Biotech Daily

Monday September 17, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH FLAT: OPTISCAN UP 11%, ALLIED HEALTH DOWN 12%**

*** BIONOMICS BUYS CANCER STEM CELLS ECLIPSE FOR $8-10m SCRIP**

*** REVA HOPES TO RIDE ABBOTT POLYMER STENT 'BOW WAVE'**

*** AUSTRALIAN ETHICAL TAKES 14% IN AVITA**

*** DISSENT AT NABI COULD AFFECT BIOTA MERGER**

*** REGENEUS ESTABLISHES PATIENT DATABASE**

MARKET REPORT

The Australian stock market was up 0.28 percent on Monday September 17, 2012 with the S&P ASX 200 up 12.5 points to 4,402.5 points.

Ten of the Biotech Daily Top 40 stocks were up, 11 fell, 12 traded unchanged and seven were untraded. All three Big Caps fell.

Optiscan was the best, up one cent or 11.1 percent to 10 cents with 29,800 shares traded, followed by Prima up 9.4 percent to 17.5 cents with 13.0 million shares traded.

Anteo climbed 6.7 percent; Prana was up 5.1 percent; Genetic Technologies and Sirtex were up more than four percent; Tissue Therapies rose 2.4 percent; Mesoblast and Nanosonics were up more than one percent; with Biota up 0.7 percent.

Allied Health led the falls, down 0.3 cents or 12.0 percent to 2.2 cents with 2.6 million shares traded.

Cellmid and Viralytics lost more than six percent; Universal Biosensors fell 4.1 percent; Alchemia and Phylogica were down more than three percent; CSL, Resmed and Sunshine Heart shed more than two percent; with Clinuvel, Cochlear, Pharmaxis, QRX and Starpharma down one percent or more.

BIONOMICS

Bionomics says it has acquired Eclipse Therapeutics for $US10 million ($A9.5 million) in scrip to develop drug candidates targeting cancer stem cells.

Bionomics said the payment would be about 23.9 million shares at 41.76 cents a share, to the San Diego, California-based Eclipse, with Eclipse shareholders including parent company Biogen Idec, owning about 6.5 percent of Bionomics' issued capital.

At Friday's closing price of 32 cents the acquisition is worth about $7,648,000.

Bionomics chief executive officer Dr Deborah Rathjen told a teleconference that the 41.76 cent figure was the six month volume weighted average price to June 30, 2012.

In a media release, Bionomics said that Eclipse was a Biogen Idec spin-off developing drug candidates targeting cancer stem cells and described cancer stem cells as "the seeds at the root of cancer" viewed by many oncologists and pharmaceutical companies as a high priority, new oncology drug frontier.

[In previous announcements, the Brisbane-based Alchemia has highlighted the impact of its Hyact technology on cancer stem cells (BD: Apr 21, 2010, Sep 28, 2011).]

Bionomics said that Eclipse's lead compound ET101 was aimed at an undisclosed cancer stem cells target which was over-expressed on most solid tumors and was expected to move into human trials in 2014.

The company said that in March 2012 Eclipse reached a development and manufacturing agreement for production of the ET101 antibody with the Swiss-based Lonza Group and that oncology antibody drugs had global sales of more than $US20 billion dollars in 2011.

In a media release Dr Rathjen said the acquisition "elevates and expands Bionomics' oncology pipeline beyond BNC105, our primary cancer drug candidate which is now at advanced clinical stages".

"It also establishes Bionomics as a global leader at the forefront of cancer stem cell therapeutics," Dr Rathjen said. "The Eclipse acquisition will provide Bionomics with an important strategic base in the US, the world's largest pharmaceutical market."

Bionomics said that since 2004, significant resources had been invested in Eclipse's cancer stem cell (CSC) drug program and the Eclipse's CSC Rx Discovery platform has been used to identify antibody therapeutics that inhibit the growth of cancer stem cells.

The company said that scientific and clinical research supported the concept that cancer stem cells were responsible for tumor initiation and recurrence and tended to be resistant to chemotherapy and other conventional forms of cancer treatment.

Bionomics said that Eclipse was founded by former Biogen Idec employees Dr Peter Chu and Dr Christopher Reyes along with Dr Jonathan Lim.

The company said that Dr Lim had been appointed a non-executive director, with Dr Chu and Dr Reyes appointed vice president us operations and cancer biology and vice president research and development biologics respectively for Bionomics.

Bionomics said that Eclipse shareholders could qualify for cash earn-outs based on achieving development success or partnering outcomes based on Eclipse assets.

The company said that Eclipse had a strong intellectual property position in cancer stem cells and acquired Biogen Idec's patent applications covering the isolation of cancer stem cells for drug discovery and continued to expand its portfolio of related patent applications.

Dr Rathjen told a teleconference that the acquisition provided an expanded team, a deeper pipeline, and placed the company at "the new frontier" in cancer treatment as well as a US presence, giving the company access to US Government grants.

Dr Rathjen said the company expected to spend $4 million on ET101 and another drug candidate ET102 in the coming 12 months.

Bionomics was unchanged at 32 cents with 176,765 shares traded.

REVA MEDICAL

Reva chief executive officer Bob Stockman says major stent competitor Abbott Laboratories' 'bow wave' effect will have a positive impact on his company.

Mr Stockman told an investor briefing in Melbourne that after 14 years and $200 million, Reva expected Conformité Européenne (CE) mark approval in mid-2014 with data from the 125-patient pivotal European trial satisfactory to gain a US Food and Drug Administration investigational new device pre-market approval for a pivotal US trial of 2,000 patients.

Mr Stockman said that Abbott had developed a bioresorbable stent and asked what the difference was between Abbott's and Reva's said: "Our stent doesn't break and can be seen."

Mr Stockman said that his company developed the slide and lock system and acquired the desaminotyrosine polycarbonate polymer material from Rutgers University in New Jersey.

He said the Reva bioresorbable stent was protected by about 280 patents.

Mr Stockman said the Abbott Absorb stent was expected to be launched in Europe by the end of 2012 and had demonstrated good data.

But he said the difference with his company's stent was that it could be more easily opened inside the artery using a balloon, than the Abbott stent and that iodine could be bonded to the Reva scaffold, allowing cardiac surgeons to see where the stent was in the vessel.

Reva's head of clinical and regulatory affairs Jeff Anderson said that the key time frame for seeing any problems in cardiac stenting was six months after insert and so far of the 26 patients in the Resolve trial most patients had passed four months and the longest implant had exceeded eight months, with no major adverse cardiac events reported.

Mr Stockman said that originally he and Mr Anderson came to Australia to meet doctors to set clinical trial structures for the 125-patient Australia, New Zealand, Europe and Brazil trial, but had decided to take the opportunity to meet investors and analysts.

"We have enough cash so we don't need to raise funds now," Mr Stockman said.

"We would like to get the retail community on board," he said.

Mr Stockman said the company proposed to distribute the Resolve2 stent in Europe beginning with a targeted roll-out to key opinion leaders, but said Reva had a long standing distribution option with Boston Scientific in which it would receive 50 percent royalties if exercised.

Mr Stockman said that Johnson & Johnson had invented the original metal stent and had appeared to have exited the market, but he believed Johnson & Johnson was waiting on the sidelines and expected the major company to return to the stent market.

He said that Abbott was the only significant competitor to the Resolve2 stent with other stents in development.

Several investors asked Mr Stockman if he expected Reva to be acquired by a major device company but he declined to respond.

Reva was untraded at 55 cents.

AVITA MEDICAL

Australian Ethical Smaller Companies Trust has increased its share-holding in Avita from 30,815,558 shares (12.94%) to 38,309,339 shares (14.20%).

Australian Ethical said that it bought and sold shares between April 18 and May 22, 2012 at a range of prices and acquired 7,659,082 placement shares for $919,090 or 12 cents a share.

Avita was unchanged at 12.5 cents.

BIOTA

Mangrove Partners Fund LP says it is “one of the largest stockholders of Nabi Biopharmaceuticals” and claims support for its dissent against the acquisition by Biota.

Posting an announcement on Nabi’s Nasdaq site, Mangrove said that both Institutional Shareholder Services and Glass Lewis & Co recommended that stockholders support it and vote against the proposed merger Nabi with Biota (BD: Apr 23, 2012).

Mangrove said that both proxy advisory firms supported its view that the proposed transaction did not deliver adequate value to Nabi stockholders and advised stockholders to vote against all six proposals in connection with the transaction at the special meeting of stockholders scheduled to be held on September 24, 2012 (US EST).

Mangrove quoted Institutional Shareholder Services saying that “Even with relatively conservative estimates, the acquisition by Biota is not clearly preferable to a liquidation scenario”.

Mangrove said that a liquidation would not only deliver equal or greater value than the proposed transaction, but will also retain all of the potential value of Nabi's remaining assets, notably the rights to Nixvax, Phoslyra royalties and the value of the public shell listing.

Mangrove said the transaction failed to deliver a takeover premium and “the consideration received from Biota represents a 15.7 percent discount for shareholders”.

Mangrove said that Biota was expected to increase the cash burn and quoted chief executive officer Peter Cook saying the company would increase research and development on early stage programs.

On August 23, 2102, Nabi told the Nasdaq and stockholder that a previous letter from Mangrove was “contrary to the facts”.

Nabi said that Mangrove owned about 3.4 percent of Nabi and “as an arbitrage hedge fund, has invested in Nabi as a liquidation play and … the transaction doesn't fit their investment thesis”.

Nabi said Mangrove “vastly overstate their case” and gave as an example the claim that the deal “fails to return to Nabi's stockholders the underlying value of the company's assets, a value that we believe to be as much as $US2.40 per share in cash”.

Nabi said that its cash assets at June 30, 2012 were valued at about $US2.40 a share “it would be inaccurate to suggest that the liquidation value of Nabi is currently $2.40 per share”.

Nabi said that if it was liquidated, a portion of its cash would be used to satisfy its current and future liabilities as well as to cover operating expenses from June 30 through the completion of a liquidation process, so stockholders would not receive a distribution of as much as $2.40 a share in a liquidation.

Nabi quoted Mangrove saying “Stockholders can receive a minimum of $US1.87 per share through an orderly liquidation” and rebutted that “it cannot be demonstrated with any certainty whether Nabi's stockholders would eventually receive a minimum of $US1.87 per share of Nabi common stock in the event of an orderly liquidation”.

“It is important to note in this context that Mangrove has sold 2.74 million of its shares of Nabi common stock in Nabi's issuer tender offer that was completed on July 30, 2012, after Mangrove tendered its entire position for sale at $US1.68 per share,” Nabi said.

Biota will hold a shareholders scheme of arrangement meeting at the Melbourne Convention Centre on September 25, 2012 (BD: Aug 9, 2012).

Biota was up half a cent or 0.7 percent to 72 cents.

REGENEUS

Regeneus says it has commissioned Adelaide's International Musculoskeletal Research Institute to implement a patient registry for its Hiqcell fat stem cell therapy.

Regeneus said that to determine the long-term safety and efficacy of the Hiqcell treatment, the registry would monitor clinical and functional outcomes of patients who had the therapy for the treatment of osteoarthritis-affected joints.

The company said that the ethics approved patient registry would collect anonymous and confidential patient information over a long period of time for clinical research.

Regeneus clinical development director Dr Richard Lilischkis said the database would be "a powerful and ongoing tool for us to build a high quality evidence base for our in-clinic autologous adipose-derived cell therapy, Hiqcell".

"Independent and senior clinical oversight and input to the development and implementation of the Hiqcell patient registry through access to clinicians associated with the International Musculoskeletal Research Institute will be invaluable," Dr Lilischkis said.

Regeneus said that Institute director and orthopaedic surgeon Prof Jegan Krishnan would oversee the patient registry.

Regeneus said that the Hiqcell treatment involved harvesting a small amount of a patient's own adipose or fat tissue, separating the regenerative cells and preparing them in under an hour for re-injection in osteoarthritic-affected joints such as knees, hips and ankles of that patient.

The company said that the extracted regenerative cells included mesenchymal stem cells and adipocytes, which work together to reduce inflammation and also promote regeneration and repair of tissue.

Regeneus is a public unlisted company.