



# Biotech Daily

Monday May 9, 2011

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: VIRALYTICS UP 10%; BENITEC DOWN 8%**
- \* **WEHI CLAIMS 'PROMISING' PHASE I COELIAC TRIAL RESULTS**
- \* **NOVOGEN EGM BACKS ISOFLAVONE SALE TO MARSHALL EDWARDS**
- \* **CEPHALON TAKES 67% OF CHEMGENEX**
- \* **STIRLING CLAIMS \$5m INDIA TELEMEDCARE DEAL**
- \* **WILSON HTM CEASES SUBSTANTIAL IN CATHRX**
- \* **JETAN CEASES SUBSTANTIAL IN FERMISCAN**

## MARKET REPORT

The Australian stock market climbed 0.29 percent on Monday May 9, 2011 with the S&P ASX 200 up 13.8 points to 4756.8 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, five traded unchanged and eight were untraded. All three Big Caps fell.

Viralytics was best, up 0.6 cents or 9.7 percent to 6.8 cents with 8.9 million shares traded, followed by Bionomics up 9.4 percent to 70 cents with 542,779 shares traded.

Heartware climbed 7.65 percent; Prima was up 6.25 percent; Starpharma was up 4.7 percent; Clinuvel, Genetic Technologies, LBT, QRX, Sunshine Heart and Tissue Therapies rose two percent or more; with Mesoblast up 1.6 percent.

Benitec led the falls, down 0.2 cents or 7.7 percent to 2.4 cents with 2.6 million shares traded, followed by Living Cell down 4.8 percent to 10 cents with 231,900 shares traded.

Phosphagenics lost 3.1 percent; Prana and Sirtex both shed 2.4 percent; with Alchemia, Nanosonics, Phylogica and Universal Biosensors down more than one percent.

## THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the first potential vaccine for coeliac disease “has shown promising results” in a phase I clinical trial, but did not release trial data.

WEHI said the vaccine was expected to move to phase II trials early next year.

The Institute said the phase I trial in Melbourne evaluated the safety, tolerability and bioactivity of the vaccine Nexvax2, which had been developed for coeliac disease, a genetically determined autoimmune disease causing an immune reaction to the gluten protein found in wheat, rye and barley.

The 34 patient, randomized, placebo-controlled, dose-ranging trial was entitled ‘A Phase I study to determine safety, tolerability and bioactivity of Nexvax2 in HLA DQ2 volunteers with celiac disease following a long-term, strict gluten-free diet’.

WEHI said the three peptides on which the vaccine was based were identified by Dr Bob Anderson from its immunology division and was being developed by US biotechnology company Immusant, of which Dr Anderson is chief scientific and medical officer.

WEHI said that Dr Anderson presented the phase I trial results at the Digestive Disease Week symposium in Chicago over the weekend and discusses the results at:

<http://www.youtube.com/watch?v=quRIF7QdmhA&list=PL3617BD7F4B61520C>.

“Nexvax2 aims to desensitize patients to the three specific peptides in gluten that we have previously identified as ‘toxic’ to people with coeliac disease,” Dr Anderson said.

Dr Anderson said the study showed that Nexvax2 was safe, well tolerated “and importantly, that it had the desired biological response in patients with coeliac disease”.

Dr Anderson said that seven of 19 patients at the 30, 60 and 90 microgram doses had gastrointestinal reactions, indicating the drug showed a similar reaction profile to gluten, with four patients generating a T-cell response to the treatment.

WEHI said that up to one percent of people were affected by coeliac disease, which was only treatable by eliminating gluten from the diet.

In coeliac disease, gluten triggers an immune response that damages the lining of the small intestine and inhibits its ability to absorb nutrients from food, the Institute said.

Dr Anderson said the vaccine would be suitable for treating about 90 percent of coeliac disease patients, those with the DQ2 genetic form of the disease.

“In our phase I trial, we saw a Nexvax2-specific T-cell response that confirms the desired bioactivity in HLA-DQ2 genotype patients,” Dr Anderson said.

“We expect the vaccine to enter phase II trials within the next 10 months, and hope to demonstrate a dramatic reduction in the body’s rejection of dietary gluten so patients can resume a normal diet and return to good health,” Dr Anderson said.

WEHI said the phase I study evaluated the effect of weekly injections of Nexvax2 over three weeks in coeliac patients on a strict gluten-free diet.

The Institute said that at the highest doses, some patients had gastrointestinal symptoms similar to what they’d experience after eating gluten products, suggesting the vaccine used the correct peptides for eventually being able to tolerate gluten.

Dr Anderson said the peptides used as part of the vaccine could also be used to improve diagnostic testing of coeliac disease.

“Diagnosing coeliac disease can be quite costly, requiring invasive tests and biopsies to confirm the disease,” Dr Anderson said.

“The results of a population study suggest that a combination of blood and genetic testing could effectively diagnose coeliac disease without these painful and invasive tests, with up to 50 percent reduction in costs as well, which creates a win-win situation,” he said.

WEHI said that Immusant is collaborating with Inova Diagnostics to develop improved serologic tests for coeliac disease and was developing a functional T-cell diagnostic designed to be used both as a stand alone test as well as a monitoring test for Nexvax2.

## NOVOGEN

Novogen shareholders overwhelmingly approved the sale of the isoflavone intellectual property to Marshall Edwards, with some dissent against directors options.

The Novogen extraordinary general meeting recorded 22,185,922 proxy votes in favor of the asset sale to its 65 percent US subsidiary and 725,007 proxy votes against.

A four part resolution issuing 375,000 options to directors William Rueckert, Peter White, Ross Youngman, Peter Scutt, were passed with 23,586,040 proxy votes (95.3%) in favor with 1,174,226 proxy votes (4.7%) against.

In its 2010 annual report Novogen said it had 102,125,894 shares on issue.

Today, the company said the isoflavone intellectual property was derived "from naturally-occurring plant compounds and the main application of these compounds has been to develop anti-cancer drugs".

Novogen said the sale was in exchange for shares in Marshall Edwards, with additional shares issued in the event of statistically significant results from the portfolio in phase II or phase III trials (BD: Apr 15, 2011).

Novogen was up one cent or 4.2 percent to 25 cents.

## CHEMGENEX

Cephalon appears to have increased its acceptances for its Chemgenex takeover bid from 202,168,837 shares (64.48%) to 208,795,490 shares (66.59%).

Cephalon said it had received acceptances for a further 6,626,653 shares in its takeover bid for Chemgenex, but had not formally received the two director's interest statements lodged on May 6, 2011, in which GBS Venture Partners managing partner Dr Geoff Brooke said he had sold 21,942,255 shares, 2,736,065 listed options and 250,000 unlisted options and Stragen Pharma chief executive officer Jean-Luc Tetard said he had sold 2,980,880 shares and 250,000 unlisted options.

Including the GBS options takes Cephalon's holding to 9,344,630 options or 85.34 percent of the listed options.

The bid is conditional on receiving 90 percent of shares and options and trading over the past fortnight appeared to be from one buyer acquiring or attempting to acquire more than 10 percent of the listed options.

Cephalon can remove conditions at any time.

Chemgenex fell half a cent or 0.7 percent to 69 cents.

## STIRLING PRODUCTS

Stirling says it has a conditional letter of intent to licence its Telemedcare vital signs monitoring devices to a company "to be incorporated and publicly listed in India".

Stirling said the existing shareholders of Telemedcare would receive a 40 percent interest in the company on establishment which would be non-dilutive for the first \$3 million and then proportionately diluted with respect to any further capital raised.

The company said that "a number of the proposed Indian subscribers to the Telemedcare special purpose Indian company are also desirous of investing in Stirling Products in order to get direct exposure to the global Telemedcare and high density aerosol pulmonary drug delivery opportunity".

Stirling said the agreement had provided for a subscription for 880 million shares in for the payment of the \$5 million or an average of 0.56 cents a share, pending shareholder approval and a range of other conditions.

Stirling was unchanged at 0.4 cents with 13.9 million shares traded.

### CATHRX

Wilson HTM Investment Group has ceased its substantial holding in Cathrx with the sale of 1,290,000 for \$258,000 or an average price of 20 cents a share.

In its previous substantial shareholder notice Wilson HTM reduced its holding from 9,816,838 shares (6.93%) to 8,265,543 shares (5.77%) selling the 1,551,295 shares at an average price of 21 cents a share.

Cathrx was unchanged at 20 cents.

### FERMISCAN

Jetan of Bellevue Hill Sydney has ceased its substantial holding in Fermiscan with the sale of 14,100,000 shares for \$66,507 or an average price of 0.47 cents a share.

In the March 23, 2011 becoming substantial shareholder notice Jetan director Greg Plummer said Jetan acquired 37,500,000 shares (6.47%) for \$75,000 or an average price of 0.2 cents a share.

Fermiscan fell 0.1 cents or 25 percent to 0.3 cents.