Biotech Daily

Wednesday September 9, 2009

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: GENETIC TECHNO UP 10%; BONE DOWN 15%**

*** CHEMGENEX'S NDA AUSTRALIA'S FIRST TRUE NEW DRUG APPLICATION**

*** BIOGUIDE BRIEF: CHEMGENEX 'ASX'S MOST UNDERVALUED BIOTECH'**

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*** MEDICAL DEVELOPMENTS LOSES CFO JONATHAN KADISH**

MARKET REPORT

The Australian stock market slipped 0.4 percent on Wednesday September 9, 2009 with the S&P ASX 200 down 1.6 points to 4522.2 points. Nineteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and two were untraded.

Genetic Technologies was best, climbing half a cent or 10 percent to 5.5 cents with 169,500 shares traded, followed by Psivida up 30 cents or 9.4 percent to $3.50. Antisense, Cytopia and Genera climbed more than eight percent; Phylogica was up 7.7 percent; Impedimed and Prana rose more than six percent; Bionomics and Tyrian were up more than five percent; Clinuvel was up 3.3 percent; Sunshine Heart rose two percent; with Alchemia, Biota, Heartware, Nanosonics, Optiscan and Pharmaxis up more than one percent.

Bone led the falls, down three cents or 15 percent to 17 cents with 75,072 shares traded, followed by Viralytics down 0.2 cents or 7.4 percent to 2.5 cents.
Chemgenex fell 4.35 percent; Cellestis lost 3.1 percent; Benitec, Cochlear and Starpharma shed more than two percent; with Novogen and Resmed down more than one percent.

CHEMGENEX

Chemgenex has completed its new drug application submission to the US Food and Drug Administration omacetaxine mepesuccinate for chronic myeloid leukemia.

Biotech Daily believes this to be the first true new drug application by an Australian company to the FDA. To the best of our knowledge, Biota's Relenza application was taken to the FDA by Glaxosmithkline, Pharmaxis's Aridol is not a therapeutic agent and other possible submissions have related to abbreviated new drug applications covering existing drugs used for new indications and/or in different formats.

Chemgenex said that if the FDA granted priority review for Omapro for patients who have failed treatment with the first-line standard of care for chronic myeloid leukemia, imatinib (Gleevec), and have developed the Bcr-Abl T315I mutation, the examination period would be about six months.

The company said that if approved for marketing by the FDA following priority review, the Omapro launch would be scheduled for mid-2010.

Chemgenex chief executive officer Dr Greg Collier said the new drug application submission was "a major milestone" in the development omacetaxine and the company was "one step closer to delivering a new treatment for patients in an area of unmet medical need".

"This submission is a significant achievement in our strategic goal to commercialize Omapro independently in the US oncology market," Dr Collier said.

Chemgenex said omacetaxine mepesuccinate, formerly known as Ceflatonin and commercially branded as Omapro, was a first-in-class cetaxine which worked differently from the first-line standard of care for chronic myeloid leukemia, imatinib, and the second-line tyrosine kinase inhibitors nilotinib and dasatinib.

Omapro has orphan drug designation in the US and the European Union and has received fast track status from the FDA.

The company said the drug demonstrated clinical benefit in chronic myeloid leukemia patients who had failed imatinib and have the T315I mutation.

Chemgenex said that if approved, Omapro would be the first treatment specifically indicated for CML T315I patients, many of whom have no therapeutic options.

Chemgenex fell three cents or 4.35 percent to 66 cents.

MARC'S SINATRA'S BIOGUIDE BRIEF NOTE: CHEMGENEX

Last May, I put a valuation of $5.50 on Chemgenex shares with an 18-month time frame for that valuation to be met.

Today, Chemgenex announced that it had completed what is the first real Australian submission of a new drug application (NDA) to the US Food and Drug Administration for its lead compound Omapro (formerly known as omacetaxine). But three months from my self-imposed deadline, Chemgenex shares are trading at 66 cents.

While it is true that this milestone is more process than a major value creation point, it is a significant achievement and a marker of what should be a much higher share price.

This is particularly so, given how difficult it is to get to NDA submission, as evidenced by Progen and Novogen ceasing their phase III trials and Neuren's Glypromate failing its phase III trial. Not to mention the premiums that even moderately successful phase III trials can bring, as evidenced by the 70 percent premium bid for Peplin.

It has been suggested that I look at Chemgenex through rose-colored glasses and given how overweight I am in Chemgenex shares, the argument may have some merit.

But Chemgenex's basic equation remains the same:
1.) There are 5000 identified chronic myeloid leukaemia (CML) patients worldwide carrying the T315I mutation for which Chemgenex is seeking approval to market Omapro;
2.) Regulatory approval seems as certain as it has been for any drug given Chemgenex's data and the extraordinary amount of independent data demonstrating the efficacy of Omapro like compounds in treating CML; and
3.) A conservative price estimate for Omapro of $US30,000 per year per patient, based on the price of Gleevec.

That gives a market size of $US150 million year, which translates into a profit of $US75 million based on a 50 percent free cash-flow. Based on profit multiples of 15-25 times, this gives a share price of $US5.75 ($A6.70) to $US9.50 ($A11.00) once a profit of $US75 million is achieved. But these are back-of-the-envelope numbers and Chemgenex isn't making $US75 million a year.

The numbers can be refined by factoring-in that about 80 percent of T315I carriers are likely to benefit from Omapro and licencing the product in Europe will see some value slip to the licensee, while the fact that first Omapro sales are a year away will reduce net present value. On the other hand, the drug is likely to cost more than $US50,000 a year, rather than $US30,000, based on the prices of second line CML treatments Sprycel and Tasigna.

While my view of Omapro for T315I indication remains the same, I have become less bullish on Omapro's chances for success as a treatment in patients who have failed two tyrosine kinase inhibitors (TKIs) and acute myeloid leukaemia (AML).

I believe most CML patients who have failed two TKIs, will simply go on to the remaining TKI they haven't failed, while Chemgenex's failure to produce results so far from its long running AML trial suggests, as does previous independent research, that AML is a tough indication for Omapro.

A new bright spot, however, is the potential use of Omapro for the treatment of minimum residual disease in CML patients being treated with Gleevec. An indication for which some independent data provides support and one that that would see Omapro used in a combination therapy.

If I were to completely revalue Chemgenex, I might temper my previous valuation a little bit, not based on what is written above, but mainly on the basis of the capital raising Chemgenex undertook at 43 cents per share earlier this year. I certainly didn't factor a capital raising at that price into my previous valuation.

All in all, I still believe Chemgenex to be the most undervalued listed life science company on the Australian stock exchange and should currently trading about $5.00.

Marc Sinatra
Analyst

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

COCHLEAR

Cochlear says it will pay $US25 million ($A29 million) for the patent rights, know-how and joint development activities with Otologics to use its technology with cochlear implants.
Cochlear chief executive officer Dr Chris Roberts said the purchase of rights to the Colarado-based Otologics technology was “particularly useful in the complex area of implantable microphones, vital for the development of a totally implantable cochlear implant”.
Cochlear said the purchase price of $US25 million was payable over the period to December 31, 2011, plus a royalty on future net sales of certain products involving an implantable microphone.
The company said $US8.5 million was paid by June 30, 2009, with the balance of the payments to be spread over the remaining period, subject to milestones.
“This purchase is an exciting step in achieving our long term goal of developing a totally implantable cochlear implant,” Dr Roberts said.
Cochlear fell $1.56 or 2.52 percent to $60.40.

PRANA

Prana says an existing shareholder will provide $6 million for its research and development programs, drug development pipeline and maintain corporate activities.
Prana said it would issue 30 million ordinary shares at 20 cents each without shareholder approval to the unnamed investor who would also receive, subject to shareholder approval, 10 million free attaching options exercisable at 30 cents and expiring in four years.
Prana said it would receive $5.7 million net of all fees and the advisers were Rodman & Renshaw and Peregrine Corporate.
Prana CEO Geoffrey Kempler said the funds would “allow Prana to continue to build its development pipeline by providing the financial flexibility to choose to advance PBT2 into the next Alzheimer’s disease clinical trial supported by either a pharmaceutical company or by investors”.
Prana climbed 1.5 cents or 6.8 percent to 23.5 cents.

FLUOROTECHNICS

Fluorotechnics has raised $1.235 million through a $1.035 million rights issue and a $200,000 placement at 28 cents a share.
Fluorotechnics said that 4,412,214 shares had been issued taking the company’s total issued capital to 30,321,852 shares.
The company said shareholders were offered one new share for every seven shares in the non-renounceable rights issue and the issue price was a 30 percent discount at that time.
Fluorotechnics said the largest subscriber to the rights issue was major shareholder Hunter Hall with an increased investment of $518,000.
The company said Hunter Hall took up its full entitlement and also partly underwrote the rights issue.
Fluorotechnics director Lars Utterman invested $150,000 as an underwriter.
Fluorotechnics’ chief executive officer James Walker said the proceeds would “form part of the company’s working capital and will primarily be used to fund our sales and marketing momentum”.
Fluorotechnics was untraded at 43.5 cents.

VICTORIA GOVERNMENT

The Victoria Government has created a new $500,000 pilot program to help small-to-medium-sized biotechnology companies compete in global markets.

Innovation Minister Gavin Jennings said in a media release that the Biotechnology International Partnering Program would provide grant assistance for eligible Victorian companies to attend recognized overseas biotechnology conferences and trade events.

“The Brumby Labor Government is taking action to ensure Victoria remains at the forefront of the Australian biotech industry by supporting the growth and global potential of our biotechnology companies,” Mr Jennings said.

Mr Jennings said the partnering program would assist Victorian companies to participate in international events such as trade fairs and conferences which may have been out of their reach previously and would allow them to the select events that best suit their needs.

“Attending these events provides opportunities for partnering and licencing deals which can help build local capabilities and facilities that will create jobs for Victorian families,” Mr Jennings said.

Mr Jennings said the program would be evaluated after 12 months.

He said the program would provide funding for expenses, airfares and accommodation, conference entry, non-confidential pitching documents, exhibition stands and other promotional costs involved with the conference.

“The biotech sector relies heavily on partnering and licencing deals to commercialize products but there are significant development and commercialization barriers that Victorian biotechnology firms face in the international arena which have been compounded by the global financial crisis,” Mr Jennings said.

“The aim of the BIPP is to give companies some assistance to overcome these hurdles and promote themselves, and Victorian biotech capabilities, to the world, he said.”

AUSTRALIAN GOVERNMENT FUTURE FELLOWSHIPS

Biological and medical sciences are the big winners of the Federal Governments Futrue Fellows award announced today by the Minister for Innovation, Senator Kim Carr.

Applications from biological sciences including biochemistry, cell biology genetics, microbiology, botany, zoology, ecology and evolution and biotechnology won 42 of the 200 fellowships with medical and health sciences taking a further 37 awards.

Senator Carr’s media release said the 200 Australian Research Council (ARC) Future Fellows were “outstanding national and international mid-career researchers”.

“The Government established the ARC Future Fellowships scheme to address the gap in opportunities for mid-career researchers in Australia, which forced many of our talented researchers to search for work overseas,” Senator Carr said.

“This first round of the ARC Future Fellowships scheme will see 159 of our best and brightest continue their world-class research at home, boosted by the four-year, fellowship, worth up-to $740,000,” Senator Carr said.

“Fellows will receive up to $135,000 for each of the 4 years [and] administering institutions will receive up to $50,000 a year for associated infrastructure and other costs,” he said.

“I am also very pleased to announce that 41 Future Fellows will come to Australia to pursue their research - 19 Australians lured home by the scheme and 22 international researchers bringing their talents to our shores,” Senator Carr said.

The media release said the Australian Government had committed $844 million over five-years from 2009 for the scheme.

Detailed information about the 200 successful Future Fellows and their research projects is at http://www.arc.gov.au/ncgp/futurefel/ft_outcomes.htm.

PROGEN

Progen has completed its phase I monotherapy dose-escalation study for its cell proliferation product, PG11047.

Progen said the study was conducted at the University of Chicago and aimed to assess the maximum tolerated dose of PG11047 as a single anti-cancer treatment for patients with advanced solid tumors.

Progen chief executive officer Justus Homburg said the completion of the study paved the way for possible phase II clinical development efforts.

The company said PG11047 was well tolerated by all 46 patients, establishing a maximum tolerated dose (MTD) of more than twice the dose used in other early-stage clinical trials of PG11047, including trials for patients with multiple myeloma and prostate cancer.

“Earlier clinical research yielded encouraging data at substantially lower dose levels than the currently determined MTD when given as a monotherapy,” Mr Homburg said.

“The recent results support the conclusion that PG11047 will have a much larger therapeutic window than previously thought,” he said.

Progen said that recruitment for its PG11047 phase Ib combination study was on schedule, with enrolment underway at 12 US sites.

The company said PG11047 provided a significant additional anti-cancer effect when combined with approved anti-cancer products, compared to the effect of the two products administered on their own.

Progen was unchanged at 58 cents.

IMMURON

Immuron says the finalization of its collaboration with Israel’s Hadasit means that clinical trials using Hadasit’s immuno-therapies will begin “within the next three months”.

Immuron has acquired Hadasit’s intellectual property over oral immuno-therapies in exchange for a 19.99 percent stake in the North Melbourne company.

The initial applications of the technology platform will be type 2 diabetes, liver cancer (hepatoma), and hepatitis C, Immuron said.

Hadasit is the technology transfer arm of Hadassah University Medical Centre which is the largest clinical research centre in Israel.

Immuron said that Hadassah’s Prof Yaron Ilan and his team had developed the concept of treating autoimmune and chronic diseases with orally delivered polyclonal antibodies.

Prof Ilan is Immuron’s medical director.

Immuron said it had a commercialized technology platform for manufacturing bulk polyclonal antibodies derived from cow colostrum that was suitable for oral delivery.

Immuron was up 0.1 cents or two percent to 5.1 cents.

MEDICAL DEVELOPMENTS

Medical Developments says chief financial officer and company secretary Jonathan Kadish has resigned and will leave the company on October 2, 2009.

Medical Developments said Mr Kadish, who was appointed last year (BD: Mar 31, 2008) was assisting in finding an appropriate successor.

Medical Developments fell one cent or 5.4 percent to 17.5 cents.