Biotech Daily

Wednesday February 15, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: LIVING CELL UP 32%, AVITA, NEUREN DOWN 4%**

*** EDITORIAL: PATRYS, CITI AND HIDING BEHIND NOMINEE COMPANIES**

*** FDA SETS ANZAC DAY FOR HEARTWARE APPROVAL HEARING**

*** BARDA PAYS BIOTA $4.3m, H1 REVENUE DOWN 3%, LOSS DOWN 31%**

*** PHOSPHAGENICS NEW OXYCODONE PATCH: 4.5 TIMES MORE DRUG**

*** HEALTHLINX DEVELOPS OVARIAN CANCER SURVIVAL BIOMARKER**

*** SUNSHINE HEART TO LIST ON NASDAQ**

*** TGA REGISTERS CELLMID ÉVOLIS HAIR PRODUCT**

*** US PATENT FOR VIRALYTICS' CAVATAK**

*** FDS PAYS $US2m FOR SCIGEN ISRAEL, HEP B VACCINE**

*** ISONEA, QUALCOMM WIRELESS CLOUD-BASED ASTHMA MONITOR**

MARKET REPORT

The Australian stock market rose 0.25 percent on Wednesday February 15, 2012 with the S&P ASX 200 up 10.6 points to 4253.4 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and four were untraded.

Living Cell was the best, up 1.6 cents or 32 percent to 6.6 cents with 964,455 shares traded followed by Cellmid up 25 percent to 1.5 cents with 40.7 million shares traded. Allied Health and Compumedics climbed more than six percent; Antisense, Impedimed and Phosphagenics were up five percent or more; Viralytics was up 4.35 percent; Genetic Technologies, Heartware and Prana were up more than three percent; with Acrux, Cochlear, CSL and Starpharma up by less than one percent.

Avita and Neuren led the falls, both down 3.7 percent to 13 cents and 2.6 cents, respectively, with 72,060 shares and 315,000 shares traded, respectively. Alchemia, Anteo, Bionomics, Clinuvel, Pharmaxis, Phylogica, QRX and Tissue Therapies shed two percent or more; Sirtex was down 1.3 percent; with Mesoblast, Resmed and Reva down by less than one percent.

BIOTECH DAILY EDITORIAL

For the fourth time in 11 trading days, Citigroup Global Markets Australia has filed a substantial shareholder notice on behalf of an unknown investor moving, but not necessarily selling or buying, Patrys shares (BD: Feb,1, 10, 13, 2012).

Each notice of Citigroup ceasing or becoming a substantial holder has been "in its capacity as prime broker … under a securities lending agreement". Today's was resuming substantial with 22,575,819 shares or 6.209 percent of the company – sufficient voting power to requisition extraordinary general meetings.

These agreements allow the trader to hide behind a nominee company and "lend" shares to Citigroup or other prime brokers for purposes that defy most investors, but could be to raise funds to buy more shares or to perform other legitimate derivative actions.

While Biotech Daily takes a dim view of arcane derivative trading, we are more concerned with a lack of transparency that flies in the face of the spirit – but not the letter – of the law.

The Australian Securities and Investments Commission 'Regulatory Guide 159: Takeovers, compulsory acquisitions and substantial holding notices' refers directly to the recommendations of the Cohen Committee (RG 159.270, 271):

'"…the intention thereof is to enable a shareholder to know who [their] co-adventurers are and the public to find out who controls the business to which they are contemplating investment or to which they are considering granting credit": Report of the Committee on Company Law Amendment UK (1945) p39.

"The substantial holding requirement promotes the principle that the acquisition of control takes place in an efficient, competitive and informed market: s602(a). But the purpose of the requirement is not limited to identifying bidders or potential bidders. The general purpose is to maintain an informed market in quoted securities."'

While there is a "guide", there does not appear to be any law to support this principle.

Citigroup does not have to disclose the identity of the original owner of the shares, nor does that owner.

It is not just tedious to report that an unknown shareholder is regularly lending, selling buying and/or transferring shares, it raises questions about the ownership of the target - or victim – company.

As previously published (BD: Jun 25, 2009): If Al Capone holds 22% of Helpful Taxation Tips Co, with Edward Kelly (19%) and Ronald Biggs (15%) but they all hide under Honest Nominees (56%) then investors might think the company benign, when it is not.

One company director told Biotech Daily that he needed to hide his holdings to prevent the Australian Taxation Office and his wife knowing how much he was worth.

The principle enshrined in the ASIC Regulatory Guide needs to be written into the Corporations Act as a mandatory disclosure.

David Langsam, Editor

HEARTWARE

Heartware says the US Food and Drug Administration will review its pre-market approval application for the Heartware ventricular assist system on April 25, 2012.

Heartware chief executive officer Doug Godshall said that the FDA circulatory system devices panel meeting "represents continued progress toward our goal of obtaining US approval of the [Heartware ventricular assist device] system for patients with end-stage heart failure".

"We look forward to discussing the efficacy and safety data for the HVAD pump with the members of the panel and the FDA review team and believe that these data underscore the potential utility of the HVAD system in improving treatment outcomes for end-stage heart failure patients," Mr Godshall said.

Heartware said the pre-market approval submission encompassed data from its pivotal Advance clinical trial, an FDA approved investigational device exemption study designed to evaluate the HVAD system as a bridge to heart transplantation for patients with end-stage heart failure.

The company said that in the Advance trial, 140 patients at 30 hospitals in the US received the Heartware investigational device between August 2008 and February 2010.

Heartware was up 6.5 cents or 3.6 percent to $1.87.

BIOTA

Biota says that it has received was $4.3 million from the US Office of Biomedical Advanced Research and Development Authority for the first three contract milestones.

Last year the Office of Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services awarded Biota wholly owned subsidiary Biota Scientific Management up to $US231 million ($A223.7 million) over five years for the advanced development of laninamivir (BD: Apr 1, 2011).

In its half year report, Biota said it expected its phase IIb clinical study of the human rhinovirus antiviral BTA798 in asthmatic subjects "completed recruitment ahead of schedule" with results expected to be available "in early Q,2 2012".

The company said that the World Health Organisation had allocated BTA798 the generic name of vapendavir.

Biota said that as part of the BARDA contract it had recruited staff with experience in advanced clinical development and manufacturing, appointed suppliers and the transfer of the manufacturing know-how from Japan to the US, including the synthesis of laninamivir produced outside Japan and the injection molding of US approved polymer inhalers.

Biota said that "considerable progress" had been made on its programs, with two phase I trials expected to begin this year.

Biota chief executive officer Peter Cook said the "key business focus has been to ensure progress under the BARDA contract and manage cash and costs until the restocking of government neuraminidase inhibitor stockpiles improve Relenza royalty income".

The company said that the "slow down in cash use, a trend which is expected to continue over the next six months".

Biota said that revenue for the six months to December 31, 2011 was down three percent to $7.8 million, compared to the six months to December 31, 2010, with net loss after tax down 31 percent to $10,996,000.

Biota said that total expenses for the six months to December 31, 2011 were $19.4 million compared to $24.8 million in the previous corresponding period, with cash at December 31, 2011 of $56.5 million.

Biota was unchanged at 76.5 cents.

PHOSPHAGENICS

Phosphagenics says that a 45-patient trial of its improved oxycodone patch delivered 4.5 times more oxycodone over 72 hours than the original prototype.

Phosphagenics said that the phase I trial of its tocopheryl phosphate mixture (TPM) oxycodone patch, developed in collaboration with partner 3M, was conducted at the Royal Adelaide Hospital's CMAX facility using a patch "half the size of the original prototype [with] the characteristics of a commercial patch".

Last year, Phosphagenics described the trial as a 65-patient phase I safety and tolerability trial (BD: Nov 21, 2011).

Phosphagenics chief executive officer Dr Esra Ogru told Biotech Daily today that the remaining subjects were "designated for the upcoming multiple dosing component of the study".

Dr Ogru said that there were no issues regarding safety or tolerability and "as always the patch was very well tolerated".

Dr Ogru said that the trial of healthy volunteers and measuring efficacy would begin in the phase III program, "but since we are working with a well-characterized opioid, we know that blood levels above 6Ng/ml start to provide efficacy".

Phosphagenics said that the trial was designed to characterize and assess the oxycodone delivery profile from a single 3-day application of the 3M developed TPM-oxycodone patch system.

In a media release to the ASX Dr Ogru said "the trial results confirm we have a viable product".

"While minor improvements will be undertaken to further optimize the patch, we will address these comfortably in the knowledge that we have produced a commercial patch with potential global impact," Dr Ogru said.

"The rate of oxycodone delivery from this new patch was exceptional and has the potential to provide longer-term pain relief from a single patch," Dr Ogru said.

"Clinically the new patch is of significant benefit from a safety and anti-abuse perspective in comparison to current oral dosage forms," Dr Ogru said.

"Our patch with the sustained delivery profile will minimize the potential for overdose, reduce the rate at which drug tolerance develops and improve patient compliance," Dr Ogru said.

"We believe that this result will be looked upon positively by both clinicians and the regulatory agencies," Dr Ogru said.

Phosphagenics senior regulatory advisor Dr Lee Simon said the delivery profile was "extremely interesting and points to the need to engage with the FDA as soon as is practically possible".

"These results indicate that Phosphagenics is well on the way to creating a unique product," Dr Simon said.

Dr Ogru said that "minor formulation changes would be undertaken to improve the final commercial product and the company had chosen to address the changes before progressing into the multiple dosing component of the clinical program.

Dr Ogru said the fully-funded phase III program was expected to start later this year, pending US Food and Drug Administration approval.

Phosphagenics said that the projected demand for the TPM-oxycodone patch was expected to exceed $1 billion a year and the current global oxycodone market was more than $3 billion a year.

Phosphagenics was up one cent or 5.3 percent to 20 cents with 7.4 million shares traded.

HEALTHLINX

Healthlinx says that a collaborative study has assessed the potential prognostic value of a new protein biomarker in routine ovarian tumor pathology specimens.

Healthlinx said that the biomarker was shown to be highly expressed in malignant ovarian carcinoma tissue from patients who had significantly better clinical outcomes and poorly expressed or absent in patients with poor clinical outcome, with a 22 percent relapse rate associated with high expression compared with 78 percent relapse rate in patients with low expression ($p < 0.001$).

The company said that the findings suggested that the biomarker might serve as a useful prognostic marker for ovarian cancer that couldn be incorporated into routine pathology assessments.

Healthlinx said the study was conducted at Brisbane's Mater Health Services, department of anatomical pathology using tissue microarrays constructed from 200 individual cases of benign and malignant ovarian cancer specimens as well as control ovarian tissue derived from the diagnostic pathology archive.

The company said that expression of the biomarker was correlated with disease-free survival period in malignant ovarian carcinoma patients for up to 80 months to establish a relationship between expression and patient outcome.

Healthlinx said that high expression of the biomarker was associated with increased survival rate at 80 months and low biomarker expression had lower survival rate at 60 months.

Healthlinx managing director Nick Gatsios said that the results enhanced his company's assets "and effectively positions the company to provide a vertical solution to the diagnosis of ovarian cancer with our Ovplex test and now potentially provide clinicians with an additional prognostic indicator with this novel biomarker".

"Furthermore, the market opportunity for this technology is greater than the diagnosis of ovarian cancer," Mr Gatsios said.

"Every patient that is diagnosed with ovarian cancer and has their tumor removed may benefit from this test which may ultimately provide important additional information relating to patient management," Mr Gatsios said.

"This technology will also allow the company to target big pharma to partner [or] to co-develop the assay as an aid in patient therapy and management decisions," Mr Gatsios said. "It also has expanded the company's intellectual property portfolio significantly."

Healthlinx said that disclosure of the identity of the marker and peer-reviewed publication of the study would be released pending submission of new patent applications.

Healthlinx was unchanged at 1.3 cents with 6.2 million shares traded.

SUNSHINE HEART

Sunshine Heart says it will begin trading on the Nasdaq a 9:30am (USEST) on February 16, 2012 under the code SSH.

The company said that following the Nasdaq listing it would maintain dual listings, with common shares trading with Chess Depository Interests (CDIs) continuing to trade on the ASX under the symbol SHC.

Sunshine Heart said that stock-holders would be able to freely convert their holdings between ASX-listed CDIs and shares of Nasdaq-listed common stock, with one share represented by 200 CDIs.

Sunshine Heart was unchanged at 3.8 cents.

CELLMID

Cellmid says it has Australian Therapeutic Goods Administration registration for its Évolis hair growth product range as listed medicine.
Cellmid said that the registration certificates the product claims of “promotes hair growth”, “helps prevent hair loss and thinning” and “restores the natural hair growth cycle”.
The company said that the registration “removed a major hurdle from the commercial launch which is now planned for May 2012 in pharmacies nationally”.
Cellmid said that TGA registration was “not only a validation of the clinical performance and safety of the products; it is also a key step towards a market, which has few products that can match the strong scientific and regulatory credentials of the Évolis range”.
The company said that the Évolis products would not require a prescription and would be sold as over-the-counter medicines in pharmacies and pharmacy chains and a distributor had been appointed with a target of making the products available for sale in up to 400 pharmacies within 12 months.
Cellmid said that current hair growth products either had serious side effects or lacked evidence of efficacy, but Évolis had safety combined with efficacy.
Cellmid said that its wholly-owned subsidiary Advangen International held exclusive manufacturing and distribution rights for the products in Australia, the US, Europe, India and South America with significant combined sales potential.
The company said it expected to launch the product outside Australia in late 2012.
In 2010, Cellmid launched the Léxilis product range containing “active ingredients of natural origin that have been shown to inhibit FGF-5, a protein responsible for the transition of the hair follicles from growth to rest phase” (BD: Dec 8, 2010).
Cellmid said that studies demonstrated that using FGF- 5 inhibitors extended the growth phase of each hair follicle and decreased the amount of hair lost, which over time should result in a fuller head of hair, with increased thickness and length.
Cellmid was up 0.3 cents or 25 percent to 1.5 cents with 40.8 million shares traded.

VIRALYTICS

Viralytics says it has been granted a US patent “covering a Coxsackie A virus capable of infecting cancer cells substantially in the absence of intercellular adhesion molecule-1”.
Viralytics chief scientific officer Dr Darren Shafren said the company’s lead compound Cavatak targeted and destroyed cancerous cells following binding to surface expressed of intercellular adhesion molecule-1 (ICAM-1).
“The generation of this novel Coxsackie A virus, that can infect cancer cells in the absence of ICAM-1 expands the range of cancers that Viralytics panel of oncolytic viruses can potentially target,” Dr Shafren said.
Viralytics said that the scope of the allowed claims covered a bio-selected form of Coxsackievirus A21 which was generated following passage in cells not expressing ICAM-1, but expressing decay accelerating factor (DAF).
The company said that decay accelerating factor expression was up-regulated on the surface of many cancerous cells including ovarian, colorectal and gastric cancers, making it a target for the newly bio-selected Coxsackievirus A21.
Viralytics said that the claims of the patent also covered specific changes induced on the surface of the Coxsackievirus A21 during the bio-selection process on DAF-expressing cancer cells believed to confer the extended scope of cancer cell targeting.
Viralytics said it expected the patent would expire on September 20, 2025.
Viralytics was up 1.5 cents or 4.35 percent to 36 cents.

SCIGEN

Scigen says it has closed the $US2 million sale of Scigen Israel and the assignment of its licencing rights for the manufacture and sale of its hepatitis B vaccine.

Scigen said that FDS Pharma LLP would pay the $US2 million in cash and would pay a royalty of five percent on future global sales.

The company said the sale would improve its cash flow “and enable the company to focus on growth of sales of recombinant human insulin as its core product, as well as developing sales of other diabetes products”.

Scigen was untraded at 4.5 cents.

ISONEA (FORMERLY KARMELSONIX)

Isonea says it will design and market a home and mobile asthma monitoring platform with Qualcomm technology.

Isonea said the new technology would combine its acoustic respiratory monitoring devices and mobile health asthma management systems with Qualcomm’s 2 Net platform, a plug-and-play connectivity gateway to the cloud-based 2 Net platform data server, to collect and transmit patient health data.

The company said that the integration would automatically and securely link patient asthma symptom and trend monitoring data to a “cloud-based” portal for physicians and caregivers, to improve asthma management and outcomes.

Isonea said the technology would allow physicians to securely access patient monitoring data, review treatment progress and medication adherence and adjust patient action plans accordingly.

Isonea chief executive officer Michael Thomas said that asthma was “a widespread and growing condition that affects 300 million people worldwide and represents a major healthcare cost burden”.

“Australia, in particular, has one of the highest prevalence rates of asthma in the world,” Mr Thomas said.

“With our smart-phone platform and Qualcomm’s end-to-end wireless systems expertise, we will provide asthma patients with the ability to monitor and report breathing distress symptoms triggered by environmental factors, as well as their response to treatment,” Mr Thomas said.

Isonea was up 0.1 cents or 20 percent to 0.6 cents with 87.1 million shares traded.