



# Biotech Daily

Friday March 27, 2009

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: CHEMGENEX UP 25.5%; BENITEC DOWN 18.5%**
- \* **CHEMGENEX OMACETAXINE '4-10 TIMES IN VITRO STEM CELL EFFICACY'**
- \* **TAIWAN WINS PROGEN-CYTOPIA EGM; CYTOPIA BLOCKED**
- \* **US TRADE COMMISSION DELAYS THORATEC'S BID FOR HEARTWARE**
- \* **ACORN INCREASES TO 8% OF PHARMAXIS**
- \* **SAFETY MED LAUNCHES 'STERILIZED FEMININE HYGIENE PRODUCTS'**
- \* **DR MICHAEL CROUCH WINS MERCK BIOBUSINESS BIO ATLANTA AWARD**
- \* **PULSE PHARMACY TO CONDUCT IM MEDICAL HEART TESTS**

## MARKET REPORT

The Australian stock market climbed 0.7 percent on Friday March 27, 2009 with the S&P ASX 200 up 25.7 points to 3,672.3 points.

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

Chemgenex was best, up 12 cents or 25.5 percent to 59 cents with 36,736 shares traded, followed by Prana up 16.7 percent to 21 cents.

Avexa and Genetic Technologies both climbed 11.11 percent to 11 cents and five cents, respectively; Starpharma was up 9.8 percent; Psivida and Viralytics were up more than eight percent; Optiscan climbed 7.14 percent; Resmed was up 6.5 percent; Acrux, Bionomics, Living Cell, Phylogica and Sirtex were up four percent or more; CSL, Genera, Pharmaxis and Progen rose more than two percent; Novogen and Universal Biosensors were up more than one percent; with Cochlear and Heartware up less than one percent.

Benitec led the falls, down half a cent or 18.52 percent to 2.2 cents with 437,020 shares traded, followed by Polartech down 16.7 percent to 10 cents.

Labtech lost 8.3 percent; Impedimed was down 5.4 percent; Biota fell 2.7 percent; with Circadian down 1.4 percent and Cellestis down 0.98 percent.

## CHEMGENEX

Chemgenex says data published in the journal 'Leukemia' shows that omacetaxine kills leukemic stem cells in vitro at four to 10 times the rate of imatinib and dasatinib.

Chemgenex said imatinib and dasatinib were the two leading drugs for chronic myeloid leukemia (CML).

The company said omacetaxine also prolonged survival in mice carrying the T315I mutation, which would normally render them resistant to all currently available drugs.

Chemgenex said the findings provided "new insights into the problem of minimal residual disease and may open the door to the development of a curative treatment strategy for some patients with CML.

The study leader at the University of Massachusetts Medical School Dr Shaoguang Li said omacetaxine "killed 90 percent of the leukemic stem cells in vitro".

"In contrast, imatinib and dasatinib, the two leading CML drugs, only controlled nine percent and 25 percent of these cancer stem cells, respectively," Dr Li said.

"We further demonstrated that omacetaxine prolonged survival in test animals carrying the T315I mutation, which would normally render them resistant to all currently available drugs," Dr Li said.

The article entitled 'Inhibitory effects of omacetaxine on leukemic stem cells and BCR-ABL-induced chronic myeloid leukemia and acute lymphoblastic leukemia in mice' was published in Leukemia, March 26, 2009 (doi:10.1038/leu.2009.52).

Chemgenex said it was developing omacetaxine as a potential treatment for a range of blood malignancies, including CML and was completing a pivotal study in chronic myeloid leukemia patients with the T315I mutation.

The company said it expected to complete its filing of a new drug application for use of omacetaxine in that population to the US Food and Drug Administration by mid-year.

Chemgenex said the chairman and professor at the University of Texas MD Anderson Cancer Center department of leukemia Prof Hagop Kantarjian described the study results as "very promising".

"While the currently licenced drugs target and disable the diseased cells in the blood stream and bone marrow, they have little, if any, affect on the primitive leukemic stem cells that are at the root of this blood cancer," Prof Kantarjian said.

Chemgenex chief executive officer Dr Greg Collier said the results of Dr Li's animal study were "very encouraging and we are currently collaborating with Prof Tessa Holyoake from the United Kingdom, to carry out similar investigations in primary human stem and progenitor cells".

"In the meantime, Chemgenex remains focused on our primary objective of developing omacetaxine as a therapeutic option for CML patients who have developed the T315I mutation and who are resistant to all first and second line [tyrosine kinase inhibitors]," Dr Collier said.

"This is the most pressing unmet medical need in the field of CML management," Dr Collier said.

Chemgenex said that in the US, 5,000 new cases of chronic myeloid leukemia were diagnosed each year and estimates suggested that by 2025, prevalence would be 300,000 cases.

The company said that while there were a number of licenced drugs, known as tyrosine kinase inhibitors, which were very effective in treating chronic myeloid leukemia, they must be administered daily for the rest of the patient's life; very few patients remain disease free when these drugs are discontinued.

Biotech Daily editor David Langsam and analyst Marc Sinatra own Chemgenex shares. Chemgenex was up 12 cents or 25.5 percent to 59 cents.

## PROGEN, CYTOPIA

Two Progen directors, Stephen Chang and chief executive officer Justus Homburg have survived Cytopia's board coup with none of the Cytopia nominated directors elected. Mr Homburg told Biotech Daily shortly after the vote that about 60 percent of shares voted in the meeting and elected to remove chairman Dr Mal Eutick, Patrick Burns, John Lee and Robert Williamson.

But the three Cytopia-nominated directors Robert Collins, Dr Damian Pethica and Tom Williams (BD: Jan 28, 2009) were not elected.

Mr Homburg said there was some consistency in the voting with the Cytopia nominated directors defeated in a 60-40 split of the vote.

It appears that interests associated with the Taiwan-based Medigen won the day for further work on PI-88 for liver cancer.

"We have very diverse groups of shareholders," Mr Homburg said.

"The hedge funds could have changed the outcome but they didn't," he said.

"We have been for too long side-tracked by events by companies wanting to take us over for the cash. We need to get on with our programs," Mr Homburg said.

"We have a pathway to get PI-88 into Taiwan – it wasn't one we had before. We might find a regional partnership for PI-88," he said.

"There is a path forward for PI-88 and out two lead compounds," Mr Homburg said.

"We have a huge library of compounds."

Mr Homburg said Progen would need to appoint a third director.

Cytopia chief executive officer Andrew Macdonald said it was "a very strange result".

"We feel it was a very strange result," Mr Macdonald said.

"We thought it could have gone one way or the other and very clearly so," Mr Macdonald said.

Control of Progen has been an ongoing saga since the company closed its phase III trial of PI-88, leaving it with about \$70 million in cash.

On January 9, 2009 the Progen Shareholders Group, which was led by Antisense chairman Bob Moses and former EG Capital partner Alison Coutts failed in its bid to spill the board.

A poll of votes showed that about 19 million votes opposed the spill resolutions with about 11 million votes in favor of the resolutions. Progen has 60,469,511 shares on issue (BD: Jan 16, 2009).

The Moses-Coutts group of Progen shareholders said they wanted to keep some of the \$70 million in the biotechnology sector to create a major anti-cancer company as well as allow Medigen to continue work on PI-88 (BD: Dec 1, 2008).

Earlier this month, Progen withdrew from its proposed merger with Avexa when proxy votes representing 30.8 million shares (51 percent) showed that of those voting, 74 percent opposed the Avexa merger, 22 percent were in favor of the merger and three percent were open (BD: Mar 9, 10, 2009).

Progen initially announced a \$20 million buyback to appease the institutions that raised capital for the PI-88 trial.

Cytopia's Andrew Macdonald proposed an uncapped buy-back at the same price of \$1.10 a share.

When the Avexa merger failed, Progen raised its offer to a \$40 million capped buy-back at \$1.10 a share.

Progen climbed 2.5 cents or 2.79 percent to 92 cents.

Cytopia was untraded at 13 cents.

## HEARTWARE

Heartware says it and Thoratec have each received “a request for additional information” in relation to the merger from the US Federal Trade Commission.

Heartware said the review was part of the US Federal Trade Commission review of Thoratec's proposed acquisition of Heartware.

The acquisition is subject to approval by Heartware stockholders and satisfaction of other closing conditions.

Heartware said the effect of the second request was to extend the waiting period imposed until 30 days after Thoratec and Heartware have substantially complied with the second request, unless that period is extended voluntarily by the parties or terminated sooner by the Federal Trade Commission.

The companies said they were “gathering information to respond promptly to the second request” and were cooperating with the review.

Both companies expect the transaction to close in the second half of 2009.

Heartware was up half a cent or 0.54 percent to 93.5 cents.

## PHARMAXIS

Acorn Capital has increased its substantial shareholding in Pharmaxis from 12,071,292 shares (6.21%) to 15,125,283 shares (7.78%).

Acorn paid \$4,460,037.58 for the 3,053,991 shares or \$1.46 a share.

Pharmaxis was up three cents or 2.1 percent to \$1.48.

## SAFETY MEDICAL PRODUCTS

Safety Medical says its 50 percent subsidiary Pureste has developed the only range of sterilized tampons, pads and panty liners to be marketed in Australia and New Zealand. Safety Medical said last year it had secured \$9.5 million from the National Australia Bank to fund the launch, marketing and mass national distribution of a range of innovative feminine hygiene products (BD: Dec 18, 2008).

The company said that “despite popular belief and consumer expectations, there are no other products of this type available in Australia and New Zealand that are sterilized”.

Safety Medical said the products would be distributed through 580 Woolworths shops.

The company said the sterilization process used “medically proven and widely accepted gamma ray technology, which is calibrated to hospital operating theatre standards”.

Safety Medical said that after packaging and sealing, sterilization removed “all traces of bacteria”.

The company said that extensive market research indicated that sterility was a key factor in the selection process for women and that the majority of women were under the misapprehension that the feminine hygiene products sold in Australia and New Zealand were sterile when they were not.

Safety Medical said Australian standards for tampons “allowed for a small amount of bacteria and/or fungal spores to be present”, but Pureste products would contain no such bacterial or fungal traces.

Safety Medical was up five cents or 58.8 percent to 13.5 cents.

## ADVANCING BIOBUSINESS AWARDS

Adelaide's TGR Biosciences' chief scientific officer Dr Michael Crouch has won the 2009 Advancing Biobusiness Awards.

In a media release, the sponsors - Merck Sharp & Dohme and Advance, which describes itself as "a global community of Australian professionals overseas committed to advancing Australia and Australians" – said the prize was worth up to \$25,000 in travel and expenses to attend the Biotechnology Industry Organisation convention, in Atlanta, Georgia, May 19-21, 2009.

A tailored program of meetings will also be scheduled for Dr Crouch with American pharmaceutical and biotechnology companies, universities and research institutes, to build international networks, knowledge and collaborations.

Merck Sharp & Dohme's director of licencing and external research Dr Kearney told Biotech Daily that the prize was established "for a senior scientist in the commercial sector who would benefit from exposure to links in the US that would allow him or her to create a network in the US of either Australian or senior business that would then translate to benefit to the commercial sector on their return to Australia".

The Merck and Advance media release said TGR Biosciences created assay, or test, technologies for the drug discovery market.

Dr Crouch said that developing new medicines required pharmaceutical companies to test millions of drug compounds to see if they were potentially effective - a process which in the past has been slow and laborious.

"Our assays are helping important new drug therapies make it to market much faster through state of the art technology that substantially increases testing efficiency," he said.

The company said its range of cell-based tests reduced operator input by allowing testing to be automated with robots, resulting in "secure business with pharmaceutical and biotechnology companies as well as public sector research laboratories".

The media release said Dr Crouch hoped to learn how he could better understand the needs of the industry including how pharmaceutical companies select drug targets, what they would like to see in a new assay approach and how they make decisions on which technologies to use.

Dr Crouch said he would like to explore potential partnerships with global players to develop tests to measure bio-markers of diseases for researchers in Australian university laboratories and research institutes.

"Research in such facilities is currently very slow and manual," Dr Crouch said.

The creation of automated assays that can determine bio-makers of diseases such as cancer will substantially improve their level of scientific discovery," he said.

Dr Kearney said Australia was recognized for its excellence in medical research and its vigorous and creative biopharmaceutical industry.

However the number of drug development projects which reach advanced clinical development is only a quarter of what would be predicted on the basis of our output in scientific literature.

"By immersing top biotechnology people in successful commercial research centres in the United States, and providing them with opportunities to share their learning back at home, we aim to build a strong Australian capability to win in this highly competitive global knowledge market," he said.

## IM MEDICAL

IM Medical says it will launch the Intelliheart test for cardiovascular disease through more than 50 Pulse Pharmacy Group pharmacies in Victoria.

IM Medical said Pulse operated more than 70 pharmacies across Australia.

The Intelliheart test launch will take place during National Heart week May 4-8, 2009.

Pulse Pharmacy chief executive officer Rohan Aujard said Intelliheart “offers Pulse the opportunity to further extend our focus on preventative medicine and wellness programs and it enables us to provide a clearer picture of the improvement in the health of our customers who are enrolled in our Meditrim weight loss program”.

IM Medical said the relationship with Pulse would enable it “to more effectively market the Intelliheart test to the general public as a tool in the fight against cardiovascular disease, Australia’s biggest killer”.

IM Medical climbed 0.1 cents or 50 percent to 0.3 cents with 48.8 million shares traded.