



Biotech Daily

Thursday March 3, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: NANOSONICS UP 7%, POLYNOVO DOWN 10%**
- * **BAXALTA: HAEMOPHILIA, IMMUNOLOGY, ONCOLOGY**
- * **64% OF BIONOMICS EGM STOPS SABBY, CVI, EMPERY BVF WARRANTS**
- * **FDA APPROVES ATCOR, SUNTECH 'OSCAR2 WITH SPHYGMOCOR INSIDE'**
- * **ANTEO TAKES UP TO \$9m BERGEN DRAW-DOWN EQUITY FACILITY**
- * **CYNATA, REGIENCE STEM CELL LOI TO PRELIMINARY AGREEMENT**
- * **MMJ PHYTOTECH EXTENDS MEDICAL CANNABIS GELPELL LICENCE**
- * **GRAHAM DURBIN SUPERANNUATION TAKES 10.6% OF GENERA**
- * **SUNSHINE HEART CHAIRMAN JOHN ERB APPOINTED CEO**

MARKET REPORT

The Australian stock market climbed 1.19 percent on Thursday March 3, 2016 with the ASX200 up 59.9 points to 5,081.1 points. Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, 10 traded unchanged and five were untraded.

Nanosonics was the best, up 12.5 cents or 6.6 percent to \$2.03 with 1.1 million shares traded.

Anteo and Ellex climbed more than five percent; Osprey rose 4.2 percent; Atcor was up 3.2 percent; Orthocell, Prima, Pro Medicus, Starpharma and Tissue Therapies were up more than two percent; Admedus and Pharmaxis were up than one percent; with Acrux and Resmed up by less than one percent.

Polynovo led the falls, down three cents or 10.3 percent to 26 cents with two million shares traded.

Mesoblast and Oncosil lost more than six percent; Cellmid fell five percent; Viralytics shed 4.4 percent; Sirtex was down three percent; Biotron, Compumedics, IDT, Impedimed and Medical Developments lost more than one percent; with Clinuvel, Cochlear and CSL down by less than one percent.

BAXALTA AUSTRALIA NEW ZEALAND

The Australia New Zealand division of Baxter spin-out Baxalta says it has a 20-product pipeline for haemophilia and other indications expected to be registered by 2020.

Speaking to a media teleconference, Baxalta's Australia New Zealand country head Heath Merlo said that the \$38 billion Baxalta was "a small company [and] a new business" focussed on rare and under-served diseases with an unmet medical need.

The Bannockburn, Illinois-based Baxalta was spun out of Baxter Bioscience last year and Mr Merlo said that Baxter retained a 19.5 percent share of the company, which was independent, while sharing some facilities and premises.

Mr Merlo said that Baxter had a presence in Australia going back many decades and Baxalta was focussed on the three key areas of haemophilia, immunology and oncology. Mr Merlo said that Baxalta had created a patient-focused model putting the patient at the centre of decision making.

"If we come to a fork in the road, we ask 'what is best for the patient?'" Mr Merlo said.

Mr Merlo said that along with existing drugs on the market such as Advate for haemophilia A, Rixubis for haemophilia B and Feiba for haemophilia inhibitor therapy, the company had a pipeline of drugs in development including BAX855 for twice weekly infusion and BX826 for once weekly or once fortnightly infusion.

Mr Merlo said that along with the immunology drugs Kiovig and Ceprotin, the company was developing drugs for pancreatic cancer, metastatic colorectal cancer, acute myeloid leukaemia and gastric cancer.

He said that there had been major advances in the treatment of haemophilia in the past 30 years but there were still about 60 percent of patients who continued to have bleeds, as well as a very low rate of diagnosis and treatment in developing countries.

Baxalta Australia New Zealand medical affairs director Dr Sabina Furber said that haemophilia A, lacking factor VIII, affected one in 5,000 males, haemophilia B, the absence of factor IX, affected one in 30,000 males, with the degree of the genetic bleeding disorder graded from mild to moderate and severe.

Dr Furber said that although there were 5,385 patients on the Australian Bleeding Disorders Registry in 2013-'14, only 1,487 patients received treatment and most were treated at specialist centres that provided "comprehensive care".

Baxalta's Chicago-based head of medical affairs for haematology Dr Len Valentino said 400,000 people globally had haemophilia, of which 80 to 85 percent had haemophilia A, and 15 to 20 percent of them would develop antibodies or inhibitors to factor VIII therapy. Dr Valentino said that about five percent of people in the developing world, including China, India, Latin America and South East Asia, were diagnosed or had access to therapies, with a significant number of people not receiving regular access to treatments and being seen on an "on-demand" basis.

Dr Valentino said that people were bleeding unnecessarily and Baxalta's aim was "a journey towards a bleed-free world", initially with the development of treatments and preventions, as well as developing new technologies including gene therapies, to reverse the disease.

Dr Valentino said that along with pegylated and fusion modified coagulation factors to provide longer duration, Baxalta was working on sub-cutaneous delivery to replace intravenous infusions and investigating gene therapies for a potential cure.

Mr Merlo said that without reimbursement an average course of treatment would cost \$60,000 to \$80,000 a year per patient in Australia and much more in the US.

He said the company had \$US6 billion in revenue in the year to December 31, 2015.

Last night on the New York Stock Exchange, Baxalta (BXLT) was up 47 US cents or 1.19 percent to \$US39.90 (\$A54.62) with 7,757,728 shares traded.

BIONOMICS

Bionomics general meeting has voted 188.4 million votes (64.1%) against resolutions to approve 16,082,988 warrants to four investment groups, with 105.3 million votes in favor. Bionomics proposed issuing warrants over 4,020,747 shares to each of the four groups, CVI Investments, Empery Asset Master, Sabby Healthcare and Biotechnology Value Fund, exercisable at 59.38 cents a share within five years of issue. Bionomics was unchanged at 31 cents.

ATCOR MEDICAL

Atcor says the US Food and Drug Administration has cleared the Oscar 2 with Sphygmocor for ambulatory blood pressure monitoring.

Atcor said that the 'Oscar 2 with Sphygmocor inside' was jointly developed with the Morrisville, North Carolina-based Suntech Medical and also measured central arterial pressure waveforms.

Last year, Atcor said that the device was granted Conformité Européenne (CE) mark for use in the European Union (BD: May 4, 2015).

Today, Atcor chief executive officer Duncan Ross said the clearance "allowed both Atcor and Suntech to actively sell Oscar 2 with Sphygmocor inside in the largest medical device market in the world".

"Our product combines industry leading patented technologies to enable physicians, researchers, and pharmaceutical companies to record and assess important information from a patient's central arterial pressure waveform and arterial stiffness indices over 24 hours," Mr Ross said.

Atcor said the device was jointly marketed with Suntech in the European Union and selected Asian countries and Atcor was marketing the product exclusively in Australia and New Zealand, with the global ambulatory blood pressure market 45,000 units a year. Atcor was up half a cent or 3.2 percent to 16 cents.

ANTEO DIAGNOSTICS

Anteo says it has an up-to \$US6.5 million (\$A8,891,000) Bergen Global Opportunity Fund draw-down equity facility.

Anteo said that the New York based Fund managed by Bergen Asset Management would make an initial investment of \$US1.5 million and \$US500,000 in 120 days, each by way of an interest-free unsecured convertible security with a 24-month maturity, and Bergen could invest up to a further \$US4.5 million over the next 24 months by mutual consent.

Anteo said that the investment would contribute to its funding for the earn out component of the acquisition of Diasource Immunoassays and working capital.

In December, Anteo said it had a EUR10 million (\$A15.2 million) convertible note from an unnamed Canadian investment house to buy Diasource (BD: Dec 18, 2015).

Today, Anteo said that the working capital would principally be used for research and development activities in diagnostics, energy and medical devices.

The company said it retained the right to agree to further investments, with no obligation to draw the facility beyond the first two tranches, and the right to terminate the agreement.

Anteo said that Bergen had agreed to certain limitations on exiting its investment.

Bergen chief investment officer Eugene Tablis said Bergen's "best investments have been made in companies in transition and we have had great experiences with Australian healthcare and biotech investments".

Anteo was up 0.3 cents or 5.2 percent to 6.1 cents with 4.7 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has a preliminary agreement, for a strategic alliance with the Tokyo, Japan-based Regience KK for Japan and certain other Asian countries.

In December, Cynata said it has a letter-of-intent for a stem cell development and commercialization alliance with Regience and the two companies had identified “a mutually beneficial business opportunity” to enter a partnership in which Regience would licence, develop and commercialise its Cymerus mesenchymal stem cell technology (BD: Dec 3, 2015).

Today, Cynata said that the agreement provided 60-days for Regience to make an initial investment of \$250,000 for new Cynata shares, based on a 25 percent premium to the 10-day volume weighted average price and subject to a 12-month escrow.

The company said the parties would co-operate to develop and commercialize the Cymerus mesenchymal stem cells technology in the relevant territory.

Cynata said that if Regience proceeded it would invest an additional \$2,250,000 in Cynata shares on the same basis, providing Regience with an exclusive two-year option to the Cymerus technology for Japan and certain other Asian countries.

The company said that Regience would be entitled to exercise the option in respect of multiple therapeutic areas, but each exercise of the option in respect of a specific therapeutic area would be accompanied by a separate exercise fee up-front fees, milestones and future royalties on product sales to be negotiated.

Cynata said that given “the broad therapeutic indications currently foreseen the ... relationship could result in revenues to Cynata of several hundred million dollars”.

Regience chief executive officer Masanori Murayama said that “by combining Regience’s expertise in regenerative medicine and connections with big pharma in Japan, we aim to bring the Cymerus technology into therapeutic use in Japan and other Asian markets,” Mr Murayama said.

Cynata was up three cents or eight percent to 40.5 cents.

MMJ PHYTOTECH

MMJ Phytotech says has an exclusive licence with the Gähwil, Switzerland-based Gelpell AG to develop and sell medicinal cannabis using Gelpell’s technology.

MMJ said the agreement, through Swiss subsidiary Satipharm AG, was “the result of higher than expected safety and performance results in the phase I clinical trial carried out on two doses of Gelpell [cannabidiol] oral capsules” (BD: Feb 11, 16, 2016).

The company said that the licence was an extension to an existing agreement with Gelpell to market and sell its oral cannabidiol (CBD) capsules throughout Europe.

MMJ said it would develop and sell medical cannabis prescription drugs using the Gelpell technology and own all the intellectual property and rights in relation to the licenced products, while Gelpell would be granted exclusive manufacturing rights.

MMJ managing-director Andreas Gedeon said the agreement was “another milestone in what has been a strong start to 2016 for the company”.

The company said that Gelpell made natural gelatin pellets under 2mm that bound and protected the CBD compound and did not contain filling and or any emulsifiers which helped to avoid irritation of gastric mucosa and achieved a constant gastrointestinal transit time, with maximized surface to volume ratio contributing to bioavailability.

MMJ said that the pellets are packed in hard gastro-resistant capsules or can be mixed directly with food like yogurt for children and elderly people.

MMJ fell half a cent or 1.75 percent to 28 cents with 1.6 million shares traded.

GENERA BIOSYSTEMS

The Hunters Hill, Sydney-based Durbin Superannuation has increased its holding in Genera from 9,250,000 shares (9.44%) to 10,541,283 shares (10.58%).

The notice, signed by director Graham Durbin, did not disclose the cost of the shares. Last year, a substantial shareholder notice from Mr Durbin also increased his holding without disclosing the cost of the shares (BD: Mar 3, 2015).

Genera was up half a cent or 1.85 percent to 27.5 cents.

SUNSHINE HEART

Sunshine Heart says it has appointed interim chief executive officer John Erb as its permanent chief executive officer and executive chairman.

In December, Sunshine Heart said that chief executive officer David Rosa had resigned with chairman John Erb appointed interim chief executive officer during the search for a permanent successor (BD: Dec 1, 2015).

Sunshine Heart said that Mr Erb had been a director since September 2012 and chairman since October 2012 and was currently the chief executive officer of cardiac medical device company Nuax Inc and from 2001 to 2006 he was the chief executive officer of congestive heart failure company CHF Solutions.

Last night on the Nasdaq, Sunshine Heart was up five US cents or 6.49 percent to 82 US cents (\$A1.12, equivalent to 0.56 cents prior to its departure from the ASX, when it was trading at 2.5 cents) with 140,803 shares traded (BD: Apr 29, 2013).