



Biotech Daily

Tuesday April 12, 2016

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PHARMAXIS UP 8%, ATCOR DOWN 8%**
- * **BIOTA STARTS PHASE IIa BTA585 RSV TRIAL**
- * **USCOM POSTS \$1m RECORD Q3 TOTAL REVENUE**
- * **NUSEP SELLS GELLS TO DYCENT SHANGHAI FOR \$170k**
- * **CANADA 2nd PATENT FOR SUDA ANTI-EMETIC SUD-002**
- * **JCP TAKES 9% OF NANOSONICS**
- * **CHARLES GOODE COMPANIES TAKE 100-268% PROFIT ON COGSTATE**
- * **PULITANO FAMILY TAKES 6% OF BLUECHIIP**
- * **MMJ TO RELEASE 17.5m VOLUNTARY ESCROW SHARES**
- * **DR ROBERT GILMOUR REPLACES NUSEP DIRECTOR MARK GELL**
- * **IMUGENE APPOINTS DR YELENA JANJIGIAN ADVISOR**

MARKET REPORT

The Australian stock market was up 0.89 percent on Tuesday April 12, 2016 with the ASX200 up 44.1 points to 4,975.6 points. Twelve of the Biotech Daily Top 40 companies were up, 15 fell, 12 traded unchanged and one was untraded. All three Big Caps fell.

Pharmaxis was the best, up two cents or 8.2 percent to 26.5 cents with 317,680 shares traded. Biotron climbed 6.45 percent; Antisense, Opthea, Osprey and Prana were up five percent or more; Nanosonics was up 3.15 percent; Compumedics and Impedimed rose more than two percent; Acrux was up 1.65 percent; with Clinuvel and Viralytics up by less than one percent.

Atcor led the falls, down 1.5 cents or 8.3 percent to 16.5 cents with 116,243 shares traded, followed by Medical Developments down eight percent to \$5.17 with 179,095 shares traded. Orthocell lost 7.3 percent; Living Cell fell 5.2 percent; Cellmid, Genetic Technologies, Starpharma and Uscom fell four percent or more; Oncosil was down 3.3 percent; Airxpanders, Mesoblast, Neuren and Pro Medicus shed two percent or more; Sirtex was down 1.3 percent; with Cochlear, CSL, Resmed and Reva down by less than one percent.

BIOTA PHARMACEUTICALS

Biota says it has begun its phase IIa challenge study of oral BTA585 for the treatment and prevention of respiratory syncytial virus infections.

BTA585 was invented in Biota's then Melbourne facility and has US Food and Drug Administration fast track designation.

In February, Biota said its 66-patient, phase I, multiple ascending dose trial of oral BTA585 for respiratory syncytial virus (RSV) showed it was generally well tolerated at all dose levels and the safety and pharmacokinetic study found no serious adverse events and no drug-related clinically-significant adverse changes in electro-cardiogram or clinical laboratory values (BD: Feb 29, 2016).

Today, the company said that the double-blind, placebo-controlled, phase IIa trial was designed to evaluate the safety, pharmacokinetics and antiviral activity of orally-dosed BTA585 in healthy volunteers challenged intra-nasally with RSV.

Biota said that following a positive test for RSV or five days after challenge, about 60 healthy adults would be randomized to receive either BTA585 or placebo, dosed twice daily for seven days and monitored for 28 days.

The company said that the primary endpoint was the "area under the curve" for the viral load in nasal wash among subjects who test positive for RSV prior to dosing.

Biota said that secondary efficacy endpoints included measures of RSV clinical symptoms and other viral load endpoints such as peak viral load and time to cessation of virus detection, as well as assessment of pharmacokinetic levels in both plasma and nasal wash.

Biota chief executive officer Dr Joseph Patti said that the phase IIa efficacy study was "just seven months after initiating our first-in-man phase I study with BTA585".

"The rapid progress of the program has been encouraging and reinforces our commitment to developing a safe and efficacious treatment for the millions of children that suffer annually from serious RSV infections," Dr Patti said.

"We expect data readout from this challenge study later this year, which will help inform our plans for a phase IIb natural exposure trial," Dr Patti said.

Biota said that respiratory syncytial virus was a major cause of acute upper and lower respiratory tract infections, including colds, pneumonia and bronchiolitis, in infants, young children and adults and each year in the US, it accounted for an estimated 2.1 million medical visits in children under the age of five, with many of the children afflicted requiring hospitalization.

The company said that there was no effective vaccine to prevent respiratory syncytial virus or recommended therapies to treat infections.

On the Nasdaq last night, Biota rose six US cents or 3.92 percent to \$US1.59 (\$A2.08 equivalent to 26.0 cents before departing the ASX) with 10,566 shares traded.

USCOM

Uscom says \$638,059 record Uscom 1A sales along with a \$366,831 Federal Tax Incentive has delivered \$1 million revenue for the three months to March 31, 2016.

Uscom executive chairman Prof Robert Phillips told Biotech Daily that the sales all referred to the Uscom 1A ultra-sonic cardiac output monitor, with sales revenue yet to be declared for the company's BP+ blood pressure assets.

Prof Phillips said that it was the company's best three months of sales on record.

The company said it had a net operating cash burn for the three months to March 31, 2016 of \$55,135, with cash of \$1,006,651.

Uscom fell one cent or 4.8 percent to 20 cents.

NUSEP HOLDINGS

Nusep says it has sold its US subsidiary Nusep Inc and its gels business to Dycent Biotech (Shanghai) Co for \$US130,000 (\$A170,305).

Nusep said that the sale included the manufacturing plant and all patents relating to the business and Dycent had placed a substantial order with Nusep to manufacture gels to provide sufficient stocks for the business during the transfer of the plant to Shanghai.

Nusep said that the manufacturing plant would be moved to Shanghai where Dycent will continue to manufacture Nuview gels.

The company said that the sale of the gels business allowed it to focus on developing its in-house assets with high intellectual property value, in particular its Spermsep technology for sperm processing for use in assisted reproductive technologies.

Nusep fell 0.1 cents or 7.7 percent to 1.2 cents.

SUDA

Suda says the Canadian Intellectual Property Office has issued a patent covering its novel oral spray of ondansetron or SUD-002.

Suda said that patent was entitled, 'Stable Anti-nausea Oral Spray Formulations and Methods', covered the composition of SUD-002 and method of use and had an expiry date of December 21, 2027.

The company said it was the second patent issued in Canada for SUD-002 oral spray to treat nausea and vomiting induced by chemotherapy, radiotherapy and in post-operative settings and was part of the intellectual property portfolio acquired from Novadel in 2013.

Suda said that the patent had been granted or was pending in other major jurisdictions.

The company said that clinical studies demonstrated that the SUD-002 spray was statistically bioequivalent to the commercially available ondansetron tablet, was well tolerated and could be conveniently administered in multiple doses.

Suda said that SUD-002 delivered statistically faster absorption compared to the tablet as defined by median time to detectable drug levels of ondansetron.

The company said it was conducting further stability studies with the formulation and was preparing for a meeting with the US Food and Drug Administration to discuss the program.

Suda chief executive officer Stephen Carter said the company was "pleased to report the issuance of this second Canadian patent for SUD-002".

"It is part of our intellectual property strategy to protect our investment in first-in-class oromucosal sprays and strengthens our efforts to secure licensing partners for this novel anti-emetic formulation," Mr Carter said.

Suda was up 0.1 cents or 4.55 percent to 2.3 cents with three million shares traded.

NANOSONICS

JCP Investment Partners says it has increased its substantial shareholding in Nanosonics from 23,775,753 shares (8.38%) to 26,655,463 shares (9.40%).

The Melbourne-based JCP said that its shares were held by National Nominees, HSBC Custody Nominees, BNP Paribas Nominees and JP Morgan Nominees.

The substantial shareholder notice said that shares were bought and sold between March 11 and April 8, 2016 with the single largest purchase 500,000 shares for \$1,042,002 or \$2.08 per share.

Nanosonics climbed seven cents or 3.15 percent to \$2.29 with 1.3 million shares traded.

COGSTATE

Two companies chaired by former ANZ Bank and Woodside chairman Charles Goode have reduced below five percent in Cogstate taking up to 268.4 percent profit.

In 2013, the companies, Ravenscourt and Beta Gamma (Walsh Street Super Fund) of Victoria Street, St Kilda, Victoria became substantial with 4,466,222 shares (5.83%) acquired at prices ranging from 19 cents to 35 cents a share (BD: Mar 5, 2013).

Today, the notice said the companies bought shares between March 31, 2013 and August 5, 2014 and on April 7, 2016 sold 1,355,705 shares for \$948,994 or 70 cents a share. Cogstate fell 1.5 cents or 2.2 percent to 66.5 cents.

BLUECHIIP

The Pulitano Family has become a substantial shareholder in Bluechiip with 11,484,292 shares or 5.93 percent of the company.

The substantial shareholder notice signed by the Melbourne-based Giuseppe Pulitano said that the shares were held by Giuseppe and Verona Pulitano, Pulitano Family Superannuation Pty Ltd and 3rd Pulitano Pty Ltd, with 5,739,233 shares acquired between March 30 and April 5, 2016 for \$143,539 or 2.5 cents a share.

In February and March, Bluechiip raised \$365,000 through a share purchase plan at 2.85 cents a share, and in December its placement raised \$450,000 at four cents, taking the total to \$815,000 (BD: Dec 17, 2015; Feb 25, Mar 8, 2016).

Bluechiip was unchanged at 2.7 cents.

MMJ PHYTOTECH

MMJ says that 17,510,000 shares will be released from voluntary escrow on April 27, 2016.

MMJ said that the shares were the second of three tranches of shares issued in relation to the 2015 Phytotech merger with MMJ Bioscience (BD: Jul 28, 2015)

The company said that the third and final tranche of 17,510,000 merger shares would remain in voluntary escrow until October 27, 2016.

MMJ company secretary Eryln Dale told Biotech Daily that the voluntary escrow shares were part of the 138,092,815 shares quoted on the ASX with a further 23,833,332 shares not quoted on the ASX and held in ASX escrow until January 21, 2017.

MMJ fell half a cent or two percent to 25 cents.

NUSEP HOLDINGS

Nusep says Dr Robert Gilmour has replaced Mark Gell as a non-executive director, effective from today.

Nusep said that Mr Gell had been a director since October 17, 2014 and the board acknowledged "the significant contribution Mr Gell has made to the company and thank him for his service ... in particular ... for his contribution in strategy, issues management, commercial development, governance and risk management".

Nusep said that Dr Gilmour had founded a number of medical device and diagnostic companies and had an industry-specific network in the US and Australia.

The company said that Dr Gilmour was a member of its scientific advisory board.

Nusep said that the board comprised executive chairman Alison Coutts, Andrew Goodall and Dr Gilmour and was working to identify and recruit additional directors.

IMUGENE

Imugene says that the New York-based Sloan Kettering Cancer Center's Dr Yelena Janjigian has joined its scientific advisory board.

Imugene said that Dr Janjigian held certifications for internal medicine and medical oncology from the New York University of Medicine and was a medical oncologist specializing in the treatment of malignancies of the gastrointestinal tract, including oesophageal and gastric cancer.

The company said Dr Janjigian had run clinical and translational studies "designed to develop a better prevention, early diagnosis, staging, and treatment strategies and has been principal investigator on a number of clinical trials conducted at ... Sloan-Kettering".

Imugene said that its scientific advisory board comprised Dr Janjigian, the Medical University of Vienna's Prof Christoph Zielinski and Prof Ursula Wiedermann and Sloan-Kettering oncologist Dr Neil Segal.

Imugene was unchanged at one cent.