



# Biotech Daily

Tuesday April 12, 2011

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN; BIOTECH EVEN:**
  - **LIVING CELL UP 21%; ADVANCED SURGICAL DOWN 37%**
- \* **LIVING CELL'S NEW PARTNER OTSUKA BRINGS \$3m DOWRY**
- \* **RESMED LAUNCHES NEW VARIABLE PRESSURE DEVICE**
- \* **ALCHEMIA: 'NO FDA NEWS IS GOOD NEWS'**
- \* **NOVOGEN REGAINS NASDAQ LISTING COMPLIANCE**
- \* **KINETIC TAKES 7% OF NANOSONICS**
- \* **ROD TOMLINSON REPLACES HELICON CHAIRMAN DR SALIBA SASSINE**

## MARKET REPORT

The Australian stock market fell 1.46 percent on Tuesday April 12, 2011 with the S&P ASX 200 down 72.5 points to 4898.7 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and six were untraded.

Living Cell was best, up two cents or 21.05 percent to 11.5 cents with three million shares traded, followed by Bionomics up 16.0 percent to 58 cents with 2.4 million shares traded, Uscom up 12 percent to 28 cents with 16,237 shares traded and Phosphagenics up 10.3 percent to 16 cents with 21.1 million shares traded.

Sunshine Heart climbed 7.3 percent; Prima was up 4.2 percent; Virax was up 3.6 percent; Alchemia, Circadian and Genetic Technologies rose more than two percent; with Resmed and Universal Biosensors up more than one percent.

Yesterday's best, Advanced Surgical led the falls, down 9.5 cents or 37.25 percent to 16 cents with 85,224 shares traded, followed by QRX down 6.6 percent to \$1.55 with 152,085 shares traded.

Antisense and Tissue Therapies lost more than five percent; Impedimed, Patrys and Phylogica fell four percent or more; Cellmid was down 3.6 percent; Acrux, Biota and Starpharma shed more than two percent; with Nanosonics and Pharmaxis down more than one percent.

## LIVING CELL TECHNOLOGIES

Living Cell will raise \$3 million through the issue of 25,000,000 shares at 12 cents a share to new partner Otsuka Pharmaceutical Factory, pending shareholder approval.

Living Cell said the Tokushima, Japan-based Otsuka Pharmaceutical Factory was the research and manufacturing arm of the Otsuka group of companies.

The company said Otsuka would be issued the shares in two tranches, with 19,000,000 shares raising \$2,280,000 to be issued as soon as practicable after receipt of the funds, which must be received no later than April 22, 2011.

Living Cell said that a \$720,000 payment would be made by the same date for an unsecured mandatory convertible note, conditional on shareholder approval to be called no later than June 30, 2011.

Living Cell said that with shareholder approval the note would automatically convert into 6,000,000 shares but if approval was not obtained, the note would be repayable with interest of 7.5 percent per annum on December 31, 2011.

The company said it would use the proceeds to fund its ongoing development and clinical trials of its Diabecell encapsulated porcine islets of Langerhans for type 1 diabetes.

Living Cell said that along with the investment, the parties had begun negotiations for a collaborative research and licence agreement for the research, development and commercialization of Diabecell in Japan and certain other Asian countries, excluding China where Living Cell has an existing relationship with Jiangsu Aosaikang Pharmaceutical Co.

Last month Jiangsu Aosaikang acquired 14,334,080 shares or 4.7 percent of the company for \$1.7 million (BD: Mar 9, 2011).

Living Cell said the Otsuka negotiations were expected to be agreed within the next six months.

Living Cell chairman and medical director Prof Robert Elliott said the company was "very pleased to welcome Otsuka as a significant shareholder ... and as our partner to expand our presence in Asia".

"We are very excited about the opportunities to work together with Otsuka to develop our product for the treatment of diabetes in Japan and Asia, potentially one of the most significant markets for us globally," Prof Elliott said.

"We will begin planning for a clinical trial in Japan, which will be a natural and exciting extension to our phase II trial in New Zealand, which is coming to conclusion," Prof Elliott said.

Living Cell chief executive officer Dr Ross Macdonald said that adding Japan to the clinical trial program would "add important new data and significantly enhance our ability to advance Diabecell to market".

"The Otsuka name is widely recognized and respected in Japan and around the world for the quality healthcare products it develops and we are very pleased to be partnering with such a strong healthcare group," Dr Macdonald said.

Otsuka managing director Hiromi Yoshikawa said that Living Cell and his company "share a common vision for the treatment of diabetes and related complications".

"We see Diabecell as a very significant opportunity to improve treatment options available in Japan and elsewhere in the world," Mr Yoshikawa said.

Living Cell was up two cents or 21.05 percent to 11.5 cents with three million shares traded.

## RESMED

Resmed says its S9 VPAP series of bilevel devices “include a range of sophisticated comfort technologies to promote long-term compliance”.

Resmed said it had launched the bilevel range of products, providing variation between two pressures, on the S9 variable positive airways pressure (VPAP) platform, as the “latest and most innovative flow generator system for treating respiratory disorders including sleep-disordered breathing”.

Sleep business vice-president Michael Farrell said that for the first time, “health care providers have one platform that can treat obstructive sleep apnea, central sleep apnea and Cheyne–Stokes respiration, as well as provide non-invasive ventilation for patients requiring ventilatory support”.

“Our goal is to increase patients’ quality of life by providing comfortable, quiet, easy-to-use and highly effective treatment,” Mr Farrell said.

“A critical element of successful treatment is long-term adherence to therapy,” Mr Farrell said.

Resmed said that historically, patients’ ability to comply with sleep or respiratory therapies was negatively affected by noisy devices, nasal dryness/congestion and breathing discomfort.

The company said that to combat these negative effects and increase patients’ ability to adhere to respiratory therapy, its new generation of bilevel devices built on features crucial to maintaining and increasing overall patient compliance.

Resmed said an enhanced easy-breathe technology and climate control system gave patients control over their own comfort settings.

Resmed was up three cents or one percent to \$3.00 with 10 million shares traded.

## ALCHEMIA

Alchemia’s share price improved, up three cents to 70 cents, on news that it had not heard anything from the US Food and Drug Administration about lead drug, fondaparinux.

Alchemia previously said it expected approval for fondaparinux by April 2011.

“While approval has not fallen within our expected time frame, Alchemia is not aware of any outstanding items that stand in the way of approval being granted,” Alchemia said.

The company said multiple site inspections were completed successfully with the most recent in January this year and no further procedural impediments were expected prior to approval.

“Alchemia anticipates the next communication from the FDA to be the product approval itself,” the company said.

“While the overall process for fondaparinux approval has significantly exceeded Alchemia’s original expectations, the company is confident of the merit of its [abbreviated new drug application] for fondaparinux and believes that the extended review period simply reflects the current, long approval times for all generic drugs in the US,” the company said.

Alchemia chief executive officer Dr Pete Smith, said “We do not believe that there is anything that we could have done to have expedited the process.”

“We remain confident of the approvability of our fondaparinux application whilst recognizing that the ultimate timing remains in the hands of the FDA,” Dr Smith said.

Alchemia closed up two cents or three percent to 69 cents.

## NOVOGEN

Novogen says that by trading above \$US1.00 for 10 consecutive business days it has returned to Nasdaq listing compliance for its American depository receipt (ADR) program. Novogen said the ADRs were listed on the Nasdaq Capital Market and each ADR was equal to five Australian-listed shares.

In July 2010, Novogen said it had received a notice from the Nasdaq advising that it was no longer in compliance with the Nasdaq listing requirements and allowing 180 days in which to correct the non-compliance (BD: Jul 23, 2010).

The company said it was granted an additional 180 calendar days to July 18, 2011, to regain compliance and last week received a further notice from the Nasdaq confirming that for the 10 consecutive business days, from March 23, 2011 to April 5, 2011, the closing bid had been \$US1.00 per ADR or greater, it had regained compliance and the matter was closed.

Novogen was up one cent or 3.2 percent to 32 cents.

## NANOSONICS

Kinetic Investment Partners has increased its substantial shareholding in Nanosonics from 13,729,317 shares (6.10%) to 16,309,608 shares (7.17%).

Kinetic said it bought and sold shares, primarily in batches of tens of thousands of shares between May 7, 2010 and April 7, 2011.

Three major acquisitions totaled 4,049,300 shares for \$3,582,166 or an average price of 88.5 cents a share.

Kinetic is part of Challenger Financial Services and its principals are Jonathan Findlay, Richard Sharp and Anthony Porto.

Nanosonics fell one cent or 1.1 percent to 91 cents.

## HELICON GROUP

Helicon says Rod Tomlinson has been appointed non-executive chairman, effective immediately.

Helicon said Mr Tomlinson would replace Dr Saliba Sassine.

Helicon was originally created to market Australian biotechnology devices in China but had two technologies refused and lost the Avita Medical Recell contract having achieved marketing approval in China (BD: Mar 29, Apr 1, May 31, 2010).

The company has effectively become a backdoor listing for Leading Edge which has two disparate technologies a respiratory assist device and a reduced pain injection (BD: Nov 10, 2010).

Helicon fell 0.1 cents or three percent to 3.2 cents with 1.6 million shares traded.