Biotech Daily

Wednesday July 17, 2013

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: LIVING CELL UP 20%, ATCOR DOWN 8%**

*** BIOTA BEGINS PHASE II 'FLU TRIAL, BOARD CHANGES, PRICE FALLS**

*** GENERA PLACEMENT, NOTES RAISE $500k, TRIALS AND TRIBULATIONS**

*** CALZADA, POLYNOVO US NOVOSORB TRIAL FOR HERNIA REPAIR**

*** SKOLKOVO TAKES BONE BNC006 FOR RHEUMATOID ARTHRITIS**

*** BENITEC AGM VOTES FOR PLACEMENT, 25-TO-1 CONSOLIDATION**

*** STARPHARMA HIRES DR TONY EGLEZOS FOR BUSINESS DEVELOMENT**

*** SOPHIE KARZIS REPLACES MEDIVAC CO SEC MALCOLM LUCAS-SMITH**

*** YING MING CHIU TAKES 5% OF NUSEP**

MARKET REPORT

The Australian stock market slipped 0.1 percent on Wednesday July 17, 2013 with the S&P ASX 200 down 4.3 points to 4,981.7 points.

Ten of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and seven were untraded.

Living Cell was the best, up 0.9 cents or 19.6 percent to 5.5 cents with 50,343 shares traded, followed by Reva up 15.5 percent to 59.5 cents with 120,678 shares traded and Impedimed up 10 percent to 11 cents with 32,000 shares traded.

Prima climbed 8.3 percent; Ellex was up four percent; Acrux, Bionomics and Neuren rose more than two percent; Clinuvel and Sirtex were up more than one percent; with Resmed up 0.2 percent.

Atcor led the falls, down 0.6 cents or 7.6 percent to 7.3 cents with 181,667 shares traded, followed by Tissue Therapies down 7.4 percent to 12.5 cents with 223,065 shares traded.

Anteo and Cellmid lost more than six percent; Allied Health, Antisense, Phylogica and Prana fell more than five percent; GI Dynamics was down 4.8 percent; Avita, Medical Developments and Nanosonics were down more than three percent; Pharmaxis and Universal Biosensors shed more than two percent; CSL, Mesoblast and Starpharma were down more than one percent; with Cochlear down 0.03 percent.

BIOTA PHARMACEUTICALS

Biota has begun a 636-subject phase II trial of its long-acting neuraminidase inhibitor laninamivir octanoate for influenza and announced board changes.

Last year, Biota moved to the Nasdaq, following its merger with Nabi Pharmaceuticals (BD: Oct 30, 2012).

The company discontinued its policy of emailing announcements to the 10,500 Australian investors it took from the ASX to the Nasdaq (BD: Nov 9, 2012).

On June 11, 2013, Biota said that the multi-national, randomized, double blind, placebo controlled, parallel arm phase II trial of laninamivir octanoate, known as the 'Igloo' trial would compare the safety and efficacy of 40mg and 80mg of laninamivir octanoate with placebo, delivered by a Twincaps inhaler in adults with symptomatic influenza A or B infection.

The company said that the trial's primary end-point was the time to alleviation of influenza symptoms, with secondary end-points including whether the use of laninamivir octanoate reduced the incidence of secondary bacterial infections compared to placebo.

Biota said it expected top-line data available "in mid-2014".

The company said that the trial was being conducted under its contract with the US Office of Biomedical Advanced Research and Development Authority (BARDA).

Biota's product development vice-president Dr John Lambert said the beginning of the "robust, multi-center phase II trial for the treatment of influenza [was] an important milestone in the clinical development of laninamivir octanoate".

"We believe that the potential for once-only inhaled dosing of laninamivir octanoate could represent a significant advantage over the five-day, twice-daily dosing associated with the currently marketed neuraminidase inhibitors to treat influenza," Dr Lambert said.

On May 6, 2013 Biota told the Nasdaq that directors Dr Raafat Fahim and Paul Bell had resigned and were replaced by Anne VanLent and Michael Dougherty.

Biota said that Ms VanLent had "extensive experience in corporate advisory and financial services roles within life sciences" and was currently president of AMV Advisors, which she founded in 2008.

The company said that previously, Ms VanLent was Barrier Therapeutics executive vice-president and chief financial officer and prior to that was Sarnoff Corp's portfolio management executive vice president, prior to that was The Liposome Company's chief financial officer and was currently a director of Integra Lifesciences, Aegerion Pharmaceuticals and Tranzyme Pharma.

The company said that Mr Dougherty had "significant corporate and operational life sciences experience" and most recently, Mr Dougherty was Kalidex Pharmaceuticals' chief executive officer and previously was Adolor Corp's chief executive officer and prior to that was a senior executive at Genomics Collaborative, Genaera Corp and Centocor.

The company said that Mr Dougherty was currently a director of Viropharma.

Immediately prior to the Nabi merger announcement, Biota was trading at 94.5 cents and fell 8.5 cents or nine percent to 86 cents with 2.2 million shares traded on the announcement (BD: Apr 23, 2012).

The company's share price was above $A1.00 on April 2, 2012 falling to 57 cents on its last day of ASX trading on October 30, 2012. Biota began trading on the Nasdaq at $US4.12 on November 9, 2012, equivalent to 49.4 cents per ASX-listed share.

The company undertook a six-to-one share consolidation and with the Nabi merger each Biota share became 0.125 of a merged Biota Pharmaceuticals share.

Last night on the Nasdaq, Biota fell six US cents or 1.8 percent to $US3.32 ($A3.60) which equates to 44.9 cents in terms of the old ASX shares, meaning that from the merger announcement to last night, Biota shares have lost 52.5 percent of their value.

GENERA BIOSYSTEMS

Genera says it has raised $500,055 through a placement of 1,231,000 shares at 10.5 cents a share and the issue of 3,708 unlisted convertible notes at $100.00 per note.
Genera said it intended to offer a second tranche of $500,000 in placement shares to participants in the placement on the same terms prior to October 31, 2013.
The company said that the notes could be converted into shares at 12.5 cents a share from September 30, 2013 until December 31, 2014 and after December 31,t 2014 at 10.5 cents a share, the notes did not pay interest during their term and were redeemable by the company until June 30, 2015 for $140.00 per note or a 40 percent annual return.
The company said that holders could redeem the notes early should it receive more than $5,000,000 in cash from a monetization related to Paptype test or any other test associated with the company's intellectual property and the notes were redeemable at June 30, 2015 at 196 percent of face value.
The company said that discussions with potential investors to fund the business plan over the next 18 months were continuing.
Genera said that "a monetization of some of the company's intellectual property rights" relating to its Paptype human papillomavirus test and RTIplex respiratory pathogen test, specifically for the US market, could be an attractive opportunity would provide material non-dilutive funding to support and fund the business plan.
Genera executive chairman Lou Panaccio said the company had "experienced some delay with our validation with the [Salomao & Zoppi Diagnosticos] group, which has been frustrated by customs problems related to the importation of our instrumentation into Brazil, as well as delays in completing the key UK 6,000 patient screening trial, [but] we continue to explore a range of commercialization opportunities with high potential for near-term revenue" (BD: Jun 6, 2012).
"Genera has made progress on a number of fronts and the capital injection … together with a successful second tranche later in the year, will fully fund the company toward the delivery of a number of significant value-creating milestones," Mr Panaccio said.
Genera said it expected that many countries would amend cervical cancer screening protocols to adopt human papillomavirus testing as the primary screening tool and there had been significant developments on a number of fronts, including in the US and Australia.
The company said that the UK clinical study of the Sirocco test was due to be completed in August but was delayed due to unavailability of materials in Europe and a pilot study to run the data produced from the Sirocco in London was of inferior quality, unique to one particular instrument and location within the facility.
Genera said it would delay the UK trial until it had "a high degree of comfort in the reliability of the software and performance of the instrument in the London laboratory".
Genera said that with Healthscope it had completed the validation of Sirocco at its Clayton laboratory using both Paptype and RTIplex and more than 800 clinical respiratory samples had been tested by Healthscope's current methods, as well as by Genera's RTIplex.
The company said the validation study demonstrated "very high concordance rates" with Healthscope's testing regime with discordant samples tested by an independent third party, demonstrating a very high concordance rate with Genera's RTIplex test and all sensitivity targets met and Healthscope had incorporated the RTIplex as their primary panel test for upper respiratory pathogens.
Genera said it had been working with Sonic Healthcare on an independent validation of the RTIplex on the Sirocco platform in Sonic's Sydney laboratory in September and it was advancing both Paptype and RTIplex to regulatory approval in Australia and Europe.
Genera was unchanged at 10.5 cents.

CALZADA, POLYNOVO BIOMATERIALS

Calzada says 100 percent subsidiary Polynovo has a feasibility agreement with an unnamed US device company to evaluate Novosorb polymers for hernia repair.
Calzada said that the study would take about six months and if successful could lead to a licence and supply agreement.
The company said that Polynovo would manufacture and supply Novosorb for the US company to commercialize, develop, market and distribute.
Calzada said that hernia repair surgery involved the implantation of a device to reinforce missing or damaged tissue and the market was split between synthetic meshes for simpler hernia repair and biologic meshes for the more complex repairs and each had specific shortcomings and limitations.
The company said Novosorb had potential advantages over existing devices used in hernia surgery, including biodegradability, biocompatibility, adjustable biophysical properties, safety profile and a reduced risk of infection when implanted.
Calzada said that the more expedient and cost effective US Food and Drug Administration 510(k) pre-market authorization regulatory pathway would be applicable for devices using Novosorb for hernia repair.
Calzada was up 0.8 cents or 11.4 percent to 7.8 cents.

BONE MEDICAL

Bone says its BN006 program for rheumatoid arthritis has been accepted as an innovation priority by the Russian Government backed non-profit Skolkovo Foundation.
Bone said the approval made it eligible for funding to support additional research in Russia.
Skolkovo Foundation head of medical programs Gelena Lifshitz said that the prevalence of rheumatoid arthritis in Russia was about one percent of the population and “an economic burden which equals the burden of cardiac arrest”.
Bone said that tumor necrosis factor (TNF) inhibitors had proven to be safe and effective for particular patients but oral forms were not available.
The company said that oral anti-TNF therapies would make the treatment more comfortable for the patients and increase compliance.
Bone was up 0.1 cents or 100 percent to 0.2 cents.

BENITEC BIOPHARMA

All resolutions relating to Benitec’s fund raising and 25-to-one share consolidation were passed easily at today’s annual general meeting.
The greatest dissent was against the consolidation and approvals for chairman Peter Francis and directors Dr Mel Bridges, Dr John Chiplin and Iain Ross to participate in the recent placement, with about seven million proxy votes against (8.05%) and about 80 million proxy votes (91.95%) in favor.
Benitec said there were 248,689,684 proxy votes at the chair’s discretion and in its most recent Appendix 3B statement the company said it had 1,151,914,043 shares on issue, meaning the opposition came from about 0.6 percent of the shares on issue.
Benitec was unchanged at 1.5 cents with 4.2 million shares traded.

STARPHARMA HOLDINGS

Starpharma has appointed Dr Tony Eglezos as business development vice-president working with existing business development vice-president Dr Paul Barrett.
Starpharma said that Dr Eglezos was most recently a senior CSL executive, as Bio-CSL's commercial operations, pharmaceuticals and in-licencing director and prior to the CSL division change was CSL's senior director of business development and licenc.
The company said that Dr Eglezos had been appointed "to expand the resources available for negotiating partnering arrangements".
Starpharma said that Dr Eglezos had worked for more than 20 years in the pharmaceutical industry in Australia, the US and Europe for CSL, Amgen, Abbott Laboratories and Abbott Australia and had contributed to the commercialization of novel pharmaceuticals in urology, neurology, nephrology, cardiology, dermatology, pain and critical care.
The company said Dr Eglezos held a Doctorate of Philosophy in immunology from the University of Melbourne and a Masters of Business Administration from the University of Technology Sydney and would take up the position in August 2013.
Starpharma fell one cent or 1.05 percent to 94 cents.

MEDIVAC

Medivac says that Sophie Karzis will replace Malcolm Lucas-Smith as company secretary, effective from today.
Medivac said that Ms Karzis was a practicing lawyer with more than 10 years experience as a corporate and commercial lawyer, and company secretary and general counsel for a number of private and public companies.
The company said that Ms Karzis was the principal of Corporate Counsel, a corporate law practice with a focus on equity capital markets, mergers and acquisitions, corporate governance for ASX-listed entities, as well as general corporate and commercial law.
Medivac said that Ms Karzis was the company secretary of a number of companies.
Medivac was untraded at 0.2 cents.

NUSEP

The Sydney-based Ying Ming Chiu has become a substantial shareholder in Nusep with the acquisition of 7,606,664 shares or 5.5 percent of the company.
Nusep was untraded at 4.5 cents.