Biotech Daily

Monday December 14, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: NOVOGEN UP 9%; OPTISCAN DOWN 11%**

*** CHEMGENEX SIGNS $137m EURO, MID-EAST DEAL WITH HOSPIRA**

*** BIOGUIDE BRIEF: A $137m POSITIVE SIGNAL FOR CHEMGENEX**

*** HAWAII CEO FILES FOR BANKRUPTCY BEFORE ACUVAX BOARD COUP**

*** OMI v RTI RETRACTABLE TRIAL BEGINS IN EAST TEXAS COURT**

*** BIOSIGNAL'S $20m FACILITY TO GO TO THE MOVIES**

*** SAFETY MEDICAL RAISES $143k; WANTED $1m**

*** AUSTRALIAN ETHICAL TAKES 8.4% OF TISSUE THERAPIES**

*** AVITA PLEADS SCHULTZ TO ASX 18% QUERY**

MARKET REPORT

The Australian stock market climbed 0.4 percent on Monday December 14, 2009 with the S&P ASX 200 up 18.8 points to 4654.0 points.

Eight of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and eight were untraded.

Novogen was best, up 4.5 cents or 8.9 percent to 55 cents with 9,988 shares traded, followed by Chemgenex climbing as much as nine cents or 9.7 percent to $1.02 before closing up four cents or 4.3 percent at 97 cents with 2.7 million shares traded.

Prima, QRX and Sirtex climbed more than three percent; Cochlear rose 2.9 percent; with Pharmaxis, Psivida and Starpharma up more than one percent.

Optiscan led the falls, down one cent or 11.1 percent to eight cents with 10,000 shares traded, followed by Tissue Therapies down 7.1 percent to 13 cents with one million shares traded.

Biota lost 6.8 percent with 2.8 million shares traded; Acrux, Cellmid, Clinuvel, Mesoblast and Nanosonics fell more than three percent; Viralytics shed 2.6 percent; with Alchemia, Bionomics, Circadian and Heartware down more than one percent.

CHEMGENEX

Hospira Inc has an exclusive licence to develop and commercialize Chemgenex's Omapro for chronic myeloid leukemia in Europe, the Middle East and parts of Africa.

Chemgenex said the Illinois-based Hospira would make an initial payment of EUR11.1 million ($A17.8 million), with the potential for up to an additional EUR74.1 million ($A119.4 million), in performance milestone payments based on the successful development and commercialization of omacetaxine mepesuccinate as well as royalties on sales following successful commercialization.

Chemgenex said that applications for marketing approval of omacetaxine mepesuccinate (Omapro) had been accepted for regulatory review in both the US and Europe for treatment of patients with chronic myeloid leukemia (CML) have failed to respond to the current standard of care treatment, imatinib mesylate and who have the Bcr-Abl T315I mutation.

Chemgenex said it would complete registration of omacetaxine in its initial indication with the European Medicines Agency (EMEA), while Hospira and Chemgenex would collaborate to explore future applications in a variety of haematological malignancies.

Chemgenex said Hospira would have responsibility for commercializing omacetaxine in the licenced territory.

Chemgenex chief executive officer Dr Greg Collier told Biotech Daily that the deal with Hospira came at a time when the company best known for its specialty generic injectable pharmaceuticals was building its oncology section with a strong sales force in Europe.

Dr Collier said the addition of Omapro to the Hospira catalog strengthened Hospira's challenge to the European oncology market.

Hospira's Europe, Middle East and Africa president Michael Kotsanis said the agreement was "a further step in Hospira's strategy to build upon our strong portfolio of oncology and hematology products".

Dr Collier said Chemgenex continued its intention to market Omapro under the Chemgenex brand in the US, pending US Food and Drug Administration approval, and the funds from the Hospira licence would assist Chemgenex's personalized medicine sales and marketing team in the US.

Dr Collier said the FDA's fast track status meant that a response from the priority review was expected in "early March" 2010.

Asked about the next drug in Chemgenex's pipeline, Dr Collier said the company was totally focused on registering omacetaxine mepesuccinate.

"Once approved, we have three CML indications acute myeloid leukemia and myelodysplastic syndrome … with evidence of efficacy in phase II trials," Dr Collier said.

"We will be concentrating on further indications," he said.

Dr Collier said a pipeline of compounds made sense for early stage development companies because each compound had a five percent chance of success, but for a drug that has shown consistent results in phase III trials, it was more important to focus on other potential indications.

In a media release Dr Collier said the licence to Hospira was "in keeping with our corporate strategy of partnering in Europe and other parts of the world, as we prepare for the launch of omacetaxine in the US, if approved".

"We look forward to working with the Hospira team to realize omacetaxine's potential in the haematology-oncology space in Europe," Dr Collier said.

Chemgenex said that omacetaxine was a first-in-class cetaxine with demonstrated clinical activity as a single agent in a range of haematological malignancies and has been granted orphan drug designations by the FDA and EMEA as well as fast track status by the FDA.

Chemgenex was up four cents or 4.3 percent to 97 cents with 2.7 million shares traded.

MARC SINATRA'S BIOGUIDE BRIEF NOTE: CHEMGENEX

When your price on a company is three times that of other analysts, you know you will either be seen as an oracle or, much more likely, an idiot.

While Chemgenex's share price has remained way, way, way below my $5.00 price target, I am sure that many have pegged my intelligence as well and truly sub-standard.

Hopefully, today's news that Chemgenex has licenced European rights of its drug, Omapro, to Hospira for an up-front payment $17.8 million, $119.4 million in further development and sales milestones plus a royalty on sales, will cause Chemgenex shares to be re-rated to a price more consistent with my view than that of the market.

The deal to me looks excellent, coming in at the higher end of my expectations of a $10-$20 million up-front payment.

While the upfront cash and milestones are good, the real money in the Chemgenex equation will come from sales.

The price for a course of Omapro is likely to be somewhere between $US50,000 and $US80,000 a year and with a royalty rate on sales likely to be in the 30-50 percent range, even modest sales of Omapro into Europe will translate into a significant bottom line for Chemgenex.

For me, though, the main point of today's announcement is that a big multi-national pharmaceutical company, after due diligence, has put its money down on the table saying it thinks those sales will occur.

Importantly, the deal's upfront component will provide Chemgenex with the resources to launch Omapro in the US on its own and yearly sales of $US50,000 to $US80,000 per patient look much better when multiplied by 100 percent rather than 30 or 50 percent.

The Hospira deal comes on the back of impressive trial data released earlier this month regarding Omapro's performance in chronic myeloid leukaemia patients carrying the T315I mutation and patients who have failed two or more tyrosine kinase inhibitors (TKIs).

Regarding the latter trial, I had felt that doctors were likely to overlook Omapro in favor of a third TKI, where possible. However, having reviewed the performance third line TKI use, Omapro looks like a much better option.

Overall, I remain confident that Chemgenex is worth the five dollars a share I believe it to be. My only fear is that I may have to wear the "idiot" tag until cash starts to flow in.

Marc Sinatra
Analyst

Marc Sinatra and Biotech Daily editor David Langsam both hold Chemgenex stock.

ACUVAX, HAWAII BIOTECH

Acuvax says the chief executive officer of 28 percent sister company Hawaii Biotech Dr Elliot Parks is taking steps to file a petition with the US Bankruptcy Court in Honolulu
"This is an unprecedented step as Hawaii Biotech Inc has been offered a number of financing alternatives" Acuvax chairman Patrick Elliott said.
Last month Acuvax requisitioned an extraordinary meeting of Hawaii Biotech shareholders to replace two directors including Dr Parks (BD: Nov 9, 2009).
Today Mr Elliott said that "one of the financial alternatives required … the CEO to step off the board of directors, along with the chair of the audit committee" and that Acuvax was "exploring legal options" against the Hawaii Biotech directors responsible.
Acuvax said that in the US, 'Chapter 11' petitions request protection of the Court to permit re-organization.
Acuvax said it intended to approach the Court with a further financing offer for the company, "as it is a valuable asset, with two drugs in the clinic and a major diagnostic revenue partnership which brought in over $US1 million in sales in the current calendar year and has strong growth prospects for the future".
Acuvax said it was also seeking co-investors to invest in Hawaii Biotech to ensure it was properly funded and that the board, budgeting, capital planning, governance and strategies focused more on commercialization of its portfolio of intellectual property.
Acuvax said Hawaii's continued operations were "very likely to be funded by post-petition financing sources who have already offered capital to the company".
Acuvax chief executive officer and Hawaii Biotech director Dr William Ardrey said Acuvax was pressing for a solid financial and strategic plan, including changes to the board to include more directors with successful transaction and revenue generation experience.
"The current [Hawaii] corporate management team has superb scientists, but failed to fully commercialize the excellent research and development results, at a time when liquidity events and strategic transactions in the vaccine industry are of very high value," he said.
Acuvax fell 0.2 cents or 12.5 percent to 1.4 cents with 1.6 million shares traded.

OCCUPATIONAL & MEDICAL INNOVATONS

Occupational & Medical's long running intellectual property battle against Retractable Technologies Inc over its Auto-Retractable Safety Syringe begins tonight in the US.
Occupational & Medical said the trial was set to begin in the US District Court for the Eastern District of Texas on December 14, 2009 and run for no more than five days.
Occupational & Medical said that Retractable Technologies Inc (RTI) had requested a jury trial and Judge Leonard Davis would hear the trial.
The company said the outcome of litigation was uncertain but it rejected RTI's remaining claims in the US proceedings and was "strongly of the view that its market leading Auto-Retractable Safety Syringe does not infringe RTI's patents and remains of the view that OMI should succeed in its defence against RTI's primary claims".
Occupational & Medical said that mediation earlier this month led to seven of nine claims by RTI being dropped.
Occupational & Medical said the two claims were that it misappropriated RTI's trade secrets and seven claimed infringements of the RTI's '584 patent.
Occupational & Medical said that additional to its defence, it was claiming that RTI was barred from claiming misappropriation of trade secrets for a number of reasons; that RTI's '584 patent was unenforceable due to its having been granted by the US Patent's Office by reason of inequitable conduct; and that RTI's '584 patent was invalid.
Occupational & Medical was untraded at 14.5 cents.

BIOSIGNAL

Biosignal says it has a $20 million draw-down equity facility from the New York-based Global Emerging Markets Global Yield Fund to become an entertainment company.
Biosignal was originally created to commercialize the eastern Australian seaweed Delisea pulchra which produces natural furanones that disable bacterial ability to colonize through interrupting microbial signaling.
Earlier this year, Biosignal said that talent management and executive production company RGM Entertainment wanted an initial public offering and Biosignal had the listed shell (BD: Jul 31, 2009).
Biosignal was untraded at 2.3 cents.

SAFETY MEDICAL PRODUCTS

Safety Medical says its share plan raised $143,000 through the issue of 3,177,768 shares at 4.5 cents a share.
The plan was intended to raise funds for a Hungarian joint venture and the company said at the time that the maximum it could raise was $1,030,056 (BD: Sep 21; Oct 28, 2009).
Safety Medical said it would attempt to place the shortfall with sophisticated and institutional shareholders.
Safety Medical was untraded at 4.3 cents.

TISSUE THERAPIES

Australian Ethical Investments has increased its substantial holding in Tissue Therapies from 8,000,000 shares (7.18%) to 9,350,224 shares (8.39%).
Australian Ethical's Smaller Companies Trust acquired the shares for $194,043.62 or an average of 14.37 cents a share.
Tissue Therapies fell one cent or 7.1 percent to 13 cents with one million shares traded.

AVITA

Avita has told the ASX that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose from 16.5 cents on December 11 13, 2009 to 19.5 cents, an 18.2 percent increase, on the same day and noted an increase in trading volume.
Avita fell one cent or 5.3 percent to 18 cents.