Biotech Daily

Thursday October 11, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BENITEC UP 7%, LIVING CELL DOWN 11%**

*** BENITEC BUYS-BACK US SPIN-OUT TACERE FOR $1.5m SCRIP**

*** GRAEME KAUFMAN TO REPLACE BIONOMICS CHAIR CHRIS FULLERTON**

*** ELLEX LOOKING TO EXPAND LASER LINE**

*** BIOTRON HIV TRIAL DELAYED; PREPARES FOR HIV/HEP C TRIAL**

MARKET REPORT

The Australian stock market slipped 0.16 percent on Thursday October 11, 2012 with the S&P ASX 200 down 7.2 points to 4,483.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and 10 were untraded.

Benitec was the best, was up 0.1 cents or 7.1 percent to 1.5 cents with 1.7 million shares traded.

Anteo climbed five percent; Genera and Universal Biosensors were up more than three percent; Acrux rose 2.35 percent; Bionomics and Clinuvel were up more than one percent; with Cochlear, CSL and Starpharma up by less than one percent.

Living Cell led the falls, down 0.6 cents or 10.7 percent to five cents, with 1.1 million shares traded, followed by Sunshine Heart down 10 percent to 3.6 cents with 1.5 million shares traded.

Optiscan lost 8.9 percent; Prana, Pharmaxis and Tissue Therapies fell more than four percent; Phylogica and Reva were down more than three percent; Ellex and Prima shed more than two percent; Biota, Heartware and Nanosonics were down more than one percent; with Alchemia, Resmed and Sirtex down by less than one percent.

BENITEC BIOPHARMA

Benitec says it will buy-back 2006 spin-out Tacere Therapeutics Inc for $1.5 million in scrip.

In 2006, Benitec licenced its gene silencing technology for treating hepatitis C to California-based Tacere in return for secured upfront payments, milestone payments, a potential royalty stream and a five percent equity stake (BD: Oct 11, 2006).

At that time Benitec chief executive officer Sue MacLeman said it was “a significant Australian biotechnology licence deal”.

In 2006 Benitec said that Tacere was founded by two former Benitec staff, Mike Catelani and Sara Cunningham Hall along with Dr John Monahan of Avigen and Dr Amit Kumar of Combimatrix.

In 2008, Benitec said it would receive a share of a $US145 million collaboration and licence agreement by Tacere with Pfizer to develop and commercialize its hepatitis C virus compound TT-033 and earlier this year said Tacere researchers had published Pfizer’s “extremely positive” pre-clinical results on the use of its technology to develop a novel therapeutic for hepatitis C (BD: Jan 18, 2008; Jan 22, 2012).

Today, Benitec said that Tacere was a privately held drug development company with a phase I/II ready program in hepatitis C using Benitec’s DNA-directed RNA interference (ddRNAi) technology.

Benitec chief executive officer Dr Peter French told Biotech Daily that “Pfizer spent three years developing [the hepatitis C program] from the laboratory through pre-clinical to phase I/II ready”.

“We are very happy to have it back,” Dr French said.

Benitec said it would acquire “Tacere's extensive [hepatitis C] program data and materials, as well as an advanced preclinical program for the eye disease macular degeneration, which also utilises the company’s ddRNAi technology”.

The company said the consideration for the acquisition would be “cash in the form of an issue of 102,321,345 new shares in Benitec Biopharma for just under $US1.5 million, plus a potential cash royalty on future licencing revenue”.

Benitec said the royalty would be 35 percent if the licence was prior to a phase II clinical study; 15 percent prior to a phase III clinical study; five percent if prior to the submission of a biologic license application to the US Food and Drug Administration; or 2.5 percent if after an application submission.

The company said that the new shares would represent 9.5 percent of the issued capital and the vendors had voluntarily agreed that 75 percent of the shares would be held subject to escrow for 12 months.

Benitec said it expected to complete the acquisition “within the next two weeks”.

The company said that Tacere's research and development director Dr David Suhy would be appointed its head of research and development.

Benitec was up 0.1 cents or 7.1 percent to 1.5 cents with 1.7 million shares traded.

BIONOMICS

Bionomics says that newly-appointed director Graeme Kaufman will replace chairman Chris Fullerton at the annual general meeting on November 14, 2012.

Bionomics appointed Mr Kaufman as a director last month (BD: Sep 18, 2012).

Bionomics said Mr Fullerton would retire from the board on December 31, 2012 “in order to devote time to new ventures”.

Bionomics was up half a cent or 1.5 percent to 33 cents.

ELLEX MEDICAL LASERS

Ellex chief executive officer Tom Spurling says the company has plans to expand its range of medical lasers, targeting the age-related macular degeneration market.

Mr Spurling told an investor meeting hosted by Macquarie Bank in Melbourne that age-related macular degeneration cost Australia up to $5 billion a year and was the leading cause of blindness in people aged 50 years and over.

Mr Spurling said that late-stage, wet, age-related macular degeneration was treatable with anti-vascular endothelial growth factor drugs, but “not much can be done until AMD progresses to blindness”.

Mr Spurling said that he expected the company’s Ellex 2RT laser to be able to treat the disease at an earlier stage.

He said that the company had received Conformité Européenne (CE) mark and trial approval for diabetic macular oedema (BD: Jul 18, 2012) and hoped to gain CE mark approval for age-related macular degeneration by July 2013.

Mr Spurling said that some ophthalmologists were likely to investigate using the same diabetic macular oedema laser off-label for age-related macular degeneration.

Mr Spurling said that the company produced a range of lasers, each for specific indications including the treatment of glaucoma, the removal of scar tissue following cataract treatment and diabetic retinopathy.

He said the Ellex lasers sold for between $20,000 and $70,000 each depending on the country, taxes and distribution agreements.

Mr Spurling said the company’s revenue for the year to June 30, 2012 of $47.5 million came primarily from the sale of its lasers.

He said that the current global ophthalmic laser market was worth about $290 million with five competitors each taking about 20 percent of the market, but Ellex was second to the Israel-based Lumenis.

Mr Spurling said that the increasing aging population and increasing obesity leading to diabetes were drivers of the eye disease market, with 20 million Americans with diabetes, 79 million Americans with pre-diabetes and 80 percent of diabetic patients developing retinopathy.

He said that a 50-patient study of the 2RT laser for aged-related macular degeneration, underway at Melbourne’s Royal Victoria Eye and Ear Hospital, had shown improved macular function and would provide the data required for the new model’s approval for that indication in Europe and the US.

Last year, Ellex reported interim 12-month results of 24 patients in the prospective clinical trial, conducted in collaboration with Centre for Eye Research Australia at the Royal Victorian Eye and Ear Hospital demonstrated clinical efficacy of Ellex 2RT in partially halting or reversing the degenerative processes which caused age-related macular degeneration (BD: May 3, 2011).

The head of macular research at the Centre for Eye Research Australia Prof Robyn Guymer said at that time: “We have observed a sustained improvement in the visual function in the majority of patients”.

Mr Spurling said today that Ellex had acquired the Australian and New Zealand distribution rights to the DRS retinal camera and there was “evidence of growing demand for retinal screening tools” which led to an increased need for laser treatment.

Mr Spurling said that medical lasers had a six to seven year life-span and Ellex was investigating a trade-in, refurbish and resale system, distributing the upgraded older model lasers to the developing world, similar to existing mobile (cell) telephone schemes.

Ellex fell half a cent or 2.6 percent to 19 cents.

BIOTRON

Biotron says its phase Ib/IIa study of BIT225 in HIV has been delayed and it is preparing a 12-patient, phase II trial of BIT225 in patients co-infected with hepatitis C and HIV.

In a 'Shareholder Update' Biotron said there had been "some delays experienced in the [24-patient] phase Ib/IIa study of BIT225 in HIV-infected patients [but], information from the trial site indicates that this study will be completed by the end of the year".

In a previous Shareholder Update on May 4, 2012, Biotron said it expected to have all 24 patients dosed by June 30, 2012.

Biotron began the trial last year (BD: Sep 29, 2011).

Today, the company said that external forces in Thailand "such as the very severe weather and our specific patient requirements have resulted in the trial taking longer than planned".

Biotron said there were stringent inclusion rules preventing some potential candidates from participating with patients needing to be HIV positive, with high virus levels but still have good T-Cell counts and no previous treatment with other HIV drugs.

The company said this patient population pool was limited.

Biotron said it hoped to begin the trial in November 2012 to produce the first efficacy data in this specific population with a significant unmet medical need and was expected to generate further efficacy data for hepatitis C genotypes 2 and 3.

The company said that until now its studies had focused on genotype 1, the most common Western world variation of the hepatitis C virus.

Biotron said that BIT225 was "apparently capable of separately targeting both viruses".

The company said that positive results from the trial had the potential to substantially increase its technology valuation and would provide important information on the impact of other anti-HIV drugs on the blood levels of BIT225.

Biotron said that trial participants must have suppressed levels of HIV and be receiving standard approved anti-retroviral drugs, but not have been treated previously with approved hepatitis C drugs, interferon and ribavirin.

The company said the patients would begin treatment with interferon and ribavirin and one week after starting the standard of care treatment, would have BIT225 added for 28 days and then would continue receiving interferon and ribavirin for up to 43 weeks, as per standard treatment guidelines.

Biotron said the trial aim was to determine whether BIT225 improved the outcome, as measured by reduction in viral loads, in this patient population, compared to treatment with interferon and ribavirin alone.

The company said the trial protocol and documentation was undergoing the approval process with the relevant hospital ethics committee.

Biotron was up 0.1 cents or 1.1 percent to 9.5 cents.