



# Biotech Daily

Monday March 30, 2009

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH UP: LABTECH UP 23%; CHEMGENEX DOWN 15%**
- \* **BIOGUIDE BRIEF: THE PROGEN PRIZE ... AND THE WINNER IS MEDIGEN?**
- \* **PROGEN APPOINTS DR WOLF HANISCH 3<sup>rd</sup> DIRECTOR**
- \* **BIOTA PARTNER PREPARES FOR JAPAN INFLUENZA MARKET**
- \* **MESOBLAST PLACEMENT RAISES \$10.8m**
- \* **NANOSONICS BEGINS SALES OF TROPHON DISINFECTION SYSTEM**
- \* **BIO-MELBOURNE NETWORK ISSUES CALL TO ALMS**
- \* **US PATENT FOR VIRALYTICS' EVATAK**
- \* **STEM CELL EGM VOTES FOR WIND-UP**
- \* **FMR, FIDELITY REDUCES TO 5.5% IN CSL**
- \* **NEUREN DIRECTOR THOMAS AMOS RESIGNS**

## MARKET REPORT

The Australian stock market fell 1.85 percent on Monday March 30, 2009 with the S&P ASX 200 down 67.9 points to 3,604.4 points. Thirteen of the Biotech Daily Top 40 stocks were up, nine fell, nine traded unchanged and nine were untraded.

Labtech was best, up 2.5 cents or 22.7 percent to 13.5 cents with 350,000 shares traded, followed by Biota up 11.1 percent to 60 cents.

Polartechncis climbed 10 percent; Pharmaxis was up 8.1 percent; Phosphagenics rose 7.7 percent; Cellestis was up 3.45 percent; Novogen and Viralytics rose more than two percent; Cochlear, Heartware, Resmed and Starpharma were up more than one percent; with Acrux, Circadian and Sirtex up less than one percent.

Chemgenex led the falls, down nine cents or 15.25 percent to 50 cents with 60,300 shares traded, followed by Prana down 9.5 percent to 19 cents.

Avexa lost 8.97 percent; Progen and Psivida were down more than six percent; Antisense fell 5.7 percent; Alchemia was down 3.45 percent; Genera and Optiscan shed more than two percent; with CSL down 0.7 percent.

## MARC SINATRA'S BIOGUIDE BRIEF: PROGEN, AVEXA, CYTOPIA

Hindsight may have 20/20 vision, but the investment community should have seen this possibility.

I, like most people, thought last Friday's vote to spill Progen's current board and replace them with Cytopia-friendly directors would go to whoever ultimately gave the most cash back to shareholders.

Those of us who did so should have looked at Progen's share registry a bit closer, made a few assumptions and thought a bit more outside the box. Then we might have had a better idea of what was to come.

The big winner from Friday's vote was the Taiwan-based Medigen, with whom Progen formerly had an alliance for PI-88.

Medigen saw its chance at up to \$4 million in milestone payments from PI-88's development all but vanish when the Progen board terminated the drug's development in the middle of last year.

PI-88 will now be resurrected and Medigen seems likely to receive at least a \$2 million milestone payment if a deal to take PI-88 to Taiwan is struck, as seems to be the plan.

The losers are numerous, starting with Cytopia which has spent a fair amount of time and money chasing Progen's cashbox.

Cytopia will need to find another source of funding within the next year and with the future of their JAK3 collaboration with Novartis soon to be decided, this task could become even more difficult than it already is, especially with the global economy in its current state.

Those shareholders who wanted to sell all their shares back to Progen at \$1.10 were probably minor losers. They may not be able to sell all their shares back, but at least they managed to get Progen to double the buy-back from the original \$20 million contained in the Avexa merger proposal to \$40 million dollars.

The big losers, however, probably weren't even at the extraordinary general meeting. They are the retail shareholders who continue to hold their Progen shares.

They now find themselves as investors in a company with early and late stage technology that the old Progen board, two members of which makeup the new three member board, didn't seem to think was worth developing or had effectively stopped developing - and with little prospect of picking up any good projects through a merger or acquisition.

Unlike most, I have tended to view the battle for control of Progen as just hard, if unpleasant, business. The only issue I have is that, at times, Progen's directors seemed more concerned with retaining their board seats than the more pressing matters facing the company.

**Marc Sinatra**

## PROGEN

Following its meeting and after the market closed on Friday, Progen appointed Dr Wolf Hanisch as the company's legally-required third director (BD: Mar 27, 2009).

Dr Hanisch is a founder and director of the unlisted CBio, former chief executive officer of Bresagen and a former director of Psiron (now Viralytics).

Previously he worked in scientific positions with IDEC Corp and Abbot Laboratories.

Progen fell six cents or 6.5 percent to 86 cents.

## BIOTA

Biota says Daiichi Sankyo will manufacture and market CS-8958 for influenza in Japan, pending the results of a phase III trial and registration approval.

Biota and the Tokyo-based Daiichi Sankyo are co-owners of the long acting neuraminidase inhibitor (LANI) and Daiichi Sankyo has signed a contract for the manufacture and marketing of the product in Japan.

Biota chief executive officer, Peter Cook, told Biotech Daily that the Japanese market for anti-influenza drugs was thought to be between \$500 million and \$1 billion a year.

Mr Cook said he was unable to determine the level of likely sales of CS-8958 but said the anti-viral drug would compete with Biota and Glaxosmithkline's Relenza as well as Roche's Tamiflu (oseltamivir).

Assuming one third of the market and a five percent royalty, Biota could expect to see \$8.25 million to \$16.5 million a year in royalties from the Japanese market alone, as well as royalties from Glaxosmithkline for Relenza sales.

Mr Cook said that CS-8958 was "the first domestically-produced drug of this type in Japan".

"Japan does not favor vaccines for influenza, preferring anti-virals," Mr Cook said.

He said the phase III pivotal trial results were expected "by mid-year".

In its media release to the ASX, Biota said it would receive "an undisclosed royalty on sales and a number of fixed sum payments on the achievement of certain sales milestones in the Japanese market".

Biota said that all other key markets for CS-8958, including the US, were available for licencing by the partners.

Biota and Daiichi Sankyo will share commercial returns from licencing outside Japan.

The company said that in 2003, it and Daiichi Sankyo merged their respective long acting neuraminidase inhibitor programs and Daiichi Sankyo retained the option to manufacture and market CS-8958 in Japan in return for funding the Japanese trials.

The molecule CS-8958 was discovered by Daiichi Sankyo.

Biota said patient enrolment of the pivotal phase III studies in Asia had been completed with results expected to be released mid year.

The results from the earlier phase II trial, reported on July 31, 2008, concluded that "inhaled CS-8958 administered once only was statistically indistinguishable from 75mg of oseltamivir administered twice daily for five consecutive days".

Biota said existing neuraminidase inhibitors for influenza required daily or more frequent dosing.

The company said that the ability to dose patients on a weekly, or even less frequent, basis offered numerous benefits.

Any stockpile of weekly-dosing drug would last longer and protect more people, in the case of an influenza pandemic and a weekly dose may improve patient compliance over a more frequent regime, Biota said.

Biota was up six cents or 11.1 percent to 60 cents.

## MESOBLAST

Mesoblast has raised \$10.81 million through a private placement to existing, “as well as new, institutional and sophisticated investors”.

Mesoblast said the funds would be used with the existing working capital, reported at December 31, 2008 to be \$9.6 million, to expand the company’s clinical trial programs for bone and cartilage regenerative products for spinal vertebral disc disease.

The company said the programs would be pursued in parallel to the ongoing phase II clinical trial in knee osteoarthritis.

Mesoblast’s executive director Prof Silviu Itescu said he “welcomed the ongoing strong support from the company’s institutional and major shareholders”.

The placement of 15.02 million shares was oversubscribed and was made at 72 cents, a 10 percent discount to the closing price on March 25, 2009.

Mesoblast was unchanged at 80 cents.

## NANOSONICS

Nanosonics says it has begun production and commercial sales of its Trophon EPR ultrasound probe disinfectant system in New Zealand and Australia.

The company said shipments of Trophon Environmental Probe Reprocessor (EPR) systems and Nanonebulant consumables, had been allocated to fulfill purchase orders placed with the distribution partners by their customers, clinical end-users of the products. Nanosonics said it had “undertaken a full sales launch to ultrasound professionals, including trade advertising and sales presentations to key opinion leaders and clinics throughout Australasia”.

The company said sales demand was being driven by the value proposition provided by the Trophon EPR system in the medical ultrasound market.

A contributing factor to the demand was the greater awareness and vigilance of mandated legislation, regulatory requirements and the significant occupational health and safety issues facing hospital and clinic staff.

Nanosonics said Trophon EPR was being included in tenders submitted by the original equipment manufacturers and Trophon EPR had been “incorporated as a condition in several new Government tenders, both in Australia and internationally”.

Nanosonics said it had begun a broad range of pre-launch activities in Europe, with first shipments expected in the next three months.

The company said it had “a strong dealer network throughout Europe” committed to commercial purchases of the Trophon EPR system.

It was expected that the Trophon EPR system would be launched in the near term into key markets in Asia, where the regulatory requirements for sale had already been met.

Nanosonics said sales demand in this region was influenced by recent guidelines issued by the US Centre for Disease Control, with the Trophon EPR system fully meeting the requirements for routine high level disinfection of ultrasound probes between patients.

Nanosonics said it was in advanced negotiations with leading distribution partners in the significant markets of North America and Japan.

The company said the Trophon EPR system is a finalist for a design award recognized by the Australian Government and the International Council of Societies of Industrial Design, Australia’s peak design assessment, which will be judged in April.

Nanosonics said its “substantial technical resources” were available for other commercial products based on its Nanonebulant platform and prototyping was well advanced for several new devices which address substantial global market needs.

Nanosonics was unchanged at 31 cents.

## BIO-MELBOURNE NETWORK

The Bio-Melbourne Network has called on its members to join the lobbying of the Federal Government in the lead up to the May Budget.

In her letter to members Bio-Melbourne Network chief executive officer Michelle Gallaher said the sector needed to have “a clear and positive message with the primary goal of raising confidence in the biotech sector to the Federal Government”.

“We believe we have an opportunity to influence debate,” Ms Gallaher said.

She said her organization was not saying that it’s too late or that the biotech industry is doomed. Good money doesn’t follow bad.

Ms Gallaher said the market definition of biotechnology was part of the problem.

“It’s too small and too easy for government to dismiss,” Ms Gallaher said.

“They won’t notice if 40 small biotech companies die when thousands of jobs are being lost elsewhere,” she said.

“But government will care if they understand that the return on their investment in basic science and research is threatened.

“For us, biotechnology is the fusion of biology and technology. It includes medical devices, agricultural, environmental biotech and mining biotech. It’s much wider than the ASX definition,” she said.

The Bio-Melbourne Network letter said the industry was “the delivery arm of the research community” and an integral part of the larger medical research community, of environmental research, food research; agriculture and environmental sciences.

The letter said Australia needed “a vibrant biotech sector to turn the government’s investment in research into products that save lives, and create jobs and wealth”.

The Bio-Melbourne Network said that life changing and wealth creating ideas such as CSL’s Gardasil, Cochlear’s bionic ear, and Biota’s Relenza all received government help to turn them from science into products and the research and the biotechnology community were calling on the Federal Government to provide additional investment including grants and research and development tax credits.

“We’re not arguing a special interest case for the biotech companies,” the letter said.

“We’re arguing that a vibrant biotech industry is essential if Australia is to ensure investments in basic science and research can be translated into improved health, products and jobs.”

In the letter Ms Gallaher called on Bio-Melbourne Network members to lobby their local politicians.

Dubbing the Finance Minister and Member of the House of Representatives for Melbourne Lindsay Tanner “the local member for medical research in Australia” Ms Gallaher said his electorate covered “more than 23 percent of Australia’s biomedical research community including all of the Parkville strip, CSL and all of the city north and west of the Yarra”.

Biotech Daily has established that there are 25 listed biotechnology companies in Mr Tanner’s electorate and many of their employees live in the area which includes the City of Melbourne, Carlton, Parkville, Kensington, Flemington, Brunswick, Fitzroy, Collingwood and Richmond.

“Contact your local member wherever you live – but again especially if you live or work in Nicola Roxon or Julia Gillard’s electorates,” the Bio-Melbourne Network said.

“We want the Federal Government to recognize the considerable value and skill of the Australian biotech sector and that it is fundamentally linked to Australia’s excellence in research and basic sciences,” Ms Gallaher said.

“Ausbiotech has called for a \$300 million investment fund,” Ms Gallaher said. “We support this. We support the Innovation Review recommendations, particularly relating to the R&D tax credit for biotechs. We need this now,” the letter said.

## VIRALYTICS

Viralytics says the US Patent and Trademark Office has granted a key patent covering the use of Echoviruses for the treatment of all cancers expressing the integrin  $\alpha_2\beta_1$  molecule. Viralytics said the granted patent was entitled 'Method of treating a malignancy in a subject via direct picornaviral-mediated oncolysis' and covered Evatak, the company's formulation of the Echovirus Type 1.

The company said the Echovirus Type 1 attached to the outside of cells, using a specific receptor on the cell's surface and it used the receptor integrin  $\alpha_2\beta_1$  to bind and infect target cells.

Types of cancer cells that express high levels of the integrin  $\alpha_2\beta_1$  molecule on their surface include ovarian, prostate and gastric cancers.

Viralytics' chief scientific officer and the inventor of the technology Prof Darren Shafren said the granting of this US patent "significantly increases Viralytics' intellectual property portfolio, which already includes both US and European patents for a subset of Coxsackie A group viruses including Cavatak, our lead product".

The US patent provides Viralytics protection until 2023.

Viralytics was up 0.1 cents or 2.7 percent to 3.8 cents.

## STEM CELL SCIENCES

Stem Cell Sciences shareholders have voted overwhelmingly to sell the company's assets to the US-based Stemcells Inc and wind-up the company (BD: Mar 3, 2009).

The three resolutions to dispose of assets, cancel London's Alternative Investment Market and ASX listings and change the company's name were passed by margins of more than 20.9 million votes to 130,635 proxy votes.

The company will cancel its admission to the two exchanges by no later than June 26, 2009 and will be reregistered as a private company limited by shares following a change of name.

Stem Cell Sciences has been in a voluntary suspension and last traded at 15 cents.

## CSL

The US-based FMR Corp and Fidelity Investments reduced their substantial shareholding in CSL from 39,606,800 shares (6.57%) to 33,268,050 shares (5.51%) on March 27, 2009. CSL fell 24 cents or 0.73 percent to \$32.75 with 1.8 million shares traded.

## NEUREN

Neuren says that Thomas Robert Amos has resigned as a director.

The announcement was not made a formal announcement to the ASX but in an Appendix 3Z final director's interest notice.

On December 24, 2008, Neuren announced that its phase III trial of Glypromate had shown no significant results (BD: Jan 16; 2009).

Neuren was unchanged at half a cent.