Biotech Daily

Wednesday December 14, 2011

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: VIRALYTICS UP 15%, USCOM DOWN 26%**

*** YM, CYTOPIA CYT387 SHOWS BENEFIT, SAFTEY IN MYELOFIBROSIS**

*** BIODIEM ACQUIRES COMPLEMENTARY SAVINE FOR CASH, SHARES**

*** PHYLOGICA PLACEMENT RAISES $2.15m**

*** CALZADA TRIES NEW INDICATIONS FOR 'FAT-BUSTER' AOD9604**

*** PROBIOMICS BIDS FOR HUNTER IMMUNOLOGY; $4.4m SHARE OFFER**

*** GI DYNAMICS ADDS 2 GERMAN CENTERS, SALES MANAGER**

MARKET REPORT

The Australian stock market fell 0.07 percent on Wednesday December 14, 2011 with the S&P ASX 200 down 2.9 points to 4,190.5 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and four were untraded.

Viralytics was the best, up five cents or 14.7 percent to 39 cents with 60,580 shares traded, followed by Antisense up 7.4 percent to 2.9 cents with 43.9 million shares traded.

Patrys climbed 5.3 percent; Avita and Genetic Technologies were up four percent or more; Anteo, Phosphagenics and Reva rose more than two percent; Acrux, Alchemia, Cochlear, CSL, Impedimed, Starpharma, Tissue Therapies and Universal Biosensors were up more than one percent; with Biota, Nanosonics and Pharmaxis up by less than one percent.

Uscom led the falls, down 2.5 cents or 26.3 percent to seven cents, with 2,500 shares traded followed by Phylogica down 0.8 cents or 14 percent to 4.9 cents with 9.4 million shares.

Allied Health and Benitec lost more than six percent; Cellmid and QRX were down more than five percent; Bionomics, Cathrx and Sirtex fell more than four percent; Clinuvel Neuren and Prana were down more than three percent; Resmed shed 2.9 percent; with Mesoblast down 0.9 percent.

YM BIOSCIENCES (INCORPORATING THE FORMER CYTOPIA)

YM Biosciences says its 166-patient ongoing phase I/II study of CYT387 for myelofibrosis has shown efficacy and safety.

YM said the results were presented in a poster session at the American Society of Hematology meeting in San Diego, California on December 12, 2011.

The Melbourne-based Cytopia was developing CYT387 when the company was acquired by the Canada-based YM for $14 million in 2009 (BD: Oct 6, 2009)

YM chief executive officer Dr Nick Glover said the study showed that CYT387 “continues to demonstrate a unique ability to render and maintain myelofibrosis patients transfusion independent for clinically-relevant periods, while also producing significant and durable improvements in their splenomegaly and constitutional symptoms”.

“In addition, [magnetic resonance imaging] results obtained from a subset of subjects confirm the meaningful improvements in splenomegaly as measured by palpation,” Dr Glover said. “CYT387 was well tolerated, with dosing up to and exceeding two years.”

The poster entitled ‘Safety and Efficacy of CYT387, a JAK1 and JAK2 Inhibitor for the Treatment of Myelofibrosis’ was co-authored by YM Biosciences and former Cytopia director of drug development Dr Gregg Smith and is available at:
http://www.ymbiosciences.com/upload_files/CYT387_poster_ASH2011_Pardanani.pdf

The poster concluded that that CYT387 was well tolerated in myelofibrosis patients for dosing periods up to and exceeding two years.

The poster said that reported adverse effects included thrombocytopenia; transient, mild dizziness; mild peripheral neuropathy; and abnormalities in liver/pancreas-related laboratory tests with treatment-emergent anemia and neutropenia described as rare.

The poster concluded that CYT387 treatment resulted in significant, durable responses in anemia, splenomegaly and constitutional symptoms at 150mg daily, 300mg daily and 150mg twice daily dose levels and although additional assessments and analyses were ongoing, 300mg daily appeared to be a safe and effective dosing regimen warranting further clinical development.

The poster reported that therapeutic benefit and safety was established in a population with multiple risk factors, including anemia and thrombocytopenia.

The poster said that CYT387 anemia benefit appeared unique among the current class of JAK1 and JAK2 inhibitors and that magnetic resonance imaging in a subset of subjects confirmed meaningful improvement in splenomegaly measured by palpation.

The poster said that complete resolution or marked improvement of common constitutional symptoms was achieved in the majority of subjects and 97 percent of patients who completed the core study continued into the extension phase.

The company said that 32 patients (19%) discontinued the core study, five for possibly or probably related adverse events, for a current overall retention rate of 81 percent, with the retention rate in the extension phase currently 79 percent.

YM said that CYT387 was an inhibitor of the kinase enzymes JAK1 and JAK2, which were implicated in a family of hematological conditions known as myeloproliferative neoplasms, including myelofibrosis and as well in numerous other disorders including indications in hematology, oncology and inflammatory diseases.

The company said that myelofibrosis was a chronic debilitating disease in which a patient's bone marrow was replaced by scar tissue and for which treatment options are limited or unsatisfactory.

YM said that both the US Food and Drug Administration and the European Commission had designated CYT387 an Orphan Drug for the treatment of myelofibrosis.

Last night on the Nasdaq YM closed up 23 US cents or 15.75 percent to $US1.69 with 7.6 million shares traded.

BIODIEM

Biodiem says it has acquired Savine Therapeutics and its antigen vaccine for a combination of shares and cash.

Biodiem chief executive officer Julie Phillips told Biotech Daily that the non-material acquisition gave her company “highly complementary” technology first developed at the Australian National University.

Ms Phillips said Savine was incorporated in 2007 to commercialize the scrambled antigen vaccine (Savine) technology which has approved patents.

Ms Phillips said she was a non-executive director of Savine.

In its media release to the ASX Biodiem said that its scientific consultant Dr Scott Thomson was a co-inventor of the Savine technology, which could be used to design antigens that were able to be incorporated into vaccines for different diseases.

The company said that starting with one or more key proteins from microbes or cancers targeted to generate an immune response, a scrambled antigen, or a Savine, was fully re-engineered and synthesized to retain key immunologically-relevant characteristics.

Biodiem said that Savine antigens were encoded as synthetic genes which, together with a delivery technology such as Biodiem's live attenuated influenza vaccine (LAIV) based vector technology could be used to design novel vaccines.

The company said the Savine technology had a number of significant potential advantages compared to alternative disease protein delivery strategies and could incorporate more than one target disease protein or antigen, which could improve disease protection.

Biodiem said the scrambling process was designed to enhance safety by removing the dangerous functions of the selected proteins, for example, cancer-associated proteins and by incorporating as much immunologically-relevant information as possible this would enhance the ability of the designed Savine to provide broader population coverage.

Ms Phillips said that the key elements of developing vaccines were a virus, a cell line to grow the virus and antigens or disease proteins.

“Biodiem now has all of these components through the live attenuated influenza virus, the mammalian cell line recently licenced and now the acquisition of the Savine antigen technology,” Ms Phillips said.

“The Savine technology will be valuable to our LAIV vector project as it will allow us to expand the number of diseases that can be targeted,” Ms Phillips said.

“In addition, Biodiem will be able to separately licence out the Savine technology in specific disease areas,” Ms Phillips said.

Biodeime said that as part of the transaction it would own the software used to design such antigens together with a number of Savine-manufactured genes, suitable for vaccines against nasopharyngeal carcinoma, which was an Epstein-Barr virus-related cancer prevalent in South East Asian cancer, tuberculosis, HIV and hepatitis C.

Biodiem was unchanged at 8.4 cents.

PHYLOGICA

Phylogica says it has raised $2.15 million through the placement of 40,533,333 shares at 5.3 cents a share.

Phylogica said that the institutional and sophisticated investors taking part in the placement would receive two free attaching options for every three new shares bought.

Phylogica said RBS Morgans was the lead manager to the capital raising.

Phylogica fell 0.8 cents or 14 percent to 4.9 cents with 9.4 million shares.

CALZADA

Calzada says its wholly owned subsidiary Metabolic Pharmaceuticals was investigating two new applications for AOD9604.

Calzada said the compound originally trialed as a fat-removal drug was being investigated for osteoarthritis, as well as muscle wasting conditions.

The company said AOD9604 could have efficacy in osteoarthritis, achondroplasia, costochondritis and applications where it could increase chondrocyte, proteoglycan or collagen production and quality as well as where it could promote or repair new cartilage tissue formation.

Calzada said that AOD9604 would also be investigated for sarcopenia, cachexia, AIDS wasting syndrome, muscular dystrophies, neuromuscular diseases, motor neuron diseases and all applications where it could promote or improve muscle, ligament or tendon mass, or any condition where a protein anabolic effect.

A 2007 Calzada (then Metabolic) phase II trial found that oral AOD9604 showed little or no efficacy in subjects compliant with a US Food and Drug Administration diet and exercise regime (BD: Feb 21, 2007).

Today Calzada said Toronto's Mt Sinai Hospital's Prof Marc Grynpas and Prof Rita Kandel would conduct proof-of-principle tests with results expected by April 2012.

The company said AOD9604 had been tested in six trials of 925 subjects with an excellent safety and tolerability record and safety studies might not be required.

Calzada was up 0.1 cents or 1.85 percent to 5.5 cents.

PROBIOMICS, HUNTER IMMUNOLOGY

Probiomics has filed its bidder's statement for the proposed takeover of Hunter Immunology and hopes to raise $4.4 million through a share offer.

Probiomics' bidder's statement said it was offering nine of its shares for one Hunter share or tranche 1 note and nine Probiomics options for one Hunter option.

Biotech Daily understands the bid is a merger of companies with synergistic technologies.

Probiomics has a capitalization of $2.9 million and said the bid valued Hunter at $29.23 million.

Probiomics said the record date of the proposed takeover is December 13, 2011 with the close of the public offer on February 6, 2012 and the Probiomics shareholders meeting expected on February 7, 2012.

The company said the takeover bid would close on March 9, with completion expected on March 28, and a change of name to Bioxyne Limited effective from March 30, 2012.

Probiomics said it originally intended to develop projects in mucosal immunology but in 2003 changed its focus to commercialize the probiotic strain Lactobacillus fermentum.

The statement said Hunter Immunology was a clinical stage company developing a range of orally-administered vaccines to reduce the number and severity of exacerbations in patients with chronic obstructive pulmonary disease.

Probiomics said the offer of up to 400 million shares at 11 cents was conditional on shareholder approvals and the bid for Hunter being declared unconditional, with directors recommending accepting the offers, conditional on 90 percent acceptances.

The company said one attaching option would come with every three shares issued, exercisable at 1.65 cents by March 31, 2013.

Probiomics said that Hunter managing director and former Nanosonics chief executive officer David Radford would be the chief executive officer of the merged group.

Hunter is a public unlisted company.

Probiomics was unchanged at one cent.

GI DYNAMICS

GI Dynamics says two German clinics have adopted its Endobarrier for weight loss and type 2 diabetes control and appointed Dirk Soeder as Germany sales manager.

GI Dynamic said it had “designated the Heart and Diabetes Center North Rhine-Westphalia at Bad Oeynhausen and the Universitätsmedizin Mannheim as the newest centers of excellence in Germany”.

The company said it certified a hospital as a centre of excellence for the Endobarrier after meeting initial qualifications of having a team experienced in treating patients with type 2 diabetes and obesity and following a rigorous training and proctorship program.

he medical director of the North Rhine-Westphalia Heart and Diabetes Centre Prof Diethelm Tschöpe said that although diabetes was often treated with diet changes and medications, including insulin, “we have found that many patients still struggle to improve their health and get their disease under control”.

Dr Tschöpe said the Endobarrier helped patients lower their blood glucose levels and lose weight.

“In many cases, it has even helped patients reduce or eliminate their use of anti-diabetic medications,” Dr Tschöpe said.

GI Dynamics said it had appointed Dirk Soeder as the sales manager for Germany responsible for overseeing the expansion of sales and marketing efforts, including identifying and establishing new centres of excellence.

The company said Mr Soeder had more than 15 years of sales experience and most recently was senior sales manager for Johnson & Johnson Medical GmbH, Ethicon Endo Surgery Deutschland where he was responsible for the endo-surgery product division.

GI Dynamics said the previously Mr Soeder was with Obtech Medical AG, where he was instrumental in bringing the Swedish adjustable gastric band to the German market.

GI Dynamics was unchanged at 91 cents.