Biotech Daily

Tuesday July 2, 2013

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: USCOM UP 35%, BENITEC DOWN 7%**

*** CIRCADIAN WINS FDA DESIGNATION FOR VEGF-D DIAGNOSTIC**

*** MAYNE BUYS US LIBERTAS FOR 'ABOUT $4m'**

*** US NIH 'FAVORS' BENITEC TT-034 HEP C TRIAL, WITH MINOR CHANGES**

*** PSIVIDA BEGINS PHASE III US UVEITIS TRIALS**

*** REGENEUS US MUSCULOSKELETAL DISORDERS DOG TRIAL**

*** LBT EXPECTS $500k PROFIT**

*** IMUGENE CONTRACTS IDT FOR LINGUET IBUPROFEN**

MARKET REPORT

The Australian stock market bounced back 2.63 percent on Tuesday July 2, 2013 with the S&P ASX 200 up 123.7 points to 4,834.0 points.

Sixteen of the Biotech Daily Top 40 stocks were up, just four fell, 12 traded unchanged and eight were untraded. All three Big Caps were up.

Uscom was the best, up six cents or 35.3 percent to 23 cents, with 5,000 shares traded, followed by Prima up 7.5 percent to 7.2 cents with 2.5 million shares traded.

Mesoblast, Pharmaxis and Starpharma were up more than seven percent; QRX was up 6.2 percent; Anteo, Neuren and Prana were up more than five percent; both Nanosonics and Phosphagenics were up 4.8 percent; CSL was up 3.2 percent; Acrux rose two percent; Heartware, Resmed and Sirtex were up more than one percent; with Clinuvel, Cochlear and Psivida up by less than one percent.

Benitec led the four companies falling, down 0.1 cents or 6.7 percent to 1.4 cents with 1.4 million shares traded, followed by Reva down 3.6 percent, Allied Health down two percent and Bionomics down 1.3 percent.

CIRCADIAN TECHNOLOGIES

Circadian says the US Food and Drug Administration has designated its VEGF-D assay kit as a humanitarian use monitoring device for lymphangioleiomyomatosis.

Circadian said that the FDA humanitarian use designation for the vascular endothelial growth factor-D (VEGF-D) assay kit was “the detection of circulating VEGF-D intended to monitor patients who have been diagnosed with lymphangioleiomyomatosis for disease progression and response to therapeutic intervention”.

The company said lymphangioleiomyomatosis (LAM) was a debilitating lung disease which affected young women, with estimates at between 1,000 and 3,000 women in the US and 100-300 in Australia.

Circadian chief executive officer Robert Klupacs told Biotech Daily that lymphangioleiomyomatosis was a degenerative cystic lung disease that could lead to collapsed lung.

“It affects the quality of life and can lead to death and has a major impact on the patient’s ability to carry out everyday activities,” Mr Klupacs said.

Circadian said that VEGF-D circulating in the blood had been shown to be a unique biomarker of the disease.

The company said that humanitarian use for devices was similar in concept to orphan drug designation status for therapeutic drugs, with humanitarian use device (HUD) defined by the FDA as a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the US per year.

Circadian said the designation enabled formal approval of a device using a regulatory approval process known as a Humanitarian Device Exemption (HDE), which “greatly accelerates marketing approval in the US compared to conventional routes” such as pre-market approval and section 510(k) pre-market approval, as formal clinical studies to show effectiveness in the approved indication were not required to be submitted.

Circadian said it was completing the development of kits to be manufactured under current good manufacturing practice and planned to submit its HDE application this year.

The company said that the VEGF-D diagnostic was being developed as an enzyme-linked immunosorbent assay (Elisa), which was suited to laboratory testing and could be used at pathology or hospital laboratories to quantify circulating levels of VEGF-D.

Circadian said that rapamycin had been shown to be effective for LAM and monitoring the condition of patients using VEGF-D as a biomarker would provide physicians with a tool to assist treatment strategies.

Mr Klupacs said the humanitarian use device designation “fast-tracks our FDA approval process while minimizing development costs and provides the opportunity to conduct clinical studies while the kit is on market generating revenue”.

“In addition, a similar registration dossier can be submitted for [Conformité Européenne] mark, providing access for sales in the European Union,” Mr Klupacs said.

“We expect to complete our regulatory submissions before the end of 2013,” Mr Klupacs said.

Mr Klupacs said that he hoped to extend the US regulatory approval to include differential diagnosis for lymphangioleiomyomatosis from other lung diseases.

Circadian was untraded at 23.5 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has acquired the Atlanta, Georgia-based generic drug distributor and marketer Libertas Pharma Inc for about $4 million to $5 million.

Mayne Pharma investment relations manager Lisa Pendelbury told Biotech Daily that the acquisition was for “less than five percent of net assets in cash and 503,493 shares”.

Ms Pendlebury said the company had net assets of about $100 million.

In a media release Mayne said that Libertas distributed and marketed a range of niche products and was highly complementary to the Metrics Products division, with six marketed and two pipeline abbreviated new drug application products distributed through the same retail pharmacy channel as Metrics with no product overlap.

Mayne acquired Metrics last year for $US105 million (BD: Nov 15, 2012).

Today, Mayne chief executive officer Scott Richards said that Libertas was acquired by an upfront payment comprising cash and a small scrip component to owner and founder Chris Schneider and a three year performance based earn-out to be funded from operating cash.

Mr Richards said that Mr Schneider would join the company as sales and marketing vice-president.

“The acquisition is favorably structured such that more than 60 percent of the total purchase price is performance based,” Mr Richards said.

“Libertas fits well with the Metrics business and further strengthens our US generics franchise, which will now distribute 15 generic [abbreviated new drug application] products and have more than 20 products in various stages of development, including seven products filed with the US FDA,” Mr Richards said.

Mr Richards said that Libertas was expected to be “earnings accretive” in 2013-’14 and was positioned to deliver further growth to the US business.

“Chris has a proven track record of sales leadership and success in the pharmaceutical industry and I am certain that he will play a key role in executing our business strategy and further accelerating the growth of the Metrics Products division,” Mr Richards said.

Mayne was up one cent or 2.3 percent to 44.5 cents with 1.5 million shares traded.

BENITEC BIOPHARMA

Benitec says the US National Institutes of Health has recommended “minor changes” to the design of its phase I/IIa trial of TT-034 for hepatitis C virus.

Benitec said that its wholly owned US subsidiary Tacere Therapeutics received the written report from the NIH’s Recombinant DNA Advisory Committee meeting on June 11, 2013 which gave a “favorable view” of the planned US-based trial of the TT-034 DNA-directed RNA interference (ddRNAi) therapeutic.

Benitec said that following minor changes made to the trial design after the recommendations of the RAC committee, it had requested a final pre-investigational new drug application meeting with the US Food and Drug Administration prior to lodging the investigational new drug application.

Benitec chief executive officer Dr Peter French said the company was “clearly pleased with the formal RAC recommendations and the move to request a final pre-IND meeting aims to ensure that Benitec, as the new sponsor, previously Pfizer, establishes a close working relationship with the FDA as we proceed to file the IND application”.

Dr French said the company was on-track to begin the trial by the end of 2013.

Benitec fell 0.1 cents or 6.7 percent to 1.4 cents with 1.4 million shares traded.

PSIVIDA

Psivida says it has begun the first of two pivotal phase III trials of its micro-insert for chronic, non-infectious uveitis affecting the posterior segment of the eye.

Psivida investor relations vice-president Brian Leedman said the two trials would enroll about 300 patients at about 15 US sites and other non-US sites.

Mr Leedman said that the micro-insert was based on the company's proprietary Durasert drug delivery system and was the same as Iluvien, licenced by Alimera Sciences and recently approved in Europe for diabetic macular oedema.

Psivida chief executive officer Dr Paul Ashton said the first three US clinical sites had begun recruiting patients.

"We are very optimistic that our micro-insert will be efficacious for the treatment of posterior uveitis with a more favorable risk/benefit profile, fewer side effects and greater ease of administration than Retisert, our current FDA-approved product for the treatment of the same disease," Dr Ashton said.

Psivida said the micro-insert was about the size of an eyelash and released the steroid fluocinolone acetonide on a sustained basis for up to 36 months.

The company said the US Food and Drug Administration had set a new Prescription Drug User Fee Act (PDUFA) date for reconsidering Alimera's Iluvien of October 17, 2013 (BD: Aug 2, 2012; May 2, 2013).

Psivida said it did not licence the micro-insert to Alimera for uveitis and was developing the product for that indication without a partner.

Psivida said the two phase III trials had a primary end-point of recurrence of posterior uveitis at 12 months and if the results were positive, the data would be used for a new drug application to the FDA.

The company said the FDA had confirmed that it would be able to reference much of the data, including clinical safety data, from Alimera's phase III clinical trials of Iluvien for chronic diabetic macular oedema.

Psivida said that posterior uveitis was an inflammatory disease of one of the layers of the eye, affected about 175,000 people in the US and could be difficult to treat, resulting in an estimated 30,000 cases of blindness in the US.

"In our uveitis trials, we expect to maintain similar efficacy to that seen in the Retisert phase III trials but with a similar side-effect profile to that seen in [diabetic macular oedema] patients in the phase III studies for Iluvien," Dr Ashton said.

"The Retisert implant is FDA approved for posterior uveitis and the micro-insert delivers the same drug as Retisert, so we expect the micro-insert to be efficacious," Dr Ashton said.

"Based on the phase III studies for Iluvien, we also expect the micro-insert to have a lower incidence of serious increased in intraocular pressure than Retisert," Dr Ashton said.

"The Iluvien studies showed an incidence of serious elevated [intraocular pressure] that was three times lower than that seen in the Retisert phase III trials and the incidence of patients requiring surgery for increased [intraocular pressure] in the Iluvien studies was seven times lower," Dr Ashton said.

"The micro-insert releases drug at a slower rate and is also easier to administer than Retisert, because the micro-insert is injected in an office visit while Retisert must be implanted in a surgical procedure," Dr Ashton said.

Psivida was up three cents or 0.7 percent to $4.09.

REGENEUS

Regeneus says it has submitted an investigational new animal drug application to the US Food and Drug Administration for Cryoshot Canine.
The company said that Cryoshot Canine was made from canine adipose-derived regenerative cells, including mesenchymal stem cells from donor animals.
Regeneus is developing a treatment for osteoarthritis in humans from fat-based stem cells, first trialed on dogs (BD: Nov 29, 2011; Apr 5, 12, 2102).
Regeneus said the Cryoshot Canine application was to the FDA's Centre for Veterinary Medicine for the off-the-shelf stem cell therapy for musculoskeletal disorders in dogs.
Regeneus head of animal health Dr Duncan Thomson said that the application was "the first official step towards product registration in the US and an important milestone in the registration process".
"It will allow us to import and ship Cryoshot Canine across state lines in the US," Dr Thomson said. "Next steps are for us to compile and submit individual dossiers to the [Centre for Veterinary Medicine] on product characterization, manufacture, safety and efficacy, as a part of a new animal drug application."
Dr Thomson said a US clinical trial in dogs was expected to begin by July 2014.
"We anticipate sales of up to 100,000 units per year to service the likely demand from veterinarians and dog owners," Dr Thomson said. "Currently in the US there is no registered off-the-shelf cell therapy for canine musculoskeletal disorders."
Regeneus is a public unlisted company.

LBT INNOVATIONS

LBT says the preliminary unaudited profit after tax for the year ending June 30, 2013 was expected to be about $500,000 compared to a $1.16 million loss in the previous year.
LBT said it had signed an agreement with Hettich AG Switzerland for a joint venture to develop and distribution its Automated Plate Assessment System (BD: Jun 25, 2013).
The company said the expected after tax profit for the year to June 30, 2013 included the $2 million signing fee and a capital gain from LBT's interest in the joint venture.
LBT was unchanged at 9.5 cents.

IMUGENE, IDT AUSTRALIA

Imugene says IDT Australia will assist with formulation and manufacture of its Linguet fast melt ibuprofen tablets.
Imugene chief executive officer Dr Nick Ede said that "locking-in manufacturing and supply is an important milestone in de-risking the development of a pharmaceutical asset".
IDT chief executive officer Dr Paul MacLeman said that Imugene's ibuprofen project "fits in nicely with IDT's strategy to generate new technology and value with industry partners".
Imugene said it was developing a 200mg ibuprofen tablet which melted in the mouth and was easier to swallow and the novel formulation was designed to address issues of unpleasant taste, mouth feel and swallowing difficulties associated with non-steroidal anti-inflammatory drugs (BD: May 23, 2103).
Imugene was untraded at 0.4 cents.
IDT was untraded at 20 cents.