Biotech Daily

Wednesday July 23, 2008

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECHS UP: NOVOGEN UP 10%, PROGEN DOWN 52%**

*** PROGEN HALTS PHASE III CANCER TRIAL; DUMPS PI-88, PI-166**

*** BIO-GUIDE BRIEF: PROGEN FAILURE HURTS US ALL**

*** ANTISENSE POTENTIAL MS COMPETITOR TRIPLES SALES**

*** FEDERAL GOVERNMENT: INAUGURAL BIONICS CONFERENCE**

*** NEW SOUTH WALES IN RACE TO DEVELOP FIRST BIONIC EYE**

*** CHEMGENEX TELLS ASX: TAKEOVER SPECULATION PUSHED PRICE**

*** GBS INVESTS IN XENOME; DR ANDREW BAKER JOINS BOARD**

*** QUEENSLAND INVESTMENT CORP SELLS RESONANCE STAKE**

MARKET REPORT

The Australian All Ordinaries Index climbed 1.7 percent on Wednesday July 23, 2008, up 85.7 points to 5,161.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and five were untraded.

Novogen was best, up 10 cents or 10.2 percent to $1.08 on very small volumes.

Alchemia, Antisense, Pharmaxis and Polartechnics climbed more than seven percent; Benitec was up 6.06 percent; Phylogica was up 5.26 percent; Ventracor climbed 4.55 percent; Clinuvel, Cochlear, Mesoblast and Psivida were up more than three percent; Arana, Bionomics, CSL and Prana rose more than two percent; with Genetic Technologies up 1.18 percent.

Progen led the falls, down 62 cents or 51.67 percent to 58 cents with 3.8 million shares traded, followed by Sunshine Heart down 20 percent to 4.4 cents and Living Cell down 10 percent to 18 cents.

Neuren lost 7.69 percent; Biota and Optiscan lost more than five percent; Agenix and Viralytics fell more than three percent; with Avexa, Chemgenex and Circadian down more than one percent.

PROGEN

Progen has discontinued its PI-88 phase III study in liver cancer, despite phase II trial data indicating safety and some efficacy.

Progen chief financial officer Linton Burns told Biotech Daily that the company had to make a commercial decision in the absence of a partner, the emergence of a competitor and slow patient recruitment.

Mr Burns said that it was difficult to convince a major pharmaceutical company to partner for a drug targeted more at Asian markets that US or European ones.

The 'Pathway' study of PI-88 in the adjuvant treatment of hepatocellular carcinoma or primary liver cancer began in March (see Biotech Daily; March 11, 2008) and was to recruit 600 patients at 65-70 hospitals in more than a dozen countries, but only 12 patients have been recruited from five centres. Existing patients will continue to receive the drug if they want to, subject to regulatory approval, a Progen media release said.

Progen said it would develop its existing compounds and acquire additional compounds and opportunities through merger and acquisition activity.

The company said a strategic review was triggered by "a number of factors that impacted the commercial return for the phase III Pathway trial".

Progen said the trial was unlikely to meet the forecast patient recruitment timetable and further delays were expected "due to slower than expected regulatory processes in China, Korea and Vietnam; slower than expected initiation of clinical sites; slower than expected recruitment of patients into active sites; and the recent launch of a competitive phase III trial, assessing Bayer/Onyx Nexavar in the same indication".

Progen said the factors "would have delayed market entry significantly and seriously impacted on the commercial return of the phase III Pathway trial".

Progen said it would seek expressions of interest in PI-88 at a regional level, initially from parties that had entered into non-disclosure agreements and due diligence on PI-88.

External trial costs this financial year were $9.8 million and the cost of discontinuing was less than $4.0 million.

Progen said a separate phase IIb trial of PI-88 for melanoma would be completed but no further development in melanoma was expected and would cost $300,000 to finalize.

Progen said it would halt development of phase I compound PI-166 for advanced liver cancer, based on an assessment of the market and Nexavar approval for the indication.

Progen said it would develop molecules with high potential value and pursue its other compounds in development including the phase I compound PG11047 for small tumors, the late preclinical 500 series compounds and the epigenetics platform.

Progen said the PG11047 trial, for patients with advanced cancers, was showing positive tolerability and dosing profiles.

The 500 series is undergoing scale-up manufacture and animal safety studies.

Progen said it would expand its gene expression modification or epigenetic compounds platform acquired through the Cellgate acquisition and pursue merger and acquisition opportunities to expand its clinical stage pipeline and announce the appointment of corporate advisers in the coming weeks.

Progen said it had an unaudited cash position of $76.7 million at June 30, 2008, excluding creditors and accruals of $6.2 million.

A trial of Progen's PI-88 combined with Taxotere (docetaxel) for prostate cancer showed efficacy, but closed due to a higher-than-expected rate of febrile neutropaenia (see Biotech Daily; February 13, 2008). At that time two patients were continuing with PI-88 treatment after completing the combination treatment.

Progen fell as low as 57 cents closing down 62 cents or 51.67 percent at 58 cents with 3.8 million shares traded.

MARC SINATRA'S BIOGUIDE: PROGEN PHARMACEUTICALS

With biotechs on their knees, the industry was dealt a further blow today with the news that Progen has discontinued development of its cancer drug, PI-88 in a phase III trial for liver cancer.

The writing has been on the wall for PI-88 for a while. With Progen's extensive efforts at partnering the drug over years failing, it chose to go it alone.

At the time of that decision, I wrote "Since potential partners, particularly the big ones, are likely to have the clearest view of PI-88, except perhaps Progen itself, one has to ask, if they weren't swayed, why should I be?" (See Biotech Daily; May 31, 2007.)

Today's news confirmed that those potential partners were right.

A deeper analysis of the announcement, however, indicates that Progen made numerous errors in its assumptions about its phase III program for PI-88 regarding its ability to conduct the trial and the market for its drug.

When you combine this with the lack of a partner and the fact that two other phase II PI-88 studies have returned negative results, it seems clear that Progen, with its inside knowledge, should have had the forethought to terminate the PI-88 program before commencement of the phase III trial, if not at the end of its positive phase II liver cancer trial.

A positive phase II trial by itself is not enough to justify progression to a phase III trial.

Drugs fail clinical trials or have their development terminated all the time. That is life in a high risk sector. But one of the big worries with ASX-listed biotechs is that they might progress a project simply because they don't want to take the share price hit and/or related fallout.

The irony is that by doing this, they will almost certainly have to a pay a bigger price later.

One could be excused for thinking that Progen is now paying that bigger price.

The market's reaction to Progen's news has been severe, discounting its price to about half of its cash backing. Although this discount is past the point of being logical, even the most rational person can understand it.

For the industry's sake, Progen's board and management will need to demonstrate that the message of today's share price crash has been clearly understood.

Mainstream investors won't take the industry seriously if they don't have faith in the decisions biotechnology companies make.

ANTISENSE

Antisense says Biogen Idec has reported global in-market net sales of Tysabri for the three months to June 30, 2008 at $US200 million, "nearly triple the same period last year".

Antisense said the reason for quoting the Massachusetts-based Biogen Idec was that both its a monoclonal antibody Tysabri and Antisense's lead drug ATL/TV1102 inhibit the same immune system protein or disease target, VLA-4, which has been demonstrated to play an important role in the progression of multiple sclerosis.

At the end of June 2008, more than 31,800 patients were on commercial and clinical Tysabri therapy worldwide. Biogen Idec previously reported that they expect to have 100,000 patients on Tysabri by 2010, Antisense said.

Antisense said that while ATL/TV1102 and Tysabri shared the same biological target, they were different drugs and it was expected that ATL/TV1102 may have advantages over Tysabri including safety, cost of therapy and convenience of dosing.

The company said ATL/TV1102 has completed its phase IIa human clinical trial and had been licenced to Israel's Teva Pharmaceuticals (see Biotech Daily June 30, 2008).

Antisense climbed half a cent or 7.69 percent to seven cents.

FEDERAL GOVERNMENT

Minister for Innovation, Industry, Science and Research Senator Kim Carr says the inaugural Medical Bionics Conference will be held in Lorne Victoria in November 2008.
A media release from the Minister's office said the conference hosted by the Bionic Ear Institute would attract medical technology researchers from across the world.
Medical bionics draws on biotechnology, engineering, information and communications technology, medicine and nanotechnology.
Senator Carr said Australia's track record in medical bionics was "internationally recognized".
"Part of this reputation has been earned as a result of the development of the world's first multi-channel bionic ear," Senator Carr said.
He said the bionic ear had improved the hearing of more than 100,000 people globally.
"Its inventor, Prof Graeme Clark, is also the founder of the Bionic Ear Institute," Senator Carr said. "Not quite so famous but equally important is the digital signal processing software developed by Dynamic Hearing, a company spun out from the Cooperative Research Centre (CRC) for Cochlear Implant and Hearing Aid Innovation."
"The technology developed through medical bionics helps create electrical or mechanical devices used to diagnose, prevent or treat diseases or physical conditions," he said.
"Artificial hearts, joint replacements and vascular stents are other examples of medical bionic products that are made in Australia," Senator Carr said.
The Conference will be held in Lorne, Victoria, November 16-19, 2008.
The Bionic Ear Institute, an independent, non-profit, medical research organization.

NEW SOUTH WALES GOVERNMENT

The Government of New South Wales says the state will be a leading player in the international race to commercialize a functional bionic eye.
A media release from Minister for Science and Medical Research Verity Firth said a Centre for Implantable Bionics would be established at the University of New South Wales in Sydney.
Ms Firth and University of New South Wales vice-chancellor Prof Fred Hilmer said the Centre would be a partnership between the State Government, the University and philanthropic supporters.
Ms Firth said the Centre for Implantable Bionics would be "a world class research centre working to create bionic implants with potential in a range of medical areas".
"This is about investing in not only a healthier community but a more innovative economy," she said.
The media release said research would include the commercialization of a bionic eye, refined bionic hearing devices and artificial heart technologies and development of electronic stimulation technology which could restore movement to the limbs of people who have suffered paralysis.
The Paul M Trainor Chair in Biomedical Engineering would be affiliated with the Centre and a search was under way for the inaugural holder of the position.
Prof Hilmer welcomed the State Government's $200,000 to help establish the Centre.
One of the Centre's first projects will be a collaboration with leaders in the biomedical industry on the commercialization of a bionic eye.
The University's Advanced Vision Prosthesis Group has been working on a bionic eye since 1997, and has produced more than 70 peer-reviewed scientific publications and filed multiple patents.
The State Government said the Centre would be functioning by next year.

CHEMGENEX

Chemgenex has told the ASX that speculation in the press and in analysts' reports regarding "corporate activity" may have had an impact in its share price. The ASX said the company's share price rose from $1.01 on July 21, 2008 to $1.18 on July 22.

Chemgenex said some reports referred to the Stragen joint venture "as a catalyst for corporate action".

The company said the extraordinary general meeting to approve an issue of shares to Stragen in accordance with these arrangements was held on July 22, 2008 and the issuance was approved (see Biotech Daily; July 22; 2008).

Chemgenex has retained Credit Suisse as a corporate adviser to assess possible commercialization strategies including licencing, partnering or corporate activities.

"The company regularly engages in confidential discussions with a number of large pharmaceutical companies to assess the potential of its products and optimize its commercialization strategy," Chemgenex said.

"The company confirms it is currently not in receipt of any commercialization proposal, other than those already disclosed to the market," Chemgenex said.

"Should any proposals be received they will be considered by the company and advised to the market," Chemgenex said.

Chemgenex fell two cents or 1.71 percent to $1.15.

XENOME

Xenome has received a convertible note placement of $6 million from GBS Venture Partners and expects to list on the ASX in 2009.

The Melbourne-based GBS Venture Partners invests in unlisted and listed high growth companies involved in innovative technologies.

Xenome is a public unlisted company developing peptide drugs for pain and inflammation.

Xenome said its lead drug candidate Xen2174 has completed safety testing in cancer patients with severe pain with results to be announced in August.

The company said it would begin a phase II clinical trial to determine the safety and efficacy of Xen2174 in post-surgical pain later this year.

Xenome said the GBS investment reflected "the increased interest that Xenome has attracted over the past year".

The company said it had completed enrolment into the Xen2174 cancer pain study, executed a discovery partnership with Amylin Pharmaceuticals, raised more than $15 million from existing and new investors and had made several appointments including chief executive officer Dr Ian Nisbet and chief medical officer Dr Wendy Martin.

The company said the funds would progress its trial program, advance other programs and prepare it for an initial public offering expected in 2009.

GBS has agreed to invest further funds as a cornerstone investor in the IPO.

Dr Nisbet said GBS brought substantial financial credibility and provided a network of clinical, regulatory, business development and investor connections said.

GBS Ventures associate director Dr Andrew Baker will join the Xenome board.

He said the company was developing drugs that could have a significant impact on the quality of life of people suffering chronic or acute pain.

"These drugs have the potential to provide improved efficacy and fewer side effects than existing pain treatments," Dr Baker said.

"They are also non-addictive, which is a significant benefit over many current drugs, where drug-dependency and abuse are major problems," Dr Baker said.

RESONANCE

Queensland Investment Corporation has ceased its substantial holding in Resonance Health selling its remaining 68,000,000 shares or 19.62 percent of the company.

Resonance general manager Liza Dunne told Biotech Daily that the shares have been sold to investors known to the company including a cornerstone investor.

Queensland Investment Corporation became substantial in Resonance on September 18, 2006 when it bought 40,000,000 shares at two cents a share. The company increased its holding to 68,000,000 shares also at two cents a share, shortly afterwards Resonance was unchanged at 1.3 cents.