Biotech Daily

Monday February 16, 2009

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: HEARTWARE UP 56%, UNIVERSAL DOWN 25%**

*** THORATEC TO PAY $429m FOR HEARTWARE; VENTRACOR IMPACT**

*** BIOGUDE BRIEF: THORATEC-HEARTWARE DEAL HURTS VENTRACOR**

*** CELLESTIS' RECORD H1 PROFIT UP 769% TO $2.9m; 1¢ DIVIDEND**

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*** ADVANCED OCULAR LOSES VLADO BOSANAC BEFORE MERGER**

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MARKET REPORT

The Australian stock market fell 1.2 percent on Monday February 16, 2009 with the S&P ASX 200 down 42.2 points to 3,516.9 points. Twelve of the Biotech Daily Top 40 stocks were up, eight fell, 11 traded unchanged and nine were untraded.

Heartware was best, reaching $1.10 before closing up 37 cents or 55.6 percent at $1.035 with 731,395 shares traded, followed by Benitec up 15.79 percent to 4.4 cents. Alchemia climbed 7.14 percent; Cellestis, Mesoblast and Progen were up more than three percent; Living Cell rose 2.11 percent; with Arana, Biota, CSL, Prana and Sirtex up more than one percent.

Universal Biosensors led the falls, down 14 cents or 25.45 percent to 41 cents with 210,937 shares traded, followed by Novogen down 21.25 percent to 63 cents and Cathrx down 11.11 percent to 48 cents. Avexa lost 8.75 percent; Peplin and Starpharma both fell five percent; Optiscan, Resmed and Viralytics shed more than two percent; with Cochlear down 1.46 percent.

HEATWARE, VENTRACOR

Thoratec Corp will acquire Heartware for $US282 million ($A429 million) half in cash and half in Thoratec common stock.
Heartware said the purchase reflected a price of $A1.32 per Heartware Chess Depositary Instrument which last traded on February 12, 2009 at 66.5 cents.
Heartware said Thoratec would provide a convertible loan facility of up to $US28 million ($A43 million) to fund ongoing operations until the close of the transaction, which is expected in the second half of 2009.
Both companies' boards have approved the transaction, which is subject to Heartware shareholder approval and other conditions, including US regulatory clearance.
Heartware's corporate development director Howard Leibman told Biotech Daily the regulatory review, primarily examining competition issues, "could take some months".
Mr Leibman said that the deal was based on Thoratec's share price and changes in Thoratec's price as well as the US-Australia exchange rate would affect the return to Heartware investors.
Mr Leibman said the 1500 Australian retail investors in Heartware would have about six months to decide whether to retain exposure to potential upside in Thoratec shares.
"Those who don't want exposure to US stock can sell on the ASX," Mr Leibman said.
Mr Leibman did not say how long Thoratec and Heartware had been involved in making the deal, but said once the decision was made "it came together very quickly".
"Something like this takes a couple of months to put together," Mr Leibman said.
"There had been friendly overtures for some time, but it all came together very quickly."
Mr Leibman said that once the deal was completed, Heartware would retain a presence in Australia. The company is continuing clinical trials in Australian hospitals.
Thoratec's president and chief executive officer Gary Burbach said the transaction was "a positive development for heart failure patients and the clinicians who treat them by combining Thoratec's portfolio of commercially approved devices with Heartware's innovative technologies".
"The use of mechanical circulatory support for the treatment of heart failure is gaining increasing adoption as a result of the positive patient outcomes and clinician enthusiasm realized with the Heartmate II," Mr Burbach said.
Heartware's chief executive officer Doug Godshall said the deal was "a positive outcome for our stockholders, our employees and heart failure patients".
Mr Burbach said the product pipeline and organizational capabilities of Thoratec and Heartware were "highly complementary" and the combination would "enable new, life-saving technologies to market more quickly and at a greater scale".
"Thoratec already has clinical, regulatory and market development teams with a proven track record of developing devices, achieving regulatory approvals and realizing commercial success," he said.
Ventracor chief executive officer Peter Crosby said the acquisition was unlikely to have a negative impact on his company's efforts to raise funds.
"Some would argue it makes us more valuable because of the price they paid for Heartware," Mr Crosby said.
He said Thoratec needed a pipeline of products, not another device earning revenue.
"What they need is a long-term pipeline. They want something for four years away," Mr Crosby said.
He said he was unable to say what impact the deal might have on Ventracor and his attempts to find funds to continue the company's trials or sell the assets to another party.
Heartware reached $1.10 before closing up 37 cents or 55.6 percent at $1.035.
Ventracor was in a voluntary suspension and last traded at 8.3 cents.

MARC SINATRA'S BIOGUIDE BRIEF: HEARTWARE, VENTRACOR

Thoratec, clearly the world's leading company in the area of circulatory assist devices, made its move to add a third generation left ventricle assist device to its product offering by coming to agreement with Heartware over the weekend to purchase the company for $US282 million or roughly, $1.32 per Heartware Chess depository interest, via a combination of cash and Thoratec scrip.

Thoratec's offer is at more than a 100 percent premium to the last price paid locally for Heartware shares and justifies the $30 million dollars ploughed into the company by institutional and sophisticated investors early in 2008.

It is a better offer than I ever thought would eventuate and one which I believe Heartware shareholders should embrace, given the difficult and expensive nature of the development of ventricular assist devices.

Since Heartware was only a brief visitor to our shores, though, a major part of this story is about what this acquisition means for our own Australian-owned and grown ventricular assist device company, Ventracor.

Sadly, I think this may well be it. When I looked at Ventracor last year (BD: Oct 27, 2008), the company was able to convince me that its technology was, at least, close to Heartware's and given its significant lead in the race to US marketing approval, Ventracor could be in a pretty good position if it could find some money.

Since then, a share purchase plan has failed, recruitment issues with their US destination therapy trial have developed and to cap off a series of negative announcements, the percutaneous lead in their most recent model of the Ventrassist the LVA4 has caused that model to be withdrawn from trials.

Interestingly, Ventracor had already seen a problem with the lead in an earlier version of Ventrassist and I am amazed that a problem with the lead has reared its head in a later model when so much focus should have been on its development.

The lead, however, is a minor problem for Ventracor, now. Thoratec's bid for Heartware, when it could have acquired Ventracor for a bargain basement price, provides a very strong signal that Heartware's technology is significantly better than that of Ventracor's.

It would be a very brave financier who would get behind Ventracor now. Cash, small device issues and clinical trial problems can be solved. It is much harder to solve an issue of apparently inferior technology.

CELLESTIS

Cellestis' net profit after tax for the six months to December 31, 2008 was up 769 percent to $2,849,000 on revenue up 88 percent to $14,920,000.
Cellestis said sales revenue increase by 92 percent to $14,465,000.
Cellestis net tangible asset per share was 20.4 cents compared with 13.5 cents for the previous corresponding period. Diluted earnings per share was up 765 percent to 2.97 cents. A dividend of 1.0 cent a share will be paid with a record date of February 27, 2009.
Cellestis was up eight cents or 3.96 percent to $2.10.

UNIVERSAL BIOSENSORS

Universal Biosensors says that with its partner Johnson & Johnson's Lifescan Inc it has decided to delay its blood glucose test launch to incorporate significant improvements.

Universal Biosensors chief executive officer Mark Morrisson told Biotech Daily he had made calls to the company's investors and commentators to assure them that the decision to delay the launch, originally expected by June 30, 2009, was in the best interest of the company and its shareholders.

"I don't think we are going to be too far behind," Mr Morrison said.

"The value of the company will be enhanced," he said.

Mr Morrisson said the updated version of the blood glucose test performed better than the original model, but due to confidentiality agreements he could not describe the nature of the technical improvements.

He said there were no problems with either the relationship with Lifescan or the original product.

Mr Morrisson said that rather than launch the original product and then release an upgrade, the company would launch the upgraded model at a later date.

In a media release, Universal Biosensors said registration of the new product could be submitted "as early as the second half of 2009" but did not commit to registration this year.

The company's release of its blood glucose test could be delayed by up tp a year.

Mr Morrisson told Biotech Daily the company's cash burn was $1.2 million a month and the company had $28 million in cash at December 31, 2008.

In the media release Universal Biosensors said that Lifescan had "chosen not to complete the registration process for the current product but to proceed to market with the improved product".

Universal Biosensors said the enhanced product was based on the same technology as the existing product and would be manufactured using the same production process, equipment and infrastructure.

The company said its staff and a Lifescan team were "working together to quickly finalize the new product".

Universal Biosensors said it had planned for a product launch by Lifescan by June 30 2009 but development work "could be finalized and the improved product ready to submit for registration as early as the second half of 2009".

"Ultimately the decision and timing of the launch will be determined by Lifescan," the Universal Biosensors media release said.

In the release Mr Morrisson said that while the existing system was "virtually ready for market, the tactical choice is to focus on the reconfigured product".

"Its improvements further increase its points of difference," Mr Morrisson said.

"Although there is an initial delay in bringing the system to market which will delay revenue, it is our view that this further improved product will achieve substantially more market share," he said.

Universal Biosensors said it was in discussions with Lifescan on the specific commercial terms for the enhanced product.

Once these discussions have been concluded, Universal Biosensors said it would be in a position to more fully update investors.

In December the company announced a further expansion of its relationship with Lifescan with a cash payment of $US2 million from Lifescan foreshadowed. The $US2 million was received in February and the company said it expected its relationship with Lifescan to further strengthen over time.

Universal Biosensors fell 14 cents or 25.45 percent to 41 cents.

MESOBLAST

Mesoblast says Singapore private healthcare provider, Parkway Group Healthcare will collaborate to commercialization Mesoblast's off-the-shelf stem cell products in Asia.
Mesoblast said the Parkway independent ethics committee approved its first registry trial evaluating the safety and effectiveness of a single injection into the knee joint of its adult stem cell product Replicart for patients with knee osteoarthritis.
The trial will be conducted within Parkway's clinical entre of excellence in Singapore.
Mesoblast said osteoarthritis was the most common musculoskeletal disorder and the leading cause of joint pain and disability among the elderly.
The company said therapies attempted to alleviate pain, but were unable to preserve the cartilage lining the joint. Many therapies are associated with severe side effects and can even cause death and joint replacement was often the only option for restoring function, Mesoblast said.
Parkway Holdings' managing director Dr Lim Cheok Peng said the registry study was the initial collaborative step in a partnership to provide credible adult stem cell therapies to patients at Parkway hospitals across Asia.
"We believe that Mesoblast's proprietary adult stem cell technology has real potential to provide novel therapies for patients with unmet clinical needs," Dr Lim said.
"It is a new medical paradigm: regenerating and rebuilding damaged tissues to address the underlying problem," Dr Lim said.
Mesoblast executive director Prof Silviu Itescu said the company was delighted to collaborate with Parkway Health.
"The experienced and rigorous clinical research environment at Parkway Health will ensure a safe and highly regulated use of Mesoblast's products within a very formal framework," Prof Itescu said.
"We intend to evaluate the potential of our unique adult stem cell technology platform in various additional indications including spinal fusion, long bone fractures and congestive heart failure," Prof Itescu said.
Mesoblast said Parkway Health operates 15 hospitals with more than 3,600 beds in Asia.
Mesoblast climbed 2.5 cents or 3.21 percent to 80.5 cents.

LABTECH SYSTEMS

Labtech's net profit after tax for the six months to December 31, 2008 was a turnaround $739,797 compared to a loss of $543,620 for the half year to December 31, 2007.
Labtech said the 462.9 percent increase in revenue to $1,963,569 was "related to the receipt of … $1.78 million under the company's licence agreement with Biomérieux".
Labtech said no further milestone payemtns were expected before June 30, 2009. A further payment of EUR2 million is expected in 2010.
Labtech was untraded at 10.5 cents.

CIRCADIAN

Circadian says it has cash of $42.1 million but its total market value for listed investments fell from $11.2 million in June 2008 to $4.7 million as at December 31, 2008.
In its half-year report to December 31, 2008, Circadian said it had reduced revenues and increased losses reflecting the change "from being a biotechnology seed investor and incubator of early stage technologies into a drug developer for treatments of cancer as well as for other high unmet medical need disease indications".
Circadian was untraded at 68 cents.

BIOPHARMICA

Biopharmica says a poster was presented at the Lorne Cancer Conference entitled 'HLS5/TRIM35 is down-regulated in breast and ovarian tumours and can regulate transactivation by steroid hormone receptors'.

Biopharmica said the research was a joint venture with Western Australian Institute for Medical Research's Dr Louise Winteringham, Robin Scaife, Jean-Philippe Lalonde, Jennifer Beaumont, Rachel Ramsdale (Molecular Discovery Systems) and Prof Peter Klinken

The company has previously said it and the Western Australian Institute for Medical Research screened 70,000 compounds which increased HLS5 levels to block the growth of cancerous cells (BD: Sep 18, 2008).

The abstract from the poster said that "transformation of normal cells into malignant tumor cells depends on progressive acquisition of genetic alterations resulting in either activation of proto-oncogenes or inactivation of tumor suppressor genes".

"Haemopoietic lineage switch 5 (Hls5) is a novel tumor suppressor gene located on chromosome 8p21, a region associated with a number of cancers including the steroid dependant breast and prostate cancers," the poster abstract said.

"The requirement for the steroid hormones estrogen and androgen, respectively, in the development of these cancers is well characterized.

"Our studies have shown Hls5 mRNA is decreased in the majority of breast cancer cell lines and in a number of breast and ovarian tumors compared to normal tissue.

"We have shown that Hls5 is able to inhibit trans-activation by both the estrogen and androgen receptors and can inhibit the activity of estrogen receptor co-activators in vitro.

"These data suggest that Hls5 has a role in down-regulating cellular steroid hormone receptor levels and reduced Hls5 expression may contribute to the increase in steroid hormone receptor levels required for the development and progression of disease."

"Screening of a chemical library to identify compounds that activate the Hls5 promoter has yielded compounds that increase Hls5 mRNA levels," the abstract said.

"These compounds are undergoing secondary screening to determine their effects on estrogen and androgen mediated activation of transcription and cell proliferation," the poster abstract said.

Biopharmica was untraded at 1.8 cents.

RESONANCE HEALTH

Resonance Health has appointed Dr Stewart Washer as a non-executive director and chairman of the board, effective immediately.

Dr Washer has more than 20 years experience in life science companies, as chief executive officer, founder and director.

Dr Washer was the founding CEO of Phylogica and left at the end of 2007 to pursue fund management and Directorships.

Dr Washer has managed the commercialization of intellectual property from Agresearch in New Zealand with 650 Scientists and $130 million revenues as Cellentis' chief executive officer.

Dr Washer's directorships include Genesis R&D, Healthlinx, Ausbiotech and Hatchtech, He is a senator of Murdoch University and a venture partner with the Swiss Inventages Fund, a EUR1.5 billion life science fund and the investment consultant with the IB Bioscience Funds.

Resonance was untraded at one cent.

BIOMD

Biomd to raise $859,000 through a one-for-two non-renounceable share offer of up to 42,954,985 shares at two cents a share.
Biomd said the funds would be used primarily to fund the current and proposed human clinical trials of Adapt bovine cardiac tissue patch, continue to fund related research and development activities and assist in the funding of regulatory requirements for late-stage product development
The record date for eligible shareholders is February 25, 2009.
The offer closes on March 27, 2009.
Biomd was untraded at 4.2 cents.

ADVANCED OCULAR SYSTEMS

Advanced Ocular says Vlado Bosanac has resigned as a director with immediate effect.
The company said Mr Bosanac was due to resign from the board pending the successful merger with International Formwork & Scaffolding Limited, however he has brought forward his resignation to focus on other business activities.
Advanced Ocular was unchanged at 0.6 cents.

AUSBIOTECH

Ausbiotech says its monthly Bio-Beers resumes for 2009 on Thursday February 19, 2009.
The casual drinks event will be held at in Melbourne's Treasury bar at the Sebel.
Bio-Beers attracts CEOs, managers, researchers and students.
The Treasury Bar at the Sebel is at 394 Collins Street, Melbourne and the event will be held on February 19, 2009 from 6pm to 9pm.