



Biotech Daily

Tuesday May 5, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP; TYRIAN UP 43%, AVEXA DOWN 15.5%**
- * **LIVING CELL: 'TWO OF SEVEN TYPE 1 DIABETES PATIENTS INSULIN-FREE'**
- * **US PATENT OFFICE WITHDRAWS BENITEC OBJECTIONS**
- * **BENITEC RIGHTS ISSUE RAISES \$1.1m**
- * **MEDICAL THERAPIES EGM PASSES SHARE ISSUES**
- * **STARPHARMA EXTENDS SHARE PLAN ONE WEEK**
- * **GIACONDA APPOINTS VINCENT SWEENEY COMPANY SECRETARY**
- * **BIO-MELBOURNE BREAKFASTS ON US PATENT REFORM**
- * **BONACCORSO FAMILY TAKES 12.5% OF KARMELSONIX**
- * **STIRLING REQUESTS 'SIGNIFICANT JOINT VENTURE' TRADING HALT**

MARKET REPORT

The Australian stock market climbed 0.19 percent on Tuesday May 5, 2009 with the S&P ASX 200 up 7.45 points to 3,890.4 points. Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, seven traded unchanged and seven were untraded.

Tyrian was best, up 0.9 cents or 42.86 percent to three cents with 77,600 shares traded, followed by Pharmaxis up 36 cents or 15.8 percent to \$2.64 with 2.5 million shares traded on last night's positive phase III cystic fibrosis results (BD: May 4, 2009).

Polartech climbed 8.7 percent; Clinuvel, Mesoblast and Universal Biosensors were up more than six percent; Alchemia and Optiscan improved more than four percent; Acrux, Bionomics, Cellestis, Living Cell, Psivida and Viralytics rose more than two percent; with Novogen up 1.12 percent.

Avexa led the falls, down 1.7 cents or 15.45 percent to 9.3 cents with 18.2 million shares traded, followed by Benitec down 13.3 percent to 2.6 cents and Cytopia down 11.1 percent to 12 cents.

Antisense lost 8.1 percent; Sunshine Heart fell 7.1 percent; Cochlear and Phosphagenics fell more than three percent; CSL, Heartware and Peplin shed more than two percent; with Biota down 1.7 percent and Resmed down 0.96 percent.

LIVING CELL TECHNOLOGIES

Living Cell's medical director Prof Bob Elliott says a second type 1 diabetes patient of the seven treated in its Russian phase I/II dose escalation trial is insulin free.

Prof Elliott told Biotech Daily he was preparing to deliver a plenary lecture on the company's encapsulated porcine islets of Langerhans cells, Diabecell, at the International Society for Cell Therapy meeting in San Diego overnight.

Prof Elliott said the company previously announced that a 37 year old female with a 15-year history of insulin dependent diabetes had become insulin free (BD: Apr 6, 2009).

The company said in an announcement to the ASX that a second patient, a 63 year old male with a five-year history of insulin dependent diabetes, was also insulin-free.

"Having two patients going off their insulin injections gives me tremendous confidence that we have a treatment which can return people with diabetes to a normal life," Prof Elliott said. "I am extremely pleased to see all blood glucose levels in their seven-point recordings to be in the normal range, even with a lower daily dose of insulin."

Living Cell said preliminary efficacy data showed normalized blood glucose levels and improved glycated haemoglobin (%HbA1c) levels with a reduction of daily insulin dose and two recipients had discontinued insulin injections.

Living Cell chief executive officer Dr Paul Tan said the dose escalation and the tightening of the quality specifications of Diabecell for the last two implants had "led to a very satisfying outcome with the recipients becoming insulin independent and we look forward to an equally positive outcome for future patients"

He expected Diabecell "to be established as a product of exceptional commercial value".

The safety and preliminary efficacy trial of Diabecell without immunosuppressive drugs intends to enroll 10 patients and is monitored by the US-based Geny Research Group.

The trial was designed for the first five patients to receive two implants of Diabecell at 5,000 islet equivalents per kg body weight (IEQ/kg) at least six months apart and for patients six to 10 to receive one implant of 10,000 IEQ/kg.

Living Cell said that based on clinical assessment, amendments were requested to optimize the treatment and patients Three, Four and Five received implants of 5,000 and 10,000 IEQ/kg, while patient Two received a third implant of 10,000 IEQ/kg.

Patients have been followed up from a minimum of 18 weeks to 96 weeks.

Patient Six failed to attend follow up after 20 weeks and attempts to follow-up continue.

There were no remarkable adverse events following implants of either dose. Repeat implants have been safe to date.

All patients show improved blood glucose control as reflected by a decrease in their glycated haemoglobin level after the implant, apart from patient six.

All blood glucose levels in the seven-point recordings at last follow-up were in the normal range for patients One, Two, Three, Four and Seven.

The mean glucose level in all patients is within the range of 5.8 to 8.2 mMol/L and at last follow up, Patient Six recorded a mean blood glucose of 9.4 mMol/L.

Patients Two and Seven have shown "an excellent response and do not require exogenously administered insulin". Patient Two's HbA1c level prior to implant was 8.2% and is currently 7.1%, her current mean blood glucose level is normal at 6.8 mMol/L.

Prior to implant Patient Seven required an average daily insulin dose of 37 units/day. This patient's HbA1c level prior to implant was 8.3% and is currently 4.8%, his current mean blood glucose level is normal at 6.6 mMol/L.

Capsules containing viable cells have been retrieved from second implants and porcine insulin has been detected in blood of patients following glucose tolerance test. The body weight of all patients during the study varied by less than 5% of their pre-implant weight.

Living Cell was up half a cent or 2.56 percent to 20 cents.

BENITEC

Benitec says the US Patent and Trademark Office has withdrawn its novelty objection to Benitec's RNAi interference US patent known as the "Graham" patent.

Benitec said the patent had been undergoing re-examination as outlined in previous announcements (BD: Apr 21, 2008; Mar 26, 2009).

The company said the only remaining objections of substance were two similar obviousness rejections based on a combination of a Carnegie Institute patent with other documents.

Benitec chief executive officer Sue MacLeman said the company was "pleased that the USPTO has finally withdrawn the novelty rejection which had been based on what was, in our view, quite a different technology".

Ms MacLeman said Benitec would expedite the appeal process.

Benitec said the next step was with its partner the Commonwealth Scientific and Industrial Research Organisation to take the re-examination to the Board of Patent Appeals to overturn the obviousness rejections, which was likely to take about 12 months with a decision unlikely until 2010.

Benitec fell 0.4 cents or 13.33 percent to 2.6 cents.

BENITEC

Benitec says its one-for-3.142 rights issue has raised \$1,086,187 through acceptances of entitlements and the shortfall with 35,539,554 new shares at three cents a share to be issued.

Benitec will also issue one free attaching option for every new share.

Benitec chief executive officer Sue MacLeman told Biotech Daily she hoped to raise a further \$2 million through the placement of the remaining 64,460,446 shortfall shares.

Ms MacLeman said that following today's announcement Benitec had more than \$2 million in cash for its RNA interference programs for HIV and hepatitis C.

MEDICAL THERAPIES

Medical Therapies' shareholders have overwhelmingly approved all extraordinary general meeting resolutions on its capital reorganization and raising.

Resolutions on issuing shares to convertible note holders and the issue of shares to raise \$3 million were passed by more than 47.8 million votes in favor with 459,500 votes or fewer against.

A resolution to approve the issue of securities to Cell Signal Inc was passed by more than 27.9 million votes to 370,000 votes.

Medical Therapies was up 0.3 cents or 15 percent to 2.3 cents.

STARPHARMA

Starpharma has extended the closing date of its share purchase plan at 26 cents a share (BD: Apr 7, 2009) from May 6 to May 13, 2009.

Starpharma said the extension was "in response to a number of requests from shareholders for replacement documentation" and was intended to ensure that these and all other eligible shareholders had the opportunity to participate in the share plan.

The revised record date is April 7, 2009 with a closing date of May 13, allotment on May 20 and trading of new shares on the ASX on May 21, 2009.

Starpharma was unchanged at 27 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says Jarmal Richard will discuss US patent law and reform and its impact on Australian companies at its May 12, 2009 Bio-Breakfast..

The Bio-Melbourne Network said patents were “a critical driver” of biotechnology business but could become a millstone around the neck of the industry in the wake of proposed US patent reform put to the Senate last month.

The Network said the chief executive officer of BIO Jim Greenwood was campaigning “to highlight the potential damage to the biotech industry if the proposed reforms get through”. The Network said that with more than a dozen major pharmaceutical patents due to expire in 2011, pharmaceutical giants were “rushing to fill diminishing pipelines with new candidates and acquire unique technologies to address the predicted major dip in profits and increase in generic competition”.

The Bio-Melbourne Network questioned how the proposed reform would affect the behavior and strategies of pharmaceutical and biotechnology companies.

The network said Mr Richard would discuss US patent litigation demographics and dynamics, likely commercial and legal implications of the proposed new US patent reform legislation, how US companies are reconfiguring their IP strategies to manage the current IP climate and what strategic issues and steps need to be taken over the next six to 12 months to best position interests in the US market.

The May 12, 2009 Bio-Breakfast will be held in the Supper Room, Melbourne Town Hall, Swanston St, Melbourne, with registration and breakfast from 7.15am and the presentation at 8am.

For further information go to www.biomelbourne.org; email npitcher@biomelbourne.org; or call Nicole Pitcher on +613 650 8800.

GIACONDA

Giaconda says Sydney Capital Partners’ partner Vincent Sweeney has been appointed company secretary.

Giaconda was untraded at 8.1 cents.

KARMELSONIX

Renlyn Bell Investments as the G&R Bonaccorso Family Trust has become a substantial shareholder in Karmelsonix, acquiring 56,766,666 shares (12.51%).

The holding was divided between Renlyn Bell and Salavante Pty Ltd (ATF GRB Superannuation Fund). No further information was provided.

Karmelsonix fell 0.2 cents or 3.92 percent to 4.9 cents.

STIRLING PRODUCTS

Stirling Products has requested a trading halt pending an announcement “in relation to a significant joint venture”.

Trading will resume on May 7, 2009 or on an earlier announcement.

Stirling last traded at 2.7 cents.