Biotech Daily

Thursday March 19, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: NOVOGEN UP 25%; BENITEC DOWN 14%**

*** VENTRACOR IN VOLUNTARY ADMINISTRATION**

*** STARPHARMA COMPLETES VIVAGEL LONGEVITY STUDY**

*** ALCHEMIA COMPOUNDS, TECHNOLOGY BUY 5-10% STAKE IN SDP**

*** FMR, FIDELITY REDUCES TO 6.6% IN CSL**

*** IMPEDIMED: JOURNAL BACKS LYMPHOEDEMA PREVENTION**

*** AUSBIOTECH: SHARE OF $83m 'TOO LITTLE TOO LATE'**

*** BIO-MELBOURNE NETWORK: '83m WELCOME, BUT WON'T GO FAR'**

*** GBS 'EYES NEW DEALS WITH $125m FUND RAISING'**

*** ACUVAX COMPLETES PANCREATIC CANCER TRIAL ENROLMENT**

MARKET REPORT

The Australian stock market climbed 1.0 percent on Thursday March 19, 2009 with the S&P ASX 200 up 33.9 points to 3,480.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, nine traded unchanged and six were untraded.

Novogen was best, up 10.5 cents or 25 percent to 52.5 cents with 145,244 shares traded, followed by Starpharma up 15.15 percent to 19 cents, Polartechnics up 14.3 percent to 12 cents and Genera up 10.3 percent to 32 cents.

Mesoblast climbed 8.2 percent; Psivida was up 7.9 percent; Tyrian was up 4.8 percent; Circadian and Pharmaxis were up more than three percent; with Impedimed and Prana up more than two percent.

Benitec led the falls, down half a cent or 14.3 percent to three cents with 320,000 shares traded, followed by Avexa down 9.1 percent to 10 cents.

Labtech lost eight percent; Cathrx was down 6.25 percent; CSL and Living Cell fell more than four percent; Cellestis, Peplin and Phosphagenics were down more than three percent; Acrux, Antisense, Clinuvel, Cochlear, Heartware, Resmed and Viralytics shed more than two percent; with Alchemia down 1.6 percent.

VENTRACOR

Ventracor has been placed into voluntary administration with Steven Sherman and John Gothard of Ferrier Hodgson acting as administrators.

Ventracor said that "despite outstanding success with its clinical trials of the Ventrassist left ventricular assist device and an exhaustive effort …to seek investors", it had not been able to attract sufficient capital to fund its operations through to June 30, 2009.

The company said it had approached more than 130 potential investors in Australia, US and Europe and a share purchase plan did not attract sufficient capital.

Ventracor said it had sought expressions of interest from parties wishing to acquire the company or take a strategic stake and more than 50 organizations were approached.

On February 27, 2009 the company reported that discussions were continuing with two parties but that any potential transaction structure would require short term funding in the form of a private placement or bridging facility.

A non-binding proposal was received for an asset purchase, but did not contemplate short term funding, and the board decided to place the company in voluntary administration.

Ventracor said it was working with regulators to resolve the February 6, 2009 voluntary field safety alert on the model LVA4, following external lead failures (BD: Feb 10, 2009), but the LVA3 continued to be implanted worldwide with modest sales.

The company said the Ventrassist LVAD had been implanted in more than 420 patients worldwide. It has Conformitée Européenne (CE) mark approval for sale in Europe and those countries that recognize that regulatory regime and has Australian Therapeutic Goods Administration approval for sale in Australia.

Ventracor chairman John Ward said the board shared with shareholders "a deep sense of sadness and regret that Ventracor has been placed into voluntary administration".

"In the midst of an unprecedented and ever worsening global financial crisis the company has not been able to raise sufficient funds to maintain its operations through to June 30, 2009," Mr Ward said.

Ventracor's chief executive officer Peter Crosby said that "despite our outstanding operational and clinical success, the inability to raise the necessary capital has resulted in the need to appoint an administrator".

"We hope that a successful outcome can be achieved … which will enable commercialization of the Ventrassist LVAD to continue, keep the jobs in Australia, and continue to bring this great Australian technology to the global market," Mr Crosby said.

Ventracor is in a voluntary suspension and last traded at 8.3 percent.

STARPHARMA

Starpharma says it has completed patient testing in a clinical trial of the length of time Vivagel retains antiviral activity remains following application.

Starpharma said the study in 12 healthy women was designed to measure the level of antiviral activity retained by Vivagel after vaginal administration and therefore how long before sex Vivagel could be applied to prevent infection.

Vaginal samples have been collected from each study participant up to 24 hours after five separate Vivagel applications and these samples were being analyzed for anti-HIV and anti-HSV-2 or genital herpes activity.

Starpharma said preliminary findings indicate that the gel was well tolerated.

Starpharma chief executive officer Dr Jackie Fairley said the trial was "very valuable in providing a surrogate for the antiviral efficacy of Vivagel in humans ahead of phase III studies" and full trial results were expected in about two months.

Starpharma was up 2.5 cents or 15.15 percent to 19 cents.

ALCHEMIA, SDP

Alchemia says SDP Technology will develop anti-cancer drugs based on its compounds targeting the enzyme sphingosine kinase 1.

A media release to the ASX said the Melbourne-based and privately owned SDP would have rights to the structural data from the initial screen and to develop molecules using Alchemia's versatile assembly on a sugar template (Vast) chemistry program.

SDP owns the intellectual property on the sphingosine kinase 1 (SK1) target.

In exchange for these rights Alchemia would be granted five percent of the fully diluted equity in SDP with a further equal tranche of shares and options if a molecule based on its chemistry was advanced into the clinic.

Alchemia said sphingosine kinase 1 had been shown to play a central role in cancer by reducing apoptosis or cell death and promoting cell proliferation and survival.

The company said SK1 was over-expressed in numerous cancers and inhibiting its activity could arrest tumor growth in preclinical models.

The media release said SDP had screened a library of compounds synthesized by Alchemia that were designed to inhibit the kinase family of enzymes.

Alchemia said SDP had identified a number of compounds with promising activity against SK1 and more detailed analysis of those compounds was underway.

Alchemia's chief executive officer Dr Pete Smith said sphingosine kinase was "a very attractive target for anti-cancer therapies".

"The project has already identified a number of active molecules and shown a strong relationship between their structure and activity," Dr Smith said.

"This is a core ability of our Vast technology which we see as offering a rapid route to novel drugs, especially when the structure of the target is unknown," he said.

"While Alchemia dramatically reduced its drug discovery activities last year to conserve cash (BD: Oct 30, 2008), we will continue to look for opportunities like this to realize value from our pre-existing assets," Dr Smith said.

SDP managing director Ian Brown said that having access to Alchemia's Vast technology enabled his company "to take a substantial leap forward in its sphingosine kinase drug discovery and development program".

"The initiative has provided opportunities quickly and efficiently and has created significant value for shareholders," Mr Brown said.

Alchemia said the discovery and clinical use of signal transduction inhibitors was "an important development in cancer therapy".

The company said SK1 was a signal transduction molecule whose function was disturbed in a wide range of cancers and hence inhibitors of this enzyme would have widespread clinical utility.

Alchemia said the partnership between Alchemia with its library of molecules and SDP with its strong intellectual property position was a significant step toward the development of such agents.

Alchemia fell half a cent or 1.6 percent to 30.5 cents with 1.0 million shares traded.

CSL

The US-based FMR Corp and Fidelity Investments reduced their substantial shareholding in CSL from 45,721,715 shares (7.58%) to 39,606,800 shares (6.57%) on March 17, 2009.

CSL fell $1.47 or 4.47 percent to $31.43.

IMPEDIMED

Impedimed says the publication of an article in the Journal of Clinical Oncology on the costs of breast cancer-related lymphoedema support its claims for US reimbursement.

Impedimed said the article, entitled 'Incidence, Treatment Costs, and Complications of Lymphoedema After Breast Cancer Among Women of Working Age: A 2-Year Follow-Up Study' was published online on March 16, 2009 and "demonstrates both the psychosocial impact of lymphoedema and the impact of the direct costs associated with lymphoedema in breast cancer patients in the first two years post operation".

Impedimed has developed a test, the L-Dex U400, that detects the signs of breast cancer-related lymphoedema.

Impedimed chief executive officer Greg Brown told Biotech Daily that the test was reimbursed in the US under a miscellaneous code that allowed the 60 percent of Americans covered by private insurance to receive reimbursement for the test.

Mr Brown said that the company was applying for its own 'category 1 current product technology code' which would provide better reimbursement for all US patients.

"The whole mantra of President Barack Obama's government is preemptive care," Mr Brown said.

"The health economics report shows the lymphoedema test's early intervention reduces costs," Mr Brown said.

He said the additional costs for women who develop breast cancer-related lymphoedema was $US14,877 to $US23,167 and that of the 250,000 new cases of breast cancer diagnosed in the US each year, 20-22 percent develop breast cancer-related lymphoedema in the first year and 35-40 percent develop lymphoedema after more than two years.

Mr Brown said the cost of the test, which is administered nine times is $US200 a test and pressure sleeves used to treat lymphoedema cost about $US70 each.

Assuming these figures are correct, Biotech Daily calculated the universal use of the Impedimed lymphoedema test could save the US health system $US644 million to $US1,164 million a year.

The Journal of Clinical Oncology report was prepared by researchers at the University of Texas MD Anderson Cancer Center and the Vanderbilt University School of Nursing in Nashville and is at: http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2008.18.3517.

"Upper extremity lymphoedema is one of the most dreaded sequelae of breast cancer treatment," the report said.

"The psychosocial impact of lymphoedema has been described to be as distressing as the initial diagnosis of breast cancer; patients with breast cancer–related lymphoedema have been found to have a lower quality of life, a higher level of anxiety or depression, a higher likelihood of chronic pain and fatigue and greater difficulty functioning socially and sexually compared with breast cancer women without lymphoedema," the report said.

"Reported incidence rates of breast cancer-related lymphoedema vary from four percent to 56 percent; the true incidence is difficult to assess because of varying criteria used to define lymphoedema and the duration of follow-up across studies."

The study concluded that although the use of claims data "may underestimate the true incidence of lymphoedema, women with BCRL had a greater risk of infections and incurred higher medical costs. The substantial costs documented here suggest that further efforts should be made to elucidate reduction and prevention strategies for BCRL".

"This publication should support the company's efforts in establishing coverage for healthcare professionals for the reimbursement of Impedimed technology in the US market," Mr Brown said.

Impedimed was up two cents or 2.86 percent to 72 cents.

AUSBIOTECH

Ausbiotech's chief executive officer Dr Anna Lavelle says the venture capital funds announced yesterday by the Innovation Minister may be "too little, too late".

Senator Kim Carr announced $83 million to be divided among more than 20 approved venture capital funds across three sectors (BD March 18, 2009).

"The Federal Government yesterday acknowledged Ausbiotech's concern for the at-risk fund-starved biotech sector, but the announcement may be too little, too late," Dr Lavelle said.

"This is a $600 million problem, with the solutions offered to date falling short," Dr Lavelle said.

"While Government measures are a welcome move, the gap in what is needed is still significant, and still leaves the sector at risk of demise," Dr Lavelle said.

She said the $600 million needed for the sector should be composed of $300 million in refundable tax credits and $300 million in competitive matched grants.

The Ausbiotech media release said "Australia is about to lose its biotech sector".

"…the gap between what is needed and what has been provided will see us lose large chunks of the biotechnology industry, resulting in many billions of dollars lost over the next 20 years, involving tens-of-thousands of highly-skilled jobs," Ausbiotech said.

The organization said that before the financial downturn, the sector was growing well, with Australia batting way above its weight, ranking sixth in the world and the number one location in the Asia Pacific region for biotechnology, as well as first in the world for clinical trials. Ausbiotech said the sector was characterized by smaller start-up companies, which need to access significant funds to bring innovations to commercialization.

This access, previously provided by private investors and the Government's Commercial Ready program has dried up, leaving promising companies vulnerable.

BIO-MELBOURNE NETWORK

Bio-Melbourne Network chief executive officer Michelle Gallaher said the $83 million was a small step in the right direction and hoped more funds would be made available.

Ms Gallaher said the $83 million "shared with the wider innovation sector will not deliver the necessary funds that the biotech sector desperately needs and which it lost with the close of the Commercial Ready program last year".

"The loss of Commercial Ready coupled with the effects of the economic downturn has deeply affected biotechs as good research projects are being mothballed and people retrenched," Ms Gallaher said.

"The depletion of the biotech sector means that Australia is at risk of losing the return on medical research effort and investment in institutions and universities which need the biotech industry to take discoveries forward to turn them into products that will save lives and jobs," she said.

"I'm concerned that the valuable Victorian biotech sector may not see much of this money and if so, it's likely to only be a few companies that are already of interest to the venture capital community," Ms Gallaher said.

"So we hope this announcement is the first in a series of packages to address the biotech sectors very urgent needs and that the government can move quickly to address this as many biotechs and their research will not survive the next six months," she said.

"The short delivery time is reasonable and expected in ICT start ups, but biotech companies rarely deliver a return within a five year timeframe," she said.

"The reality is that only a few biotechs will be the likely to capture the interest of Innovation Investment Follow-on Fund," Ms Gallaher said.

GBS VENTURE PARTNERS

GBS Venture Partners says it is “actively looking for new life science deals after raising nearly $125 million for its GBS Bioventures IV Fund.

GBS managing director Brigitte Smith said the raising was “an excellent result in an extremely difficult climate”.

“We are delighted that our investors chose to support us again and endorsed the strategies pursued by GBS over the past decade,” Ms Smith said. “Despite the difficult economic climate, there are some really exciting investment opportunities in this sector.”

“Australia has traditionally boasted a competitive advantage in the life sciences by having cutting edge technology and highly skilled and dedicated people working in this field.

“As a consequence, the Australian industry has a well deserved reputation for being an innovator in medical and clinical research and a proven capacity to continually develop new therapies and medical devices,” Ms Smith said.

GBS has previously invested in Peplin, Cogstate, Pharmaxis, Chemgenex, Hatchtech, Sunshine Heart and Portland Orthopaedics, among others.

The focus of investments by the Bioventures IV Fund will be companies in Australia or New Zealand, or US companies that have operations in or technologies from Australasia.

Ms Smith says the current mark-down of listed companies created the opportunity to maximize returns to investors over the medium to long term.

“We are looking at a time horizon of four to seven years, and will then seek to lock in the returns either by an IPO in Australia or overseas on the Nasdaq, for example, or by a trade sale,” Ms Smith said

The GBS media release said the closing of the 10-year fund brought the total under management to more than $400 million.

GBS is a private company.

ACUVAX

Acuvax says full patient enrolment has been completed ahead of schedule in the clinical trials of RP101 for late stage pancreatic cancer patients.

Acuvax (formerly Avantogen) said the trials of 153 patients at 50 study sites were being conducted by the US-based Sciclone Pharmaceuticals.

Acuvax said the North American rights to RP101 were licenced to Sciclone, with up front payments of about $3 million already received.

The company said Sciclone was covering all the development costs for the RP101 program, including costs of the US Food and Drug Administration-approved trials.

Acuvax chief executive officer Dr William Ardrey said enrolment was completed “several weeks ahead of schedule”.

“Following the excellent results of the West Nile Virus vaccine trials announced by our affiliate Hawaii Biotech, we are pleased to see other products in our portfolio such as RP101 advancing ahead of schedule under the current clinical trails undertaken by Sciclone,” Dr Ardrey said.

Acuvax said that royalty and milestone payments were due as RP101 advanced through its trial program.

Acuvax was untraded at 3.1 cents.