



# Biotech Daily

Thursday December 2, 2010

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: QRX UP 14%; LBT DOWN 6%**
- \* **LOUISE ASHER APPOINTED VICTORIA'S INNOVATION MINISTER**
- \* **VIRALYTICS CAVATAK ON FDA 'CLINICAL HOLD' FOR DIALOGUE**
- \* **USCOM TO RAISE \$3m; PHIL KIELY CHAIRMAN; NEW DISTRIBUTORS**
- \* **ATCOR RIGHTS ISSUE RAISES \$953k, \$387k TO GO**
- \* **CALZADA FINDS \$US20m BLACK MARKET FOR 'FAT BUSTING' AOD9604**
- \* **HEALTHLINX APPOINTS SOUTH KOREAN DISTRIBUTOR**
- \* **BIO-MELBOURNE BREAKFASTS ON UNIVERSAL BIOSENSORS**
- \* **NEURODISCOVERY HOPES TO PLACE \$430k; APPOINTS ROBERT HOBBY**
- \* **IMPEDIMED REQUESTS FUNDING TRADING HALT**
- \* **FERMISCAN DISSENT ON REMUNERATION, SHARE ISSUE**

## MARKET REPORT

The Australian stock market was up 1.95 percent on Thursday December 2, 2010 with the S&P ASX 200 up 89.6 points to 4676.2 points. Eighteen of the Biotech Daily Top 40 stocks were up, nine fell, eight traded unchanged and five were untraded. All three Big Caps were up.

QRX was best, up 14.5 cents or 14.3 percent to \$1.16 with 210,821 shares traded, followed by Antisense and Genetic Technologies both up 12.5 percent to 0.9 and 3.6 percent, respectively, and with 33,000 and 489,000 shares traded, respectively.

Cellmid and Prana both climbed 7.7 percent; Universal Biosensors was up 5.3 percent; Optiscan was up 4.9 percent; Phylogica, Sirtex and Tissue Therapies rose more than two percent; with Biota, Cochlear, CSL, Nanosonics, Resmed and Starpharma up more than one percent.

LBT led the falls, down 0.5 cents or 5.6 percent to 8.5 cents with 45,000 shares traded, followed by Phosphagenics and Prima, both down 4.55 percent to 10.5 cents with 495,050 and 2.2 million shares traded, respectively. Chemgenex, Genera and Viralytics shed more than two percent; with Psivida down 1.8 percent.

## VICTORIAN GOVERNMENT

The newly-elected Victorian Government of Premier Ted Baillieu has appointed Louise Asher as the Minister for Innovation, responsible for biotechnology.

Ms Asher is the Member of the Legislative Assembly for Brighton and has also been appointed as the Minister for Small Business, Tourism and Major Events.

Ms Asher previously served as the Minister for Small Business and Minister for Tourism in the Kennett Government from 1996 to 1999.

Ms Asher was the Deputy Leader of the Opposition until the Liberal Party and National Party Coalition formed Government following the election on November 27, 2010.

According to the Parliament of Victoria website, Ms Asher holds a Bachelor of Arts and a Masters of Arts from the University of Melbourne, as well as a Diploma of Education and a Bachelor of Economics from Monash University.

Ms Asher is married to former Victoria National Party Member of Parliament Ron Best who is a director of Mayne Pharma, formerly Halcygen Pharmaceuticals.

### Bio-Melbourne Network Comments:

The Bio-Melbourne Network welcomed Ms Asher to the Innovation portfolio and Victoria's biotechnology industry.

"It is refreshing to see Innovation placed hand-in-glove with Small Business at last," the Network said.

"The proposed restructure of the Department of Innovation Industry and Regional Development to the Department of Business and Innovation is masterful, demonstrating a clear understanding of the small and middle-sized enterprise profile of many biotechs in Victoria," the Bio-Melbourne Network said.

## VIRALYTICS

Viralytics says the US Food and Drug Administration has completed its initial review of the Cavatak phase II trial investigational new drug application and will ask further questions. Viralytics said it lodged its initial application on November 1, 2010 for a phase II trial of Cavatak in patients with late stage melanoma.

The company said that at the end of the 30-day review period, the FDA notified that it would lodge a series of questions in a letter to Viralytics and indicated that the trial may not proceed as planned.

Viralytics said that once the FDA requested further details, the planned trial was delayed and was on "clinical hold" until the questions were answered to the satisfaction of the FDA.

The company said the FDA had the right to continue to request further information and there was no time frame on this dialogue.

Viralytics said it was common for the FDA to request further information and ask questions on the submission and the company would enter into a direct and interactive dialogue with the US regulator.

Viralytics said that once it had satisfactorily resolved the FDA issues and a "complete response letter" was accepted by the Agency, the clinical hold would be lifted and the clinical trial could proceed.

The company said it was continuing its review of potential clinical research organizations to manage the trial on our behalf, proceeding to identify potential clinical trial investigators and in the process of having the bulk Cavatak stock vialled in preparation for the phase II trial in patients with late stage melanoma.

Viralytics fell 0.1 cents or 2.9 percent to 3.3 cents with 4.6 million shares traded.

## USCOM

Uscom will appoint Phil Kiely as executive chairman replacing founder Robert Phillips on the finalization of a \$3 million capital raising expected early in 2011.

Mr Phillips will remain in the board as the director of medical science.

Mr Phillips told Biotech Daily that the private placement of up to 10 million shares at 30 cents a share was to several high net worth individuals of which Mr Kiely was one.

Mr Phillips said Mr Kiely had extensive experience in technology sales and was "ideal" to lead the company.

In a media release Uscom said the placement would be in two tranches with the second tranche requiring shareholder approval and would be followed by a share purchase plan for existing shareholders.

The company said the first tranche would raise \$1,881,180 through the issue of 6,270,600 shares and the balance would be subject to shareholder approval.

Mr Phillips owns about 40 percent of Uscom and the total number of shares on offer will increase from 41,804,047 to 50,000,000, diluting his holding and providing greater liquidity in the company's shares.

Uscom said Mr Kiely was a former managing director of Oracle Corporation for Australia and New Zealand, with 25 years experience in the information technology arena.

"The biotech sector has a lot to learn from the experiences of the [information and communications technology] sector in the rollout of products," Mr Kiely said.

Mr Kiely's nominated entity will be granted four million, five-year options in equal tranches with exercise prices at 75 cents, \$1, \$2 and \$3.

Mr Phillips said the incentive package was structured to reward exceptional performance and the options would be subject to shareholder approval.

Uscom said Mr Kiely would "drive the new sales and marketing programs" and hire a new chief executive officer.

Uscom said it had signed its first new distributor agreement in the North American market, with Medical Dynamics and was "poised to sign three additional distributors in the next few weeks" giving the company coverage of up to 75 percent of the US market.

Uscom said it was reviewing the performance of all distribution partners in Asia and Europe to achieve greater sales and its current exclusive worldwide distributorship with Spacelabs would expire on December 12, 2010.

Uscom was unchanged at 40 cents.

## ATCOR MEDICAL

Atcor says it has received applications for 13,617,995 shares or about \$953,000 of the expected \$1.34 million in its fully underwritten rights issue at seven cents a share

Atcor said the applications comprised \$745,000 in entitlement acceptances and \$208,000 as applications for additional shares and all valid applicants would receive their full entitlement and any additional shares applied for through the offer.

Atcor said the shortfall of 5,538,949 shares would be issued to clients of Taylor Collison.

Atcor chief executive officer Duncan Ross said the rights issue combined with \$1 million share placement in October, "provides us with the funds to develop the business through to self-sustainability" (BD: Oct 20, 2010).

"The cash raised will be directed towards funding working capital needs associated with a change in the nature of pharmaceutical receivables, leasing model versus up front capital, accelerating our product development program and supporting reimbursement activities in the US," Mr Ross said.

Atcor was unchanged at eight cents.

## [CALZADA, METABOLIC PHARMACEUTICALS](#)

Calzada says black market sales of the 'fat-buster' drug AOD9604 from China are estimated at 85 grams per month with an estimated value up to \$US20 million.

Calzada said it wanted to review the potential of AOD9604 as a regulated drug or as a cosmetic and wholly-owned subsidiary Metabolic Pharmaceuticals was looking at the potential of AOD9604 in the obesity and bone health markets.

Between 1998 and 2007, Metabolic invested about \$50 million in attempting to develop AOD9604 as an obesity treatment, Calzada said.

While AOD9604 showed early promise in treating obesity in clinical trials it failed to reach the chosen efficacy end point in a large phase II trial in February 2007, the company said. Calzada the failure to meet its endpoints in that trial "may have been due to ineffective administration of the drug as an oral tablet formulation".

Calzada contracted the Hong Kong-based Global Insight Kong to conduct research into the black market sales of AOD9604.

Global Insight said sales of sub-cutaneous injections of AOD9604 were to distributors, gymnasiums, weight control centres, private clinics and individual athletes, bodybuilders and the obese in the US, Canada, Australia, Russia, the UK and Germany.

Calzada said the five major manufacturers of AOD9604 in the Shanghai region of China sold about 85 grams of AOD9604 a month with purity-related pricing in the range \$US540 to \$US2,625 per gram.

The review said it was usually sold in 2mg vials and the estimated value of sales was between \$US1.5 million per annum at the bulk rate and more than \$US20 million a year at milligram quantities, with the total world market is likely to be much larger.

Calzada said it did not condone the black market use and the drug has not been approved by any regulator for human use and enforcing its intellectual property position "may be possible, but the cost of doing so is prohibitively high at this time".

Calzada said the back market for AOD9604 demonstrated there was a high demand for the as yet unproven product.

Regulatory approval had potentially long timeframes and high capital requirements and Calzada said it continued to investigate ways to maximize the value of the AOD9604 drug. The company said the two main paths forward were as a regulated drug for either obesity or osteoporosis through the traditional pharmaceutical development process or developing it as a cosmetic or a food additive.

The second strategy would enable taking products to market in a more timely manner and with substantially lower development costs.

Calzada said that the Phosphagenics licence for the transdermal use of AOD9604 was an example of this strategy, with product launch planned for the first half of calendar 2011.

Calzada was up 0.1 cents or 3.7 percent to 2.8 cents.

## [HEALTHLINX](#)

Healthlinx says Seoul Clinical Laboratories will distribute its Ovplex ovarian cancer diagnostic in South Korea.

Healthlinx said distribution would begin when the test was approved by the South Korea Food and Drug Administration following the successful completion of a 220 patient study that began earlier this year.

The company said the deal would result in Seoul Clinical Laboratories co-funding part of the study and Seoul Clinical Laboratories in exchange for an exclusive licence to distribute Ovplex in South Korea.

Healthlinx was up 0.2 cents or 2.4 percent to 8.6 cents.

### NEURODISCOVERY

Neurodiscovery says it will place 10,750,000 shares at four cents a share to raise \$430,000 from sophisticated investors for working capital.

The company said it would also issue 4,000,000 unlisted options with an exercise price of six cents, expiring on January 31, 2012 at no cost, subject to shareholder approval.

Separately the company said Robert Hodby had been appointed as joint company secretary, effective today.

Neurodiscovery fell 0.1 cents or 2.3 percent to 4.3 cents.

### IMPEDIMED

Impedimed has requested a trading halt pending an announcement "in relation to the outcome of a proposed capital raising".

Trading will resume on December 6, 2010 or on an earlier announcement.

Impedimed last traded at 82 cents.

### BIO-MELBOURNE NETWORK, UNIVERSAL BIOSENSORS

Universal Biosensors chairman Andrew Denver will discuss the transition of his company following the launch of its first product at the December Bio-Melbourne Bio-Breakfast.

Johns & Johnson company, Lifescan has taken the Universal Biosensors developed One Touch Verio blood glucose meter to market and Universal has recently announced the next product in development, a diagnostic for blood clotting (BD: Nov 29, 2010).

The Bio-Melbourne Network said that Universal Biosensors had "reached a transitional point in its evolution" with the retirement of its chief executive officer Mark Morrison and the launch of the One Touch Verio in Europe and Australia.

The Network said Mr Denver would talk about the changing landscape of Universal Biosensors and its strategic goals and the next phase meant that numerous refinements were setting the scene for its future success.

The December 7 2010 Bio-Breakfast will be held at The Supper Room, Melbourne Town Hall, corner Swanston & Collins Streets, Melbourne, with registration from 7.15am.

For more information or to book go to: <http://www.biomelbourne.org/events/view/160>.

Universal Biosensors was up eight cents or 5.3 percent to \$1.60.

### FERMISCAN

The Fermiscan annual general meeting resolution to issue of 150,000,000 shares to Antus Capital was defeated on proxy votes, but passed "on a show of hands".

Fermiscan said that share issue was opposed by 25.76 million proxy votes (64.1%) with 14.44 million proxy votes (35.9%) in favor.

The remuneration report was opposed by 9.5 million proxy votes (23.6%) with 30.74 million proxy votes (76.4%) in favor and all other resolutions were passed overwhelmingly.

Fermiscan's most recent Appendix 3B share issue announcement said there were 143,506,671 shares on issue, meaning that the strongest opposition came from 17.95 percent of all shares on issue.

Fermiscan is in a suspension and last traded at three cents.