Biotech Daily

Monday May 10, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CELLMID UP 14%; AVEXA DOWN 75%**

*** AVEXA DROPS ATC, LOSES DR JULIAN CHICK, CALL FOR BOARD SPILL**

*** BIOGUIDE BRIEF: AVEXA'S APRICITABINE - A BUSTED FLUSH**

*** SIRTEX 9-MONTH REVENUE DOWN; PROFIT UP; UNIT SALES UP 15%;**

*** RELEVARE (CNSBIO) $25m IPO FOR NEUROPATHIC CANCER PAIN DRUG**

*** USPTO UPHOLDS GENETIC TECHNOLOGIES NON-CODING DNA CLAIMS**

*** FEDERAL $2.4m FOR BIOTECH, BIO-FUELS, CROPS, FOOD ADDITIVES**

*** JM TAKES 11% OF GENERA**

*** QRX CLOSER TO CONTROLLED RELEASE DUAL OPIOID**

MARKET REPORT

The Australian stock market climbed for the first time in six trading days, up 2.7 percent on Monday May 10, 2010 with the S&P ASX 200 up 119.1 points to 4599.8 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and eight were untraded.

Cellmid was best, up 0.3 cents or 13.6 percent to 2.5 cents with 1.4 million shares traded, followed by Sunshine Heart up 0.4 cents or 13.3 percent to 3.4 cents with 85,000 shares traded and Sirtex up 51 cents or 10.2 percent to $5.50 with 64,038 shares traded.

Compumedics climbed 9.7 percent; Phosphagenics was up 8.3 percent; Antisense rose 6.25 percent; Circadian and Tissue Therapies were up more than five percent; Biota, Chemgenex and Living Cell climbed more than four percent; Prima was up 3.6 percent; Cochlear rose 2.3 percent; with Nanosonics and Psivida up more than one percent.

Avexa led the falls, falling as much as 9.5 cents or 79.2 percent, but closed down nine cents or 75 percent to three cents with 122.4 million shares traded, followed by Cathrx down one cent or 5.7 percent to 16.5 cents with 700 shares traded.

Cellestis and Clinuvel fell more than four percent; Prana lost three percent; Genetic Technologies, Heartware and Viralytics shed more than two percent; with Acrux, Novogen and Resmed down more than one percent.

AVEXA

Avexa has dropped its lead phase III program of apricitabine or ATC for HIV, the chief executive officer Dr Julian Chick has resigned and a board spill has been requested.

Avexa said it would "cease any further development of … ATC following the unsuccessful conclusion of partnering discussions with global pharmaceutical companies".

While Avexa has been able to demonstrate that apricitabine has efficacy and that of the 36 patients who successfully completed the phase II study, "94 percent [34 patients] maintained undetectable viral loads up to week 144", the 24-week data from its phase III HIV trial showed a non-significant positive clinical benefit for apricitabine compared to the standard of care, 3TC (BD: Feb 4, 5 and 15, 2010).

Avexa said detailed results from the phase III trial were provided to interested parties to secure a licencing transaction but on May 6, 2010, the last party involved in the process said it did not intend to submit a term sheet.

"Consequently, the board of Avexa has resolved to cease all activities for this program," the company said.

Avexa said it had begun a strategic review of its remaining programs, primarily HIV integrase and hepatitis C and intended to consider suitable merger, acquisition, in-licencing opportunities and other corporate initiatives.

The company said it had taken "immediate action to reduce costs".

Avexa said that chief executive officer Dr Julian Chick resigned from the board, effective immediately, but would continue as chief executive officer until May 31, 2010.

Chairman Nathan Drona told Biotech Daily that Dr Chick's resignation was his own decision and he was not asked to leave.

Mr Drona said he would continue to pursue other options to return shareholder value from apricitabine and continue discussions with smaller regionally focused companies.

Avexa said that key reasons that potential partners did not proceed to the term sheet stage included the time and capital required to secure regulatory approval might be too large given other drugs in the marketplace and other potential factors such as perceived risks around US market exclusivity.

The company said the required ATC dose might be too high when used in combination with existing HIV drugs, making it difficult to be combined into one pill with some other HIV drugs and an inability to determine the level of activity of ATC when used in combination with a number of new active drugs on the market (which mask the level of activity).

Avexa said it had about $26.6 million at March 31, 2010 and expected to have $23 million at June 30, 2010 after allowing for liabilities and redundancy and restructuring costs.

Avexa said it had received a request for a general meeting to remove chairman Nathan Drona as a director and appoint Steven Crowley and Bruce Hewett as directors.

Avexa said it was "assessing the notice received and will inform shareholders of future action once it has completed that assessment".

Mr Drona was appointed a director in April, 2008 at which time the company said he was "an experienced international investment banker in the life sciences industry and has successfully advised numerous companies in the US, Europe, and Australia in mergers and acquisitions strategy".

Avexa said at that time the Mr Drona had "strong capital markets background, expertise in licensing and [mergers and acquisitions]".

He was appointed chairman in October 2008 (BD: Apr 17, Oct 6, 2008).

Mr Drona said he did not believe the request for meeting was in any way related to the news that the company had been unable to licence apricitabine.

Avexa fell as low as 2.5 cents but closed down nine cents or 75 percent to three cents with 122.4 million shares traded.

MARC SINATRA'S BIOGUIDE BRIEF: AVEXA

Well, Avexa put on a brave face and moved from phase II trials into phase III trials with no partner and little data to show that their anti-HIV drug, apricitabine (ATC), was any better than Lamivudine (3TC), the current market stalwart.

The brave face came out again when they cut the phase III trial short, expressing the view that this would find them a partner. They then had to drag it out, one more time, when the shortened phase III data failed to demonstrate that apricitabine was superior to 3TC - but we will still find a partner, they said.

In the end, they didn't find a partner and the Apricitabine development program was guillotined while Avexa's chief executive officer Dr Julian Chick fell on his sword.

A company tries and fails to partner a drug after phase II trials, but still decides to go into phase III trials. Where have I heard that before? Ah, yes, Progen. Now wouldn't it be humorous if Progen and Avexa had merged? I like black humor.

There is a lesson in here and it is, stay away from small biotechs that move into phase II trials without a partner or without extremely good reasons for going it alone. If a bunch of companies look at a project, but fail to in-licence it after phase II trials, the project is almost certainly a dud.

The only thing that surprised me from today's announcement by Avexa was that chairman Nathan Drona survived the cull. When he arrived at Avexa he was billed as the man who could complete the business side of apricitabine's development - capital raisings, licencing, mergers and acquisitions. A man with his skills should have known long before today's announcement that Avexa's chances of finding a partner for apricitabine were slim, at best. Yet the apricitabine program rolled on.

The only good news to come out of this story is that Avexa was able to raise enough capital from Apricitabine believers in the past that they have enough money to keep their board employed after apricitabine's demise.

Marc Sinatra
Analyst

SIRTEX

Sirtex says unit sales were up 14.7 percent for the nine months to March 31, 2010 compared to the previous year, while revenue fell and profit was up.
Sirtex said foreign exchange impacted on its revenue which fell 1.5 percent to $47.2 million, while the operating profit before tax and excluding foreign exchange, interest and UWA settlement for the year to date was up 12 percent from $11.3 million to $12.7 million.
The company did not provide net profit after tax figures.
Profit Sirtex said it had $38.7 million in cash at March 31, 2010.
Sirtex chief executive officer Gilman Wong said the company was "increasing investment in growth initiatives and internal capabilities to take the business to the next level in the coming years".
"As a business we are still in the very early stages of our growth phase and still have a significant way to go in penetrating the market to realize the full potential of SIR-Spheres microspheres targeted radioactive treatment for people suffering from liver cancer," Mr Wong said.
Sirtex climbed 51 cents or 10.2 percent to $5.50.

RELEVARE PHARMACEUTICALS

Relevare (formerly CNSBio) hopes to raise up to $25 million in an initial public offer on the ASX to fund a phase IIb/III trial of CNSB015 for neuropathic pain in cancer.

Relevare said that neuropathic pain in cancer patients was a “multi-billion dollar market opportunity” and the company was also targeting sensory neuropathic pain in HIV.

Relevare’s chief executive officer Mark Blumling told Biotech Daily that the company hoped to raise up to $20 million in the public offer with stock worth up to $5 million available for oversubscriptions and the funds should take the company to the end of the first trial in 2012, as it prepared an investigational new drug application (IND) for the US Food and Drug Administration (FDA).

Relevare or flupirtine is an aminopyridine potassium channel modulator that has been available in Germany for more than 20 years.

Mr Blumling said the drug had not had patent approval or regulatory approval as a treatment for neuropathic pain, although it had been used in other indications such as inflammatory pain.

He said the drug had a body of evidence that it was safe and Relevare had conducted two small clinical trials of eight and 11 patients as well as preclinical testing and the data showed a trend towards efficacy with a reduction in pain over time.

Mr Blumling said CNSBio was originally a Monash University spin-out.

He said the appropriate dose would probably be about 150mg four times a day and the company would initially focus on an oral from as an adjunct to opiates or in combination.

He said that the patients in the planned 288-patient trial would have their pain measured with a standardized neuropathic pain questionnaire.

The European and Australian trial is expected to begin recruitment from October 2010 to October 2011, with the last patient follow-up to take about six months and then a further three months for data collation, with results available by July 2012.

Mr Blumling said he expected the FDA would want a second larger trial and his company was hoping to lodge its IND by October 2011.

Mr Blumling said that the state-owned Queensland Biotechnology Fund (QBF) was the initial seed investor and the company had about $3 million.

Once the capital raising had been completed he expected the prospective market capitalization to be about $50 million.

Mr Blumling said there was a very large unmet need with about one million people in the US alone, with cancer-related neuropathic pain.

Relevare’s chairman is former Ramsay Health Care managing director Pat Grier.

Mr Blumling was previously a director of US merchant bank Burrill &Co, founded Hyperion Therapeutics and began his career at Smith Kline Beecham.

Non-executive directors are QBF’s Matt Morgan and Greenhill’s Solutions LLC managing director Mark Gossett, who was previously a vice-president with Virology Franchise, Johnson & Johnson’s Tibotec Therapeutics and Sanofi Aventis.

Biodiem’s chief financial officer Richard Wadley is the company’s chief financial officer and company secretary.

Mr Blumling said that Relevare’s chief medical officer Dr David Jackson was responsible for 12 new drug applications to the FDA of which seven were pain drugs. Dr Jackson most recently served as Adolor Corp’s chief medical officer and previously was with Omnicare Clinical Research, American Cyanamid, AH Robbins and Johnson & Johnson’s Janssen.

Relevare’s director of development and regulatory affairs is Dr Stephanie Edmondson who joined CNSBio in 2006 and previously headed a scientific research team at Melbounre’s Murdoch Children's Research Institute and Royal Children's Hospital.

The company has a strong scientific advisory board.

GENETIC TECHNOLOGIES

Genetic Technologies says the US Patent and Trademark Office has upheld all the claims in the re-examination of its core non-coding DNA patent.

Genetic Technologies said the US Patent and trademark Office (USPTO) up held the claims of patent No 5,612,179 (known as the '179 patent) without amendment.

Last year the USPTO issued an "office action" relating to one of its non-coding DNA analysis technologies patents. Genetic Technologies said that the first non-final office action said that seven of the 36 claims of '179 entitled 'Intron sequence analysis method for detection of adjacent and remote locus alleles as haplotypes' were the subject of the re-examination (BD: Jun 30, 2009).

Today Genetic Technologies said that all of the claims of the US '179 patent were valid, intact and enforceable.

Genetic Technologies' chief executive officer Dr Paul MacLeman said the decision "is the best possible result for the company".

"We were not expecting to hear back from the USPTO so soon," Dr MacLeman said.

"The USPTO's blanket rejection of all of the arguments put forward by our challengers reinforces the strength of the patent," Dr MacLeman said.

The company said the '179 patent had been challenged in both US and German courts, with both cases settled on terms favorable to Genetic Technologies, with no narrowing or alterations to the patents.

"This result is ideal timing … in light of the company's recent announcement of its new US assertion program," Dr MacLeman said.

Genetic Technologies fell 0.1 cents or 2.3 percent to 4.3 cents.

FEDERAL GOVERNMENT

The Minister for Innovation Senator Kim Carr says eight Australia-India collaborative projects will receive $2.4 million from the Indo-Australian Biotechnology Fund.

A media release from Senator Carr's office said the Indo-Australian Biotechnology Fund was part of the $65 million Australia-India Strategic Research Fund and matched funding would be provided by the Indian Government.

"Some of the leading scientists in biotechnology will form partnerships to tackle the big issues facing communities in Australia and India - such as growing healthy crops and making wheat and rice more resistant to disease," Senator Carr said.

The Minister's media release said the funded projects fund included approaches to develop an effective hepatitis C vaccine; identification of diagnostic and prognostic biomarkers to improve management of diabetic ulcers; a collaboration on sustaining crop productivity; engineering disease-resistance in wheat and rice; assessing the role of cyanobacteria in solar bio-fuel and carbon sequestration; along with "nutraceuticals", functional foods; and bioremediation.

For further information on the fund go to www.innovation.gov.au.

GENERA BIOSYSTEMS

JM Financial Services has increased its substantial shareholding in Genera from 5,212,190 shares (9.41%) to 5,936,055 shares (10.72%)

Genera was untraded at 61 cents.

QRX PHARMA

QRX says that a trial of Moxduo CR (controlled release) confirms which of the various experimental formulations provided the optimum duration of drug levels in the blood

QRX said the phase I study compared the rate at which key components of the formulation were absorbed, distributed, metabolized and eliminated by the body to the pharmacokinetic profile of 20mg sustained release Oxycontin.

The company said the pharmacokinetic results were encouraging and the profile was consistent with expectations for a twice-daily formulation.

QRX said the data from the study would significantly help it and its manufacturing partner, Patheon Inc finalize the target release profile for the product and finalize the composition of prototype Moxduo CR tablets.

The company said the formulation was designed to provide 12 hours of pain relief in patients suffering from moderate to severe chronic pain including cancer, lower back, osteoarthritis and neuropathic.

QRX chief executive officer Dr John Holaday said the company was on-track to finalizing the Moxduo CR tablet by the end of this year and to be in a position to initiate phase II trials shortly after.

QRX was up one cent or 0.9 percent to $1.13.