Biotech Daily

Monday March 16, 2009

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH DOWN: AVEXA UP 46%; CATHRX DOWN 13.5%**

*** AVEXA: 87% OF PHASE IIb HIV PATIENTS 'IN GOOD HEALTH'**

*** CYTOPIA'S ANDREW MACDONALD: PROGEN BOARD SHOULD HAVE QUIT**

*** FLUOROTECHNICS' NEW CEO PROMOTED TO M-D, DIRECTOR RESIGNS**

*** FLUOROTECHNICS 1-FOR-11 RIGHTS ISSUE TO RAISE $1.5m**

*** SOLAGRAN RAISES ROPREN DROPS DOSE**

*** EURO-PATENT FOR NEURODISCOVERY'S NSL-043**

MARKET REPORT

The Australian stock market climbed 0.1 percent on Monday March 16, 2009 with the S&P ASX 200 up 3.2 points to 3,348.4 points.

Nineteen of the Biotech Daily Top 40 stocks were up, eight fell, five traded unchanged and eight were untraded.

Avexa was best, up 3.3 cents or 45.8 percent to 10.5 cents with 4.8 million shares traded, followed by Living Cell up 22.22 percent to 11 cents, Phosphagenics up 18.18 percent to 13 cents and Cytopia up 10 percent to 11 cents.

Optiscan and Psivida climbed more than eight percent; Alchemia was up 4.35 percent; Polartechnics improved 3.16 percent; Biota, Clinuvel, Cochlear and Universal Biosensors rose more than two percent; Novogen was up 1.22 percent; with CSL up 0.76 percent.

Cathrx led the falls, down five cents or 13.51 percent to 32 cents with 43,293 shares traded followed by Antisense down 12.5 percent to 3.5 cents.

Genetic Technologies lost 8.1 percent; Mesoblast fell 6.9 percent; Nanosonics was down 3.6 percent; Benitec, Chemgenex, Peplin, Pharmaxis, Sirtex and Viralytics shed more than two percent; with Heartware and Progen down more than one percent.

AVEXA

Avexa says 87 percent of patients in its phase IIb trial of apricitabine for HIV have been measured with virus levels “below detectable”.

Avexa chief executive officer Dr Julian Chick told Biotech Daily that of the 39 patients who completed the 96 week data period “most have returned to good health” from being symptomatic with HIV.

“Some of the patients had HIV levels of more than 100,000 copies per mL and are now below detectable,” Dr Chick said. He said the standard used for detectable level was 400 copies per mL, but 50 copies per mL was also used.

In its media release, Avexa said all patients continued to receive apricitabine (ATC) treatment and patients’ CD4 cells, which normally were destroyed by HIV, continued to increase in number over the 96 weeks.

At week 96, the average number of CD4 cells was around 500 to 600 cells/µL, very close to the levels of an uninfected, healthy individual, Avexa said.

Avexa said no resistance to apricitabine had been identified after 96 weeks of dosing; CD4 cells in patients continued to rise with ongoing treatment; no apricitabine-related serious adverse events were reported; and there were no withdrawals from the trial due to side effects associated with apricitabine.

Avexa’s chief scientific officer and the inventor of both apricitabine and its predecessor 3TC, Dr Jonathan Coates, said the data provided “compelling evidence that ATC provides meaningful and sustained efficacy for at least two years”.

“In over 20 years of HIV drug development I cannot recall another drug where a signature resistance mutation is still absent after two years of dosing,” Dr Coates said.

“Many patients who have difficulties with their HIV treatment regime start to forget or avoid taking all the doses, which obviously affects the control of the disease,” Dr Coates said.

“The fact that 95 percent of patients are correctly taking ATC after two years, without difficulty, is clear evidence that ATC can provide a safe, easy to take, effective and well tolerated addition to their therapy,” Dr Coates said.

Avexa said all the patients originally assigned to the 3TC arm of the study, but who later switched to ATC had remained on ATC for more than 72 weeks without returning to 3TC.

The company said that despite the availability of new classes of drugs for the treatment of HIV, 90 percent of patients and their doctors chose to continue to use ATC rather than switch treatments. This provides a strong endorsement for ATC, Avexa said.

“We are pleased with the progress of ATC to date, not only in this phase IIb trial, but also with our ongoing phase III trial,” Dr Chick said.

“2009 promises to be an exciting year for Avexa with our first data set from ATC’s phase III trial due in the second quarter,” Dr Chick said.

“The clinical progression of the advanced programs, together with grant funded earlier stage assets has the company well positioned to realize its potential,” he said.

Avexa said the phase IIb extension study was an open label trial for patients who completed the phase IIb study. All patients continued to take 800mg of apricitabine twice daily, with other HIV medications as required.

Patients who entered the phase IIb trial had already failed their HIV treatment, including 3TC and some had failed multiple previous HIV treatments.

In the phase IIb trial, patients originally received either 600mg ATC, 800mg ATC, or 150mg 3TC, all twice daily.

From week 24, all patients received 800mg ATC twice daily and have continued to 96 weeks of treatment in the phase IIb extension study.

The final endpoint of the phase IIb extension study is at week 144.

Avexa was up 3.3 cents or 45.8 percent to 10.5 cents with 4.8 million shares traded.

PROGEN, CYTOPIA

Cytopia chief executive officer Andrew Macdonald says Progen's board should have resigned last week and should not make any major decisions until after the March 27, 2009 board spill meeting.

Speaking at a media lunch in Melbourne, Mr Macdonald said most Progen investors were unhappy with the board's performance as evidenced by the overwhelming vote against the merger with Avexa and the company should not have announced a doubling of the share buy-back last week (BD: Mar 9, 2009).

Progen expanded its proposed $20 million buy-back to a $40 million buy-back at $1.10 a share representing 60 percent of the Progen share register or 36 million shares.

"We don't know why they have done it and don't believe they should have done it," Mr Macdonald said.

He said that any director seeing the results of the vote on the Avexa merger should have resigned.

"Most investors in Progen are very unhappy with performance of the board," Mr Macdonald said.

"I think the failure of the Avexa merger was a resounding defeat for the board," Mr Macdonald said.

"It reflects poorly on the whole biotech sector," he said.

Mr Macdonald said the March 27 meeting was to bring about substantial change at Progen with three new directors who would conduct an uncapped buy-back and then assess the company with the first consideration a merger with Cytopia.

Mr Macdonald refused to estimate how much money would be left of Progen's $70 million cash after either a $40 million or uncapped buy-back.

"We'd like to see a substantial amount left in the kitty but we'll have to wait and see."

He said the Cytopia shareholders' group was "still supportive if the uncapped buy-back".

Mr Macdonald said the new directors, if elected, might not be able to change the terms of the buy-back, depending on how it was structured.

He said the failed merger with Avexa would cost Progen about $1.2 million including the $500,000 break fee payment to Avexa.

But Mr Macdonald said he did not believe that Progen's liabilities were so great that nothing would be left in the company after an uncapped buy-back.

He said there was "nothing in the half-year results or full-year results indicating any material liabilities".

Mr Macdonald said that if the three Cytopia proposed directors were elected and merger completed, the company would review the combined drug pipeline and licence, sell or develop the technologies as appropriate.

He specifically said there was interest in Progen's 500 series compounds.

Cytopia climbed one cent or 10 percent to 11 cents.

Progen fell 1.5 cents or 1.71 percent to 86 cents.

FLUOROTECHNICS

Following his appointment on March 5, 2009 as chief executive officer, James Walker has been appointed managing director.

Executive director and chief sales and marketing officer Günter Thesseling has resigned as a director to "focus fully on his [chief sales and marketing officer] function as the company seeks to continue its revenue growth and, consequently", Fluorotechnics said.

Fluorotechnics was untraded at 80 cents.

FLUOROTECHNICS

Fluorotechnics hopes to raise up to $1.5 million through a one-for-11 non-renounceable share rights offer of up to 2,195,169 shares at 70 cents a share.
Fluorotechnics said directors and senior management had committed to acquire 43 percent of the issue and the funds would be used “to strengthen the Company’s balance sheet and fund ongoing sales and marketing costs”.
Fluorotechnics said sales expectations for the 2008-‘09 financial year “remain unchanged at approximately $4 million”.
Fluorotechnics raised $8 million of a proposed $12 million at its $1 per share initial public offering last year (BD: Sep 4, Oct 24, 2008).
The company said the 70 cent a share offer was a 12.5 percent discount to its closing price of 80 cents on March 13, 2009.
The record date for eligible shareholders is March 24, 2009.
The offer opens on March 25 and closes on April 8, 2009.

SOLAGRAN

Solagran says its Ropren drops will be composed of 6g per course instead of the previously announced 5g.
The company said that it had previously reported that 40kg a month of “high quality Bioeffective R” derived from conifer green needles equated to 8,000 courses of 5g per course of Ropren drops per month or 96,000 courses a year (BD: Sept 5, 2008).
Solagran said that at an average retail price of $US1,000 a course, this would equate to a revenue potential of $US100 million a year.
“The actual production and further testing of Ropren drops has provided a slight negative variance to the actual grams per course,” Solagran said. “A course will now contain 6g.”
The company said the objective for the 2010 financial year was to produce at Tomsk and sell around the world the equivalent of 40kg a month of high quality Bioeffective R.
Solagran said it did “not intend to make a precise sales forecast for the 2010 financial year but are in the process of implementing a three-part marketing strategy before June 30, 2009” beginning with Russian sales. The company said Ropren drops were registered as a hepato-protector and pharmaceutical product in Russia.
Samples had been delivered to three hospitals in Moscow and three hospitals in St Petersburg for trials with the purpose of identifying efficacy and a possible wider spectrum of applications beyond liver disease.
Due to the difficult financial circumstances in Russia, details of budgeted health expenditure and particularly that for new products has been delayed. Some small orders from hospitals totaling 160 courses have been supplied with Ropren drops.
Sales of Ropren drops outside Russia and within Europe “are possible in certain circumstances” Solagran said.
The company said an overseas subsidiary had reached an initial agreement with an internet sales company to market and supply Ropren drops over the internet from a site based in Europe.
Solagran said it had made a concerted effort to build up its data bank of clinical trial results available in English and the result was a body of documents showing the results of clinical trials conducted to international protocols that cover the areas of liver diseases, alcoholism, hepatitis B, hepatitis C and age-related cognitive decline and neurodegenerative conditions such as Alzheimers disease.
Solagran said there was 42kg of high quality Bioeffective R held in stock at Tomsk.
Solagran fell 2.5 cents or 23.81 percent to eight cents.

NEURODISCOVERY

Neurodiscovery says European authorities have granted “the key patent for its neuropathic pain development program NSL-043/SD118”.

Neurodiscovery said the program had entered the national phase for patent protection in key territories.

The company said NSL-043/SD118 was being jointly developed by Neurodiscovery and its wholly owned subsidiary Neurosolutions under a collaboration agreement with the Tokyo-based Sosei Group.

The patent was filed jointly by Sosei and Neurosolutions and described the use of the agent in the treatment of hyper-algesic conditions such as neuropathic pain.

Neurodiscovery said NSL-043/SD118 was previously under clinical investigation in Japan for a different indication and demonstrated a potential use as an oral therapy in neuropathic pain through a re-profiling collaboration.

The company said phase I clinical trials had been completed and good safety and tolerability were confirmed in both single-ascending and multiple-ascending dose studies.

Neurodiscovery fell 0.1 cents or 2.44 percent to four cents.