



# Biotech Daily

Monday May 16, 2011

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: OPTISCAN UP 21%; VIRALYTICS DOWN 18%**
- \* **PSIVIDA: ALIMERA REAPPLIES TO FDA FOR ILUVIEN FOR DME**
- \* **NARHEX, CHINA ACADEMY PARTNER ON DG17 FOR HIV; 7.5m OPTIONS**
- \* **NANOSONICS SIGNS GE SALES DEAL; LOSES CEO DAVID RADFORD**
- \* **CEPHALON TAKES 76% OF CHEMGENEX SHARES, 86% OPTIONS**
- \* **USCOM EXTENDS EUROPEAN DISTRIBUTION**
- \* **ANTEO LOSES CHAIRMAN; TRANSOCEAN CEASES; ASX 16% QUERY**
- \* **CALZADA TELLS ASX NEWS MAY HAVE PUSHED PRICE 92%**
- \* **AVITA REQUESTS CAPITAL RAISING TRADING HALT**
- \* **COMPUMEDICS APPOINTS BOB DASPIT US SALES MANAGER**
- \* **MASSACHUSETTS MUTUAL LIFE REDUCES TO 11% OF NOVOGEN**
- \* **BIONOMICS APPOINTS MELANIE YOUNG CFO, CO SEC**

## MARKET REPORT

The Australian stock market fell 1.3 percent on Monday May 16, 2011 with the S&P ASX 200 down 61.4 points to 4650.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and four were untraded. All three Big Caps fell.

Optiscan was best, up 0.9 cents or 20.9 percent to 5.2 cents with 124,667 shares traded, followed by Advanced Surgical up 13.0 percent to 26 cents with 20,447 shares traded, Benitec up 12.0 percent to 2.8 cents with 1.3 million shares traded. Cathrx climbed 10.5 percent; Cellmid, QRX and Universal Biosensors were up more than three percent; with Mesoblast and Sirtex up more than one percent.

Viralytics led the falls, down 1.8 cents or 18.0 percent to 8.2 cents with 31 million shares traded, followed by Antisense down 16.7 percent to one cent with 1.7 million shares traded and Sunshine Heart down 12.7 percent to 5.5 cents with 1.35 million shares traded. Compumedics lost 10.5 percent; Bioniche fell 9.35 percent; Phosphagenics and Prana were down more than six percent; Prima fell 4.4 percent; Circadian, Patrys and Tissue Therapies were down more than three percent; Alchemia, Biota and Genetic Technologies shed more than two percent; with Nanosonics, Resmed and Starpharma down more than one percent.

## PSIVIDA

Psivida says licensee Alimera Sciences has resubmitted a new drug application to the US Food and Drug Administration for Iluvien for diabetic macular oedema.

Psivida said the May 12, 2011 resubmitted application addressed questions raised in the complete response letter of December 2010.

On December 24, 2010, Psivida said the FDA rejected the application for Iluvien (fluocinolone acetonide intravitreal insert) for diabetic macular oedema, with the complete response letter asking for analyses of safety and efficacy data through to month 36 of the study, including exploratory analyses in addition to those previously submitted, to further assess the relative benefits and risks of Iluvien (BD: Jan 16, 2011).

Psivida said at that time the application contained data to month 24 of its phase III trial and Alimera was preparing the 36 month analyses that the FDA has requested.

Today, Psivida said that Alimera reported that this would be a class 2 resubmission expected to be completed within six-months from the date it was received and was intended to address the FDA request for safety and efficacy data to month 36 of the study.

The company said that Alimera reported data from a subgroup of patients with chronic diabetic macular oedema at last week's Association for Research in Vision and Ophthalmology meeting (BD: May 5, 2011) which was also provided to the FDA with additional information regarding controls and specifications on the manufacturing, packaging and sterilization of Iluvien.

Psivida said that on approval of Iluvien it would be entitled to receive a \$US25 million milestone payment from Alimera and 20 percent of net profits, as defined, on sales of the drug by Alimera.

Psivida chief executive officer Dr Paul Ashton said that if approved, Iluvien would be the company's third FDA-approved product.

"We are also working on several earlier stage technologies including bioerodible systems to deliver proteins and small drug molecules for macular degeneration and glaucoma," Dr Ashton said.

Psivida said Alimera reported that deficiencies in good manufacturing practice observed during facility inspections at two of Alimera's third-party manufacturers of Iluvien noted in the FDA complete response letter had been resolved and that no further action was required.

Psivida was untraded at \$3.95.

## NARHEX LIFE SCIENCES

Narhex says its 50 percent Chinese joint venture Xi'an Hex will collaborate with the Academy of Medical Science of China on its anti-HIV drug DG17.

Narhex said the agreement was with the Academy's Biomedicine Technology Research institute, which would partner in the development and approval of DG17.

The company said initial work would be verification of the manufacturing and testing of DG17 so it could be reviewed and approved for further animal and human testing, effectively duplication the work already done in Australia, to comply with Chinese regulatory authorities.

Narhex said it would issue 2,500,000 unlisted options each to directors Peter Christie, Peter Nash and David Mandel, subject to shareholder approval.

The company said the options would be exercisable at two cents per option up to three years from the date of issue and conditional on not being exercised for 12 months and the share price exceeding five cents a share for 10 consecutive trading days.

Narhex was up half a cent or 25 percent to 2.5 cents with 1.8 million shares traded.

## NANOSONICS

Nanosonics says it has executed its contract with GE Healthcare for the exclusive distribution of the Trophon EPR in the North American and Canadian healthcare markets. Nanosonics said last year that the agreement provided GE Healthcare with non-exclusive original equipment manufacturer co-sales of the Trophon EPR ultrasound cleaning system with GEHC ultrasound consoles in other countries outside the US and Canada (BD: Sep 21, 2010).

Nanosonics said at that time that GE Healthcare was the leading supplier of ultrasound equipment in the US and Canada, had global leadership in obstetric and gynaecological applications and the alliance provided for "further product development opportunities [for] GEHC's customers".

Today, Nanosonics said the contract with was the basis for a near term launch of the Trophon EPR into the lucrative North American market with commercial sales targeted to begin by July 2011.

Nanosonics said it had an agreement with GE Healthcare in respect of non-exclusive distribution rights for the European market whereby the Trophon unit can be included as a bundled offering together with GE products.

A strategic roadmap has been developed for the first staged release of products into Europe targeting an agreed list of priority countries.

Nanosonics fell one cent or 1.2 percent to 81 cents.

## NANOSONICS

Separately, Nanosonics said that following consultation with the board chief executive officer David Radford has resigned from the company.

Nanosonics said the details of Mr Radford's departure were "yet to be finalised and all parties are working collaboratively to ensure a smooth transition".

The company said that director Dr Ron Weinberger would be appointed as interim chief executive officer.

Nanosonics said Dr Weinberger was instrumental in leading the development of both the company's platform technologies and the roll out of its flagship Trophon EPR ultrasound probe cleaning system.

The company said Dr Weinberger was in the US working with GE in finalizing the marketing technical and support plans for the US launch of the Trophon EPR.

Mr Radford told Biotech Daily that he had achieved his commercialization targets with Nanosonics and wanted to consolidate two or more biotechs into one, creating a strong portfolio and then take them to an initial public offering on the ASX.

The Sydney-based Mr Radford said he had been with Nanosonics since June 2008 and prior to that was with GE Healthcare.

## CHEMGENEX

Cephalon says it has increased acceptances for its Chemgenex takeover bid from 233,362,049 shares (74.42%) to 237,357,795 shares (75.70%).

Cephalon said it had increased Chemgenex listed options acceptances from 9,410,275 options (85.94%) to 9,414,430 options (85.98%).

The bid is conditional on receiving 90 percent of shares and options.

Cephalon can remove conditions at any time.

Chemgenex was unchanged at 69 cents.

## USCOM

Uscom says it has appointed Genesys Medical Solutions as its distributor in the UK and Dutchmed as its distributor in Eastern Europe.

Uscom said it had "several impressive reference sites" in the UK for its ultra-sonics cardiac output monitor, but Genesys would "leverage these to extend its reach across the entire country".

The company said Dutchmed had a strong sales organization covering Bulgaria, Romania, Moldavia, Hungary, Poland and Slovakia.

Uscom said that both distributors had experience in selling innovative healthcare products into those hospital departments where it was finding best traction in paediatrics, emergency and intensive care.

Uscom executive chairman Phil Kiely said he had met the principals of both organizations and had "confidence in their ability to quickly exploit the opportunities for Uscom".

"Each have developed credible sales operations with knowledge of patient monitoring devices and well established contacts with clinicians who can make use of our monitor," Mr Kiely said.

"It is also imperative that we begin to advance our offering into the burgeoning markets of Eastern Europe," Mr Kiely said.

Uscom said it had also signed Prhoinsa to cover its Spanish opportunities and was in negotiation with several companies in Germany.

The company said it had previously announced the appointment of Vok Medical Systems to cover the Russian market.

Uscom was untraded at 25 cents.

## ANTEO DIAGNOSTICS

Anteo says James Henderson will step down as chairman, Richard Martin will be interim chairman and Sandra (Sam) Andersen has been appointed as a non-executive director.

A company related to Mr Henderson has been selling down its Anteo shares and has ceased its substantial holding (see below).

Anteo said Ms Andersen was "a highly experienced senior executive and company director" and was recently the managing director of Eyecare Partners, an ASX-listed company with 41 optometry businesses and a staff of 300 people.

The company said Ms Anderson had held senior roles in a number of listed technology companies, and senior executive positions at the ANZ, NAB and Commonwealth banks and was "well networked within the finance community".

Anteo said Ms Andersen was a non-executive director and chaired the audit and risk committees of Grain Growers, Rural Finance Corp and Victorian Rail Track.

The company said Mr Henderson had stepped down as non-executive chairman "to pursue his other interests which are requiring him to travel overseas on an increased basis".

Anteo said Mr Henderson had been pivotal in its success and he was instrumental in securing the necessary capital for the company.

Separately, Transocean ceased to be a substantial shareholder selling 19,760,000 shares for \$2,167,547 or an average price of 10.97 cents a share.

James Henderson and Jelonex investments are related parties to Transocean.

In its last substantial shareholder notice, Transocean said it held 40,179,262 shares or 5.27 percent of the company (BD: May 2, 2011).

Anteo fell 0.7 cents or 7.9 percent to 8.2 cents with 48.2 million shares traded.

### ANTEO DIAGNOSTICS

Anteo has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 7.4 cents on May 12, 2011 to 8.6 cents on May 13, 2011, a 16.2 percent increase and noted an increase in trading volume.

Anteo said there was an off-market transfer of 11 million shares on May 13 that could have contributed to the increase in the volume of shares reported traded on that day.

### CALZADA

Calzada has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 6.5 cents on May 6, 2011 to 12.5 cents on May 13, 2011, a 92.3 percent increase, and noted an increase in trading volume.

Calzada said that apart from announcements to the ASX about its subsidiaries Polynovo, Metabolic and Novoskin, articles were published in both The Australian newspaper and the Brisbane Courier Mail on May 10 regarding Novoskin's biodegradable temporizing matrix.

Calzada was unchanged at 10 cents.

### AVITA MEDICAL

Avita has requested a trading halt pending an announcement about the "finalizing of a capital raising".

Trading will resume on May 18, 2011 or on an earlier announcement.

Avita last traded at 15 cents.

### COMPUMEDICS

Compumedics says it has hired Bob Daspit as its new US national sales manager.

Describing the appointment as "a major milestone" in support of its stated strategy to substantially expand the existing Compumedics sales force" the company said Mr Daspit would be based at the company's US headquarters in Charlotte North Carolina, and had more than 10 years experience in senior sales leadership roles at three global medical device companies.

The company said Mr Daspit had managed large sales teams and had "a proven track record of exceeding sales budgets and delivering key milestones, with particular emphasis on developing national accounts".

Compumedics said Mr Daspit had sales experience in a wide array of medical devices, with particular emphasis on neuro-diagnostics products, which was a critical platform for the company, with the recently released Neuvo long-term electroencephalogram monitoring system.

Compumedics fell 1.1 cents or 10.5 percent to 9.4 cents.

### NOVOGEN

Massachusetts Mutual Life Insurance Co has reduced its substantial holding in Novogen from 12,744,689 shares (13.08%) to 11,552,712 shares (11.31%).

Novogen was unchanged at 23 cents.

## BIONOMICS

Bionomics has appointed Melanie Young as chief financial officer and company secretary. Bionomics said Ms Young had more than 12 years experience, with six years in the medical device field, including the last two years as chief financial officer of Ellex Medical Lasers, covering all facets of the company's global finance function.

The company said that Ms Young had "considerable commercial experience in listed company reporting requirements, international finances and working capital management". Bionomics said Ms Young had experience in negotiating distributor agreements, due diligence, cost reduction strategies and improving operating efficiencies.

The company said that previously Ms Young had worked for Deloitte and held a Bachelor of Commerce degree from Melbourne's Deakin University.

Ms Young replaces Trevor Thiele who joined Bionomics in December 2009.

Bionomics was unchanged at 63 cents with 1.4 million shares traded.