Biotech Daily

Tuesday March 3, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN; PHOSPHAGENICS UP 5%, GENETIC DOWN 14%**

*** STEMCELLS BUYS STEM CELL SCIENCES FOR $7m**

*** BIOGUIDE BRIEF: STEM CELL SELLS ALL BUT SHELL TO STEMCELLS**

*** EASTLAND MEDICAL RETURNS RIGHTS FUNDS, RAISE $4-6m**

*** KV'S WOES FORCE SOLE FOCUS ON ACRUX'S EVAMIST**

*** HALCYGEN SUPER-GENERIC BEATS ORIGINAL; LICENCE TALKS**

MARKET REPORT

The Australian stock market fell 0.95 percent on Tuesday March 3, 2009 with the S&P ASX 200 down 30.9 points to 3,219.2 points.

Seven of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and 12 were untraded.

Phosphagenics was best, up 0.5 cents or five percent to 10.5 cents with 13,750 shares traded.

Labtech and Polartechnics climbed more than four percent; Prana was up 3.12 percent; CSL rose 2.76 percent; with Avexa and Nanosonics up more than one percent and Cochlear and Pharmaxis up less than one percent.

Genetic Technologies led the falls, down 0.5 cents or 14.29 percent to three cents with 30,350 shares traded, followed by Novogen down 13.33 percent to 52 cents and Benitec down 12.5 percent to 3.5 cents.

Circadian lost 9.7 percent; Cathrx was down 8.9 percent; Antisense fell 5.7 percent; Cellestis, Peplin and Resmed were down more than three percent; Clinuvel, Heartware, Progen and Viralytics shed more than two percent; with Biota down 1.08 percent and Arana down 0.36 percent to $1.36 with 3.8 million shares traded.

STEM CELL SCIENCES

Stemcells Inc will acquire Stem Cell Sciences' trading subsidiaries and assets for about $US4,849,000 ($A7,074,200).

The acquisition by the Palo Alto, California-based Stemcells includes specified ancillary agreements, assets, properties and rights.

Stem Cell Sciences said payment would be 2,650,000 shares of Stemcells common stock and $US715,000 of waived loan entitlements.

The acquisition price is based on Stemcells' Nasdaq closing price on February 27, 2009 of $US1.56 per share, but the stock closed overnight on March 2, 2009 at $US1.42.

Stem Cell said the deal was subject to customary conditions, including shareholder approval, which will be sought at a meeting on March 27, 2009 at Daniel Stewart & Company, Becket House, 36 Old Jewry, London at 11am.

Stem Cell said that directors and other stockholders representing more than 30 percent of shares "have irrevocably agreed to vote in favor of the transaction".

Approval by Stemcells' stockholders is not required.

Stemcells works on the discovery and development of tissue-derived cell products and will acquire Stem Cell Sciences proprietary cell technologies relating to embryonic stem cells, induced pluripotent stem cells (IPS) and tissue-derived adult stem cells; expertise and infrastructure for providing cell-based assays for drug discovery and screening, including automated robotic production and manipulation of stem and progenitor cells; patented gene insertion technology, for use in drug screening and for applications in cell and gene therapy; the SC Proven media formulation and reagent business, including proprietary media; a portfolio of more than 20 patent families relevant to cell processing, reprogramming and manipulation and gene targeting; and existing business and licence relationships with companies such as Merck and Millipore, among others.

President and chief executive officer of Stemcells Martin McGlynn said "the industrial logic of this acquisition is compelling".

"Stemcells has established itself as a world leader in tissue-derived stem and progenitor cells for therapeutic uses, while Stem Cell Sciences has focused on non-therapeutic applications for embryonic and tissue derived stem cells, such as cell-based assays for drug discovery and screening," Mr McGlynn said.

"This proposed acquisition will combine three distinct stem cell platforms, adult, embryonic and IPS cells, for both therapeutic and drug discovery applications and will position Stemcells to diversify and pursue near-term commercialization opportunities while continuing to develop our cell-based therapeutic products," Mr McGlynn said.

Stem Cell Sciences chief executive officer Dr Alastair Riddell said Stemcells Inc was "the logical home for our businesses".

Stemcells will acquire most of the operating assets and liabilities of Stem Cells, including operations in Cambridge, UK and Melbourne, Australia, and substantially all its intellectual property portfolio. Most full-time staff will continue with Stemcells.

The transaction is expected to close within two months and Stem Cell Sciences will distribute proceeds from the sale of the acquisition shares to stockholders.

Stem Cell suspension on London's Alternative Investment Market has been lifted. Should the meeting approve the resolutions, trading would be cancelled on June 29, 2009.

The ASX requires the company to publish a preliminary report for the year to December 31, 2008 by February 27, 2009. Given the circumstances the board does not intend to prepare this report and there is no expectation for trading on the ASX to be resumed with removal from the ASX on June 29, 2009, Stem Cell Sciences said.

Stem Cell was as high as $1.09 on April 30, 2007 with an Australian market capitalization of $32,935,602 and a UK value about $25 million. It last traded at 15 cents.

MARC SINATRA'S BIOGUIDE: STEM CELL SCIENCES

Heartware is off to Thoratec and Arana probably to Cephalon, while Progen is likely to end up with either Avexa or Cytopia. Consolidation in the sector has well and truly begun.

Now, Stem Cell Sciences is likely to become a shell after US-based Stemcells Inc agreed to relieve the company of "substantially" all of its assets and liabilities in exchange for 2,650,000 Stemcell Inc shares, presently valued at roughly $5.5 million.

Stem Cell Sciences only listed in Australia in early 2007 and promptly began chewing through the $12 million it raised in its listing, with its declining revenue unable to buffer its expenditure at all. It simply seemed to be trying to do too much as evidenced by the nine broad categories of products and services they offered, without matching expenditure to revenue.

There is no question Stem Cell Sciences has some very good technology as evidenced by its list of collaborators who include or included Pfizer, Sanofi Aventis and Merck. Its recent breakthrough in the production of rat stem cells is also another testament to the company research skills.

Unfortunately, it is not enough to have good technology or researchers, you must also be able to organize them into a functional company and turn the work product into cash. This is where Stem Cell Science fell down and quite badly at that.

So, what are Stem Cell Sciences investors likely to get back? That is hard to say. After the transaction, the plan is to wind Stem Cell Sciences down. On today's figures, the ultimate sale of the Stemcells Inc holding should yield about 18 cents per share.

But since we don't know what will be left on Stem Cell Sciences books after the transaction or what the winding down costs will be, the payout may vary considerably from that number.

Biotech Daily editor David Langsam owns shares in Stem Cell Sciences.

EASTLAND MEDICAL SYSTEMS

Eastland Medical will return the funds from its rights issue having secured a mandate from RM Corporate Finance to arrange $4 million to $6 million.
Eastland said the money would fund the Artimist sub-lingual anti-malaria clinical treatment and to meet its ongoing requirements for its domestic operations.
The RM Corporate mandate is in addition to the $750,000 convertible note, principally for working capital, announced on January 31, 2009, the company said.
Eastland said it had received "significant interest from various potential investors and brokers" and looked forward to concluding its funding arrangements as soon as possible.
The company said it expected the clinical trial would be "a fast track entry to the market", supported by a product pre-qualification application to the World Health Organisation.
Eastland said its advisors were confident that the results of the trial and the effectiveness of Artimist in the treatment of complicated and uncomplicated malaria in children would be positive and expect to be in a position to claim that would be the most effective treatment available.
Eastland climbed 0.1 cents or 1.85 percent to 5.5 cents.

ACRUX

Acrux says its Evamist menopause treatment remains unaffected by the business restructuring being undertaken its US licencee, KV Pharmaceutical.

Acrux said KV subsidiary, Ther-Rx, continued "to actively promote and distribute Evamist", which is manufactured by a third party (BD: Feb 2, 2009).

Evamist is known as Ellavie outside the US

KV announced the restructuring of its business following a number of product recalls and the suspension of manufacturing and shipment of its products.

Acrux said that on March 2, 2009, the US Food and Drug Administration and KV Pharmaceutical entered into a consent decree, which stipulated the actions required to resume manufacturing (see: www.kvpharmaceutical.com).

Acrux said that on February 5, 2009 KV commenced a reduction in its manufacturing and corporate workforce and KV had initiated a reduction and re-alignment of its sales force to be structured specifically around the promotional needs of Evamist.

Acrux chief executive officer Dr Richard Treagus told Biotech Daily that the main issue was that KV had "clarity and certainty" about the way forward with the FDA.

"The important thing is that the uncertainty over the FDA's decision has been removed," Dr Treagus said.

He said that while the company was addressing its manufacturing issues for the FDA Evamist was the sole product being marketed by KV and generating revenue for KV.

Dr Treagus said the marketing team was selling Evamist to doctors and specialists who understood that the product was manufactured by a third party and was not affected by KV's problems.

He said sales had grown consistently over the past year with the only dips in sales over Thanksgiving and Christmas and that up 2,500 prescriptions were being written each week.

Each prescription is worth $US43.00 ($A67.22) with royalties ranging from "low single digits to double digits" as sales increased.

In its media release to the ASX Acrux said the smaller and more focused sales force was "dedicated to actively promoting Evamist and it will continue to achieve an approximate 90 percent coverage of the total oestrogen replacement therapy prescription market in the US".

The company said the Ther-Rx marketing team responsible for the marketing and promotional support of Evamist was unaffected by the changes.

Acrux said KV Pharmaceutical was "positive on the potential for Evamist and expects that the weekly growth in prescriptions will continue".

The company said sales were "below expectations" but weekly prescriptions for Evamist had grown consistently since launch up to 2,500 scripts per week

In light of its restructuring, KV has elected not to proceed with investment in the development of additional metered dose transdermal spray products, as cited in the August 2008 agreement (BD: Aug 12, 2008).

All rights to those products now revert to Acrux and Acrux retains full access to the Evamist US registration dossier for commercialization of Ellavie in the rest of the world.

Dr Treagus said the Duomist combination hormone replacement therapy and five unspecified products reverted to Acrux and he would move to partner those products with other companies as soon as possible.

Acrux was unchanged at 45 cents.

HALCYGEN

Halcygen says it has completed dosing and recruitment of three pivotal pharmacokinetic studies scheduled under its investigational new drug application.

Halcygen said the US Food and Drug Administration-approved trials of 108 people produced "excellent results" indicating that: the rate and extent of absorption of itraconazole from 50mg SUBA-itraconazole capsules is correspondent to that from 100mg Sporanox capsules; itraconazole was absorbed from SUBA-Itraconazole capsules in the fed and fasted state; inter-patient variability was greater with Sporanox.

After multiple dosing to achieve steady state, 100mg of SUBA-itraconazole was comparable to 200mg of Sporanox, the recommended dose.

Halcygen said that as a result of work on its half dose (50mg) formulation in 2008, the benefits of SUBA-itraconazole to patients indicated a reduced incidence of side effects compared to Sporanox; SUBA-itraconazole may be taken on an empty stomach while Sporanox must be taken after a meal; and SUBA-itraconazole can be in an easier to swallow capsule.

Halcygen said initial analysis indicated that SUBA-itraconazole was nearly 100 percent bio-available compared to Sporanox which has about 55 percent bioavailability, so, high absorbing patients in the population were limited on how much drug would be absorbed into their blood stream when taking SUBA-itraconazol, as a result of the "half-dose" form.

Halcygen said this was important for improved safety of itraconazole-based products".

Halcygen said that as a result of the pharmacokinetic program, it would pursue a dual registration strategy and would simultaneously seek approval in the US and Europe.

Through an amendment to its investigational new drug application, Halcygen has commenced an onychomycosis (fungal infection of the toe nail) clinical study in up to 91 patients to study safety and efficacy of SUBA-itraconazole, aimed at building further evidence and support for the advantages that SUBA-Itraconazole.

Halcygen chief executive officer Dr Roger Aston said the initial registration strategy for SUBA-itraconazole was "designed to launch a non-inferior product, clinically comparable to the market's leading product Sporanox".

"We are now of the view that we have an excellent alternative to Sporanox with potential safety advantages," Dr Aston said.

"Our task now is to seek registration whilst ensuring we can benefit in the market from the advantages demonstrated by SUBA-itraconazole," Dr Aston said.

"Clearly, we need to satisfy both US and EU regulatory requirements for product approval and there is still a possibility that a phase III study may be required by either the FDA or European authorities, for product registration," he said.

Halcygen will be meeting both FDA and EU regulators for further guidance and to discuss the way forward for SUBA-Itraconazole in coming months".

Halcygen said the US-based trials had led to "licencing interest from several companies for the distribution of SUBA-itraconazole in certain territories".

The global market for itraconazole is more that $US600 million a year.

Halcygen fell 5.5 cents or 35.48 percent to 10 cents.