblinded.

Acuvax fell 0.2 cents or 9.1 percent to two cents.

## HEARTWARE INTERNATIONAL

Heartware says the US Food and Drug Administration has approved an expansion of clinical trial sites for its US bridge-to-transplant trial.

The company said the FDA approved a total of 40 clinical sites to evaluate the Heartware ventricular assist device (HVAD) in end-stage heart failure patients requiring circulatory support to bridge them to a heart transplant.

Heartware chief executive officer Doug Godshall said the company had "strong interest from high caliber transplant centers that want to join our … trial, [but] we could not previously accommodate them due to our existing 28 clinical site limitation".

"Receipt of FDA approval enabling expansion from 28 to 40 clinical sites allows us to accept many of these additional sites prior to the completion of enrolment which we project will occur in the first half of 2010," Mr Godshall said.

Heartware said it had 22 clinical sites initiated in the US with 69 patients implanted in the 150 patient study.

The company said heart failure was one of the leading causes of death in the developed world and congestive heart failure affected five million people in the US with 550,000 new cases diagnosed each year.

Heartware said that despite new treatments, the number of patients who died from this disease was "of epidemic proportion".

The company said cardiac transplantation was the most effective therapy for the treatment of advanced end stage heart failure, but it was limited by the lack of available donors.

Heartware said that during the last decade, bridging to cardiac transplantation with implantable left ventricular assist devices had gained wider clinical acceptance and these cardiac pumps were used to extend life expectancy for patients who might otherwise deteriorate while awaiting a donor heart.

Heartware climbed four cents or 4.3 percent to 98 cents.

## LABTECH SYSTEMS

Labtech has received the first royalty payment of $111,350 from Biomérieux as part-payment for sales of its Microstreak applicators in 2009.

Labtech chairman Bob Finder said the first payment of royalties for Microstreak applicators used in the Previ Isola instruments sold by Biomérieux was "a major milestone in the company's history".

"Significant revenues may be generated by these ongoing royalties as the use of the patented disposable applicators grows in clinical laboratories throughout the world over the next few years," Mr Finder said.

Labtech said the Previ Isola was launched in December 2008 and the company said it was beginning to receive income from royalties for the disposable Microstreak applicators used with the instrument.

The company said the agreement with Biomérieux provided for a double-digit percentage royalty to be paid on sales of applicators.

As well as further royalties from the Microstreak applicators, a milestone payment of $3.4 million was expected in April 2010.

Labtech said it had received $6.67 million in milestone payments from Biomérieux for the development and manufacturing establishment of the Previ Isola automated microbiology agar plate streaker that incorporates the Microstreak applicator.

Labtech said Biomérieux had ongoing responsibility for the manufacture, marketing and distribution of Previ Isola and there were no further obligations on Labtech.

Labtech fell half a cent or 3.6 percent to 13.5 cents.

## PATRYS

Patrys says it has acquired the rights to commercialize the gastric cancer antibody product SC1 from Debiovision Inc.

Patrys said it renamed the product PAT-SC1 and said it had been shown to provide a significant survival benefit to gastric cancer patients treated with the product in a trial at Germany's University of Wurzburg Medical Centre.

The company said the acquisition "immediately transforms Patrys' internal product pipeline from preclinical to clinical status by adding a product that has already generated positive human clinical trial data".

University of Wurzburg surgical oncologist Dr Bertram Illert said the anti-cancer benefits of PAT-SC1 were shown in a clinical trial, in which 35 gastric cancer patients were treated with a small, single dose of PAT-SC1 prior to surgical removal of the patients' tumors.

"These patients obtained a meaningful survival benefit relative to a historic control group of patients who had their tumors surgically removed but who did not receive PAT-SC1," Dr Illert said. "As a more specific example, I have recently seen a patient who lived cancer free for seven years after treatment with PAT-SC1, where without treatment his life expectancy was 15 months."

Patrys said there were no broadly effective treatments for gastric cancer and 80 percent of patients died within five years of diagnosis.

Patrys said it would take 12 months to reach large scale production levels of PAT-SC1, at which time it would take the product into phase II trials for gastric cancer.

Patrys fell half a cent or 3.6 percent to 13.5 cents.

## BENITEC

Benitec has an option from California cancer centre City of Hope to exclusive rights to five US patents and patent applications for use with a T-cell project.

Benitec said the patents underpinned its second HIV program - a multi-project effort at City of Hope to investigate HIV-based vector delivery of anti-HIV RNA to CD4 T-cells.

This study is separate from the City Of Hope, Benitec collaboration on gene modified stem cells. Benitec said the T-cell project was a different approach to the stem cell study, through the alteration of HIV progression by the manipulation of T-cells.

The company said the T-cell project would provide a measure of the degree of T-cell gene marking which might be correlated to changes in HIV levels or even disease outcome.

Benitec said both approaches provided potentially effective options for HIV therapy, and the approach used clinically will depend on individual patient needs.

Benitec said the City of Hope granted an option to obtain an exclusive worldwide licence to a suite of patent rights held by City of Hope for use with T cells.

If the option is exercised, City of Hope will grant Benitec an exclusive, worldwide royalty-bearing licence to research and develop, manufacture, use, offer for sale, import and sell products in the field as defined in the licence.

Benitec said a phase I safety and feasibility clinical study was planned to begin by the end of 2009 at the City of Hope and the manufacturing of T-cell product would be completed at the University of Pennsylvania.

The trial will assess whether the vector in T-cells had an adequate safety profile and that the production and release of this large number of T cells was feasible.

The patents are 'Nucleolar targeting of therapeutics against HIV'; 'Ribozymes targeted to human CCR5 mRNA'; 'Methods and kits for synthesis of siRNA expression cassettes'; 'Methods for producing interfering RNA'; and 'Adenoviral VA1 Pol III'.

Benitec was up 0.3 cents or six percent to 5.3 cents with 2.7 million shares traded.

## MEDICAL THERAPIES

Medical Therapies will supply its IP14 antibodies to Japan's Kumamoto University in return for first rights to review and commercialize any new data and invention.
The rights acquired by Medical Therapies include patenting rights of any invention at the company's option.
Medical Therapies said researches at Kumamoto University would gain access to Medical Therapies' IP14 antibodies which were "well-characterized and have high affinity to midkine, which will facilitate more accurate results and could lead to further new inventions".
Medical Therapies said it would gain access "to the data generated from the validation projects conducted by the outstanding experts in midkine research at Kumamoto University".
Medical Therapies would have the first right to commercialize any novel findings from the research projects.
Medical Therapies chief executive officer Maria Halasz said the agreement would add momentum to the clinical validation programs of her company's cancer diagnostic portfolio.
The company said the validation and research work would be funded entirely by Kumamoto University with Medical Therapies contribution limited to the supply of the IP14 antibody from its existing inventory.
The planned midkine research programs span a number of fields over several years.
Medical Therapies was up 0.2 cents or 7.4 percent to 2.9 cents with 2.4 million shares traded.

## AVITA MEDICAL

Avita says the Japan Patent Office has granted a patent entitled: 'Improved drug delivery device and methods therefore'.
Avita said the patent had "broad applicability and related to the incorporation of feedback and incentive mechanisms into devices for the improved delivery of medications and biologically active substances via the inhalation pathway".
The company's Funhaler spacer was acquired with Visiomed in the Clinical Cell Culture merger and uses a spinning disc and whistle to encourage non-compliant children to use their asthma spacers.
Avita said the patent covered more applications than just the Funhaler.
Avita said there was a need for improved delivery devices with inhalation being the pathway of choice for many medications and biologically active substances.
The company said delivery of medication for the treatment and control of respiratory disease, diabetes and hypertension, as well as the delivery of anti-virals, anti-biotics and other biologically active substances were emerging opportunities for the technology.
Avita chief executive officer Dr William Dolphin said the delivery of medication through the inhalation pathway was "becoming the technique of choice for a range of medical conditions".
"Additionally, the delivery of living cells in aerosol suspension via inhalation has tremendous potential for applications in regenerative medical technologies," Dr Dolphin said.
The company said the intellectual property covered under the patent expanded and complemented its existing patented technology and follows patents granted in the US, China and Taiwan.
Avita was unchanged at 16.5 cents.

## RESONANCE HEALTH

Resonance Health has appointed Simon Panton as a non-executive director, effective immediately.

Resonance said Mr Panton had been “a strong supporter of the company and the Ferriscan technology over a number of years and [was] a major shareholder of Resonance Health”.

The company said Mr Panton had skills in business and marketing and ran his own business.

Resonance was unchanged at 1.8 cents.