Biotech Daily

Monday March 19, 2012

Daily news on ASX-listed biotechnology companies

VALE DR ANDREW BAKER 1961 – 2012

*** ASX, BIOTECH UP: REVA UP 17%, PRIMA DOWN 6%**

*** DR ANDREW BAKER**

*** FDA ALLOWS 54 MORE HEARTWARE BRIDGE-TO-TRANSPLANT PATIENTS**

*** USCOM UNVEILS NEW OXYGEN MONITOR; ADDS CHINA AGENTS**

*** CALZADA, POLYNOVO WOUND TREATMENT TRIAL UNDERWAY**

*** QRX, ACTAVIS SEAL DEAL, AWAIT JUNE FDA PDUFA DATE**

*** ELLIOTT TAKES ABOUT 14% OF REVA**

*** SINGAPORE PATENT FOR ALLIED, CELXCEL ADAPT PROCESS**

*** BIONICHE TAKES $19m 15% CAPITAL ROYALTY LOAN**

*** NUSEP LOSES DIRECTOR WILLIAM SPEE**

MARKET REPORT

The Australian stock market climbed 0.34 percent on Monday March 19, 2012, with the S&P ASX 200 up 14.6 points to 4290.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, nine fell, 13 traded unchanged and five were untraded.

Reva was the best, up 9.5 cents or 16.7 percent to 66.5 cents, with 6.1 million shares traded.

Ellex climbed 7.9 percent on an investor presentation; Biota was up 5.9 percent; Allied and Prana were both up 3.3 percent; Acrux, Mesoblast, Phosphagenics and Psivida rose more than two percent; Anteo, Cochlear, CSL and Genetic Technologies were up more than one percent; with Clinuvel, Resmed and Starpharma up by less than one percent.

Prima led the falls, down 1.5 cents or 6.25 percent to 22.5 cents with 6.1 million shares traded.

Phylogica fell 4.1 percent; Nanosonics lost 3.7 percent; Impedimed, Patrys, Sirtex and Tissue Therapies shed two percent or more; Compumedics was down 1.25 percent; with Universal Biosensors down 0.7 percent.

DR ANDREW BAKER BSc PhD (March 23, 1961 – March 18, 2012)

GBS partner and chairman of Spinifex Pharmaceuticals, Dr Andrew Baker, died yesterday from cancer.

GBS Venture Partners said that Dr Baker joined the company in 2002 and had previously worked in research and management roles with industry leaders Genentech, Bayer and Johnson & Johnson.

GBS co-founder and managing partner Dr Brigitte Smith told Biotech Daily that Dr Baker was “an understated man, with a wicked sense of humor, which we all enjoyed immensely”.

“He had an incredible breadth of knowledge across many fields of science,” Dr Smith said.

“As an investor, Andrew managed to bring everyone around to his way of thinking without conflict, through the quality of his thinking and his calm but deliberate style,” Dr Smith said.

“Andrew dealt with his illness with incredible bravery and good grace. He was still working at GBS and with the companies of which he was a director just a week before he died.

“We will all miss him terribly,” Dr Smith said.

GBS said that Dr Baker was a director of GBS portfolio companies Hatchtech, Verva, and Xenome, as well as Spinifex.

“Andrew was very proud to have been involved in founding some of those companies listed,” Dr Smith said. “As most of them will report phase II data in the next 12 months, it's very tough that he won't be with us to see what happens.”

Friend and colleague at GBS, Dr Joshua Funder, said that “Andrew combined a passion for improving patient outcomes with deep scientific insight and sound business judgment”.

“His legacy includes essential roles in bringing multiple new medical therapies to human clinical trials and developing products which have the potential to treat major global diseases such as cancer, neuropathic pain, acute pain, diabetes and headlice.

“Andrew was a leading light in Australian biotechnology, helping bring together the best science, management, finance and clinical development to develop new medicines and therapeutic devices.

“He was a cherished friend and colleague who will be sadly missed,” Dr Funder said.

Dr Baker earned his Bachelor of Science in genetics at the University of Sydney and a Doctorate of Philosophy from the Australian National University and had several published articles on DNA enzymes, catalytic nucleic acids and catalytic molecules.

Dr Baker is survived by his wife Nancy Hancock, and their children Claire and Sam.

Biotech Daily is deeply saddened by the loss of a colleague, so long before his time.

HEARTWARE INTERNATIONAL

Heartware says the US Food and Drug Administration has approved a fourth group of 54 patients, in its bridge-to-transplant clinical trial under a continued access protocol and was an investigational device exemption supplement

The company said the FDA had granted three prior allotments of 54 patients each in April and September 2010 and 94 patients in January 2011 (BD: Jan 25, 2011).

Heartware said the ‘Advance’ bridge-to-transplant trial was evaluating its ventricular assist device (HVAD) for patients with end-stage heart failure and 140 patients at 30 US clinical sites had received the pumps, making it the largest bridge-to-transplant pivotal trial.

Heartware said it submitted a pre-market approval application for the HVAD system for the bridge-to-transplant indication in December 2010 (BD: Jan 16, 2011) and an FDA Circulatory System Devices Panel would review the application on April 25, 2012.

Heartware was untraded at $1.84.

USCOM

Uscom has unveiled it oxygen cardiac output monitor (Oxycom) to measure oxygen delivery adding to its ultra-sonic cardiac output monitor (Uscom).

Uscom executive chairman Rob Phillips told Biotech Daily that the company had discussed the Oxycom technology several years ago but the company had focused on the roll-out of the Uscom system.

Mr Phillips said that there had been an increased interest in non-invasive methods of assessing cardiac oxygen output.

Mr Phillips said that invasive central catheters were used to measure cardiac oxygen output in sepsis and “any area where heart failure is a concern or when cardiac output drops”.

“Oxycom is non-invasive and about as sensitive as any other existing non-invasive pulse oximetry,” Mr Phillips said.

“But what is different is that Oxycom is combined with our very accurate ultra-sonic cardiac output monitor,” Mr Phillips said.

“Being a highly accurate non-invasive measure of oxygen delivery, Oxycom is the method of choice for management of sepsis in adults in children and has already been adopted in several US intensive care units in major public teaching hospitals,” Mr Phillips said.

Uscom said that Pacific Medical was the Asia Pacific distributor for both Uscom and Oxycom and had doubled the number of sub-distributors in China to 14 companies.

Uscom said that the expansion had been driven by the appointment of Herbert Cheng to the staff of Pacific Medical as head of business development in China.

The company said that Mr Cheng was tasked to review the Chinese distribution as well as recruit new distributors.

Uscom said it had representation in 14 of the 23 provinces of China, with a further six provinces being evaluated for possible distributor signings.

The company said that Pacific Medical was responsible for 50 percent of all worldwide Uscom user sales in 2011 and the increase in distribution in China was expected to increase sales over the next 12 months.

“I have just returned from three weeks with Pacific Medical Systems in China and we are aggressively expanding on this wave of increased spending as the quality of Chinese health care continues to improve with the adoption of sophisticated practice leading technology such as Uscom,” Mr Phillips said.

Uscom was untraded at 8.5 cents.

CALZADA

Calzada says wholly-owned subsidiary, Polynovo Biomaterials has recruited four of 20 patients in its pressure sores vacuum-assisted closure clinical trial (BD: Feb 6, 2012).

Calzada said that the trial was “the first human clinical trial involving Novosorb”.

The company said that four patients had been recruited and three were undertaking vacuum-assisted closure treatment.

Calzada said it expected recruitment to progress at the rate of one patient a week until the target enrolment of 20 patients was reached in July 2012.

The company said the maximum period of treatment was eight weeks, with 10 patients treated with Novosorb foam dressings and 10 patients treated with the current market leading product, Granufoam.

Calzada was up 0.9 cents or 17.0 percent to 6.2 cents.

QRX PHARMA

QRX says it has finalized the licence and option agreement with Actavis Inc to commercialize Moxduo immediate release (IR) in the US (BD: Jan 22, 2012).
QRX said the final agreement followed the December 20, 2011 signing of a binding letter of intent secured by a $US6 million non-refundable upfront fee to QRX.
QRX chief executive officer Dr John Holaday said the company was “focusing our ongoing energies towards supporting Actavis as we approach our PDUFA date and prepare for the anticipated launch of our first product, Moxduo IR, in the third quarter”.
The company’s Prescription Drug User Fee Act (PDUFA) meeting is scheduled for June 25, 2012, when the US Food and Drug Administration will complete its review of the company’s new drug application.
QRX was unchanged at $1.83.

REVA MEDICAL

Reva says that Elliott Management has agreements to buy $US24 million $A22.64 million) of Reva’s Australian and US shares from existing shareholders.
Reva said the Australian Chess depositary instruments were bought at 50 cents each, equal to $5.00 per common share, in privately transactions arranged by M M Dillon & Co.
The company said the transaction was expected to close by March 23, 2012.
In its most recent Appendix 3B ASX filing, Reva said there were 330,862,030 CDIs, assuming all shares of common stock were held as CDIs, implying that with about 45.3 million CDIs and equivalents, Elliott will hold about 13.7 percent of Reva.
Reva did not provide specific numbers of shares and CDIs to be acquired.
Reva said it did not issue or sell any additional CDIs or shares and the transaction did not change the number of shares quoted on the ASX.
The company said that Elliott Management was a New York investment fund with assets under management of about $US19.2 billion, with current shareholders including Medtronic and each purchaser independently participated in the transaction.
Reva said there were no sales of CDIs or shares by members of its management or board of directors.
Reva was up 9.5 cents or 16.7 percent to 66.5 cents with 6.1 million shares traded.

ALLIED HEALTHCARE GROUP

Allied Health says its tissue engineering and regenerative medicine division Celxcel has been granted a patent in Singapore for its Adapt tissue engineering process.
Allied said that the Singaporean patent for the Adapt tissue engineering process (TEP) process added to the existing granted patents in Australia, New Zealand and China.
The company said the technology was protected by patent filings globally, including the US, Europe, Japan, Israel and Canada.
Allied Health’s managing director Lee Rodne said the patent “continues to grow the overall family of patents in key markets for the Adapt-TEP platform technology”.
Celxcel chief executive officer Bob Atwill said that his division had “a robust patent position around our current platform technology and we continue to pursue filings to cover our future portfolio of products”.
Allied said that the Adapt process was a platform used across a number of tissue types for cardiovascular, pelvic floor reconstructions and hernia repair applications and was being evaluated for use in orthopaedics and as a scaffold to grow and deliver stem cells.
Allied was up 0.1 cents or 3.3 percent to 3.1 cents with 462,425 shares traded.

BIONICHE LIFE SCIENCES

Bioniche says it has “accepted an offer “of $US20 million ($A18.9 million) in financing from investment funds managed by US-based Capital Royalty.

Bioniche said that Capital Royalty had agreed to provide a five-year loan to facilitate corporate growth and support its capital requirements.

The company said the terms include a 15 percent interest rate, with a portion deferred and capitalized for the first three years of the term of the loan.

Bioniche said that an additional royalty interest of two percent would be paid to Capital Royalty on all product sales revenues for the term of the loan, with principal repayments of eight equal installments beginning in June, 2015.

Bioniche said that the transaction was expected to close on or around April 5, 2012.

Bioniche chairman Graeme McRae said that Capital Royalty had “expressed its confidence in the company through this strategic investment”.

“Through the due diligence process, Capital Royalty has demonstrated an excellent understanding of our business and commercialization program,” Mr McRae said.

“It is particularly gratifying to be able to receive such an investment with no dilution of our equity shareholders,” Mr McRae said.

Bioniche was untraded at 62 cents.

NUSEP

Nusep says that following the appointment of Andrew Goodall as a director on March 14, 2012, William Spee has resigned today from the board.

Nusep said that Mr Spee had been “a strong supporter of the company since joining the board in September 2009 as both a board member and a significant shareholder”.

The company said the board changes related to the expected establishment of its Singapore plasma fractionation facility.

Nusep was unchanged at 3.1 cents.