

Biotech Daily

Thursday April 3, 2014

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH UP: REVA UP 10%, LIVING CELL DOWN 9%

* CORRECTION: EDITORIAL

- * REVA AIMS FOR FIRST-IN-MAN FANTOM STENT TRIAL THIS YEAR
- * 3-MONTH SIRTEX DOSE SALES UP 18%, 39th CONSECUTIVE QUARTER
- * MAYO STUDY BACKS ATCOR SPHYGMOCOR FOR HEART FAILURE
- * REVA AGM FOR 75k DIRECTOR OPTIONS
- * SOLAGRAN APPOINTS LODGE FOR RESURRECTION

MARKET REPORT

The Australian stock market edged up 0.12 percent on Thursday April 3, 2014 with the S&P ASX 200 up 6.6 points to 5,409.9 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, 13 traded unchanged and three were untraded.

Reva was the best, up 1.5 cents or 10.3 percent to 16 cents with 376,571 shares traded.

Atcor climbed 8.7 percent; QRX was up 7.6 percent; Clinuvel rose six percent; Tissue Therapies was up 4.55 percent; Anteo, Neuren, Prana and Starpharma rose two percent or more; CSL, Osprey, Pharmaxis and Sirtex were up more than one percent; with Alchemia and Cochlear up by less than one percent.

Living Cell led the falls, down 0.7 cents or 9.09 percent to seven cents with 20,000 shares traded.

Universal Biosensors lost 7.7 percent; Antisense and Medical Developments fell more than six percent; IDT, Oncosil and Uscom were down more than three percent; Patrys shed 2.3 percent; Bionomic and Genetic Technologies were down more than one percent; with Benitec and Resmed down by less than one percent.

CORRECTION: BIOTECH DAILY EDITORIAL

In last night's Editorial a paragraph referred to BDI-20 companies that had major technology failures through non-significant phase II or III trial results and included Phosphagenics.

Phosphagenics has not had a drug failure in a clinical trial.

In an email, Phosphagenics said that the insulin program was dropped because "the enthusiasm of big pharma companies to find non-injectable delivery systems for insulin plummeted". Biotech Daily believes this is the first time this has been stated publicly. The mistake was made by the sub-editor and Biotech Daily apologizes unreservedly for any misunderstanding.

The sub-editor has donated his epidermis to medical research.

REVA MEDICAL

Reva chief executive officer Bob Stockman says he hopes to begin an up to 125-patient Conformité Européenne (CE) mark trial of the Fantom coronary stent by April 2015. Last week, Reva closed its Rezolve programs and laid-off 40 staff members working on those programs to focus on the smaller diameter Fantom bio-resorbable, x-ray-visible polymer scaffold (BD: Mar 27, 2014).

Today, in a telephone conference call Mr Stockman said that the change from Rezolve to Fantom was forced by "rapid shifts in the market" and the bio-resorbable scaffold needed to compete with metal stents, which were inherently stronger, but permanent.

Mr Stockman said that it was not prudent to spend investors money on a product that would not be competitive.

"The capital and time invested in rezolve has not been wasted," Mr Stockman said. Mr Stockman said that Reva had been working on the Fantom scaffold "for a long time" and later told Biotech Daily that the company began work in June and July 2013. "The Fantom began to show promise in October in laboratory bench and early animal testing," Mr Stockman said.

He said that the polymer was the same as in the Rezolve stents, but by changing the design from the slide and lock system and making the struts much smaller, the company was able to reduce the overall diameter, making the scaffold more competitive.

Mr Stockman said that the Fantom scaffold was being designed fro use both in the larger cardiac care market as well as peripheral arterial disease in legs.

Mr Stockman said the company had \$14 million in cash that would last it about 12 months but would need to raise a minimum of \$20 million.

Reva was up 1.5 cents or 10.3 percent to 16 cents.

SIRTEX MEDICAL

Sirtex says SIR-Spheres for liver cancer dose sales increased 18.2 per cent for the three months to March 31, 2014 compared to the previous corresponding period.

Sirtex did not provide the value of the increased sales but in its full year report for the 12 months to June 30, 2013 said that 7,299 total dose sales provided \$84 million in revenue or an average of \$11,508 per dose (BD: Aug 15, 2013).

Today, Sirtex said dose sales increased in all regions, compared to the same period last year, with Americas growth of 25.8 percent, Europe, Middle East and Africa up 3.6 percent and Asia Pacific up 8.6 percent.

Sirtex said it had reported 39 consecutive quarters of dose sales growth.

Sirtex was up 22 cents or 1.4 percent to \$16.15 with 240,603 shares traded.

ATCOR MEDICAL

Atcor says that a 50-patient, six month study has shown that its Sphygmocor system is useful for managing chronic heart failure.

Atcor said that the Mayo Clinic and University of Arizona Medical Center study examined the treatment of heart failure patients guided by central blood pressure waveform analysis, as measured by its Sphygmocor non-invasive measure of central aortic blood pressure and arterial stiffness.

The company said that patients who received medical therapy for heart failure which was guided by a central augmentation index, a measure of arterial stiffness and pressure afterload on the heart, were able to be treated more effectively with current standard medications, compared to when traditional methods using brachial cuff or upper arm blood pressure were applied.

The study, entitled 'A Randomized Pilot Study of Aortic Waveform Guided Therapy in Chronic Heart Failure' was published in the Journal of the American Heart Association and is available at: <u>http://jaha.ahajournals.org/content/3/2/e000745.full</u>.

"Maximization of goal-directed medical therapy in heart failure patients may enhance afterload reduction and lead to reverse remodeling, while additional medicine titration based upon aortic pressure data improves exercise capacity in patients with heart failure," the article concluded.

Atcor said that using the central augmentation index to guide therapy resulted in a clinically significant improvement in exercise capacity, that is, peak oxygen consumption, with no increased risk of hypotension or loss of kidney function.

The company said that the increase in exercise capacity was on par with the results of alternative heart failure treatments such as cardiac resynchronization therapy, by implanting a pacemaker.

Atcor said the study was first randomized controlled trial to manage therapy using central aortic pressures in heart failure patients.

The company said that adjustments to the patient's medication were made at monthly intervals.

Atcor said that the primary study endpoint was improved exercise capacity, demonstrating reduced risk and improved quality of life for heart failure patients.

The company quoted the authors conclusion that "aggressive afterload reduction guided by aortic pressure waveform assessment was associated with improved exercise capacity and greater utilization of established [heart failure] therapies, even in the setting of maximal guideline directed medical therapy".

"These beneficial effects were observed even among patients with excellent blood pressure control at study entry, suggesting that clinically relevant improvements in exercise capacity, arterial loading, and potentially ventricular remodeling can be achieved with more liberal use of vasoactive therapies in [heart failure]," Atcor quoted the authors. Atcor chief executive officer Duncan Ross said that heart failure was "a chronic, high cost condition that has the attention of payers, physicians and patients alike".

"This trial shows that physicians can manage patients with chronic heart failure more effectively using the central pressure waveform," Mr Ross said.

"The study also demonstrates the importance of measuring central aortic blood pressures, as measured by a fully featured waveform, to fully understand what is happening in the arterial system and at its intersection with the heart," Mr Ross said.

"Atcor's ultimate goal is to have these central pressure measurements more widely adopted in pre- hypertension and early-stage hypertensive patients, allowing earlier intervention and preventing advancement to this stage of disease," Mr Ross said. Atcor was up one cent or 8.7 percent to 12.5 cents.

REVA MEDICAL

Reva will vote to grant five directors 15,000 options each, elect two directors and approve the 10 percent placement capacity.

Reva said it proposed to grant 15,000 options each to directors Brian Dovety, Anne Keating, Gordon Nye, James Schiro and Robert Thomas, with an exercise price of the share price on the date of grant, vesting in four three-monthly installments within 10 years of the grant.

The company said that it would ask shareholders to approve named executive compensation as well as the amended 2010 equity incentive plan and issue and transfer securities under the plan.

Reva's notice of meeting said it would also seek shareholder approval to re-elect directors Mr Dovey and Ms Keating.

The meeting will be held at the AGL Theatre, Museum of Sydney, Cnr Phillip and Bridge Streets, Sydney, May 13, 2014 at 10.30am (AEST).

SOLAGRAN

Solagran says it has appointed the Melbourne-based Lodge Partners as its adviser and broker and plans to resume trading on the ASX at the earliest possible time.

Last year, Solagran appointed former Alchemia and Progen executive Dr Darren Schliebs as its chief executive officer, (BD: Nov 26, 2013).

Solagran describes itself as a "healthcare and wellness company" based in South Melbourne.

The company was developing a treatment for liver cancer, Alzheimer's disease and a raft of other indications based on its Siberian pine needle extract Ropren and 'Bioeffectives' (BD: Feb 25, 2009; Feb 5, 2010).

Despite claims of expected large contracts and the building of a manufacturing plant in Russia, Solagran was suspended by the ASX for failing to lodge accounts on two occasions (BD: Mar 1, 2011; Mar 9, 2012).

In February 2012, Solagran said it would form a joint venture with Russia's Art Life to develop and manufacture food additive products using its conifer needle extract 'Bioeffectives' and quoted Art Life founder and owner Prof Alexander Avstrievskih "forecasting revenues in the order of \$US100 million [\$A93.6 million] for 2012".

Despite Solagran personnel joining Bioprospect, an agreement between the two companies relating to the use of Bioeffectives was terminated with Bioprospect alleging it could source the same pine needle extract cheaper elsewhere and the two companies were involved in litigation (BD: Jun 28, Aug 5, Sep 20, Oct 27, 2010). Solagran remained suspended at 3.9 cents.