Biotech Daily

Wednesday April 17, 2013

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: BENITEC, OSPREY, UNIVERSAL UP 8%, IMPEDIMED DOWN 25%**

*** BIOTA CUTS 30% STAFF, CLOSES PROGRAMS, MOVES OFFICE**

*** CALZADA, POLYNOVO TRIAL: NOVOSORB 'BEATS GOLD STANDARD'**

*** NANOSONICS SIGNS TOSHIBA TO DISTRIBUTE TROPHON EPR IN UK**

*** CONSOLIDATED CONSEGNA RETURNS TO CGP CODE**

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*** SUNSHINE HEART PLACEMENT RAISES $13.5m**

*** CDPP v JM GOES TO CANBERRA HIGH COURT FULL BENCH**

*** GENETIC TECHNOLOGIES PLEADS SCHULTZ, OLD NEWS TO ASX**

*** BAILLIE GIFFORD TAKES 12.7% OF COCHLEAR**

*** MESOBLAST APPOINTS PROF ERIC ROSE DIRECTOR**

MARKET REPORT

The Australian stock market climbed 1.09 percent on Wednesday April 17, 2013 with the S&P ASX 200 up 53.8 points to 5,004.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and five were untraded.

Benitec, Osprey and Universal Biosensors all climbed 7.69 percent to 1.4 cents, 42 cents and 70 cents, respectively, with 8.8 million shares, 20,533 shares and 67,877 shares traded, respectively. Pharmaxis was up 5.3 percent; GI Dynamics and Starpharma were up more than four percent; Allied Health, Cellmid, Clinuvel and Viralytics were up more than three percent; CSL rose two percent; with Nanosonics and Prima up more than one percent.

Impedimed led the falls, down two cents or 25 percent to six cents, with 215,837 shares traded. Tissue Therapies lost 6.7 percent; Phylogica fell five percent; Avita fell 4.8 percent; Prana and Sirtex shed more than two percent; with Acrux, Anteo, Bionomics, Compumedics, Heartware and Genetic Technologies down more than one percent.

BIOTA PHARMACEUTICALS

Biota says it will cut 30 percent of its staff, shift focus from early-stage research to clinical-stage development and relocate headquarters to Atlanta, Georgia.

When Biota first announced the merger with Nabi, executives stressed the importance of Nabi's Rockville, Maryland office as being close to the US Food and Drug Administration offices in Washington DC (BD: Apr 23, 2012).

Today Biota said that it expected to complete the relocation to Atlanta in May, 2013.

Biota said that key components of the strategy included, but were not limited to:

continuing to develop of laninamivir octanoate for influenza A and B infections under the Office of Biomedical Advanced Research and Development Authority (BARDA) contract;

reducing the existing preclinical programs by focusing preclinical activities on developing an oral antiviral for respiratory syncytial virus and an oral and intravenous antibiotic targeting gyrase and topoisomerase IV (GyrB/ParE) with activity against gram-negative and multi-drug resistant bacterial pathogens;

concluding preclinical work on hepatitis C non-nucleoside polymerase inhibitors and antibiotics for gram-positive bacterial infections, and pursue out-licencing of the programs;

completing the evaluation of clinical and regulatory pathways for vapendavir to determine whether to continue its late-stage clinical development for the reduction of exacerbations caused by human rhinovirus in asthma or chronic obstructive pulmonary disease patients;

pursuing in-licencing, acquisition, co-development, and other similar collaborative clinical-stage development opportunities; and

reducing costs to deploy resources to clinical-stage development programs.

Biota chief executive officer Russell Plumb said the steps were "to establish a strong financial and operational foundation from which to leverage our [influenza] franchise and balance our development pipeline with more differentiated, clinical-stage development programs".

"This strategy is designed to streamline our portfolio of preclinical programs, conserve capital, and focus our operations on advancing or securing development programs that we believe can best drive shareholder value over the next several years," Mr Plumb said.

Mr Plumb was appointed chief executive officer of the merged entity last year and despite the company having about 10,000 Australian shareholders has not yet met with retail investors (BD: Nov 15, 2012).

Biota said that the workforce reduction by 30 percent would be "implemented immediately", reducing the number of its employees and contractors "over the next several quarters".

The company said that the reduction would be concentrated on research and development functions dedicated to drug discovery, but other areas of the organization, including general and administrative positions, would be affected.

The company said it expected to record a charge of about $US2.0 million in the three months to June 30 2013 related to termination benefits, with an annual reduction in salaries and benefits of about $3.8 million on an ongoing basis, reducing the base burn from operations substantially.

Biota said it expected to have cash, cash equivalents and short-term investments of about $US62-$US67 million at June 30, 2014.

The company said it expected to begin its phase II trial of laninamivir octanoate in the Southern Hemisphere by July 2013 and based on the results of toxicological studies, it did not intend to advance BTA-C286, its lead respiratory syncytial virus (RSV) fusion inhibitor, into development, but it expected to continue preclinical development of several back-up RSV fusion inhibitors in 2014.

On the Nasdaq last night Biota fell one US cent or 0.2 percent to $US4.18.

CALZADA, POLYNOVO BIOMATERIALS

Calzada says the first Polynovo Novosorb clinical trial has shown its wound product outperformed 'the gold standard' dressing, Granufoam.

Calzada said that the prospective, randomized, controlled study of Novosorb foam as a wound dressing for topical negative pressure for chronic and complex pressure sores enrolled 18 patients with 20 pressure sores were treated.

The company said that 10 pressure sores were treated with Novosorb foam and 10 were treated with Granufoam.

Calzada said that the Novosorb dressings met the primary outcome of the study demonstrating the safety of the foam and its efficacy as a topical negative pressure interface.

The company said that Novosorb topical negative pressure foam demonstrated advantages over Granufoam including reduced dressing fragmentation; reduced risk of infection; reduced trauma on dressing removal, such as difficulty and bleeding; and reduced undesirable dressing retention in the wound.

Calzada said that the findings were "significant as they demonstrate that the Novosorb foam dressings have the potential to address serious concerns raised by the [US Food and Drug Administration] in relation to complications arising from currently used [topical negative pressure] dressings", including infection resulting from foam fragments remaining in the wound and bleeding on dressing removal.

The company said that those attributes were "major commercial arguments favoring the use of Novosorb dressings over the current treatment alternatives".

Calzada said that the topical negative pressure dressings market was estimated at $400 million a year.

The company said that Polynovo intended to file for 510(k) regulatory clearance in the US by October 2013 with the objective of authorization by April 2014.

Calzada was up 1.2 cents or 21.8 percent to 6.7 cents with two million shares traded.

NANOSONICS

Nanosonics says it has signed Toshiba Medical Systems as a non-exclusive distributor of its Trophon EPR ultrasound probe cleaning system in the UK.

Nanosonics chief executive officer Dr Ron Weinberger said Toshiba would launch the ultrasound probe disinfection technology in April 2013 and the company would continue to sell directly into the UK market.

Toshiba general manager Mark Hitcham said that Trophon EPR was "complementary to the Toshiba range of ultrasound machines … [and would play] an important role in reducing infection control risk across the healthcare system".

"This strategic engagement with Toshiba will give Trophon EPR greater exposure within this market and facilitate adoption of Trophon EPR as the standard-of-care in probe decontamination," Dr Weinberger said.

Nanosonics was up half a cent or 1.1 percent to 46.5 cents.

CONSEGNA GROUP

Consegna says it will return to trading under the ASX code of CGP from tomorrow, April 18, 2013.

Consegna said that following the one-to-five consolidation there were 286,209,511 shares on issue.

Consegna was untraded at 3.4 cents.

AMPLIPHI BIOSCIENCES

Ampliphi says it will collaborate with Intrexon Corp “to create new generation of bacteriophage-based therapeutics for antibiotic resistant infections”.

Last year, Ampliphi acquired Sydney’s Special Phage Services to develop phage-based therapies for antibiotic-resistant infection (BD: Sep 10, 2012).

The Richmond, Virginia-based Ampliphi said at that time that the resultant wholly-owned subsidiary Ampliphi Australia Pty Ltd would have a management team led by Ampliphi’s Phil Young as chief executive officer, with Octa Phillips director Jeremy Curnock-Cook as chairman and have operations in the US, UK and Australia.

Today, an Ampliphi spokesperson told Biotech Daily that the Sydney team would work with the Blacksburg, Virginia-based Intrexon, a synthetic biology company that uses proprietary technologies to provide control over cellular function.

In a media release Ampliphi and Intrexon said the collaboration would develop new bacteriophage-based therapies to target specific antibiotic resistant infections.

Ampliphi said that the collaboration sought to develop bacteriophage-containing human therapeutics for use in the treatment of bacterial infections associated with acute and chronic wounds, the treatment of acute and chronic Pseudomonas aeruginosa lung infections, and the treatment of infections of Clostridium difficile.

Ampliphi said it would receive an exclusive licence to Intrexon’s technology and expertise toward the standardized production of wild type phages, as well as for the design and production of genetically modified bacteriophages.

The company said that Intrexon would apply its technologies, including the Ultravector platform, DNA and RNA engineering, protein engineering, inducible gene systems, genome engineering, and cell systems engineering, to Ampliphi’s bacteriophage programs.

STARPHARMA

Starpharma says the US Patent and Trademark Office has granted three patents and China has allowed one patent strengthening and expanding its drug delivery platform.

Starpharma said the composition of matter patents protected its dendrimer technologies for drug delivery to 2029 in the US.

The company said that China’s patent office had allowed a similarly broad, drug delivery-related patent which would be granted following an administrative process and provided protection in China until 2027.

Starpharma chief executive officer Dr Jackie Fairley said the patents added to Starpharma’s “considerable dendrimer intellectual property portfolio and expands the company’s patents on drug delivery-related applications”.

“They provide a firm footing for the commercialization of our drug delivery technology, via our internal programs and work with partners including some of the largest global pharmaceutical companies,” Dr Fairley said.

Starpharma was up 4.5 cents or 4.2 percent to $1.12.

SUNSHINE HEART

Sunshine Heart says its placement at $US5.25 a common share has raised about $US14.0 million ($A13.5 million).

Sunshine Heart said the underwritten public offering of 2,875,000 shares closed with the full over-allotment of 375,000 shares also placed.

Sunshine Heart was up 0.1 cents or 4.2 percent to 2.5 cents.

COMMONWEALTH DIRECTOR OF PUBLIC PROSECUTIONS v JM

The appeal to the High Court of Australian in the matter of the Commonwealth Director of Public Prosecutions versus JM is listed to be heard in Canberra on May 7 and 8, 2013.
The High Court Business Registry list said that the case, described as M73/2012, was an appeal from the Supreme Court of Victoria (Court of Appeal).
An officer of the Commonwealth Director of Public Prosecutions previously told Biotech Daily that the matter related to "the meaning of an artificial price" in relation to Section 1041A of the Corporations Act (BD: Dec 14, 2012).

GENETIC TECHNOLOGIES

Genetic Technologies has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price climbed from 7.3 cents on April 15, to 8.8 cents, a 20.55 percent increase, on April 16, 2013, and noted an increase in trading volumes.
Genetic Technologies told the ASX that it had published a media release on April 15, detailing a Brevagen study presented at a conference in March 2013 (BD: Apr 16, 2013).
Genetic Technologies fell 0.1 cents or 1.1 percent to 8.7 cents.

COCHLEAR

The Edinburgh-based Baillie Gifford & Co and associates have increased their substantial holding in Cochlear from 6,652,068 shares (11.66%) to 7,240,484 (12.69%).
Baillie Gifford traded shares between November 19, 2012 and April 10, 2013, with the two largest acquisitions 67,434 shares for GBP3,247,222 or $A74.18 a share on November 21, 2012 and 28,686 shares for GBP1,237,678 or $A63.35 a share on April 8, 2013.
Baillie Gifford became substantial in Cochlear in 2011 and has continued acquiring shares (BD: Aug 19, Oct 25, 2011; Feb 3, Oct 3, 31, Nov 20, 2012).
Cochlear fell 19 cents or 0.3 percent to $59.81 with 607,996 shares traded.

MESOBLAST

Mesoblast says it has appointed Prof Eric Rose as a director "a world leader in cardiovascular medicine".
Mesoblast said Prof Rose was the chairman and chief executive officer of Siga Technologies and Life sciences executive vice-president MacAndrews & Forbes.
The company said that from 2008 to 2012 Prof Rose was the chairman of the Mount Sinai School of Medicine's Department of Health Evidence and Policy.
Mesoblast said that from 1994 to 2007, Prof Rose was the chairman of the Department of Surgery at Columbia Presbyterian Center of New York Presbyterian Hospital and from 1982 to 1992, led its heart transplantation program.
The company said Prof Rose pioneered heart transplantation in children in 1984 and had investigated alternatives to heart transplantation, including xeno-transplantation and heart pumps and was the chairman of Circulite, a developer of left ventricular assist devices.
The company said that Prof Rose had authored or co-authored more than 300 scientific publications and received more than $25 million in National Institutes of Health grants.
Mesoblast was unchanged at $5.66.