Biotech Daily

Tuesday May 14, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PHYLOGICA UP 25%, LIVING CELL DOWN 6%**

*** RESMED PAYS SYDNEY UNI $25m FOR PATENT DISPUTE, TWO CHAIRS**

*** UNILIFE CONTRACT, UP 128%, TRADING HALT, CLARIFY, DOWN 18%**

*** PHARMAUST RAISES $500k**

*** PHARMAXIS MEETS FDA ON BRONCHITOL TRIAL**

*** PHOSPHAGENICS, US AGRICULTURE COLLABORATE ON MASTITIS**

*** BIONICHE TO DIVEST ANIMAL HEALTH BUSINESS**

*** REVA APPOINTS MICHEL VANBRABANT M-D INTERNATIONAL**

*** GENERA RE-APPOINTS RICHARD HANNEBERY FOR CORP DEVELOPMENT**

MARKET REPORT

The Australian stock market was up 0.21 percent on Tuesday May 14, 2013, with the S&P ASX 200 up 10.7 points to 5,221.0 points.

Eleven of the Biotech Daily Top 40 stocks were up, 14 fell, 13 traded unchanged and two were untraded. All three Big Caps were up.

Phylogica was the best, up 0.4 cents or 25.0 percent to two cents with 1.5 million shares traded, followed by Psivida up 14.8 percent to $3.10 with 12,647 shares traded and Patrys up 12.5 percent to 2.7 cents with 1.3 million shares traded.

Neuren climbed 7.7 percent; Osprey was up 5.6 percent; Optiscan and Pharmaxis were up more than three percent; Circadian, Cochlear, Heartware and Nanosonics rose more than two percent; CSL was up 1.2 percent; with Acrux and Resmed up by less than one percent.

Living Cell led the falls, down 0.3 cents or six percent to 4.7 cents, with 612,500 shares traded.

Tissue Therapies fell four percent; Alchemia, Clinuvel, Prima and Starpharma lost more than three percent; Allied Health, Anteo, Genetic Technologies, Mesoblast and Sirtex shed more than one percent; with Reva, QRX and Viralytics down more that one percent.

RESMED

Resmed says it will pay $25 million to the University of Sydney to support research into sleep-disordered breathing as part of an intellectual property dispute.

Resmed said that the funding would establish two perpetual academic chairs called the Resmed Chair of Sleep Medicine for sleep-disordered breathing with a focus on chronic disease and the Resmed Chair of Biomedical Engineering with an emphasis on bioinformatics research, as well as funding for research in related areas.

The agreement also provided for the settlement of proceedings between the parties in the Australian Federal Court regarding a dispute over an earlier licensing agreement.

Sydney University's 2011 annual report said the University commenced proceedings against Resmed in the Federal Court in January 2007, over a 1991 licence agreement relating to an invention for use in masks used to treat sleep apnea.

The University said it alleged that masks manufactured by Resmed infringed a patent held by the University, that Resmed misused confidential information which was provided by the University, that Resmed misused the intellectual property which was the subject of the 1991 licence agreement and that improvements to the licenced intellectual property rightfully belong to the University and claimed damages for unpaid royalties, damages or an account of profits for patent infringement and an order that Resmed transfer certain patents and designs relating to sleep apnea masks to the University.

The University said that Resmed denied its products infringed the University's patent, that it misused information which was confidential, or that it misused the licenced intellectual property.

Today, Resmed chief executive officer Michael Farrell said that sleep-disordered breathing affected one in five adults and he looked forward to the University's research "revealing new information on how to battle this costly and life-threatening condition".

The University of Sydney's vice-chancellor Dr Michael Spence said this agreement "would allow the University to further develop its path-finding research in these critically important areas, as well as provide future opportunities for our researchers".

Resmed was up one cent or 0.2 percent to $5.09 with 4.3 million shares traded.

UNILIFE

Pre-filled syringe manufacturer Unilife climbed 128 percent after announcing a supply contract, which the company qualified today, before retreating as much as 21.6 percent.

Overnight on the Nasdaq, Unilfe was up 76 US cents or 25.33 percent to $US3.76 with 10,002,800 shares traded and up 104.3 percent from the May 9 close.

On May 10 and 13, Unilife published its third quarter report and a conference call transcript in which chief executive officer Alan Shortall said the company was "getting ready to announce our first major long-term supply contract for the Unifill syringe".

"Negotiations for this agreement are complete and all terms have been agreed upon, with the execution copy now being routed for signature by both parties," Mr Shortall said.

"I expect this agreement will establish Unilife as one of the leading suppliers of pre-filled syringes in our industry," Mr Shortall said.

Today, Unilife said that "as stated in our 'Unilife Q3 Conference Call and Slides' announcement … the anticipated commercial supply contract … has not yet been signed".

"As a result, investors should not rely on the information concerning the commercial supply contract until an announcement is made upon signature of the contract, which will detail the material terms of the contract."

Unilife fell as much as 16 cents or 21.6 percent to 58 cents, before closing down 13 cents or 17.6 percent at 61 cents with 6.3 million shares traded.

PHARMAUST

Pharmaust says it has raised $500,000 through the issue of 50,000,000 shares at one cent a share to clients of Peloton Capital.
Pharmaust said that due diligence on the proposed acquisition of Pitney Pharmaceuticals was continuing, with shareholder meeting materials expected to be distributed by early June with a shareholder meeting due by early July 2103 (BD: Apr 30, 2013).
Pharmaust was untraded at 1.2 cents.

PHARMAXIS

Pharmaxis says it will meet US Food and Drug Administration representatives this week to discuss the next clinical trial to secure approval for Bronchitol for cystic fibrosis.
In March, the FDA refused approval of Bronchitol for cystic fibrosis on the basis of the data from two trials presented at that time (BD: Mar 19,2013).
Today, Pharmaxis chief executive officer Gary Phillips said the meeting with the FDA's Division of Pulmonary, Allergy and Rheumatology Products in Maryland was "an opportunity for a structured discussion with the FDA on key points of its evaluation of the company's new drug application and the pathway for approval of Bronchitol".
Mr Phillips said Pharmaxis was seeking guidance to design a trial that would meet the FDA's requirements to approve Bronchitol for cystic fibrosis.
"It will also remove uncertainty about the time and investment required to access the valuable US market where Bronchitol has orphan drug designation providing for seven years of market exclusivity from approval," Mr Phillips said.
Mr Phillips said the meeting would allow the company to finalize a business review and implement a phased restructuring based around the expected delay to US revenue and the approval paths for Bronchitol in cystic fibrosis and bronchiectasis.
Mr Phillips said the review would be announced by the end of May 2013.
Pharmaxis was up half a cent or 3.3 percent to 15.5 cents with 2.4 million shares traded.

PHOSPHAGENICS

Phosphagenics says it will collaborate with the US Department of Agriculture's Agricultural Research Service to develop and trial products targeting bacterial mastitis in dairy cows.
Phosphagenics said that with the Agriculture's Agricultural Research Service (ARS) it would formulate and evaluate products containing active ingredients in combination with its tocopheryl phosphate mixture (TPM) to enable superior absorption and efficacy.
The company said that the products would include the formulation trialed in 2012 with good results, as well as a formulation containing a vitamin D derivative.
Phosphagenics said that the 2102 preliminary study by ARS demonstrated that directly infusing the vitamin D derivative into infected quarters of the mammary gland in infected dairy cows was able to significantly lower bacteria counts and symptoms of mastitis and showed that cows treated with the derivative exhibited superior milk production.
The company said that US trials would begin in mid-2013 with ARS researchers examining the effects and efficacy of intra-mammary infusion of TPM products.
Phosphagenics chief executive officer Dr Esra Ogru said that mastitis typically affected about 15 percent of the world's dairy herd at any given time and in the US alone, economic losses resulting from the infection were estimated at $US2 billion a year.
Dr Ogru said that the current standard-of-care for mastitis was antibiotic treatment, but there were widespread concerns around antibiotic resistant bacteria.
Phosphagenics was unchanged at 12.5 cents.

BIONICHE LIFE SCIENCES

Bioniche says it has engaged US-based Evercore Partners to assist in its divestment of its animal health business.

In March, Bioniche said it would reorganize its human health division into a wholly-owned private subsidiary Bioniche Therapeutics Corp to be a standalone unit and allow direct external investment to support research and development, commercialization and acquisition opportunities.

Primarily a veterinary company, Bioniche's phase III human health product Urocidin for bladder cancer was returned to the company last year, by licencee Endo Pharmaceuticals (BD: Nov 6, 2012, Jan 20, March 8, 2013).

Bioniche has refused to call an extraordinary general meeting requisitioned by shareholders representing more than five percent of its issued capital (BD: Apr 29, May 6, 2013).

Today, Bioniche said that Evercore specialized in merger and acquisition transactions, divestitures and restructurings.

The company said that the decision to divest the animal health business was taken "following several months of discussion … related to unlocking corporate value for the benefit of all shareholders and following the receipt of several unsolicited offers to purchase the business".

Bioniche chairman James Rae said that "three large Animal Health companies have now expressed interest, in writing, in executing a purchase of the company's animal health business".

The company said it had built its animal health business over 34 years to the point where it was profitable before research and development, with a successful mix of products primarily in livestock reproduction, immuno-therapeutics, equine performance and companion animals.

Bioniche said that it was "actively engaged in discussions with potential partners for its phase III bladder cancer product Urocidin which would unlock value for Bioniche Therapeutics Corp".

"Since learning that the company was regaining the global rights to Urocidin, more than 30 companies have expressed an interest in marketing the product and discussions with these companies are at various stages," Bioniche said.

"Such partnership arrangements generally include up-front and milestone payments, as well as financial support for development costs to offset additional clinical trial work that the company is required to complete for successful commercialization of Urocidin," Bioniche said.

The company said that "a preliminary equity investment offer and a preliminary licencing offer have been received in relations to Bioniche Therapeutics Corp and Urocidin, respectively".

Bioniche said that with regard to Bioniche One Health and the animal health and food safety vaccine manufacturing centre at its headquarters in Belleville Ontario, the company "has had preliminary discussions with companies that have an interest in potential partnerships around Econiche, the E. coli O157 cattle vaccine and around manufacturing capacity in the vaccine manufacturing centre.

Bioniche did not say what assets it would retain once the human health, animal health and the animal health and food safety vaccine manufacturing were spun out or divested.

Bioniche was untraded at 19 cents.

REVA MEDICAL

Reva has appointed Michel Vanbrabant as its managing director international, responsible for commercial planning activities for the 2014 launch of its bioresorbable stent.
Reva said that Mr Vanbrabant would be based in Brussels, Belgium and had extensive experience commercializing medical devices.
The company said that Mr Vanbrabant spent more than 10 years at Guidant Corp, now Abbott Laboratories, where he began as a sales representative for vascular intervention and held increasing roles of responsibility in sales, marketing, and management before becoming country manager for France.
Reva said Mr Vanbrabant joined St Jude Medical Corp as cardiology marketing director, responsible for Europe, the Middle East, Asia, and Canada, before being appointed senior director for the neuro-modulation division.
The company said that Mr Vanbrabant was most recently Pneumrx European sales and marketing vice-president.
Reva fell one cent or 1.85 percent to 53 cents.

GENERA BIOSYSTEMS

Genera says it has appointed Richard Hannebery as its executive director of corporate development.
Genera executive chairman Lou Panaccio said that Mr Hannebery was a director of the company from 2005 to 2008, prior to the company's listing on ASX and was previously corporate development director responsible for the initial agreements struck with both Healthscope and Sonic Healthcare.
Mr Hannebery said Genera had "tremendous latent value in its Ampasand technology platform".
"The two lead products developed to date possess attractive economics and we are confident that we can replicate this with additional tests that will be added to the menu," Mr Hannebery said.
"The Paptype simultaneous genotyping [human papillomavirus] assay is well positioned as government healthcare agencies around the world move closer to adoption of [human papillomavirus] testing as the primary screening tool in the fight against cervical cancer in women," Mr Hannebery said.
"Our challenge now is to deliver attractive commercial distribution deals, both direct and via well-credentialed third parties, to ensure that shareholders receive an outstanding return on the capital they have entrusted with Genera in bringing the Ampasand technology to market," Mr Hannebery said.
Genera was untraded at 9.5 cents.