Biotech Daily

Monday August 10, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: COMPUMEDICS UP 31%, CATHRX DOWN 11%**

*** VALE LIVING CELL FOUNDER DAVID COLLINSON (24.8.1949 - 7.8.2009)**

*** ASTRAZENECA DUMPS BIOTA RSV DRUG**

*** BIOTA LANI PHASE III SUCCESS**

*** METABOLIC: PROGRAMS CUT, POLYNOVO TO STAND ALONE**

*** BIOPHARMICA ACQUIRES ALL OF HLS5; DEVELOPS ANTI-MITOTIC DRUG**

*** SUNSHINE HEART IMPLANTS AORTA CUFF IN TWO WOMEN**

*** SUNSHINE HEART PLACEMENT, RIGHTS ISSUE TO RAISE UP TO $9.85m**

*** TGA APPROVAL FOR ADVANCED SURGICAL ACCESS DEVICE**

*** AGENIX CONVERTIBLE NOTES RAISE $1m**

*** NOVOGEN'S EUROPEAN PATENT CLAIMS UPHELD**

MARKET REPORT

The Australian stock market rose 0.11 percent on Monday August 10, 2009 with the S&P ASX 200 up 4.7 points to 4304.1 points. Sixteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and four were untraded. All three Big Caps were up.

Compumedics was best for the second trading day in a row, up four cents or 30.8 percent to 17 cents with 340,500 shares traded, followed by Psivida up 13.3 percent to $3.40.

Benitec climbed more than 11 percent; Phylogica rose 10 percent; Alchemia was up 8.6 percent; Tissue Therapies was up 7.7 percent; Sunshine Heart rose 6.25 percent; Biota was up 5.3 percent; Novogen and Optiscan were both up 4.3 percent; Chemgenex climbed 3.45 percent; Genera, Prana, Resmed and Starpharma rose more than two percent; with Cochlear and Peplin up more than one percent.

Cathrx led the falls, down four cents or 11.1 percent to 32 cents with 11,145 shares traded followed by Tyrian down 10 percent to 1.8 cents. Impedimed lost 6.7 percent; Clinuvel and Sirtex were down more than three percent; Antisense, Nanosonics and Progen shed more than two percent; with Acrux and Circadian down by more than one percent.

DAVID COLLINSON, LIVING CELL TECHNOLOGIES

Living Cell founder and director David Collinson died at his home on August 7, 2009 after a long battle with melanoma.

Originally a clothing manufacturer, Mr Collinson told Biotech Daily that he founded the company following the discovery that his then two year-old son had type 1 diabetes and he was determined to find a cure for the disease.

Living Cell said in an obituary for its founder that Mr Collinson established the predecessor company Diatranz in 1987 with Prof Bob Elliott, Living Cell's medical director.

Living Cell said that the Collinson family experienced first-hand the difficulties of daily management of the disease and the impact it had on the lifestyle of a young child.

On learning the possible medical complications for his son, Mr Collinson visited Prof Elliott's surgery and subsequently committed himself and his money to fighting diabetes.

Mr Collinson was the company's chief executive officer and continued as a non-executive director until his death.

Living Cell said he had the vision of a radical approach to treating diabetes by replacing insulin producing cells lost as a result of the disease and believed it should be possible to restore to normal the life of diabetes sufferers.

Living Cell said Mr Collinson worked tirelessly for the company, promoting the cause to investors worldwide to join the crusade against diabetes.

"His persistent enthusiasm endured to the last weeks of his life as he fought against disseminated melanoma," Living Cell said.

Prior to his death, Mr Collinson was made an honorary member of the Royal Society of New Zealand, a Paul Harris Rotary Fellow and received a commendation from the vice-chancellor of the University of Auckland for his contribution to medical science.

Living Cell said his cheerful presence at the company would be missed.

Living Cell said its staff shared the loss with Mr Collinson's wife Jenny, son Simon, daughter Natalie and his family.

Biotech Daily is deeply saddened by the loss of an inspired biotechnology company founder and one of our first subscribers.

BIOTA BTA9881

Biota says the Astrazeneca has halted work on BTA9881 for respiratory syncytial virus on safety grounds, while Daiichi Sankyo has favorable results for its LANI flu drug.

Biota said the phase I trial of its respiratory syncytial virus (RSV) anti-viral drug, BTA9881 showed strong oral bioavailability but "the BTA9881 drug profile overall did not meet the desired safety margin required to continue development of this compound".

The company said BTA9881 was the first of a new class of fusion inhibitors developed by Biota to enter clinical trials and exhibited "approximately 100 percent oral bioavailability in humans and a safety profile in humans comparable to placebo at the doses examined".

Biota said the pharmacokinetic profile indicated a very long plasma half life in humans.

The company said Astrazeneca's primary interest in its respiratory syncytial virus program was BTA9881 and Astrazeneca had "provided notice to Biota that it will terminate the licence and collaboration agreement as soon as practical".

Biota said all rights in the program would revert to Biota and it intended to invest $3 million in 2009-'10 for the development of back-up compounds and to re-licence the program.

Biota was up 11 cents or 5.3 percent to $2.17.

BIOTA LANINAMIVIR

Separately Biota said the Asian phase III clinical trials showed that a single dose of long acting neuraminidase inhibitor CS-8958 or 'laninamivir' was as effective as multiple doses of oseltamivir or Tamiflu.

Biota said laninamivir was co-owned with Daiichi Sankyo and the phase III trial showed that a single inhaled dose of laninamivir was "as effective as oseltamivir administered orally twice daily for five days".

The company said that a parallel phase II/III trial of CS-8958 in paediatric patients also met the primary and secondary endpoints compared to oseltamivir.

Biota's managing director Peter Cook said the success of the multifaceted phase III trials in Asia was significant.

The trial was conducted by Daiichi Sankyo in Japan, Taiwan, Hong Kong and Korea and enrolled about 1,000 adult patients who had confirmed, naturally acquired influenza A or influenza B.

Patients were distributed equally to receive 20mg laninamivir as a single inhaled dose, 40mg of laninamivir as a single inhaled dose or 75mg of oseltamivir twice daily for five days.

The primary end point of the trial was time to symptom resolution and the secondary end point was time for body temperature to return to normal.

Biota said both doses of laninamivir were as effective as oseltamivir and were well tolerated.

The phase II/III double-blind paediatric study of laninamivir was conducted in Japan in 180 children aged at nine years or younger and also compared the safety and efficacy of 20mg or 40mg of laninamivir as a single inhaled dose, with oseltamivir administered at a dose of 2mg/kg twice daily for five days.

Biota said the primary and secondary end points were the same as those used in the adult study and both doses of laninamivir were equivalent to oseltamivir and were well tolerated by paediatric patients.

There was also a trend towards the single inhaled doses of 20mg or 40mg of laninamivir showing a faster time to the alleviation of influenza illness than oseltamivir.

Biota said that a recent paper in the journal 'Nature' published by University of Tokyo virologist Yoshihiro Kawaoka indicated that laninamivir was also active against the swine-originated influenza A H1N1 virus.

Daiichi Sankyo has the rights to manufacture and market laninamivir in Japan and funded the Japanese trials and was seeking approval from the Japanese regulatory authority to market laninamivir in Japan, with a submission expected by March 2010.

A clinical study for prophylaxis of influenza is expected to commence in Japan in late 2009.

Biota said it would will receive an undisclosed royalty on sales and a number of fixed sum payments on the achievement of certain sales milestones.

Biota said it would continue to advance the clinical development program required to support registration in North America and Europe.

The company said the US National Institutes of Health had committed a total of $US5.6 million to support the western clinical development program and a licencing partner was being sought for all markets outside Japan, including the US.

Under their agreement Biota and Daiichi Sankyo will share commercial returns from licensing outside Japan.

METABOLIC

Metabolic has reviewed the ownership of 60 percent subsidiary Polynovo and is considering how to create a stand alone company.

Metabolic director George Cameron-Dow told Biotech Daily that the primary options were either a reverse takeover of an existing company or a new listed entity.

Metabolic said in a release to the ASX that it held 60 percent of Polynovo, Xceed Capital held 25.5 percent, with the Commonwealth Scientific and Industrial Research Organisation holding 14.5 percent.

Metabolic said the best long term structure for Polynovo was "one in which it is not dependent on Metabolic for its funding requirements".

"It is expected that this will also unlock the value in Metabolic given the significant discount to net cash at which Metabolic shares currently trade," the company said.

Metabolic said it would provide funds for Polynovo to continue its product development programs and meet its financial commitments over the next year.

Metabolic said Medtronic Vascular and Polynovo had terminated a partnering and licencing agreement on the Novosorb biodegradable polymer for potential application in stent design for cardiovascular disease and all of Polynovo's intellectual property and rights would return to the company.

Polynovo's acting chief executive officer Laurent Fossaert said the termination was "disappointing" but the company would "actively pursue new opportunities to licence Novosorb in the biodegradable stent field".

Metabolic said Polynovo's deals with Smith and Nephew to use Novosorb in fracture fixation and bone void fillers were on target for their respective development timelines.

The company said Novosorb was being tested by Biomet for multiple applications and the burns temporising matrix product had reached the construction of an animal trial to be run by Adelaide joint venture partner Dr John Greenwood.

Metabolic said delays in clinical work on the dermal filler Novofill were "largely due to the facility move and technical difficulties in developing Novosorb in a form that can be delivered through a very narrow gauge needle" but progress had been made and once validated would the joint venture to begin pre-clinical work.

Metabolic said that a 2006 external administrative error at the time of assignment of six families of patent applications from the CSIRO to Polynovo, led to the lapse of a European patent application related to the in-situ cure application of Novosorb and an application for reinstatement was underway.

Metabolic said that some legacy assets had commercial appeal, but the intention was not to commit substantial funding to them and out-licence the technology where appropriate.

Metabolic said AOD9604 was a peptide drug derived from human growth hormone which had two potential applications, osteoporosis and obesity.

Metabolic was considering licencing AOD9604 to a partner with the capability of managing the long and expensive human trials required for osteoporosis drugs.

Metabolic said the oral delivery trial of AOD9604 for obesity was terminated in 2007 but there was potential use of alternative non-oral delivery routes and the company had received proposals on these approaches from external parties (BD: Feb 21, 2007).

Metabolic said it would discontinue the oral peptide delivery platform to conserve funds and the neural regeneration peptides collaboration with Neuren was also on hold.

Metabolic said it had retained its cash reserves at $11.3 million and cut expenditure so most costs were covered by interest received on term deposits.

Metabolic said the share price did not reflect underlying assets and it had about 3.7 cents a share in cash in addition to a controlling stake in Polynovo and the legacy assets.

Metabolic was unchanged at 2.9 cents with 1.4 million shares traded.

BIOPHARMICA

Biopharmica has acquired all rights to anti-cancer compound HLS5 from the University of Western Australia and has appointed Dr Robin Scaife to develop anti-mitotic cancer drugs
Biopharmica said an agreement with the University replaced the HLS5 collaborative research and technology farm-in agreement giving Biopharmica the outstanding 16 percent of the intellectual property held by the University in the HLS5 project and its derivatives in exchange for a royalty on commercialization.
Biopharmica said it alone would fund the development of the projects.
The company said new commercially targeted projects had been spun-out of the original program as a result of the last four years of research which included a possible new anti-cancer therapeutic and a new anti-cancer strategy.
Biopharmica said the most recent development in the anti-mitotic cancer therapeutic area addressed a market in which current clinically approved anti-mitotic drugs such as Taxol and Velban had revenue of more than $US1 billion a year.
As part of the agreement cancer cell biology researcher Dr Robin Scaife has been appointed lead scientist on the anti-mitotic project.
The company said Dr Scaife was previously employed by the University of Western Australia and would continue his research as a full time employee and would be in charge of the Biopharmica laboratory at the Western Australian Institute for Medical Research.
Biopharmica chairman David Breeze said discussions had been “initiated with international companies with the objective of licencing and development of these projects … within this financial year”.
The company said a new class of anti-mitotic drugs, discovered by Dr Scaife had undergone “extensive development toward pre-clinical testing of anti-cancer activity”.
Detailed analyses of chemical analogues yielded a new drug that exhibited nearly 1000 times the biological activity of the initial compound derived by screening of a chemical library, Biopharmica said.
The company said the new drug had recently undergone testing in animals to rule out adverse toxic side-effects and animals exposed to very high levels of the drug exhibited no signs of acute toxicity and the anti-mitotic drug was “primed for pre-clinical testing of anti-tumor activity”.
Biopharmica was as high as 5.5 cents, closing up 2.4 cents or 92.3 percent at five cents.

SUNSHINE HEART

Sunshine Heart says the Jewish Hospital in Louisville, Kentucky has implanted C- Pulse aorta cuff pumps in two female patients.
Sunshine Heart said the women aged 58 and 55, respectively, were the company’s first female patients in the US Food and Drug Administration approved clinical trial and brought the total number of implants to four.
The C-Pulse system was implanted by the chief of the division of thoracic and cardiovascular surgery at the University of Louisville Prof Mark Slaughter.
Sunshine Heart chief executive officer Don Rohrbaugh said enrolling the first two female patients was “significant” because although women accounted for nearly half of all hospital admissions for heart failure “only 25 percent of these patients are typically involved in heart failure studies”.
“C-Pulse can be an important new therapy for women suffering from heart failure since they typically survive longer than men with the disease but commonly have more illness, more frequent hospitalizations and a poorer overall quality of life,” Mr Rohrbaugh said.
Sunshine Heart was up 0.4 cents or 6.25 percent to 6.8 cents.

SUNSHINE HEART

Sunshine Heart hopes to raise up to $9.85 million through a $1.75 million placement along with a three-for-five rights issue at four cents a share.

The placement of 43,758,664 shares at four cents a share was expected to raise $1.75 million while the rights issue would have up to 202.5 million shares at the same price to raise $8.1 million.

Sunshine Heart said commitments to participate in the rights issue of about $4.65 million have been received from existing shareholders, which, combined with the placement proceeds will enable the company to raise a minimum $6.4 million through the placement and rights issue.

Cornerstone shareholders CM Capital and GBS Venture Partners have committed to subscribe for their entitlement, together amounting to about $4.2 million.

Sunshine Heart said the timetable for the rights issue and placement would be released.

The company said the funds would be used to complete its 20 patient US trial and prepare its Conformitée Européenne (CE) mark application.

ABN Amro Morgans Corporate is lead manager to the placement and rights issue.

ADVANCED SURGICAL DESIGN AND MANUFACTURE

Advanced Surgical says it has Class IIa approval from the Australian Therapeutic Goods Administration for its peripheral access device.

Advanced Surgical said approval meant that the device, which provided surgeons with vascular access, could be used to trial isolated organ and isolated limb chemotherapy.

The company said TGA approval also permitted it to make the peripheral access device available to hospitals in Australia, Europe, Asia and South America “with the potential to save thousands of lives through innovative cancer therapy”.

Advanced Surgical said the device had been developed by “to trial a ground-breaking enhancement of the cancer treatment called ‘isolated organ perfusion’ that has been in use since the 1950s”.

The company said the peripheral access device allowed for multiple uses of balloon catheters or tubes that are inserted into the arteries for treatment.

Advanced Surgical said the current method of putting a catheter into an artery required extensive surgical intervention and was usually only able to be done once or twice for each patient.

The company said the new development would allow isolated chemotherapy to be applied as often as required to a specific area, such as the liver or a limb.

Advanced Surgical said isolated organ chemotherapy can be used instead of the traditional method of cancer therapy where chemotherapy drugs are spread throughout the entire body.

With isolated organ perfusion, the chemotherapeutic drugs are confined to the part of the body affected by cancer, the company said.

Advanced Surgical said the peripheral access device would allow a trial of multiple treatments for each patient using isolated organ perfusion with the potential for improved cure rates.

Advanced Surgical fell half a cent or 1.59 percent to 31 cents.

AGENIX

Agenix says it has raised $1,000,000 through the private placement of unlisted convertible notes to two existing sophisticated shareholders.
Agenix said the funds would provide immediate term working capital to fund the ongoing operations of the company including the Chinese business operations and supporting our efforts to sell or otherwise divest the Thromboview diagnostic intellectual property.
The company said the interest on the principal of the notes at the coupon rate of 10 percent a year, would be payable quarterly in arrears or on conversion.
Agenix said that subject to shareholder approval, the principal of the notes and the accrued interest would automatically convert into shares at 0.5 cents a share.
The company said it was finalizing its 2007-'08 financial report with the auditors and expects to lodge this report and send notices for the annual general meeting shortly.
Agenix said it was progressing the December 2008 half year accounts and its 2008-'09 financial report with a view to reinstate the shares to trading at the earliest opportunity.
Agenix is in a voluntary suspension and last traded at 1.7 cents.

NOVOGEN

Novogen the European Patent Office has upheld its 2004 patent around the use of isoflavone phyto-oestrogen extracts of soy and clover as nutritional supplements.
Novogen said it had received the written findings from the European Patent Office hearing in Munich, which ended on July 8, 2009, in which the Opposition Division of the Office agreed on claims for the Novogen Isoflavone patent.
The company said the Opposition Division found that the subject matter of the patent claims were both enabled and exhibited an inventive step over the prior art.
Novogen said it was important that "the upheld claims largely reflect the claims of the original patent granted by the European Patent Office in 2004".
The upheld claims were for the use of an isoflavone phyto-oestrogen extract of soy or red clover, wherein the extract comprised isoflavones selected from genistein, daidzein, biochanin A or formononetin, for the manufacture of a medicament for administration in a variety of doses and/or dosing cycles for the treatment of pre-menstrual syndrome or symptoms associated with menopause.
Novogen said a decision by the Vienna Commercial Court reinforced European patent law that food supplements were not excluded by the term 'medicament' and the Court found a red clover isoflavone menopause product, Vitalady, infringed the Novogen patent.
The company said the court granted a provisional injunction against Vitalady accepting that a nutritional food supplement can be considered a medicament under European patent law.
"The EPO decision will encourage further innovative research into food supplement products and further the development of original thinking about food supplementation to enhance human health," Novogen said.
Novogen was up three cents or 4.3 percent to 73 cents.