Biotech Daily

Tuesday June 15, 2010

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: BIOTA UP 12%, BONE DOWN 19%**

*** HEALTHLINX OVARIAN CANCER TRIAL; HEALTHSCOPE DISTRIBUTOR**

*** CONDITIONAL APPROVAL FOR HEARTWARE DESTINATION TRIAL**

*** SUNSHINE HEART'S FIRST MINIMALLY INVASIVE C-PULSE IMPLANT**

*** RESONANCE'S FERRISCAN AVAILABLE ON UK 'CHOOSE AND BOOK'**

*** NEURODISCOVERY TO SELL UK REVENUE POSITIVE BUSINESS**

*** PLATYPUS CEASES SUBSTANTIAL IN SIRTEX, JUST**

*** FLUOROTECHNICS DOWNGRADES 2009-'10 REVENUE ESTIMATE**

*** GENESIS PLACEMENT TO RAISE $446k**

*** KARMELSONIX EXPECTS $352k JUNE QUARTER SALES**

*** BENITEC APPOINTS CSO DR PETER FRENCH CEO**

MARKET REPORT

The Australian stock market slipped 0.01 percent on Tuesday June 15, 2010 with the S&P ASX 200 down half a point to 4505.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, 12 traded unchanged and four were untraded.

Biota was best, up 13 cents or 12.3 percent to $1.185 with 1.8 million shares traded, followed by Cathrx up 10 percent to 22 cents with 127,500 shares traded.

Sunshine Heart climbed 9.1 percent; Antisense was up 7.1 percent; Nanosonics, Novogen and Virax were up more than five percent; Sirtex climbed 4.95 percent; Circadian was up 3.3 percent; Heartware rose 2.99 percent; with Cochlear, Optiscan and Resmed up one percent or more.

Bone led the falls, down 2.5 cents or 18.5 percent to 11 cents with 29,399 shares traded, followed by Phylogica down 1.5 cents or 15.8 percent to eight cents with 219,000 shares traded and Uscom down 12.5 percent to 35 cents with 50,000 shares traded.

Genera fell 5.3 percent; Alchemia and Chemgenex fell more than four percent; Living Cell was down 3.85 percent; LBT and Tissue Therapies shed more than two percent with Cellestis down one percent.

HEALTHLINX

Healthlinx will begin an international trial of its Ovplex test for ovarian cancer and says the test will be distributed through Healthscope's 340 collection centres.

In a series of announcements Healthlinx said the trial was partly funded by $750,000 Victoria Government grant and would screen 1150 samples using the current five biomarker panel and an additional two biomarkers including AGR2 (BD: Feb 10, 2010).

Healthlinx said the multi-site, multi-centre trial would test whether the two new biomarkers could increase the sensitivity and specificity of Ovplex to greater than 97 percent.

The company said the study was powered to allow direct determination of sensitivity and specificity and will include collaborators from Australia, Singapore and the UK.

The company said the existing five biomarker test delivered 92 percent sensitivity and 94 percent specificity for the diagnosis of early stage (stage I and II) ovarian cancer.

Healthlinx managing director Nick Gatsios said that the development of the Ovplex test built on existing technology and would further test the panel's two new biomarkers.

"We already have the best in class ovarian cancer test and what we want now is to improve the performance of the panel even further," Mr Gatsios said.

Mr Gatsios told Biotech Daily that Ovplex was not intended be a universal screening test but rather a first line diagnostic when symptomatic patients present to the general practitioners with bloating, pelvic mass and pelvic pain.

Mr Gatsios told a Melbourne brokers and analysts lunch that the global market for the test was worth $440 million and he hoped to win 10 percent of that, but "not for 36 months".

His presentation showed that Ovplex was available in the UK, India, Thailand, Malaysia, Indonesia and Australia with China and the US as the next target markets.

Healthlinx said in its media release that biomarker trials had shown that Ovplex was a superior performing alternative to CA-125 alone for the detection of ovarian cancer.

The Healthlinx media release said the biomarker trial centres included Melbourne's Mercy Hospital, Queensland's Mater Hospital, the National University of Singapore, London's Essex and Southend hospitals and Liverpool Hospital.

The first stage of the study will use 450 samples from collaborators in Victorian, Western Australian and Singapore.

"We are confident this technology will save hundreds if not thousands of lives of women globally," Mr Gatsios said. "Earlier detection is the answer and we believe that this study will prove the clinical utility of Ovplex."

Healthlinx said the resumption of Australian distribution of the Ovplex test followed the acquisition of ARL Pathology by Healthscope in September 2009.

Mr Gatsios said that ARL's Ovplex testing facilities had been relocated to Healthscope's laboratory in Clayton and testing was suspended during the move, which "was protracted because of the complicated nature of the technology involved".

Mr Gatsios said he was delighted with the partnership and the test would realize its true potential with Healthscope.

Healthscope Pathology's chief operating officer Paul Waterson said he was confident the collaboration would extend the test's reach to a much wider Australian market.

"We have a national sales force committed to ensure GPs right around the country know this blood test is available through Healthscope Pathology," Mr Waterson said.

The Ovplex test is available with a GP referral for $200.

About 1400 Australian women are diagnosed with ovarian cancer each year and 800 women die annually from the disease. Globally, 230,000 new cases were diagnosed each year, with more than 142,000 women dying because 75 percent of cases were not diagnosed until late stage disease, the company said.

Healthlinx was up 1.5 cents or 14.3 percent to 12 cents with 1.8 million shares traded.

HEARTWARE INTERNATIONAL

The US Food and Drug Administration has granted Heartware conditional approval for a destination therapy clinical study for its ventricular assist device.

Heartware said the investigational device exemption trial was designed to enroll up to 450 patients at 50 US hospitals and would be a randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of the Heartware Ventricular Assist System as a destination therapy in advanced heart failure patients.

The company said the study would enroll patients with end-stage heart failure who had not responded to standard medical management and who were ineligible for transplantation.

Heartware chief executive officer Doug Godshall said that beginning the destination therapy study was “an important milestone toward our goal of expanding the universe of potential patients that could benefit from less invasive circulatory support systems”.

“We have been gratified by the support received from all of the prestigious cardiac centers that have participated in our bridge-to-transplant trial and we believe that this study, the largest head-to-head [ventricular assist device] clinical trial to date, will be compelling for cardiologists, surgeons and end-stage heart failure patients,” Mr Godshall said.

Patients in the study will be randomly selected to receive either the Heartware Ventricular Assist System or, as part of a control group they will be implanted with any alternative left ventricular assist device (LVAD) approved by the FDA for destination therapy, in a two to one ratio.

Heartware said each patient receiving either its system or the control LVAD would be followed to the primary endpoint at two years, with a subsequent follow-up period extending to five years post implant.

The company said the primary endpoint of the trial is stroke-free survival at two years, defined as alive on the originally implanted device, transplanted or explanted due to patient recovery.

Heartware said the secondary endpoints included adverse events such as bleeding and infection, as well as functional status, hospitalization, assessment of neuro-cognitive function and patient quality of life.

The company said there were “three minor open questions raised by the FDA which were the conditions for approval” but did not cite the conditions in the media release.

Heartware said patient enrollment could begin immediately, subject to institutional review board approvals at trial centers.

The company said the principal investigators were the University of Pennsylvania Hospital’s Prof Mariell Jessup and the University of Michigan Medical Center’s surgical director of the adult heart transplant program Dr Francis Pagani.

Heartware said that 17 centers had received institutional review board approval in the past 30 days for participation in the continued access protocol for its US bridge-to-transplant study, making a total of 24 centers which were able to participate.

The company said that since FDA approval of the continued access protocol, 11 US patients had been implanted.

Enrollment in the bridge-to-transplant study concluded in February, with the six-month follow-up period for patients expected to be completed in August, the company said.

Heartware said it expected to submit its pre-market authority request to the FDA to approve the Heartware System for the bridge-to-transplant indication by the end of 2010.

Heartware was up six cents or three percent to $2.07.

SUNSHINE HEART

Sunshine Heart says the first minimally-invasive implant of the C-Pulse heart assist system was performed on June 3, 2010.

Sunshine Heart said that all previous implants were done with a full sternotomy or open chest procedure.

In a series of Australian investor briefings the company's chief executive officer David Rosa said the new procedure reduced operating and recovery times significantly (BD: Jun 3, 2010).

Sunshine Heart said the first minimally-invasive implant was the company's ninth C-Pulse aorta cuff procedure and was performed on a female patient by Dr Mark Slaughter of Louisville Hospital.

Mr Rosa said the implant was "an important milestone".

"This implant procedure represents the next step in our overall goal to provide a minimally invasive therapy for Class III/IVa heart failure patients," Mr Rosa said.

"We believe this procedure offers less procedural risk than other approved heart failure technologies and will make it more attractive for patients and physicians to choose our therapy," Mr Rosa said.

Dr Slaughter said the C-pulse system was "ideal for a minimally invasive approach".

"Combined with the fact it has no blood contacting surfaces it provides a good alternative for patients with advanced heart failure," Dr Slaughter said.

"We believe we are now beyond the early challenges usually encountered in enrolling the early patients for a trial," Mr Rosa said.

"While there is still more work to be done, we are certainly pleased with the recent increase in the pace of enrolments as the results from the first patients come through," Mr Rosa said. "We have recently added several new centers and we expect they will start enrolling in the near term."

He said with greater enrollment consistency, the company would provide updates when appropriate as opposed to announcing each implant individually.

Sunshine Heart was up 0.3 cents or 9.1 percent to 3.6 cents.

RESONANCE HEALTH

Resonance says its Ferriscan service for quantifying iron overload is available through the UK's National Health Service referral scheme 'Choose and Book'.

Resonance said the scheme enables general practitioners and specialists across the UK to book patients for a Ferriscan at participating hospitals and allowed doctors to make an appointment on-line while the patient was with them.

Resonance said the Whittington Hospital in London was the first participating hospital to provide the Ferriscan service through the Choose and Book system and the company was working to expand the number of participating hospitals.

The company said the on-line booking service would "better enable doctors to diagnose and manage the condition haemochromatosis" which it said was present in about one in 250 of the UK population.

Resonance said the condition caused the absorption of excessive iron from the diet, resulting in iron loading in major organs, primarily the liver.

The company said patients with other forms of iron overload were usually managed by specialist haematologists, but patients with hereditary haemochromatosis were often managed by general practitioners and providing Ferriscan access to these doctors opened a new market for Ferriscan.

Resonance was up 0.1 cents or five percent to 2.1 cents.

NEURODISCOVERY

Neurodiscovery says that pending shareholder approval it will sell its services business to a management buy-out team of staff from Neurosolutions and the University of Warwick.
Neurodiscovery said the management buy-out team has agreed to pay GBP485,000 ($A850,000) with GBP150,000 on settlement, a further GBP190,000 on settlement through the sale of the buy-out team's shareholding in Neurodiscovery, GBP40,000 six months after settlement, GBP45,000 12 months after settlement and GBP60,000 via GBP4,000 15-monthly installments from settlement.
The company said the sale of the revenue business would require shareholder approval because the buy-out team comprises substantial holders in the company.
The company said that if the sale was approved it would hold about $1.85 million in cash and have no material liabilities and would be in a position to explore additional opportunities over the coming months.
Neurodiscovery said that in March it was assigned 100 percent ownership of its pain drug NSL-101 from its 100 percent subsidiary Neurosolutions (BD: Mar 18, 2010).
The company said two phase II trials had been conducted with one showing it prevented pain associated with root planing and scaling, a dental procedure used to combat periodontitis.
Neurodiscovery said that in the second trial, for the treatment of pain caused by the extraction of wisdom teeth, "the company was unable to measure NSL-101's efficacy due to unexpected confounding factors".
The periodontitis trial demonstrated that NSL-101 is a highly effective analgesic and was well tolerated, the company said.
It was found to be equally effective as the local anaesthetic gel currently applied to patients but with the added benefit of no adverse effects.
The company said it was conducting a strategic review of the program to determine the best path forward and was in discussions with a number of parties.
Neurodiscovery said Japan's Sosei Corp had taken 100 percent of NSL-043 for neuropathic pain, but for the life of the existing granted NSL- 043 patent, a percentage of any future revenue would be paid to Neurodiscovery.
Neurodiscovery said it was originally formed to exploit specialist expertise in electrophysiology and encompassed running a cash-flow positive services business that could build a pipeline of drug candidates in therapeutic areas, such as for the treatment of pain and subsidize the costs of clinical development of the pipeline.
The company said the services business helped fund its development activities without the need to raise significant capital from the markets.
Neurodiscovery said it had been "exploring potential restructuring opportunities to identify a sustainable platform from which to generate future shareholder wealth".
Having obtained clinical data with NSL-043 and NSL-101, the board concluded that there was not a continuing need to build the pipeline.
Neurodiscovery was untraded at 3.4 cents.

SIRTEX MEDICAL

Platypus Asset Management has dropped below a 5.0 percent holding in Sirtex, selling 16,595 shares for $82,841 or an average price of $4.99 a share.
Platypus said it became 5.02 percent substantial in Sirtex on March 19, 2010 having bought 2,801,137 shares between September 17, 2009 and March 17, 2010 for $14,515,881 or an average price of $5.18.
Sirtex was up 25 cents or 4.95 percent to $5.30.

FLUOROTECHNICS

Fluorotechnics says it won't achieve the previous sales estimate of $5 million for the year ending June 30, 2010.

Replying to an ASX Appendix 4C query last year, the company said it was "experiencing increasing sales and is satisfied that it has sufficient funds available to fund its activities and expects to be cash flow positive in the first quarter of calendar 2010" (BD Nov 17, 2010).

Today, Fluorotechnics said its major markets were in Europe and the US, "both of which have been hit hard by the global financial crisis".

The company said the global financial crisis had "curtailed expenditures by our potential customers, thus extending the sales process for our products".

Fluorotechnics said that progress on the strategy of converting opinion leaders to adopt the company's HPE Tower System was "satisfactory".

While many orders for the HPE Tower System were pending, a cautious approach to their early completion has been taken by the directors, the company said

Fluorotechnics fell one cent or 7.7 percent to 12 cents.

GENESIS RESEARCH AND DEVELOPMENT

Genesis says it expects to raise $446,278 through the placement of 7,437,941 shares at six cents each, the same price as the share purchase plan (BD: Mar 15, 2010).

Genesis said the placement was likely to be completed within the next two weeks.

In May the company suspended its New Zealand operations due to lack of funding (BD: May 3, 2010).

The company said it was in discussions with the new investor about the possible future focus of research and development efforts and the financing required.

Genesis said that when discussions were concluded a proposal would be presented to shareholders.

Genesis said it reviewed a number of other proposals that did not involve an ongoing presence of Genesis in New Zealand but none had comparative potential benefits to current shareholders.

The company said discussions were continuing with a number of groups who were considering investment in Solirna Biosciences to allow the further development of its single stranded gene silencing technology.

Other Genesis assets, including its equity interest in Real Time Genomics and royalty rights, will be retained by Genesis until value can be realized for shareholders.

Genesis was untraded at three cents.

KARMELSONIX

Karmelsonix says that since the May 2010 launch of its wireless Pulmotrack and Wholter products sales for April to June 2010 were expected to be $US300,000 ($A352,091).

Karmelsonix said it was expected that the rate of sales would "continue to increase over the coming quarters" as awareness of its products spread "and their acceptance as being valuable devices for the monitoring and management of asthma also continues to grow".

The company said the rate of growth was "dependent to a large degree on the continued acceptance of the devices by the medical communities … and at the same time, achieving recognition by the insurance companies who provide reimbursement for the use and interpretation of diagnostic tests".

Karmelsonix was unchanged at 2.1 cents.

BENITEC

Benitec has appointed its chief scientific officer Dr Peter French as its chief executive officer, effective immediately.

Dr French was appointed part-time chief scientific officer in August 2009 (BD: Aug 3, 2009) while he was Fermiscan's chief scientist.

Benitec said Dr French had 33 years experience in medical research and development in cell and molecular biology and biotechnology.

The company said that Dr French had been extensively involved in managing and leading its three key research and development programs in HIV/AIDS at the City of Hope Medical Center in the US, the hepatitis B program with Biomics Biotechnologies in China and the lung cancer program at the University of New South Wales.

Benitec said Dr French had managed its intellectual property portfolio.

The company said Dr French held an MBA in Technology Management and a PhD in cell biology and had conducted cell and molecular research in a broad range of areas relevant to Benitec's DNA-directed RNAi based therapeutic technology, including cancer, HIV/AIDS, neurobiology, immunology and inflammatory disease.

Benitec said Dr French obtained his PhD in 1987 for work performed at the Commonwealth Scientific and Industrial Research Organisation on the characterization of the keratin composition of the developing wool fibre.

In 1989 Dr French became principal scientific officer and manager of Sydney's St Vincent's Hospital's Centre for Immunology.

Benitec said Dr French founded the stem cell storage company Cryosite and held leadership roles at Probiomics and Fermiscan.

The company said Dr French's initial fixed remuneration package would be $265,000 a year, including superannuation along with short term and long term incentives.

Benitec was unchanged at 3.3 cents.