Biotech Daily

Tuesday April 19, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 6%; LBT DOWN 12.5%**

*** CODA RAISES $18m FOR WOUND TREATMENT**

*** SUNSHINE HEART ON-TRACK FOR MAJOR MILESTONES IN 2011**

*** MEDIGEN TRIAL APPROVED; PAYS PROGEN MILESTONE**

*** AVITA EXPANDS SALES TO RUSSIA, NETHERLANDS, PORTUGAL**

*** TRANSOCEAN, DIRECTOR JAMES HENDERSON REDUCE IN ANTEO**

MARKET REPORT

The Australian stock market fell 1.4 percent on Tuesday April 19, 2011 with the S&P ASX 200 down 68.6 points to 4793.3 points.

Seven of the Biotech Daily Top 40 stocks were up, 19 fell, 10 traded unchanged and four were untraded. All three Big Caps fell.

Antisense was best, up 0.1 cents or 6.25 percent to 1.7 cents with 7.8 million shares traded, followed by Living Cell up four percent to 13 cents with 1.4 million shares traded.

Clinuvel climbed 3.7 percent; Cathrx and Viralytics rose two percent or more; with Circadian and QRX up by less than one percent.

LBT led the falls, down 0.8 cents or 12.5 percent to 5.6 cents with 60,000 shares traded, followed by Heartware down 10.2 percent to $1.975 with 54,392 shares traded and Advanced Surgical down 10 percent to 18 cents with 32,391 shares traded.

Benitec and Genetic Technologies lost seven percent or more; Bionomics, Prana and Prima fell more than four percent; Patrys, Starpharma and Tissue Therapies were down more that three percent; Impedimed shed 2.2 percent; with Acrux, Biota, Cellestis, Mesoblast, Nanosonics, Pharmaxis and Sirtex down one percent or more.

CODA THERAPEUTICS

New Zealand-founded, California based Coda Therapeutics has raised $US19.2 million ($A18.2 million) for a second phase II trial of its venous leg ulcer drug treatment.

Coda Therapeutics is a private venture capital-backed company supported by the Princeton, New Jersey-based Domain Associates, New Zealand's Biopacific Ventures and Melbourne's GBS Venture Partners.

GBS managing partner Dr Geoff Brooke told Biotech Daily that Coda's Nexagon wound healing technology originated at the University of Auckland's Department of Ophthalmology.

In May 2010, Coda said its phase II, three-arm trial randomized 98 patients at multiple sites to receive low or high dose Nexagon treatment or vehicle, in addition to compression bandaging or standard-of-care.

Coda said in its announcement that after three applications over a four-week treatment period, high-dose Nexagon demonstrated a 69 percent reduction in the size of venous leg ulcers.

The company said that the "complete healing of 31 percent of wounds seen in the high-dose treatment arm was five times higher than complete healing in the vehicle arm".

Coda said no drug-related adverse events were observed in either the low or high dose arms, confirming favorable safety results from previous preclinical and phase II clinical studies.

Coda said the active ingredient in Nexagon was CODA001, a natural, unmodified antisense oligonucleotide that down-regulates the key gap junction protein connexin43 to dampen inflammatory responses and enhance healing.

The company said that chronic, poorly healing wounds were characterized by too much continuing connexin43 expression and that suppression by Nexagon could improve wound healing.

Coda said Nexagon was applied topically to stop over-production of the protein connexin43.

The company said it was working under an FDA-approved investigational new drug application to generate clinical data in support of eventual regulatory approval for marketing.

Coda chief executive officer Brad Duft said the financing would "allow us to take essential steps for the development of Coda".

"In particular, we will now conduct a large phase II multi-center venous leg ulcer trial in the United States, New Zealand and Australia with Nexagon, our lead product for chronic wound patients," Mr Duft said.

"In addition, we will continue the preclinical development of our product portfolio in our research laboratories," Mr Duft said.

Last year, the Queensland-based Tissue Therapies reported that five of 30 patients had complete healing in fewer than 24 days in its Western Australian venous ulcer trial, with average ulcer healing of 43 percent (BD: Sep 30, 2010).

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily today that outside the trial protocol a further five patients achieved total wound in 40 days of treatment.

Dr Mercer said that his company's wound treatment was considered a device by the US Food and Drug Administration as it was an "extra-cellular matrix protein that replaced what was there before the wound occurred and was 'replacing a structure'".

Dr Mercer said his company's treatment wound have a faster regulatory path than a drug and was far cheaper to produce.

Coda is a private company.

SUNSHINE HEART

Sunshine Heart chief executive officer Dave Rosa says his company is on-track to deliver several key milestones this year including European and US regulatory applications.

Mr Rosa said there had been concern that the European authorities might not consider the recently-completed, 20-patient C-Pulse aorta cuff pump feasibility study sufficient, but he had been informed that the data would be accepted and he expected Conformité Européenne (CE) mark approval by the end of this year.

Mr Rosa told an investor and media meeting in Melbourne, hosted by RBS Morgans, that a draft of the application for a pivotal US 270-patient trial had been completed and Sunshine Heart would meet with the US Food and Drug Administration in May, with the expectation of beginning the trial by April 2012.

He said the trial would take about 26 months to enroll.

Mr Rosa said the US pivotal trial would cost about $36 million with the likelihood of $4 million in reimbursements for implanted C-Pulse devices.

He said a major fund-raising would be required and agreed with Biotech Daily's calculation of more than $30 million by the end of 2011.

He told the meeting that 30 sites had been targeted and the patients would be randomized in equal numbers with pharmacological optimal medical therapy as the control.

Mr Rosa said the primary endpoint would be a reduction in re-hospitalizations due to heart failure related events.

He said Sunshine Heart would market the trial to patients through radio and newspaper advertising.

Mr Rosa said that so far there had not been a single heart failure-related re-hospitalization of the 20 patients in the feasibility trial, which he said was very encouraging, but he could not expect that to continue indefinitely.

Mr Rosa said there were about 1.3 million people in the US in stage III heart failure who were untreated and would potentially be suitable patients for the C-Pulse device.

He said that World Health Organisation data from several years ago suggested that there were 23 million heart failure patients globally, with about five million patients in Europe.

Mr Rosa said the data from the feasibility trial would be presented at the Heart Failure Society meeting to be held in Boston in September 2011.

He said the efficacy endpoints for the feasibility trial included a reduction in New York Heart Association classification, improvements in quality of life as determined by the Minnesota quality of life questionnaire, a six minute walk and a reduction in oxygen volume while exercising at maximum capacity on a treadmill.

Mr Rosa said the last two measures overlapped and would be refined for the pivotal trial.

Mr Rosa said several of the feasibility trial centres did not appear to be active in recruiting patients and those that had performed the minimally invasive surgery technique had become enthusiasts for the technology.

He said the procedure currently took 45 minutes but further refinements were expected to reduce the time to 30 minutes and the current hospital stay of four days could be reduced to two to three days.

Mr Rosa said Sunshine Heart expected to complete development of its next generation single unit driver by October 2011.

Mr Rosa said the company originally expected to have the fully-implantable C-Pulse system ready by July 2012, but that had been brought forward 12 months to July 2011.

The new device would be powered by a transcutaneous energy transfer system with a similar insertion method and care requirements of a pacemaker.

Sunshine Heart was unchanged at 5.2 cents.

* Biotech Daily editor David Langsam owns shares in Sunshine Heart.

PROGEN PHARMACEUTICALS

Progen says it will receive an undisclosed milestone payment following Taiwanese approval for Medigen's phase III PI-88 liver cancer trials.
Progen said Medigen Biotechnology Corp had licenced PI-88 and the Taiwan Food and Drug Administration had approved a phase III trial in hepatocellular carcinoma.
In 2008, Progen halted its own phase III trial of PI-88 for live cancer citing the absence of a partner, the emergence of a competitor and slow patient recruitment (BD: Jul 23, 2008).
Medigen had an agreement with Progen relating to the drug and a protracted battle ensued for the funds Progen had raised for the trial and control of the drug.
Today Progen said the Medigen trial was designed to confirm the efficacy and safety of PI-88 in the adjuvant treatment of hepatocellular carcinoma after surgical resection.
Progen said the phase II study results for the same indication were published in 2009 in the Journal of Hepatology.
The company said the phase III trial would be a randomized, placebo-controlled trial enrolling about 500 subjects, with the majority from Asia.
Progen said disease-free survival would be the primary endpoint for efficacy, with secondary endpoints of time to recurrence, tumor recurrence rate and overall survival.
Progen said the trial was expected to be conducted in Taiwan, South Korea, China, Hong Kong and some countries in Europe.
Progen was up one cent or 3.1 percent to 33.5 cents.

AVITA MEDICAL LTD.

Avita says it has expanded its Recell wound treatment sales and marketing operations to Russia, The Netherlands and Portugal.
Avita said it had previously established commercial operations in Australia, France, Germany and the United Kingdom.
The company said it had been focusing its international sales and marketing efforts on surgeons in these countries to develop a group of key opinion leaders and centres of excellence for the use of the Recell spray-on skin and provide peer-to-peer training centres for other surgeons.
Avita chief executive officer Dr William Dolphin said spray-on regenerative therapy was packages in "an easy-to-use bedside kit for clinicians".
Avita said more than 3,500 patients had been treated with Recell for burns, hypo and hyper-pigmentation, scar revisions and aesthetic skin rejuvenation procedures.
Avita said JSC Intermedics had been appointed the distributor for Russia, Aviquimica had been appointed in Portugal and Laser Vision in The Netherlands.
Avita was untraded at 12 cents.

ANTEO DIAGNOSTICS

Transocean Securities and Anteo direct James Henderson reduced their substantial holding in Anteo from 57,703,654 shares (7.72%) to 57,081,369 shares (7.49%).
Mr Henderson as a director of Transocean said 622,285 were sold on-market for $47,024 or an average price of 7.56 cents per share.
Anteo fell 0.1 cents or 1.4 percent to seven cents with 5.2 million shares traded.