



# Biotech Daily

Tuesday October 27, 2009

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: ANTISENSE UP 25%; PHYLOGICA DOWN 12%**
- \* **AUSBIOTECH OPENS WITH EMPHASIS ON GOVERNMENT INVESTMENT**
- \* **BIONOMICS PHASE I ANTI-ANXIETY DRUG BNC210 SAFE, TOLERATED**
- \* **BIOTRON HAS ONE QUARTER CASH**
- \* **UNILIFE MARKETS READY-TO-FILL SYRINGES AS UNIFILL**
- \* **LIVING CELL RUSSIAN DIABETES TRIAL 'CONTINUES POSITIVE RESULTS'**
- \* **FEDERAL GOVERNMENT INQUIRY TO 'BOOST CLINICAL TRIALS'**
- \* **DR BRUCE GRAY DIVIDES SIRTEX AGM; NEW SINGAPORE PLANT**
- \* **ROCKEBY REQUESTS OPERATIONS, RESTRUCTURE TRADING HALT**

## MARKET REPORT

The Australian stock market fell 1.6 percent on Tuesday October 27, 2009 with the S&P ASX 200 down 76.8 points to 4753.5 points.

Eleven of the Biotech Daily Top 40 stocks were up, 13 fell, 12 traded unchanged and four were untraded.

Antisense was best, up 1.4 cents or 25 percent to seven cents with 2.7 million shares traded, followed by Genetic Technologies up 10 percent to 5.5 cents.

Cathrx climbed 8.3 percent; Nanosonics was up 5.15 percent; Circadian and Heartware were up more than two percent; with Bionomics, Living Cell, Phosphagenics and Resmed up more than one percent.

Phylogica led the falls, down 1.5 cents or 12 percent to 11 cents with 250,000 shares traded, followed by Cytopia down 9.1 percent to 10 cents.

Sunshine Heart lost eight percent; Viralytics lost 6.1 percent; Compumedics and Uscom were both down 5.41 percent; Acrux and Clinuvel fell more than four percent; Avexa, Chemgenex and Mesoblast shed more than two percent; with CSL down 1.9 percent.

## AUSBIOTECH

Victoria's Minister for Innovation Gavin Jennings says government investment in biotechnology and innovation creates a multiplier effect for gross domestic product. Opening the Life Sciences Investment Summit at Ausbiotech's 2009 Conference at the Melbourne Convention Centre, Mr Jennings told local and foreign investors that Deloitte's Impact Assessment of the Science Technology and Innovation Initiative showed "the Victorian Government's investment in science and technology has created thousands of jobs and will contribute to an economic benefit to Victoria of \$1.7 billion".

"We have invested extensively in this sector," Mr Jennings said. "We recognize that biotech is one of the critical industries we want to build."

"We have accumulated a critical mass and momentum that will be irresistible," he said.

"The Deloitte report shows that for every dollar of Victorian Government investment the contribution to our economy has been up to \$3.56," Mr Jennings said.

"That demonstrates the importance of our Government's sustained investment in science and technology projects and shows clearly we should continue this investment well into the future," he said.

A Victorian Government media release said that Deloitte's report analyzed the Government's \$620 million investment and projected the economic benefits from the Science Technology and Innovation (STI) program between 1999-2014 would be \$1.7 billion to gross state product; \$1.2 billion in additional funds and co-investments that would not have come to Victoria in the absence of the STI Initiative; \$815 million in private consumption; and 7610 one-year full-time jobs.

Mr Jennings said the Victorian Government's investment included contributions towards major infrastructure such as the Australian Synchrotron and the Bio 21 Institute.

Ausbiotech chief executive officer Dr Anna Lavelle said that the Investment Summit was supported by both the Victoria State Government and the Federal Government, principally through the Department of Trade (Austrade) as well as sponsorship from RBS Morgans (formerly ABN Amro Morgans) and the ASX.

Dr Lavelle said that companies should pay particular interest to the Federal Government's proposed research and development tax credit plan ensure they had input to the consultation process.

Dr Lavelle said that when planning the Summit and Conference, late last year there were concerns that the global financial crisis might dent the attendance numbers and viability of the Conference, but that has not been the case.

She said that there had been more than 3,000 requests for partnering meetings with the first day – tomorrow – already fully-booked. Dr Lavelle said there were 110 guest investors at the Summit, of which 32 were from overseas.

The Federal Parliamentary Secretary for Trade and Parliamentary Secretary to the Prime Minister Anthony Byrne said his government understands the importance of investment in life sciences.

Mr Byrne praised past Australian achievements in health and medicine from Howard Florey to MacFarlane Burnet and Prof Elizabeth Blackburn as well as CSL, Biota and Resmed. He said Australia had more than 400 core biotechnology companies of which more than half were linked to publicly funded research institutions.

Mr Byrne said the future of the industry was based in the creativity of people to invent, develop and commercialize ideas.

"We want to ensure good ideas don't go to waste. The Commonwealth Commercialization Institute will help fund ideas," Mr Byrne said.

The Conference will be formally opened with a reception at Government House tonight and continues until October 30, 2009.

## BIONOMICS

Bionomics says a phase I trial of its anti-anxiety drug BNC210 shows it is safe, well-tolerated and had “no clinically significant adverse events”.

Bionomics said it had completed the first stage of its phase I clinical trial of BNC210 in groups of healthy male volunteers at the Royal Adelaide Hospital’s Pain and Anaesthesia Research Clinic.

The company said the primary objectives of the trial to evaluate the safety, tolerability and the pharmacokinetics of BNC210 were all met.

Bionomics said that BNC210 in doses up to and including 1200mg was safe and well tolerated with no clinically significant adverse events reported.

The administered doses of BNC210 achieved blood levels consistent with the anxiolytic activity of BNC210 observed in preclinical models of anxiety.

Bionomics said that having met the key objectives of oral bioavailability and safety at dose levels that equate to preclinical activity, it would seek approval to progress to the next stage of the clinical trial in order to delineate the full spectrum of BNC210 safety through evaluation of higher dose levels.

The potential effects of BNC210 on mood and anxiety levels would also be assessed as a secondary objective in the healthy volunteers, the company said.

Bionomics said it expected to complete the trial by the end of 2009, pending approval.

Bionomics said anxiety was a common debilitating condition affecting 40 million adult patients in the US alone, with a global market value of up to \$US15 billion.

The University of Adelaide’s professor of clinical pharmacology and the trials’ principal investigator Prof Paul Rolan said the first clinical testing of BNC210 in man “has made important progress with the confirmation that the drug is orally bio-available, with drug levels being measured in blood that are consistent with levels which show suppression of the symptoms of anxiety in preclinical models”.

“To date it is remarkably well tolerated and it is intended that this will be tested further in the next stage of the trial,” Prof Rolan said.

“There have been no fundamentally new and effective treatments for anxiety for decades. Of the treatments we do have, many patients are burdened by side-effects,” Prof Rolan said.

Bionomics was up half a cent or 1.75 percent to 29 cents.

## BIOTRON

Biotron says its net operating cash burn for the three months to September 30, 2009 was \$435,000 with cash at the end of the quarter of \$516,000.

Biotron did not disclose any other available financing and no one was to discuss the matter at the time of publication.

Biotron was unchanged at 11 cents.

## UNILIFE MEDICAL SOLUTIONS

Unilife has begun filing of international trademarks for Unifill, which will become the market brand for its portfolio of ready-to-fill safety syringes.

Unilife said the product was previously referred to as the Unilife Ready-to-Fill Syringe or Unilife Prefilled Syringe and would be marketed as the Unifill syringe.

The company said it intended to market other products in its development pipeline and targeted for supply to pharmaceutical companies under the Unifill brand name.

Unilife fell three cents or 2.65 percent to \$1.10.

## LIVING CELL TECHNOLOGIES

Living Cell says its Russian phase I/IIa clinical trial has continued to show positive results with low and medium doses of its Diabecell pig islets of Langerhans for type 1 diabetes. Living Cell said the study “prompted improvements to the product and the implant procedure” which have been incorporated into its New Zealand phase II trial.

The company said eight insulin dependent diabetes patients had received between one and three implants of Diabecell without remarkable adverse events.

The company said that one patient remained insulin free after 100 weeks of follow-up and a second patient had a 26 percent reduction in insulin dose after 54 weeks of follow up.

The company said three patients had reductions of 15, 12 and 10 percent after 120, 88 and 82 weeks respectively.

One patient was non-compliant and declined follow-up, one patient had an eight percent increase in insulin dose after 36 weeks and the last patient had no change after 12 weeks.

Living Cell chief executive officer Dr Paul Tan said the first trial in Russia “has shown safety of repeated or top-up implants if required”.

“The preliminary data also showed that we have not reached the optimum dose regimen. The New Zealand trial involves higher initial doses in patients with more brittle diabetes and frequent hypoglycaemic episodes,” Dr Tan said.

Dr Tan said the data from Russia and New Zealand should define the right dose.

The Moscow trial began in 2007 and was intended to enroll up to 10 patients.

Living Cell was up half a cent or 1.56 percent to 32.5 cents.

## FEDERAL GOVERNMENT

The Australian Government says it will “boost Australia’s profile as a preferred destination for clinical trials”.

In a joint media release Innovation Minister Senator Kim Carr and Health Minister Nicola Roxon said an “action group [had been created] to cement the nation’s position as a good place for the conduct of clinical trials”.

“Phase I to IV trials are worth \$450 million each year to Australia,” Ms Roxon said.

“Global rationalization trends and emerging competition from low-cost centres threaten Australia’s long term competitiveness as a destination for pharmaceuticals clinical trials,” Ms Roxon said.

Senator Carr said that the action group would be asked to identify ways to ensure: coordinated, nationwide approaches to clinical trials and performance measures; streamlined ethics approvals systems; national patient referral networks; and better ways to approve, establish and conduct clinical trials.

“The flow-on investment from clinical trials is a significant contributor to Australia’s R&D effort,” Senator Carr said.

“As well as the health benefits for patients receiving early access to new medicines, pharmaceuticals companies are more likely to conduct later stage trials in Australia if early stage trials for that compound have already been conducted here,” Senator Carr said.

The action group will be co-chaired by the Parliamentary Secretary for Innovation and Industry, Richard Marles and the Parliamentary Secretary for Health, Mark Butler.

The media release said the group would report by March 31, 2010.

The group will include members of the Pharmaceuticals Industry Working Group and be supported by officials from the Innovation and Health departments.

The media release said the initiative responded to the calls from the Pharmaceuticals Industry Strategy Group convened by the Federal Government.

## SIRTEX MEDICAL

The Sirtex annual general meeting was again divided with founder and former chairman Dr Bruce Gray voting against two of four resolutions.

The company separately announced it would open a manufacturing facility in Singapore. Dr Gray and Sirtex have been involved in a protracted legal dispute involving the University of Western Australia (BD: Sep 8, Oct 7, 2009).

Sirtex's involvement in the legal dispute has been settled other than an outstanding matter of costs for part of the dispute.

Dr Gray has previously sought to have Sirtex chairman Richard Hill removed from the board and has used his substantial shareholding to oppose motions at previous meetings.(BD: Jul 7, 2009; Oct 24, 2006).

According to Sirtex's 2008 annual report Dr Gray held 17,332,283 shares or 31.08 percent of the company.

At today's meeting 18,615,062 votes (45.1%) opposed the remuneration report while 22,638,930 (54.9%) supported the adoption of the report.

Non-executive director Grant Boyce was elected with 23,999,730 votes (58.0%) in favor and 17,380,108 votes (42.0%) against.

The resignation and appointment of auditors was passed overwhelmingly.

Sirtex chief executive officer Gilman Wong said planning for the Singapore facility was underway and was expected to be operational within 18 months.

Sirtex said it had manufacturing facilities in the US and Australia for its SIR-Spheres microspheres for liver cancer.

"The new manufacturing facility will improve logistics as well as provide additional capacity to support growth around the world, especially in the fast growing Asia Pacific market," Mr Wong said.

"We have recently opened operations in South Korea and India and expect regulatory approval in Taiwan in the coming months," Mr Wong said.

"We are also at an early stage in our plans to enter the China market," he said.

Mr Wong told shareholders the company was in a strong financial position, with continuing good growth in product sales and new opportunities.

"With no debt and \$30.7 million in cash, Sirtex Medical is positioned to build on our strengths, opening new markets and creating product extensions," Mr Wong said.

Last week Sirtex said it would pay shareholders a fully franked dividend of two cents a share, plus a special dividend of five cents a share (BD: Oct 19, 2009).

Sirtex was unchanged at \$6.20.

## ROCKEY BIOMED

Rockeby has requested a trading halt pending an announcement in relation to the company's "operations and restructuring".

Trading will resume on October 29, 2009 or on an earlier announcement.

Rockeby last traded at 1.1 cents.