



# Biotech Daily

Monday June 21, 2010

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: PATRYS UP 23%, TISSUE THERAPIES DOWN 7%**
- \* **BIONOMICS ANTI-ANXIETY BNC210 4-FOLD UPTAKE WITH FOOD**
- \* **HEALTHLINX BEGINS SOUTH KOREAN OVPLEX TRIAL**
- \* **PHARMAXIS PHASE III CYSTIC FIBROSIS TRADING HALT**
- \* **JM FINANCIAL REDUCES, DILUTED 1.9% IN GENERA**
- \* **SIMON McKEON APPOINTED CSIRO CHAIRMAN**
- \* **BIO-MELBOURNE'S BIO-BREAKFAST GOES GREEN**
- \* **BIOPROSPECT RAISES \$422k, HOPED FOR \$3.3m**

## MARKET REPORT

The Australian stock market climbed 1.3 percent on Monday June 21, 2010 with the S&P ASX 200 up 60.7 points to 4612.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and six were untraded.

Patrys was best, up 2.5 cents or 22.7 percent to 13.5 cents with 145,000 shares traded, followed by Cellmid up 0.3 cents or 14.3 percent to 2.4 cents with 1.9 million shares traded.

Living Cell climbed 8.5 percent; Bionomics, Novogen and Optiscan were up more than five percent; Bone was up 4.35 percent; Cathrx, Chemgenex, and Psivida were up more than three percent; Clinuvel rose 2.1 percent; with CSL, Heartware and Starpharma up more than one percent.

Tissue Therapies led the falls, easing from last week's highs, down 1.5 cents or 7.3 percent to 19 cents with 204,500 shares traded, followed by Prima down one cent or 7.1 percent to 13 cents with 13.9 million shares traded.

Virax lost five percent; Phosphagenics fell 3.7 percent; Cellestis, Genetic Technologies, Phylogica, Resmed and Universal Biosensors shed two percent or more; with Acrux down 1.35 percent.

## BIONOMICS

Bionomics says a phase I pharmacokinetics trial of anti-anxiety compound BNC210 has shown a four-fold uptake when administered with an approved high-fat meal.

Bionomics said the study examined the effect of food on the pharmaco-kinetics, tolerability and pharmaco-dynamics of BNC210 in three healthy male volunteers.

The volunteers were fasted and received doses of 300mg of BNC210.

One week later, the same three subjects were dosed with 300mg of BNC210 following the consumption of a meal following US Food and Drug Administration guidelines.

Bionomics said the administration of 300mg of BNC210 with food produced a 4.1 fold increase in exposure of BNC210, as measured by blood drug levels.

The company also trialed the volunteers on 600mg, 1200mg and 2000mg doses with food and compared the blood drug levels with earlier fasted data, showing similarly increased rates of blood drug level.

According to a US Food and Drug Administration guidance for Industry on food-effect bioavailability "food can change the bioavailability of a drug by various means, including delay gastric emptying, stimulate bile flow to aid absorption, change gastrointestinal pH, change luminal metabolism of a drug substance and physically or chemically interact with a dosage form or a drug substance".

The FDA recommended high-calorie, high-fat meals in food-effect studies.

"An example test meal would be two eggs fried in butter, two strips of bacon, two slices of toast with butter, four ounces of hash brown potatoes and eight ounces of whole milk. Substitutions in this test meal can be made as long as the meal provides a similar amount of calories from protein, carbohydrate, and fat and has comparable meal volume and viscosity," the FDA said.

Bionomics said the aim of the trial was to determine whether administration of BNC210 with food altered blood levels of the drug and said that the increased exposure when BNC210 was given with food expanded the potential dosing range.

Bionomics chief executive officer Dr Deborah Rathjen said that many drugs were taken either with food or following a meal.

Dr Rathjen said the trial helped identify the doses to be used in the planned phase Ib studies of BNC210 and suggested that lower doses of BNC210 might be effective when the drug was given with food.

"This latest data also confirms the results of the initial phase I clinical trial of BNC210 which indicated that BNC210 was well tolerated at high doses and free of significant side-effects," Dr Rathjen said.

Bionomics said the placebo-controlled and blinded trial was conducted in healthy male volunteers at the Pain and Anaesthesia Research Clinic within the Royal Adelaide Hospital with Prof Paul Rolan as the principal investigator.

The company said that secondary objectives of this trial included the evaluation of potential biomarkers showing BNC210 effects, such as the determination of stress hormone levels.

Bionomics said these tests were in progress with data expected by October 2010.

Two phase Ib clinical trials of BNC210 were expected to begin at the same time evaluating BNC210 effects when anxiety was induced in healthy subjects, with the second trial evaluating BNC210 effects on the brain using electroencephalograph measurements.

The company said the trials would continue to study whether side effects such as sedation or memory impairment were associated with the administration of BNC210.

To date BNC210 administration has not been associated with clinically significant side effects, the company said.

Bionomics was up 1.5 cents or 5.4 percent to 29.5 cents.

## HEALTHLINX

Healthlinx will conduct a 220-patient biomarker registration-directed trial of its Ovplex ovarian cancer diagnostic in South Korea.

Healthlinx said the trial would be conducted by Sungkyunkwan University School of Medicine's Prof Byoung-Gie Kim as principal investigator, who was also the director of the Gynaecological Cancer Center at Samsung Medical Center.

The company said Prof Kim helped secure other institutions for the trial including the Asan Medical Centre and Seoul National University Hospital.

Healthlinx said the study would take 12 to 14 months and then it would begin the process of submissions to the South Korean Food and Drug Administration.

Healthlinx managing director Nick Gatsios said that his company had worked for the past nine months for on trial.

Mr Gatsios said Prof Kim was one of South Korea's "leaders in the field of ovarian cancer" and appointing him as principal investigator "proves that what we have developed is a world class product [and that] key opinion leaders and ethics committees around the world are approving studies to further validate Ovplex and deliver better health outcomes to women".

The company said a successful South Korean study would give Healthlinx its fourth jurisdiction, accessing a market estimated at approximately 250,000 tests.

Healthlinx said South Korea had a greater than 10 percent growth rate in newly diagnosed ovarian cancer cases over the past four years.

The company said that in 2004 ovarian cancer was not one of the top 10 cancers but in the five years to 2009 ovarian cancer was the eighth most lethal cancer in South Korea with projections suggesting that it could reach number five within the next three years.

Healthlinx said the growth in newly cases of ovarian cancer suggested that Ovplex had a significant market opportunity in South Korea.

Healthlinx was up half a cent or 4.2 percent to 12.5 cents.

## PHARMAXIS

Pharmaxis has requested a trading halt "pending the announcement of results from its second international phase III trial of Bronchitol in patients with cystic fibrosis".

Trading will resume on June 23, 2010 or on an earlier announcement.

Pharmaxis last traded at \$3.12.

## GENERA BIOSYSTEMS

JM Financial Group has reduced its substantial holding in Genera and been diluted through the release of escrow shares.

JM Financial bought and sold shares between May 14 and June 21 reducing its substantial shareholding from 5,936,055 shares (10.72%) to 5,549,113 shares (8.85%).

On June 11, 2010 Genera released 7,276,723 shares from escrow taking its total shares on issue to 62,670,278 shares and diluting JM Financial's holding.

Genera was unchanged at 55 cents.

## COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Federal Government has appointed Simon McKeon as chairman of the Commonwealth Scientific and Industrial Research Organisation board.

Innovation Minister Senator Kim Carr said Mr McKeon was the executive chairman of the Melbourne office of Macquarie Group and would take up his position from June 28, 2010, succeeding Dr John Stocker.

Senator Carr said Mr McKeon had a background in business, law and high-profile aid organizations that "make him ideally suited for the position".

"His ability to combine financial expertise with philanthropic pursuits gives him a perspective that will be of great benefit to CSIRO," Senator Carr said. "He will help set the future direction of Australia's pre-eminent research organization."

Mr McKeon was the founding president of the Australian Takeovers Panel, chair of MS Research Australia, chairman of Business for Millennium Development and a director of Visionfund International, the Global Poverty Project and Red Dust Role Models.

Mr McKeon has degrees in law and commerce from the University of Melbourne and prior to joining Macquarie, was a solicitor with Blake Dawson Waldron in Sydney.

Senator Carr's office said Mr McKeon was helmsman of the world's fastest sailboat, the Macquarie Innovation and chairman of Essendon Football Club's Hutchison Foundation.

He was an advisor for Melbourne's 2008 Homeless World Cup and patron of Melbourne's tender for the 2009 World Parliament of Religions, as well as a director of World Vision Australia and the Archbishop of Melbourne's Relief and Development Fund.

## BIO-MELBOURNE NETWORK

The Bio-Melbourne July 13 Bio-Breakfast will discuss the role of biotechnology in driving environmental technology.

The industry organization said the Environmental Biotechnology Cooperative Research Centre was one of few organisations researching and commercializing environmental biotechnology innovations.

The Cooperative Research Centre's intellectual property and commercialization manager Dr Brenton Hamdorf will discuss the biotechnology that he has commercialized and what he sees as the potential for biotechnology in green technology, the Bio-Melbourne Network said.

The Network said the Environmental Biotechnology Cooperative Research Centre set itself the challenge of generating at least seven novel technologies or innovations to be adopted by industry over the seven year life of the Centre.

The Network said that intellectual property group Griffith Hack's Janelle Borham would give an overview of the patent landscape in this clean technologies and emerging trends.

Bio-Melbourne Network chief executive officer Michelle Gallaher said environmental biotechnology was "fast becoming the new leading edge of the biotechnology sector".

"Governments around the world are offering increased funding for environmental research, particularly in areas in which a commercial outcome may be realized," Ms Gallaher said.

"Australia has a strong research base in biotechnology with an estimated 4.5 percent of Australia's biotech research being undertaken to address environmental applications, and this figure is increasing," Ms Gallaher said.

The Bio-Melbourne Bio-Breakfast will be held in The Supper Room at Melbourne Town Hall, Swanston Street, Melbourne on July 13, 2010.

Registration from 7:15am with the presentation from 8am.

For more information and to register go to: <http://www.biomelbourne.org/events/view/137>.

## BIOPROSPECT

Bioprospect says its share purchase plan raised \$422,180 through applications for 23,454,484 shares at 1.8 cents a share.

In April, Bioprospect said the maximum number of shares in the plan was “intended to be 150,000,000, raising \$3.3 million” (BD: Apr 30, 2010).

Bioprospect said the funds would be used for development and commercialization projects of Agripro products including GI-Guard Oral Paste which was a conifer green needle complex for gastro intestinal care in horses and a topical gel for wound treatment in horses.

Bioprospect has a deal with Solagran for the conifer green needle complex over-the-counter cure-all.

Bioprospect was unchanged at 1.7 cents with 1.4 million shares traded.